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# The Federal Circuit Bar Journal

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# Is “Willful Blindness” the New “Recklessness” after *Global-Tech*?

Lorelei D. Ritchie\*

## Introduction

In 2009, the Court of Appeals for the Federal Circuit changed the landscape for trademark parties involved in claims of fraud on the United States Patent and Trademark Office (“USPTO”). With the issuance of its decision in the case *In re Bose Corp.*,<sup>1</sup> the court neatly upped the ante for plaintiffs to show knowledge and willful intent.<sup>2</sup> However, as the dust began to clear from the case and follow-on litigation ensued, one question remained open. Exactly what level of knowledge is required to plead and prove these claims of fraud on the USPTO? Is recklessness sufficient? Might there even be another possibility? A footnote in *Bose* suggested the court did not “resolve this issue,”<sup>3</sup> thereby leaving it for future courts to decide. This Article provides a framework for courts to use in approaching that decision.

The discussion begins with an analogy from patent law. As explained below, the Supreme Court appears to be increasingly aligning patent law with general jurisprudence. In 2011, in *Global-Tech Appliances, Inc. v. SEB S.A.*,<sup>4</sup> the Supreme Court furthered this pattern by applying the willful blindness doctrine, borrowed from criminal law, to a case involving “actively induc[ed] infringement”<sup>5</sup> in patent law.<sup>6</sup> As explored by this Article, patent and trademark (as well as copyright) law share common historical and legal origins. Accordingly, it seems appropriate to cross-apply doctrines between them,

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\* Judge Lorelei D. Ritchie sits on the U.S. Trademark Trial and Appeal Board. All writings in this Article are the exclusive work of this author, and do not reflect the views of the Trademark Trial and Appeal Board or any other governmental person or agency. The author wishes to thank Professors Lee Petherbridge and Mark A. Lemley, Judge Ronald Lew, and Chief Judge Randall Rader for their comments and commentary. Any mistakes are solely the province of the author.

<sup>1</sup> 580 F.3d 1240 (Fed. Cir. 2009).

<sup>2</sup> *Id.* at 1245–46.

<sup>3</sup> *Id.* at 1246 n.2.

<sup>4</sup> 131 S. Ct. 2060 (2011).

<sup>5</sup> See 35 U.S.C. § 271(b) (2006) (“Whoever actively induces infringement of a patent shall be liable as an infringer.”).

<sup>6</sup> *Global-Tech*, 131 S. Ct. at 2069.

including, possibly, the doctrine of willful blindness recently adopted by the Supreme Court.

If the Supreme Court truly intends to align patent law with other areas such as criminal law, as shown in the *Global-Tech* case, this Article considers that it would further have us extend that logic in deciding matters in the historically related areas of patent and trademark law (as well as copyright). Indeed, Congress itself has indicated that it views trademark law as being related to patent law.<sup>7</sup> Federal courts have followed this reasoning in cross-applying doctrines between the three areas of intellectual property law.<sup>8</sup> Accordingly, this Article considers the meaning and viability of willful blindness for claims of fraud on the USPTO, while also considering recklessness and higher levels of knowledge as possible standards for scienter.

Part I discusses the case for aligning patent law with general jurisprudence, specifically exploring the normative objectives of patent law and ways the Supreme Court has, in recent years, attempted to better harmonize patent jurisprudence with general principles of civil procedure, contracts, and other areas of law. Part II discusses the case for aligning patent law with sisters copyright and trademark, reviewing the historical and legal connections between patent, copyright, and trademark law. Part III discusses willful blindness principles from the 2011 Supreme Court *Global-Tech* case, delving into the recent decision and cross-applying the doctrine of willful blindness from criminal to patent law. Part IV discusses the state of fraud in trademark law, including the complexities of the Trademark Trial and Appeal Board, *In re Bose*, a case that changed the landscape of fraud on the USPTO, and the outstanding issue of scienter in fraud. Finally, Part V explores applying the heightened standard of willful blindness, borrowed from patent law. This section brings together the discussions from the prior four sections in considering whether the holding from *Global-Tech* should be applied to trademark law in the context of fraud on the USPTO and, if so, how that might be accomplished.

## **I. The Case for Aligning Patent Law with General Jurisprudence**

The normative values of patent law are subjects of ongoing debate amongst courts, Congress, and academics. Generally, patent law must balance various incentives.<sup>9</sup> Inventors—and more frequently their assignees—must be

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<sup>7</sup> See *infra* notes 35–37 and accompanying text.

<sup>8</sup> See discussion *infra* Part II.

<sup>9</sup> See *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). The Supreme Court has stated the competing objectives of patent law:

First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions to stimulate further innovation and to permit the public to practice

rewarded with patents for their protectable ideas, as an incentive to create and invest in technology development.<sup>10</sup> The public must then be offered full disclosure of the inventive steps, with the assurance that only truly patentable inventions will receive the exclusionary patent grant.<sup>11</sup> Finally, competing inventors and companies must be allowed their own opportunities to obtain patents on improvements and work-around technology.<sup>12</sup> Of course, all this begs the question of how these countervailing balances should be weighed.

Economic efficiency demands that patent protection be made both available and subject to legal challenge. On the one hand, patents are necessary to encourage investment in various industries that bring products and processes of great value to the consuming public.<sup>13</sup> On the other hand, invalid patents must not be permitted to dominate the marketplace.<sup>14</sup> Accordingly, the Supreme Court has mandated that, while patents are entitled to a presumption of validity,<sup>15</sup> once invalidity is proven in court, challenged patents are rendered unenforceable against even third parties.<sup>16</sup> As a normative value, predictability is of prime importance both to the patentee and to potential infringers, who must make business decisions based on the validity and enforceability of patents.

The Federal Circuit hears virtually all appeals of district court patent cases (as well as appeals from the USPTO). So, absent a grant of certiorari, it tends to be the final arbiter in interpreting patent law and jurisprudence.<sup>17</sup> As a

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the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public. *Id.*

<sup>10</sup> *See id.*

<sup>11</sup> *See id.*

<sup>12</sup> *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

<sup>13</sup> *See Aronson*, 257 U.S. at 262.

<sup>14</sup> *See id.* at 264 (referring to the “desirability of encouraging licensees to challenge the validity of patents”); *see also* Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System: Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989, 992-94 (2004) (examining the economic cost of weak and invalid patents).

<sup>15</sup> *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 335 (1971).

<sup>16</sup> *See id.* at 350.

<sup>17</sup> *See Holmes Grp., Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 829-30 (2002). Formed in 1982, the Court of Appeals for the Federal Circuit has exclusive jurisdiction over patent appeals (with some exceptions, such as patent claims brought only as a counterclaim). *See id.* at 834; *Bruno v. United States*, 744 F.2d 753, 754 (11th Cir. 1984) (discussing the formation of the Federal Circuit). As provisions take effect on passage of the new patent reform act of 2011, the Federal Circuit will have an even broader jurisdiction on patent appeals to all those “arising under” the patent statute, including patent arguments raised as counterclaims. *See* Mark A. Lemley, *Things You Should Care About in the New Patent Statute*, SOC. SCIENCE RESEARCH NETWORK, 3 (Sept. 16, 2011), <http://ssrn.com/abstract=1929044>.

consequence, there are some who believe that patent law lacks benefits that other areas of law have, including the opportunity to be heard by various circuits and, perhaps, to learn from circuit splits.<sup>18</sup> Congress, meanwhile, has been up in arms over the past few years, with members endorsing numerous patent reform bills.<sup>19</sup> One such bill finally became law in 2011 and will significantly affect the practice of patent law in the United States.<sup>20</sup> Many people, from business owners to scholars, agree that the current patent system has significant problems.<sup>21</sup> But even within the typical dividing lines, there is no clear agreement on solutions.

At the same time, the Supreme Court has indicated an interest in aligning patent law with principles of general jurisprudence and social utility.<sup>22</sup>

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<sup>18</sup> See, e.g., Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 Nw. U. L. REV. 1619, 1641, 1649–50 (2007) (arguing that patent law might, with the addition of at least one other circuit hearing patent appeals, benefit from more competition between courts); cf. R. Polk Wagner & Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. PENN. L. REV. 1105, 1111–12 (2004) (discussing how the jurisprudence of the Federal Circuit has become increasingly polarized). At least one judge on the Federal Circuit has noted efforts to normalize its jurisprudence. S. Jay Plager, *The Price of Popularity: The Court of Appeals for the Federal Circuit 2007*, 56 AM. U. L. REV. 751, 755 (2007) (“The Circuit has professed to want to bring its patent jurisprudence into line with the rules applicable to federal civil litigation generally, and in some respects has succeeded.”).

<sup>19</sup> See, e.g., Patent Reform Act of 2009, S. 610, 111th Cong. (2009); Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009); Patent Reform Act of 2008, S. 3600, 110th Cong. (2008); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2006, S. 3818, 109th Cong. (2006).

<sup>20</sup> See Leahy-Smith America Invents Act, Pub. L. No. 112-19, § 3(b), 125 Stat. 284, 285–87 (2011) (to be codified at 35 U.S.C. § 102) (changing American patent registration from a first-to-invent to a first-inventor-to-file system).

<sup>21</sup> See, e.g., *Patent Trolls: Fact or Fiction?: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 109th Cong. 7, 18, 26 (2006) (statements of Edward R. Reines, Esq., Weil, Gotshal & Manges, LLP, Paul Misener, Vice President for Global Pub. Policy, Amazon.com, & Chuck Fish, Vice President & Chief Patent Counsel, Time Warner); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 591 (1999) (discussing a patent system “in crisis”).

<sup>22</sup> See, e.g., *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391–92 (2006) (emphasizing that traditional principles of equity apply to injunctions in patent law). Still, general jurisprudence and social utility are themselves not always clearly aligned. See, e.g., *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 636–37 (2008) (presuming primacy of patent exhaustion doctrine over the right of parties to construct own contract); see also Lorelei Ritchie, *Reconciling Contract Doctrine with Intellectual Property Law: An Interdisciplinary Solution*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 105, 119, 144–45 (2008).

In its 2005 case, *Merck KGaA v. Integra Lifesciences I, Ltd.*,<sup>23</sup> the Supreme Court expanded what is effectively a statutory fair use doctrine in patent law to cases where the purported infringement may lead to drug discovery and development.<sup>24</sup> In 2006, *eBay Inc. v. MercExchange, L.L.C.*<sup>25</sup> modified the nearly century-old presumption of injunction in patent cases, thereby tipping the scales toward compulsory licensing.<sup>26</sup> In 2007, *MedImmune, Inc. v. Genentech, Inc.*,<sup>27</sup> the Court once again ruled in favor of normalizing patent jurisprudence with general law, condemning the standard of declaratory judgment that had been used in patent law by the Federal Circuit in favor of that generally used in civil litigation.<sup>28</sup> Likewise, in the 2011 case *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*,<sup>29</sup> the Court resisted the argument that universities should automatically be vested title to federally-funded inventions, noting instead that patent rights belong first to inventors.<sup>30</sup> Indeed, the opinion stated it is by operation of *contract* law that inventions may be assigned to employers, including universities receiving funds under the Bayh-Dole Act.<sup>31</sup> In short, the Supreme Court has repeatedly recognized that the objectives of patent law must not be applied in a legal vacuum.

Finally, in *Global-Tech*, also decided in 2011, the Supreme Court “borrowed” the doctrine of willful blindness from criminal law and applied it to patent law, where the Court found that standard to be useful, and the existing patent law to be lacking.<sup>32</sup> This evidences the Court’s increasing desire to align patent law with principles of general jurisprudence, a generally wise and appropriate course. This Article will explore further the *Global-Tech* case in Part III.

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<sup>23</sup> 545 U.S. 193 (2005).

<sup>24</sup> *Id.* at 202. In reaching its decision, the *Merck* Court relied heavily on 35 U.S.C. § 271(e). *Id.* It reads, in relevant part:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

35 U.S.C. § 271(e) (2006).

<sup>25</sup> 547 U.S. 388 (2006).

<sup>26</sup> *Id.* at 392–93.

<sup>27</sup> 549 U.S. 118 (2007).

<sup>28</sup> *See id.* at 132 n.11.

<sup>29</sup> 131 S. Ct. 2188 (2011).

<sup>30</sup> *Id.* at 2197.

<sup>31</sup> *Id.* at 2199.

<sup>32</sup> *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068–69 (2011).

## II. The Case for Aligning Patent Law with Sisters Copyright and Trademark

Patent and copyright law are sister bodies of jurisprudence, with common origins stemming from the very beginning of U.S. law. The Founding Fathers placed the two hand-in-hand in the Constitution<sup>33</sup> and Congress enacted the first patent and copyright acts in 1790.<sup>34</sup>

Patent and trademark law also have common historical and legislative origins in the United States. Both were placed under common stewardship of the USPTO, which is charged with granting patents and trademarks.<sup>35</sup> Both also fall under the jurisdiction of the Federal Circuit when applicants seek to appeal the rejection of their patent and trademark applications by the USPTO.<sup>36</sup> So similar are the two areas of law that Congress has in recent years considered consolidating the Lanham Act, which governs trademark rights and infringement, into Title 35, alongside patents.<sup>37</sup>

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<sup>33</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>34</sup> Act of May 31, 1790, ch. 15, 1 Stat. 124, Act of Apr. 2, 1790, ch. 7, 1 Stat. 109.

<sup>35</sup> See 37 C.F.R. § 11.1 (2010) (defining terms concerning the governance of the practice of both patent and trademark law before the USPTO).

<sup>36</sup> See 15 U.S.C. § 1071(a) (2006); 28 U.S.C. § 1295(a)(4)(A)–(B) (2006); 35 U.S.C. § 145 (2006). Trademark applicants may also appeal to the district courts in their regional circuits, see 15 U.S.C. § 1071(b), though many choose to appeal to the Federal Circuit, because the judges are known for their expertise with intellectual property law. Banks Miller & Brett Curry, *Expertise, Experience, and Ideology on Specialized Courts: The Case of the Court of Appeals for the Federal Circuit*, 43 LAW & SOC'Y REV. 839, 840 (2009) (“[W]hen it comes to highly specialized, technical areas of law, the ideological consistency of judicial decisionmaking may also be influenced by a judge’s familiarity with the intricacies of abstruse legal subject matter.”). Either way, the process is the same for both patent and trademark applicants. See 15 U.S.C. § 1071; 35 U.S.C. § 145.

<sup>37</sup> In 2006, Representatives Sensenbrenner and Conyers introduced such a bill in the House Judiciary Committee. See STAFF OF H. COMM. ON THE JUDICIARY, 109TH CONG., A BILL TO ENACT CERTAIN LAWS RELATING TO TRADEMARKS AND OTHER INTELLECTUAL PROPERTY AS SUBTITLES III AND IV OF TITLE 35, UNITED STATES CODE, AND TO REDESIGNATE THAT TITLE AS “PATENTS, TRADEMARKS, AND OTHER INTELLECTUAL PROPERTY” (2006), available at <http://uscde.house.gov/cod/t35/20060425bill.pdf> (Discussion Draft No. 1). The bill’s accompanying explanation expressed the bill’s objective of “conform[ing] with original intent,” and in order to consolidate patent and trademark law in order to “reflect the emergence of intellectual property law as a distinct field of law” and a “cohesive unit.” STAFF OF H. COMM. ON THE JUDICIARY, 109TH CONG., EXPLANATION OF A BILL TO ENACT CERTAIN LAWS RELATING TO TRADEMARKS AND OTHER INTELLECTUAL PROPERTY AS SUBTITLES III AND IV OF TITLE 35, UNITED STATES CODE, AND TO REDESIGNATE THAT TITLE AS “PATENTS, TRADEMARKS, AND OTHER INTELLECTUAL PROPERTY” 1 (2006), available at <http://uscde.house.gov/cod/t35/20060425exp.pdf>.



Courts have, accordingly, frequently applied doctrines from one area of intellectual property to another. Examples include the doctrines of misuse,<sup>38</sup> contributory infringement,<sup>39</sup> licensee estoppel,<sup>40</sup> and first sale.<sup>41</sup> Considering the common historical origins, legislative treatment, and obvious similarities between patent, copyright, and trademark law, this cross-application of doctrines seems to be an appropriate pattern. The Supreme Court has made the case for sharing doctrines several times over the years, including in the landmark 1984 case *Sony Corp. of America v. Universal City Studios, Inc.*<sup>42</sup> There, the Court extended the doctrine of vicarious infringement from patent to copyright law, noting that “[t]he closest analogy is provided by the patent law cases to which it is appropriate to refer because of the *historic kinship* between patent law and copyright law.”<sup>43</sup> Keeping with this approach, the Court’s 2006 *eBay* opinion turned to copyright law for guidance when considering the viability of presumptive injunctions in patent law.<sup>44</sup> In so doing, the Supreme Court neatly discarded nearly a century of patent precedent in favor of a better standard articulated in copyright law.<sup>45</sup> Cross-applying again, courts have, in turn, applied the concepts of *eBay* to trademark and copyright law.<sup>46</sup> In the 2011 *Global-Tech* case, the Supreme Court implicitly

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<sup>38</sup> See, e.g., *Lasercomb Am., Inc. v. Reynolds*, 911 F.2d 970, 972–73 (4th Cir. 1990) (applying the doctrine of patent misuse to a copyright case concerning software).

<sup>39</sup> See, e.g., *Sony Corp. of Am. v. Universal City Studios, Inc.* 464 U.S. 417, 435, 439 (1984) (applying patent principles to copyright law in a vicarious infringement case), *superseded by statute*, Digital Millennium Copyright Act, Pub. L. No. 105-304, 112 Stat. 2860.

<sup>40</sup> See, e.g., *Twin Books Corp. v. The Walt Disney Co.*, 877 F. Supp. 496, 500 (N.D. Cal. 1995) (quoting *Harris v. Emus Records Corp.*, 734 F.2d 1329, 1333 (9th Cir. 1984)) (extending the Supreme Court’s abolition of “licensee estoppel” in patent law to copyright), *rev’d on other grounds*, 83 F.3d 1162 (9th Cir. 1996).

<sup>41</sup> See, e.g., *Allison v. Vintage Sports Plaques*, 136 F.3d 1443, 1448 (11th Cir. 1998) (discussing the applicability of the first sale doctrine across patent, copyright, and trademark law).

<sup>42</sup> 464 U.S. 417 (1984), *superseded by statute*, Digital Millennium Copyright Act, Pub. L. No. 105-304, 112 Stat. 2860.

<sup>43</sup> *Id.* at 439 (emphasis added).

<sup>44</sup> *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006).

<sup>45</sup> See *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 430 (1908) (establishing the precedent). Since the Supreme Court’s *Continental Paper Bag* decision, an injunction had been the presumed remedy in patent law. See *eBay*, 547 U.S. at 391 (quoting *MercExchange, L.L.C. v. eBay Inc.*, 401 F.3d 1323, 1339 (2005), *vacated*, 547 U.S. 388 (2006)) (highlighting the Federal Circuit’s general rule of issuing injunctions in patent cases, absent exceptional circumstances).

<sup>46</sup> See *Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 31 (1st Cir. 2011) (applying *eBay* to a trademark case); *Salinger v. Colting*, 607 F.3d 68, 77 n.6 (2d Cir. 2010) (ruling that the principles of equity set forth in *eBay* apply to copyright cases and noting that “the First, Eleventh, and Fourth Circuits have applied *eBay* in copyright

accepted that patent law should follow, or at least look to, copyright law as a guide,<sup>47</sup> and further discussed the standard considered for copyrighted works in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*<sup>48</sup>

Finally, the Federal Circuit itself has looked to both copyright and trademark law for guidance in applying patent law.<sup>49</sup> The Federal Circuit has similarly cross-applied *from* patent law, analogizing and applying patent principles to trademark law.<sup>50</sup> Accordingly, just as the Supreme Court has been normalizing patent law with general jurisprudence—ideally with the Federal Circuit and lower courts following suit—courts should continue to harmonize patent, copyright, and trademark law with one another as much as possible.

### III. Willful Blindness Principles from the 2011 Supreme Court *Global-Tech* Case

In the 2010–2011 term, the U.S. Supreme Court heard arguments for *Global-Tech Appliances, Inc. et. al. v. SEB S.A.*<sup>51</sup> The question presented on certiorari was described as follows:

Whether the legal standard for the state of mind element of a claim for actively inducing infringement under 35 U.S.C. § 271(b) is “deliberate indifference of a known risk” that an infringement may occur, . . . or “purposeful, culpable expression and conduct” to encourage an infringement.<sup>52</sup>

The company SEB invented an innovative deep fryer sold in the United States under the brand “T-Fal.”<sup>53</sup> Due to a clever design that kept the external

cases”); *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211, 1228 (11th Cir. 2008) (concluding that the principles of *eBay* applied to a request to preliminarily enjoin alleged trademark infringement).

<sup>47</sup> *Global-Tech Appliances, Inc. et. al. v. SEB S.A.*, 131 S. Ct. 2060, 2067 (2011).

<sup>48</sup> *Id.*; 545 U.S. 913 (2005).

<sup>49</sup> See *In re Seagate Tech., LLC*, 497 F.3d 1360, 1370 (Fed. Cir. 2007) (en banc) (discussing the standard of scienter applied by “sister circuits” in copyright law); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006) (quoting *Metro-Goldwin-Mayer Studios, Inc.*, 545 U.S. at 932); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (drawing an analogy from trademark fraud in establishing “but for” materiality in patent inequitable conduct).

<sup>50</sup> See, e.g., *In re Bose Corp.*, 580 F.3d 1240, 1244–45 (Fed. Cir. 2009) (“The principle that the standard for finding intent to deceive is stricter than the standard for negligence or gross negligence, even through announced in patent inequitable conduct cases, applies with equal force to trademark fraud cases.”).

<sup>51</sup> *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011).

<sup>52</sup> Petition for Writ of Certiorari at i, *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011) (No. 10-6) (quoting *Metro-Goldwin-Mayer Studios, Inc.*, 545 U.S. at 937).

<sup>53</sup> *Global-Tech*, 131 S. Ct. at 2064.

surfaces cool, SEB sought and obtained a patent on the product.<sup>54</sup> Sunbeam, a competitor, sought to meet SEB’s success in the marketplace and asked Pentalpha (a wholly-owned subsidiary of Global-Tech) to supply it with deep fryers that met certain specifications.<sup>55</sup> In order to develop a product for Sunbeam, Pentalpha purchased an SEB deep fryer in Hong Kong and copied all but the cosmetic features.<sup>56</sup> Because the deep fryer was purchased in a foreign market, it lacked the U.S. patent markings.<sup>57</sup> After copying the design, Pentalpha retained an attorney to conduct a right-to-use study.<sup>58</sup> However, Pentalpha did not tell the attorney that it had copied the design directly from the SEB product.<sup>59</sup> The attorney failed to find SEB’s U.S. deep fryer patent in the patent search.<sup>60</sup>

After Pentalpha began selling its product in the United States to Sunbeam and other resellers, SEB sued Sunbeam for direct patent infringement.<sup>61</sup> Sunbeam informed Pentalpha of the lawsuit, but Pentalpha continued to sell its product.<sup>62</sup> After settling its lawsuit with Sunbeam, SEB sued Pentalpha for, among other things, actively inducing infringement by Sunbeam and the other various resellers in violation of 35 U.S.C. § 271(b).<sup>63</sup>

The jury found for SEB.<sup>64</sup> Pentalpha sought a new trial on the grounds that it did not “actually know” of SEB’s patent until it received notice of SEB’s lawsuit against Sunbeam.<sup>65</sup> The district court rejected Pentalpha’s arguments, as did the Federal Circuit on appeal.<sup>66</sup> The Federal Circuit stated that, by its actions, Pentalpha had “deliberately disregarded a known risk” that SEB may have had a U.S. patent on the SEB deep-fryer.<sup>67</sup> Such disregard, the Federal Circuit held, “is not different from actual knowledge, but is a form of actual knowledge.”<sup>68</sup>

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<sup>54</sup> *Id.* at 2063.

<sup>55</sup> *Id.* at 2064.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* SEB also claimed a theory of direct infringement by Pentalpha, which was not at issue before the Supreme Court. *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1377 (Fed. Cir. 2010), *aff’d sub nom.* *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011).

<sup>68</sup> *Id.*

The Supreme Court granted certiorari to decide the question of what, if any, level of scienter should be required under § 271(b) for a finding of induced patent infringement.<sup>69</sup> As a preliminary matter, the Court relied on a dictionary definition of the statutory term “induce” to find that “at least some intent is required.”<sup>70</sup> By taking a step as practical as looking in the dictionary,<sup>71</sup> the Court thus already evidenced an interest in keeping a realistic reign on patent law. Otherwise stated, the Court showed its intent to harmonize the principles of patent law with those of general jurisprudence and equity. Indeed, after holding that knowledge is required and thoroughly discussing the need to maintain internal consistency *within* patent law,<sup>72</sup> the Court established the exact level of knowledge required and went on to explain why it was also perfectly reasonable to borrow a doctrine—where one appeared to be lacking—from *outside* patent law.<sup>73</sup>

The Supreme Court chose to apply a standard of scienter that satisfied the knowledge requirement but was not being applied in the sphere of patent infringement.<sup>74</sup> Willful blindness, the Court held, a doctrine from another field entirely, struck the right balance in requiring sufficient knowledge, without requiring a party to literally evidence *actual knowledge*.<sup>75</sup> The Court stated:

The doctrine of willful blindness is well established in criminal law. Many criminal statutes require proof that a defendant acted knowingly or willfully, and courts applying the doctrine of willful blindness hold that defendants cannot escape the reach of these statutes by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances. The traditional rationale for this doctrine is that defendants who behave in this manner are just as culpable as those who have actual knowledge.<sup>76</sup>

The Court went on to say that “[g]iven the long history of willful blindness and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement under 35 U.S.C. § 271(b).”<sup>77</sup> As to exactly what “willful blindness” means, the Court acknowledged that various regional circuits have “articulat[ed]

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<sup>69</sup> *Global-Tech*, 131 S. Ct. at 2063.

<sup>70</sup> *Id.* at 2065.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 2068 (discussing, with historical basis, the knowledge requirement for § 271(c) infringement and concluding that “it follows that the same knowledge is needed for induced infringement under § 271(b),” because the provisions have a “common origin”).

<sup>73</sup> *Id.* at 2068–69.

<sup>74</sup> *Id.* at 2069.

<sup>75</sup> *Id.* at 2068–69.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.* at 2069.

the doctrine” in “slightly different ways.”<sup>78</sup> However, the Court did provide guidance by specifying “two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.”<sup>79</sup> With those basic requirements, the Supreme Court suggested, willful blindness has:

an appropriately limited scope that *surpasses recklessness* and negligence. Under this formulation, a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can *almost be said to have actually known* the critical facts. By contrast, a *reckless defendant is one who merely knows of a substantial and unjustified risk of such wrongdoing* and a negligent defendant is one who should have known of a similar risk but, in fact, did not.<sup>80</sup>

Finding an exact standard to be lacking in patent law, the Supreme Court borrowed this standard of willful blindness from criminal law and applied it to the case.<sup>81</sup> The Court held that, in deliberately copying an overseas model of SEB’s deep fryer, Pentalpha’s actions met the willful blindness standard, as did its decision not to tell the attorney doing the patent search that it had copied SEB’s product.<sup>82</sup> Based on this standard, the Court found no need to remand the case for a new trial and simply affirmed the holdings of the lower courts.<sup>83</sup>

## IV. The State of Fraud in Trademark Law

### A. The Complexities of the Trademark Trial and Appeal Board

The Trademark Trial and Appeal Board (“TTAB”) is the administrative tribunal within the USPTO that hears and decides *ex parte* appeals, as well as *inter partes* trials on oppositions, cancellations, and concurrent use trademark proceedings.<sup>84</sup>

The breadth of subject matter in TTAB proceedings is as wide as the variety of goods and services in U.S. commerce, ranging from computer software, to perfume, to medical devices.<sup>85</sup> Substantively, the TTAB judges and the attorneys who practice before them must parse through complex concepts

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<sup>78</sup> *Id.* at 2070.

<sup>79</sup> *Id.* See discussion on meaning of “willful blindness” *infra* Part V.A.

<sup>80</sup> *Id.* at 2070–71 (emphasis added) (first citation omitted) (citing MODEL PENAL CODE, §§ 2.02(2)(c)–(d) (1985)).

<sup>81</sup> See *id.* at 2071.

<sup>82</sup> See *id.*

<sup>83</sup> See *id.* at 2072.

<sup>84</sup> See *Trademark Trial and Appeal Board*, U.S. PATENT & TRADEMARK OFFICE, <http://www.uspto.gov/trademarks/process/appeal/index.jsp> (last visited Oct. 28, 2011).

<sup>85</sup> In 2010, for example, the TTAB issued precedential decisions involving complex issues with goods or services in all of these categories. See *In re Iolo Techs. LLC*, 95 U.S.P.Q.2d (BNA) 1498 (T.T.A.B. 2010) (computer software); *Toufigh v. Persona Parfum Inc.*, 95

like likelihood of confusion, involving the same type of analysis as trademark infringement, fraud, descriptiveness and misdescriptiveness, allegations of inappropriate subject matter, abandonment, and functionality, as well as other claims.<sup>86</sup> Procedurally, cases can be equally convoluted. In inter partes cases especially, the TTAB follows the Federal Rules of Evidence and the Federal Rules of Civil Procedure, requiring parties to observe the same discovery rules used in federal district courts.<sup>87</sup>

In inter partes cases, discovery can be intricate, particularly where a great deal is at stake for the parties and where highly complex technical and/or substantive trademark issues are involved.<sup>88</sup> There are times when a trademark dispute can jeopardize a whole product line, or even an entire company.<sup>89</sup> Thus, parties often exchange voluminous financial and other documents over the months or years of an ongoing TTAB proceeding, sometimes under protective order.<sup>90</sup> A number of parties choose to include expert testimony as well, whether on technical, linguistic, or other issues.<sup>91</sup>

Accordingly, as a result of frequent motions practice, depositions (in discovery and at trial), and voluminous records, TTAB judges and the attorneys who practice before them become experts on the complex substance of trademark law, the convoluted procedure of federal civil law, and the intricacies of the USPTO.<sup>92</sup>

Although litigants may appeal TTAB decisions to the federal district courts or to the Federal Circuit,<sup>93</sup> the TTAB has repeatedly referred to the Federal

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U.S.P.Q.2d (BNA) 1872 (T.T.A.B. 2010) (perfume products); *Edwards Lifesciences Corp. v. Vigilanz Corp.*, 94 U.S.P.Q.2d (BNA) 1399 (T.T.A.B. 2010) (medical devices).

<sup>86</sup> See, e.g., *In re Hotels.com, L.P.*, 573 F.3d 1300, 1301 (Fed. Cir. 2009) (descriptiveness); *Eco Mfg. LLC v. Honeywell Int'l*, 295 F. Supp. 2d 854, 863 (S.D. Ind.), *aff'd*, 357 F.3d 649 (7th Cir. 2003) (inappropriate subject matter, functionality); *In re Iolo Techs.*, 95 U.S.P.Q.2d (BNA) at 1501 (likelihood of confusion); *Toufigh*, 95 U.S.P.Q.2d (BNA) at 1874, 1876 (abandonment, fraud).

<sup>87</sup> See 37 C.F.R. §§ 2.120(a), 2.122(a) (2010).

<sup>88</sup> See John M. Murphy, *Playing the Numbers: A Quantitative Look at Section 2(d) Cases Before the Trademark Trial and Appeal Board*, 94 TRADEMARK REP. 800, 819 (2004).

<sup>89</sup> See Harold R. Weinberg, *Is The Monopoly Theory of Trademarks Robust or A Bust?*, 13 J. INTELL. PROP. L. 137, 148 (2005) (“A strongly-ingrained trademark is an entrance barrier if it bars competitors from entering the market for the trademarked product.”).

<sup>90</sup> See Murphy, *supra* note 88 at 801, 810 n.49, 817.

<sup>91</sup> See *id.* at 804–05 (discussing expert testimony of English professors and regarding the use of consumer survey results).

<sup>92</sup> See, e.g., *DaimlerChrysler Corp. v. Am. Motors Corp.*, 94 U.S.P.Q.2d (BNA) 1086 (T.T.A.B. 2010) (demonstrating the complexity of trademark cases before the TTAB).

<sup>93</sup> 15 U.S.C. § 1071 (2006).



Circuit as its “primary reviewing court.”<sup>94</sup> Accordingly, the TTAB looks most closely to jurisprudence from the Federal Circuit for guidance on the laws of trademark registration and registrability. In that regard, although appeals from the TTAB comprise a small percentage of the Federal Circuit’s jurisdiction,<sup>95</sup> they represent an important area of the court’s overall jurisdictional basis, in no small part because of its close association with patent law, with jurisdiction over such disputes being one of the major rationales for the court’s creation in 1982.<sup>96</sup> The Federal Circuit characterizes the bulk of its cases (44 percent) as being in some area of “intellectual property,” followed by administrative law appeals (37 percent).<sup>97</sup> Appeals from the TTAB fall into both categories.<sup>98</sup> Accordingly, it appears quite logical, even axiomatic, that the TTAB and those who practice before it should look to Federal Circuit cases (in addition to those of the Supreme Court) for bearing on TTAB proceedings, not only in the field of trademark appeals, but also the area of intellectual property more generally and administrative law.

Meanwhile, although the TTAB refers to the Federal Circuit as its “primary reviewing court,” it is not the only statutorily authorized reviewing court for TTAB proceedings.<sup>99</sup> This begs the question—what happens if there is a circuit split on an issue of trademark registrability? That issue is addressed, *infra*, in Part IV.C.

### **B. *In re Bose*: The Federal Circuit Standard**

In 2009, the Federal Circuit changed the landscape of fraud on the USPTO.<sup>100</sup> For years, the trademark community had restlessly been anticipating a Federal Circuit case that would test the scienter requirement set up by the TTAB in

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<sup>94</sup> See, e.g., *In re Giovanni Food Co.*, 97 U.S.P.Q.2d (BNA) 1990, 1992 (T.T.A.B. 2011); *Edwards Lifesciences Corp. v. Vigilanz Corp.*, 94 U.S.P.Q.2d (BNA) 1399, 1414 (T.T.A.B. 2010); *Fiat Grp. Auto. S.p.A. v. ISM Inc.*, 94 U.S.P.Q.2d (BNA) 1111, 1113 (T.T.A.B. 2010); *Safer Inc. v. OMS Invs. Inc.*, 94 U.S.P.Q.2d (BNA) 1031, 1036 (T.T.A.B. 2010); *DaimlerChrysler*, 94 U.S.P.Q.2d (BNA) at 1089 n.6; *Giersch v. Scripps Networks Inc.*, 90 U.S.P.Q.2d (BNA) 1020, 1024 (T.T.A.B. 2009).

<sup>95</sup> *Appeals Filed, by Category, FY 2010*, U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT, [http://www.cafc.uscourts.gov/images/stories/the-court/statistics/Caseload\\_by\\_Category\\_Appeals\\_Filed\\_2010.pdf](http://www.cafc.uscourts.gov/images/stories/the-court/statistics/Caseload_by_Category_Appeals_Filed_2010.pdf) (last visited Oct. 10, 2011).

<sup>96</sup> See Brian Dean Abramson, *A Question of Deference: Contrasting the Patent and Trademark Jurisdiction of the Federal Circuit*, 29 TEMP. J. SCI. TECH. & ENVTL. L. 1, 17–18 (2010).

<sup>97</sup> *Appeals Filed, by Category, FY 2010*, *supra* note 95.

<sup>98</sup> See Abramson, *supra* note 96, at 8 n.46.

<sup>99</sup> 15 U.S.C. § 1071 (2006).

<sup>100</sup> See *In re Bose Corp.*, 580 F.3d 1240 (Fed. Cir. 2009).

*Medinol v. Neuro Vasx, Inc.*,<sup>101</sup> and applied in follow-on cases.<sup>102</sup> Many practitioners were uneasy with what they believed was a lessened scierer requirement being used by the Board post-*Medinol*. These critics finally got their chance to hear a challenge to that standard with *In re Bose*.<sup>103</sup> The American Intellectual Property Law Association (“AIPLA”) was quick to file an amicus brief with the Federal Circuit stating what it believed should be the stronger standard of scierer used to find fraud.<sup>104</sup>

In the TTAB proceeding, Bose had initiated an opposition against Hexawave alleging, among other things, likelihood of confusion with Bose’s registered marks, including WAVE.<sup>105</sup> Hexawave counterclaimed for cancellation of WAVE, asserting that Bose had committed fraud in its trademark renewal application by claiming use on all goods identified therein when, in fact, Bose was no longer using the mark WAVE “in commerce” (within the meaning of the Lanham Act<sup>106</sup>) on audio tape recorders and players.<sup>107</sup> Testifying under oath, the general counsel for Bose admitted that the company was no longer manufacturing and selling the identified goods under the WAVE mark, but he stated that he believed Bose was using the mark in commerce, because it was continuing to repair and ship goods that had been previously sold and, in some cases, were still under warranty.<sup>108</sup> The Board concluded that: (1) the repairs did not constitute use in commerce; (2) the general counsel’s belief that they did was not reasonable; and (3) the misstatement was material to the renewal application.<sup>109</sup> Accordingly, the Board found that Bose had committed fraud on the USPTO.<sup>110</sup>

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<sup>101</sup> 67 U.S.P.Q.2d (BNA) 1205, 1209 (T.T.A.B. 2003), *abrogated by* DaimlerChrysler Corp. v. Am. Motors Corp., 94 U.S.P.Q.2d (BNA) 1086 (T.T.A.B. 2010).

<sup>102</sup> *See, e.g.*, Hachette Filipacchi Presse v. Elle Belle LLC, 85 U.S.P.Q.2d (BNA) 1090, 1094 (T.T.A.B. 2007).

<sup>103</sup> *In re Bose*, 580 F.3d at 1244–45.

<sup>104</sup> Brief for American Intellectual Property Law Association as Amicus Curiae Supporting Appellant, *In re Bose Corp.*, 580 F.3d 1240 (Fed. Cir. 2009) (No. 2008-1448). The AIPLA brief advocated a five-part common-law fraud test: (1) false representation; of (2) a material fact; (3) made with the intent to deceive; where there is (4) reliance; and (5) resulting injury. *Id.* at 1–2.

<sup>105</sup> *Bose Corp. v. Hexawave, Inc.*, 88 U.S.P.Q.2d (BNA) 1332 (T.T.A.B. 2007), *rev’d*, *In re Bose Corp.*, 580 F.3d 1240 (Fed. Cir. 2009).

<sup>106</sup> *See* 15 U.S.C. §§ 1051–1129 (2006).

<sup>107</sup> *Bose Corp.*, 88 U.S.P.Q.2d (BNA) at 1335.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 1242–43.

<sup>110</sup> *Id.* at 1243. The Board sanctioned Bose by cancelling its WAVE mark registration. *Id.*



On appeal, the Federal Circuit reviewed the legal conclusions of the Board *de novo* and the factual conclusions for substantial evidence.<sup>111</sup> Throughout its decision, the Federal Circuit strongly emphasized the heightened proof needed to find fraud on the USPTO, concluding that fraud can only be found where a party (1) knowingly makes a (2) false statement; of (3) material fact; with (4) intent to deceive the USPTO.<sup>112</sup> The claim, it clarified, must be “proven ‘to the hilt’ with clear and convincing evidence.”<sup>113</sup>

The Federal Circuit found that the statement that Bose was selling the audio tape recorders and players in commerce was indeed false.<sup>114</sup> It also found that Bose had not disputed that the statement was material.<sup>115</sup> Accordingly, the only remaining question was whether the statement was made knowingly and with “intent to deceive the [USPTO].”<sup>116</sup> After all, the Federal Circuit explained, mere falsity does not fraud make.<sup>117</sup> The Federal Circuit noted that “absent the requisite *intent to mislead* the [USPTO], even a material misrepresentation would not qualify as fraud under the Lanham Act warranting cancellation.”<sup>118</sup> Otherwise stated, “[t]here is no fraud if a false misrepresentation is occasioned by an honest misunderstanding or inadvertence without a willful intent to deceive.”<sup>119</sup>

It is incumbent on a court, then, to find scienter. That is, the court must find that the false statement was knowingly made with intent to deceive the USPTO.<sup>120</sup> The Federal Circuit specifically rejected the language adopted by the *Medinol* line of cases, where the Board had applied a “should know” or “should have known” standard.<sup>121</sup> The Federal Circuit equated this with

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<sup>111</sup> *In re Bose Corp.*, 580 F.3d 1240, 1243 (Fed. Cir. 2009). Because the original appellee, Hexawave, did not appear, the PTO sought and obtained leave from the Federal Circuit to participate as a party. *Id.* Accordingly, the style of the case was changed to *In re Bose*.

<sup>112</sup> *Id.* at 1243–45.

<sup>113</sup> *Id.* at 1243 (quoting *Smith Int’l, Inc. v. Olin Corp.*, 209 U.S.P.Q. (BNA) 1033, 1044 (T.T.A.B. 1981)).

<sup>114</sup> *Id.* at 1246.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.* at 1245–46.

<sup>117</sup> *Id.* at 1246.

<sup>118</sup> *Id.* at 1243 (emphasis added) (citing *King Auto., Inc. v. Speedy Muffler King, Inc.*, 667 F.2d 1008, 1011 n.4 (C.C.P.A. 1981)).

<sup>119</sup> *Id.* at 1246.

<sup>120</sup> *Id.* at 1245.

<sup>121</sup> *Id.* at 1244–45.

a “simple negligence standard”<sup>122</sup> that would not be sufficient to satisfy the knowledge needed to find a willful intent to deceive.<sup>123</sup>

The Federal Circuit just as specifically declined to address whether a recklessness standard might be acceptable. The only place in the decision that discusses recklessness is a footnote wherein the court stated:

The [USPTO] argues that under *Torres*, making a submission to the [USPTO] with reckless disregard of its truth or falsity satisfies the intent to deceive requirement. *We need not resolve this issue here.* Before [Bose’s general counsel] submitted his declaration in 2001, neither the [USPTO] nor any court had interpreted ‘use in commerce’ to exclude the repairing and shipping [sic] repaired goods. Thus, *even if we were to assume that reckless disregard qualifies*, there is no basis for finding [Bose’s general counsel’s] conduct reckless.<sup>124</sup>

Vigorously dismissing “should know” (and “should have known”), the Federal Circuit thus appears to have deliberately left open the question of “reckless disregard” and, along with it, a bundle of questions about what that might even mean in this context. However, this was done in a footnote in dictum, and whether the court truly intended to leave the question open for future interpretation remains unclear. If so, any court intending to apply a recklessness standard would need to reconcile it with the rather condemning language surrounding the footnote and supporting the holding, in short requiring that the subject conduct must be both “knowing” and made with “willful intent to deceive.”<sup>125</sup>

### C. The Outstanding Issue of “Recklessness” in Fraud

The Restatement of Torts defines “recklessness” as the “conscious disregard” of a substantial risk of serious harm.<sup>126</sup> One commentator has noted that

<sup>122</sup> *Id.* at 1244. The Federal Circuit acknowledged that the Board had been relying on the exact wording of “knows or should know” from the earlier Federal Circuit ruling of *Torres v. Cantine Torresella S.r.l.*, 808 F.2d 46, 49 (Fed. Cir. 1986). See *Bose*, 580 F.3d at 1245.

<sup>123</sup> *Bose*, 580 F.3d at 1246.

<sup>124</sup> *Id.* at 1247 n.2 (emphasis added).

<sup>125</sup> *Id.* at 1245–46.

<sup>126</sup> RESTATEMENT (SECOND) OF TORTS § 500 (1965) states:

The actor’s conduct is in reckless disregard of the safety of another if he does an act or intentionally fails to do an act which it is his duty to the other to do, knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent. . . . Special Note: the conduct described in this Section is often called “wanton or willful misconduct” both in the statutes and judicial opinions. On the other hand, this phrase is sometimes used by courts to refer to conduct intended to cause harm to another.

*Id.* (emphasis added).

“‘[r]ecklessness’ is one of the oldest concepts in Anglo-American tort law, and it is also one of the most poorly understood.”<sup>127</sup> As all students learn in law school, it theoretically falls on the spectrum somewhere between negligence and an intentional tort.<sup>128</sup> However, applying this concept is not always so simple.

In fact, many federal courts have applied the recklessness standard as an appropriate scienter requirement for fraud claims, albeit in other contexts.<sup>129</sup> In one recent case involving a securities fraud claim, the Supreme Court assumed without deciding that the scienter requirement could be satisfied upon a showing of “deliberate recklessness.”<sup>130</sup> The Court determined that “‘a reasonable person’ would deem the inference that [petitioner] acted with deliberate recklessness . . . ‘at least as compelling as any [plausible] opposing inference.’”<sup>131</sup> In securities fraud cases, courts have also foregone the deliberate recklessness standard for one of simple recklessness.<sup>132</sup>

Federal courts have also applied recklessness as a scienter requirement to cases of common-law fraud.<sup>133</sup> One earlier Supreme Court case referred to

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<sup>127</sup> Geoffrey Christopher Rapp, *The Wreckage of Recklessness*, 86 WASH. U. L. REV. 111, 111 (2008) (noting that courts have applied recklessness variably, sometimes with negligence, sometimes with intentional torts).

<sup>128</sup> *Id.* at 116 & n.17 (citing ARTHUR BEST & DAVID W. BARNES, BASIC TORT LAW: CASES STATUTES AND PROBLEMS, 128 (2d ed. 2007) (“In terms of fault or blameworthiness, recklessness falls in between intentional tort and negligence.”); DOMINICK VETRI ET AL., TORT LAW & PRACTICE 17 (3d ed. 2006) (“Recklessness is a more culpable type of fault than negligence and usually can be invoked in accident situations where the conduct shows a conscious disregard of a high risk of harm. Recklessness falls somewhere between intentional misconduct and negligence on the culpability continuum.”)).

<sup>129</sup> *See, e.g.*, *Ottmann v. Hanger Orthopedic Grp., Inc.*, 353 F.3d 338, 343 (4th Cir. 2003) (citing various circuits’ adoptions of recklessness as scienter for securities fraud).

<sup>130</sup> *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1323–24 (2011).

<sup>131</sup> *Id.* at 1325 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2011)) (finding sufficient culpability alleged to allow a securities class action to go forward).

<sup>132</sup> *See In re J.P. Jeanneret Assocs., Inc.*, 769 F. Supp. 2d 340, 354 (S.D.N.Y. 2011) (“A ‘strong inference’ of scienter can be established through factual allegations showing ‘motive and opportunity to commit fraud’ or ‘strong circumstantial evidence of conscious misbehavior or recklessness.’” (quoting *In re AOL Time Warner, Inc. & ERISA Litig.*, 381 F. Supp. 2d 192, 218 (S.D.N.Y. 2004))).

<sup>133</sup> Under Massachusetts common-law, for example, it is sufficient if a defendant “‘acted with a high degree of recklessness’ as to the truth of the matter.” *In re Access Cardiosystems, Inc.*, 404 B.R. 593, 650 (Bankr. D. Mass. 2009) (finding that investors had alleged insufficient knowledge, and overly optimistic claims were not “false representations”). A district court applying Pennsylvania law recently found simple “recklessness” to be sufficient for fraud, stating that, “[i]n Pennsylvania, a claim for fraud must allege: ‘(1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false.’” *PPG Indus., Inc. v. Generon IGS*,

“recklessness, tantamount to fraud” as an appropriate common-law standard.<sup>134</sup> Accordingly, it seems not atypical for courts to apply recklessness as a standard of scienter in fraud.

Federal courts have also accepted a scienter requirement based on varying levels of recklessness for cases involving bankruptcy fraud.<sup>135</sup> Some federal bankruptcy courts require gross recklessness,<sup>136</sup> while others find mere reckless disregard to be sufficient.<sup>137</sup>

Interestingly, in some areas of common-law fraud, there appears to be a minority view of strict liability of fraud, thereby making even a showing of recklessness unnecessary.<sup>138</sup> In one case, the court stated:

It is important to emphasize that, in Minnesota, the element of scienter, or intent to deceive, or *even recklessness*, is not necessary to actionable fraud. As the Minnesota Supreme Court stated . . . : “It is immaterial whether a statement made as of one’s own knowledge is made innocently or knowingly. An intent to deceive no longer is necessary. Nor is it necessary to prove that defendants knew the representations were false. . . . *It is not necessary that the statement be recklessly or carelessly made.* It makes no difference how it is made if it is made as an affirmation of which defendant has knowledge and it is in fact untrue. The right of recovery in a case of this kind is based on the fact that such statement, being untrue in fact, relied upon by the other party

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Inc., 760 F. Supp. 2d 520, 527 (W.D. Pa. 2011) (quoting *Manning v. Temple Univ.*, No. Civ. A. 03-4012, 2004 WL 3019230, at \*10 (E.D. Pa. Dec. 30, 2004)) (discussing state and federal cases, and finding fraud sufficiently alleged to survive a motion to dismiss). Similarly, “[u]nder Ohio law, it is not necessary that the defendant have actual knowledge that a statement is false. It is sufficient if the statement is made with utter and reckless disregard for whether it is true or not.” *Dunn Appraisal Co. v. Honeywell Info. Sys., Inc.*, 687 F.2d 877, 883 (6th Cir. 1982) (finding fraud based on misrepresentations regarding viability of computer); *see also State ex rel. Quest Diagnostics, Inc. v. Indus. Comm’n*, 2011-Ohio-78, 2011 WL 193423, at ¶ 62 (finding no intent to defraud even where the form was filled out by someone other than the claimant).

<sup>134</sup> *Lord v. Goddard*, 54 U.S. (13 How.) 198, 209 (1852).

<sup>135</sup> Note that the wording of the Bankruptcy statute simply exempts from discharge money taken under “false pretenses, a false representation, or actual fraud.” 11 U.S.C. § 523(a)(2)(A) (2006). It does not provide a standard of scienter for finding the fraud. Rather, this has been developed by case law. *See, e.g., Palmacci v. Umpierrez*, 121 F.3d 781, 787 (1st Cir. 1997).

<sup>136</sup> *See, e.g., In re May*, 448 B.R. 197, 200 (Bankr. W.D. Mich. 2011) (finding no fraud where a person had taken cash advances on a credit card shortly before filing for bankruptcy, because there was no showing of at least “gross recklessness”); *In re Metzger*, 442 B.R. 121, 124 (Bankr. S.D. Ohio 2010) (using a gross recklessness standard in finding no fraud in the cashing of a check).

<sup>137</sup> *See, e.g., In re Ireland*, 441 B.R. 572, 585 (Bankr. W.D. Ky. 2011) (finding no fraud by one debtor, because she “did not have a reckless disregard for the truth” of financial statements).

<sup>138</sup> *See, e.g., Clements Auto Co. v. Serv. Bureau Corp.*, 444 F.2d 169, 176 (8th Cir. 1971) (affirming in part damages based on misrepresentations).

in entering into the transaction, has resulted in the loss to him which he should not be required to bear.”<sup>139</sup>

This is not to say that the post-*In re Bose* Federal Circuit will or should apply recklessness as a scienter requirement for fraud on the USPTO. For these claims, courts will have to decide for themselves the meaning of recklessness (or “reckless disregard”) and whether or not the standard should be applied given the language of *In re Bose*. In this regard, it is interesting to note that the Federal Circuit has not categorically rejected the concept of recklessness as a scienter requirement. Rather, the court recently determined, in an en banc opinion, that willful infringement (in patent law) may be found with a showing of objective recklessness.<sup>140</sup>

Accordingly, whether the Federal Circuit truly left open the option of reckless disregard as a standard for scienter for claims of fraud on the USPTO will be decided, perhaps after much haranguing, by courts in cases to come.

District courts have taken note that the Federal Circuit clearly and overtly intended to raise the bar on finding fraud.<sup>141</sup> Several post-*In re Bose* cases have noted a heavy burden of proof, and some have specifically stated that it is higher now than it was before.<sup>142</sup> One court declined to find fraud, despite allegations that the registrant had knowledge that another had used a confusingly similar mark at the time they signed the affidavit of federal registration denying that anyone else had the “right to use” it.<sup>143</sup> Another court similarly declined to find fraud with regard to a registrant’s sworn statement of exclusivity

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<sup>139</sup> *Id.* (emphasis added) (quoting *Swanson v. Downing*, 86 N.W.2d 716, 720–21 (Minn. 1957)).

<sup>140</sup> *In re Seagate Tech., LLC*, 497 F.3d 1360, 1370–71 (Fed. Cir. 2007) (en banc) (relying on copyright law as outlined by “sister circuits” for support, and the Restatement of Torts’ definition of “reckless”).

<sup>141</sup> See e.g., *WMH Tool Grp. Inc. v. Woodstock Int’l*, No. 07-cv-3885, 2009 WL 6825247, at \*7 n.3 (N.D. Ill. Dec. 9, 2009) (referring to *In re Bose* as having “discredited” the previous, lessened scienter standard used by the Board).

<sup>142</sup> See e.g., *Scooter Store Inc. v. SpinLife.com, LLC*, 777 F. Supp. 2d 1102, 1110, 1113 (S.D. Ohio 2011) (finding *In re Bose* established a high standard, whereby applicant must knowingly make a material false statement with “intent to deceive”); *Bauer Bros. LLC v. Nike Inc.*, 98 U.S.P.Q.2d (BNA) 1160, 1164 (S.D. Cal. 2011) (relying on *In re Bose* for stronger fraud standard); *Spin Master v. Zobmondo Entm’t*, No. 2:07-cv-00571, slip op. at 15 (C.D. Cal. Feb. 22, 2011) (order granting motion for summary judgment on fraud counterclaim) (stating that “[t]he burden to prove fraud is ‘heavy’”); *Alliance Bank v. New Century Bank*, 742 F. Supp. 2d 532, 551 (E.D. Pa. 2010) (referring to *In re Bose* as having clarified the “heavy burden of proof” in fraud); *WMH*, 2009 WL 6825247, at \*7 n.3 (referring to *In re Bose* as having “discredited” the previous lesser scienter standard used by the Board).

<sup>143</sup> *Scooter Store*, 777 F. Supp. 2d at 1110, 1111–13.

of use, despite allegations that the registrant was “fully aware of the historical significance and origin” of the words contained in the mark.<sup>144</sup>

The TTAB has similarly applied a heightened standard of fraud on the USPTO post-*In re Bose*.<sup>145</sup> However, the TTAB has also apparently taken the Federal Circuit’s *In re Bose* footnote at face value, accepting that the court did not decide the issue of recklessness or reckless disregard, and indeed may “assume that reckless disregard qualifies.”<sup>146</sup> The TTAB stated this in its own footnote in a post-*In re Bose* decision, explaining that, although the standard for scienter has been heightened by *In re Bose*, “[s]till open is the question whether a submission to the [USPTO] with reckless disregard of its truth or falsity would satisfy the intent to deceive requirement.”<sup>147</sup> It is worth noting that Professor J. Thomas McCarthy’s oft-cited treatise also states that the questions of whether reckless disregard may satisfy the scienter requirement in light of footnote two of *In re Bose* remain to be determined.<sup>148</sup> Citing the footnote, his treatise refers to the issue as “[r]emaining unclear”<sup>149</sup> and “[r]emaining to be determined.”<sup>150</sup>

Interestingly though, not every court has changed its scienter requirement for fraud on the USPTO post-*In re Bose*. In a case issued in the summer of 2011, the Second Circuit discussed the scienter requirement for finding fraud

<sup>144</sup> *Bauer Bros.*, 98 U.S.P.Q.2d (BNA) at 1164–65.

<sup>145</sup> See e.g., *M.C.I. Foods Inc. v. Bunte*, 96 U.S.P.Q.2d (BNA) 1544, 1547 (T.T.A.B. 2010) (quoting *In re Bose Corp.*, 580 F.3d 1240, 1243 (Fed. Cir. 2009)) (discussing the need to distinguish between a “false” representation and a “fraudulent” one”); *Toufigh v. Persona Parfum Inc.*, 95 U.S.P.Q.2d (BNA) 1872, 1876 (T.T.A.B. 2010) (quoting *In re Bose*, 580 F.3d at 1243) (noting the proposition that petitioner bears a heavy burden in proving falsity in fraud); *Meckatzer Lowenbrau Benedikt Weiss KG v. White Gold LLC*, 95 U.S.P.Q.2d (BNA) 1185, 1188 (T.T.A.B. 2010) (denying a motion to dismiss, and finding fraud sufficiently pleaded with “information and belief” coupled with “results of an investigation”); *DaimlerChrysler Corp. v. Am. Motors Corp.*, 94 U.S.P.Q.2d (BNA) 1086, 1089 (T.T.A.B. 2010) (finding “petitioner’s reliance on *Medinol* is no longer appropriate”); *Qualcomm Inc. v. Flo Corp.*, 93 U.S.P.Q.2d (BNA) 1768, 1770 (T.T.A.B. 2010) (dismissing a post-*In re Bose* fraud claim, because allegations that a party “‘knew or should have known’ were false or misleading are insufficient”); *Asian & W. Classics B.V. v. Selkow*, 92 U.S.P.Q.2d (BNA) 1478, 1479 (T.T.A.B. 2009) (fraud must be pleaded “with particularity” and not as a “mere possibility”); *Enbridge v. Excelerate Energy LP*, 92 U.S.P.Q.2d (BNA) 1537, 1540 (T.T.A.B. 2009) (citing *In re Bose*, 580 F.3d at 1246) (fraud cannot be found without a “willful intent to deceive”).

<sup>146</sup> See *In re Bose Corp.*, 580 F.3d 1240, 1246 n.2 (Fed. Cir. 2009).

<sup>147</sup> *Daimler Chrysler*, 94 U.S.P.Q.2d at 1089 & n.5 (citing *In re Bose*, 580 F.3d at 1244–45).

<sup>148</sup> See 6 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 31:66, at 31-149, 31-152 (4th ed. 2011).

<sup>149</sup> *Id.* § 31:61, at 31-143.

<sup>150</sup> *Id.* § 31:66, at 31-152.



on the USPTO.<sup>151</sup> Stating the elements of fraud (and upholding a jury verdict against the defendants), the Second Circuit held the applicable standard to be that “[t]he person making the representation knew *or should have known* that the representation was false (‘scienter’).”<sup>152</sup> In so stating, the Second Circuit neatly ignored *In re Bose*’s admonition to refrain from using the “should have known” standard in cases of fraud on the USPTO.<sup>153</sup> This can be presumed to be deliberate, because the Second Circuit cited, among other sources (including a previous version of McCarthy’s work), the *In re Bose* case itself.<sup>154</sup> Presumably, the Second Circuit intended to part from the Federal Circuit on the scienter requirement, although it did not specifically state that it was disagreeing with *In re Bose*, indeed, citing it for support. Accordingly, there appears to be a circuit split on the scienter requirement for the time being, at least between the Second Circuit and the Federal Circuit, potentially allowing parties to take advantage of that split on appeal from the TTAB (or perhaps in choosing venue for district court cancellation proceedings). It remains to be seen how other regional circuits will react to *In re Bose* and which direction they will follow. Meanwhile, even within the *In re Bose* line, it is unclear exactly how high a level of knowledge is sufficient, and whether recklessness or reckless disregard qualify to find fraud.

## V. Applying Willful Blindness—a Higher Standard—from Patent Law

### A. Defining the Doctrine of Willful Blindness

Meanwhile, there is a stronger standard that should be considered by courts seeking a higher level of scienter than recklessness. In *Global Tech*, the Supreme Court stated clearly that willful blindness is different from, and more demanding than, recklessness or negligence.<sup>155</sup> As noted in Part III, the Court gave some specific guidance, noting that, although willful blindness is characterized in “slightly different ways” by the various regional circuits, it may be broken down into “two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.”<sup>156</sup>

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<sup>151</sup> See *Patsy’s Italian Rest., Inc. v. Banas*, Nos. 08-4487-cv(L) & 08-4774-cv(XAP), 2011 WL 3687887, at \*12 (2d Cir. Aug. 24, 2011).

<sup>152</sup> *Id.* (emphasis added).

<sup>153</sup> *In re Bose Corp.*, 580 F.3d 1240, 1244–45 (Fed. Cir. 2009).

<sup>154</sup> See *Patsy’s Italian Rest.*, 2011 WL 3687877, at \*13.

<sup>155</sup> *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2070 (2011).

<sup>156</sup> *Id.*

Indeed, the regional circuits have given slightly different interpretations to the term “willful blindness,” primarily (though not exclusively) in criminal law,<sup>157</sup> and will no doubt continue to do so. These various interpretations can be instructive in deciding on a proper willful blindness standard for fraud on the USPTO. This section provides a survey of willful blindness definitions used by various federal circuit courts of appeals.

The First Circuit has defined “willful blindness” as “aware[ness] of a high probability” that an act is illegal, which the defendant(s) “consciously and deliberately avoided learning.”<sup>158</sup> It stated that “[w]illful blindness *serves as an alternate theory on which the government may prove knowledge.*”<sup>159</sup>

In contrast, the Second Circuit has created a “conscious avoidance doctrine,” similar to “willful blindness,” which provides:

that a defendant’s knowledge of a fact required to prove the defendant’s guilt may be found when the jury “is persuaded that the defendant consciously avoided learning that fact while aware of a high probability of its existence.” In such circumstances, a conscious avoidance instruction to the jury “*permits a finding of knowledge* even where there is no evidence that the defendant possessed actual knowledge.”<sup>160</sup>

The Third Circuit has stated that “willful blindness” requires an “element of knowledge,” which would be satisfied if the government proved “the defendant closed his eyes to what would otherwise have been obvious to the defendant. . . . *Stated another way, the defendant’s knowledge of a fact or circumstance may be inferred from his willful blindness to the existence of that fact and circumstance.*”<sup>161</sup>

In *United States v. Schnabel*,<sup>162</sup> the Fourth Circuit held that “[t]he willful blindness instruction allows the jury to *impute the element of knowledge* to the defendant if the evidence indicates that he purposely closed his eyes to avoid knowing what was taking place around him.”<sup>163</sup>

The Fifth Circuit finds “knowledge” from willful blindness appropriate where “(1) the defendant was subjectively aware of a high probability of the existence [of a fact]; and (2) the defendant purposefully contrived to avoid learning of the [fact].”<sup>164</sup>

The Sixth Circuit has upheld a willful blindness instruction, noting “this circuit has repeatedly upheld the district court’s knowledge instruction on

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<sup>157</sup> *See id.* at 2070 n.9.

<sup>158</sup> *United States v. Perez-Melendez*, 599 F.3d 31, 41 (1st Cir. 2010).

<sup>159</sup> *Id.* (emphasis added).

<sup>160</sup> *United States v. Svoboda*, 347 F.3d 471, 477–78 (2d Cir. 2003) (emphasis added) (quoting *United States v. Samaria*, 239 F.3d 228, 239 (2d Cir. 2001)).

<sup>161</sup> *United States v. Stadtmauer*, 620 F.3d 238, 253 (3rd Cir. 2010) (emphasis added).

<sup>162</sup> *United States v. Schnabel*, 939 F.2d 197, 203 (4th Cir. 1991).

<sup>163</sup> *Id.* at 203 (emphasis added).

<sup>164</sup> *United States v. Scott*, 159 F.3d 916, 922 (5th Cir. 1998).



the basis that it prevents a criminal defendant from escaping conviction merely by *deliberately closing his eyes* to the obvious risk that he is engaging in unlawful conduct.”<sup>165</sup>

The Seventh Circuit has upheld instruction and conviction on what the court refers to as an “ostrich instruction:”

*Knowledge may be inferred* from a combination of suspicion and *indifference to the truth*. If you find that the defendant had a strong suspicion that things were not what they seemed or that someone had withheld some important facts, yet shut his eyes for fear of what he would learn, you may conclude that he acted “knowingly” . . . [but] not . . . if he was merely negligent in not discovering the truth.<sup>166</sup>

The Eighth Circuit has defined “willful blindness,” in the context of upholding conviction and jury instruction, by stating:

[T]he government may prove that the defendant . . . *acted knowingly* by proving . . . that this defendant *deliberately closed her eyes to what would otherwise have been obvious to her*. No one can avoid responsibility for a crime by deliberately ignoring what is obvious. . . . Stated another way, a person’s knowledge of a particular fact *may be shown from a deliberate or intentional ignorance* or deliberate or intentional blindness to the existence of that fact.<sup>167</sup>

Similarly, in *United States v. Heredia*,<sup>168</sup> the Ninth Circuit upheld the willful blindness instruction and conviction. There, the court explained that:

deliberate ignorance, otherwise known as willful blindness, is categorically different from negligence or recklessness. A willfully blind defendant is one who took *deliberate* actions to avoid confirming suspicions of criminality. A reckless defendant is one who merely knew of a substantial and unjustifiable risk that his conduct was criminal; a negligent defendant is one who should have had similar suspicions but, in fact, did not.<sup>169</sup>

Therefore, the court held that “willful blindness is tantamount to knowledge.”<sup>170</sup>

The Tenth Circuit has stated that willful blindness depends on “whether there was a conscious purpose to avoid enlightenment.”<sup>171</sup>

Finally, the Eleventh Circuit has determined that:

A “deliberate ignorance” instruction is appropriate when “the facts . . . support the inference that the defendant was aware of a high probability of the existence of the fact in question and purposely contrived to avoid learning all of the facts in order to have a defense in the event of a subsequent prosecution.”<sup>172</sup>

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<sup>165</sup> *United States v. Holloway*, 731 F.2d 378, 381 (6th Cir. 1984) (per curiam) (emphasis added).

<sup>166</sup> *United States v. Draves*, 103 F.3d 1328, 1333 (7th Cir. 1997) (emphasis added).

<sup>167</sup> *United States v. Florez*, 368 F.3d 1042, 1044 (8th Cir. 2004) (emphasis added).

<sup>168</sup> 483 F.3d 913 (9th Cir. 2007) (en banc).

<sup>169</sup> *Id.* at 918 n.4 (citation omitted).

<sup>170</sup> *Id.* at 922 n.13.

<sup>171</sup> *Griego v. United States*, 298 F.2d 845, 849 (10th Cir. 1962).

<sup>172</sup> *United States v. Perez-Tosta*, 36 F.3d 1552, 1564 (11th Cir. 1994) (quoting *United States v. Rivera*, 944 F.2d 1563, 1571 (11th Cir. 1991)).

In many of the above-cited cases from the regional circuits, the crime at issue involved fraud, and the courts readily applied willful blindness as an appropriate standard of scienter.<sup>173</sup> Accordingly, it would not be a great stretch for a court in any jurisdiction to apply the doctrine to other types of fraud, including fraud on the USPTO. There is precedent, even in Federal Circuit jurisprudence, for a standard akin to willful blindness, including opinions finding conduct to be willful.<sup>174</sup> Although these statements were made in the context of patents, the Federal Circuit has shown its acceptance of cross-applying relevant doctrines between patent and trademark law.<sup>175</sup> Accordingly, to cross-apply a doctrine from patent jurisprudence, where appropriate, to trademark law, is also acceptable and indeed prescient.<sup>176</sup>

## **B. Other Legal Bases for Considering Willful Blindness in Trademark Law**

The doctrine of willful blindness has also been applied by regional circuits in various trademark cases as a substitute for actual knowledge.<sup>177</sup> Furthermore, the Second Circuit has quoted the Seventh Circuit's statement that "willful

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<sup>173</sup> Note, too, that most of these cases were cited by the Supreme Court in *Global-Tech* as grounds for cross-applying willful blindness to patent law. See *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2070 n.9 (2011).

<sup>174</sup> See e.g., *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics Inc.*, 976 F.2d 1559, 1581 (Fed. Cir. 1992) (stating that "[a]s this court warned in *Ryco*, '[a]n alleged infringer who intentionally blinds himself to the facts and law, continues to infringe, and employs the judicial process with no solidly based expectation of success, can hardly be surprised when his infringement is found to have been willful.'" (quoting *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1429 (Fed. Cir. 1988))). Of course, as noted *supra* in Part IV.C, the Federal Circuit has indicated that it would find willfulness on even the lowered scienter of recklessness. See *In re Seagate*, 497 F.3d 1360, 1369–71 (Fed. Cir. 2007) (en banc) (relying for support on copyright law as outlined by "sister circuits," as well as on the Restatement of Torts' definition of recklessness).

<sup>175</sup> See *supra* note 49 and cases cited therein.

<sup>176</sup> See *In re Bose Corp.*, 580 F.3d 1240, 1244–45 (Fed. Cir. 2009) ("The principle that the standard for finding intent to deceive is stricter than the standard for negligence or gross negligence, even though announced in patent inequitable conduct cases, applies with equal force to trademark fraud cases.").

<sup>177</sup> See *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93, 109 (2d Cir. 2010) (finding that willful blindness would not act as a shield for finding knowledge); *Fonovisa v. Cherry Auction Inc.*, 76 F.3d 259, 265 (9th Cir. 1996) (borrowing persuasive Seventh Circuit precedent in applying willfully blind as the standard for contributory trademark infringement); *Chanel, Inc. v. Italian Activewear of Fla., Inc.*, 931 F.2d 1472, 1476 (11th Cir. 1991) (accepting the district court's reference to the Seventh Circuit's willful blindness standard in a counterfeit claim); *Louis Vuitton S.A. v. Lee*, 875 F.2d 584, 590 (7th Cir. 1989) (reversing with direc-

blindness is equivalent to actual knowledge for purposes of the Lanham Act.”<sup>178</sup> Indeed, if this is so, as various regional circuits have held, then it may be no great stretch to apply willful blindness as a standard of knowledge in cases of fraud on the USPTO, a matter clearly contemplated by the Lanham Act.<sup>179</sup>

### C. Finding the Right Scierter for Fraud on the USPTO

In the aftermath of *In re Bose*, courts have been left to determine which scierter requirement is applicable to trademark parties involved in claims of fraud on the USPTO. The Federal Circuit clarified that fraud can only be found where a statement was made knowingly and with “intent to deceive the [USPTO].”<sup>180</sup> However, arriving at the proper level of knowledge is not always a simple matter. Courts are left with three possibilities.

First, courts could insist on a very strict interpretation of the word “knowing.” In this scenario, only the highest and strictest interpretation of the word would satisfy a post-*In re Bose* finding of fraud. Combining the high standard of scierter with the need for a “willful intent to deceive,”<sup>181</sup> courts may simply find that post-*In re Bose* plaintiffs cannot adequately plead or prove fraud without showing the requisite knowledge of its falsity.

Second, courts could determine that a lower level of recklessness or reckless disregard satisfies the post-*In re Bose* scierter requirement of knowledge. The *In re Bose* opinion itself noted that the court did not “resolve this issue,”<sup>182</sup> thereby leaving it open for future courts to decide. In one post-*In re Bose* case, the TTAB likewise noted that the possibility of applying reckless disregard as a scierter requirement is “[s]till open,”<sup>183</sup> a sentiment echoed by Professor McCarthy’s treatise.<sup>184</sup> As noted in Part IV.C, federal courts have applied recklessness to other areas of fraud, including securities fraud, bankruptcy

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tions for findings on damages in sale of counterfeits, the appellate court noted that “[w]illful blindness is knowledge enough.”)

<sup>178</sup> *Tiffany (NJ)*, 600 F.3d at 110 (quoting *Hard Rock Café Licensing Corp. v. Concession Servs., Inc.*, 955 F.2d 1143, 1149 (7th Cir. 1992) (“To be willfully blind, a person must suspect wrongdoing and deliberately fail to investigate.”)).

<sup>179</sup> See 15 U.S.C. § 1064(3) (2006).

<sup>180</sup> *In re Bose*, 580 F.3d at 1245.

<sup>181</sup> *Id.* at 1246.

<sup>182</sup> *Id.* at 1246 n.2.

<sup>183</sup> *DaimlerChrysler Corp. v. Am. Motors Corp.*, 94 U.S.P.Q.2d (BNA) 1086, 1089 n.5 (T.T.A.B. 2010).

<sup>184</sup> See MCCARTHY, *supra* note 148, §§ 31:61, 31:66.

fraud, and common-law fraud.<sup>185</sup> Additionally, the Federal Circuit itself has allowed it as a scienter requirement in other contexts.<sup>186</sup>

A third, and somewhat intriguing possibility, arose in the 2011 Supreme Court *Global-Tech* decision. There, the Court instructed the Federal Circuit and district courts to borrow the willful blindness standard from criminal law where an appropriate one was lacking in patent law.<sup>187</sup> This Article suggests that courts consider further extending this option to trademark cases, specifically where there are claims of fraud on the USPTO.

This Article has discussed the appropriate efforts of the Supreme Court to harmonize patent law with general jurisprudence, a goal clearly sought in *Global-Tech*.<sup>188</sup> It has also discussed the appropriate efforts of the Supreme Court and the lower courts—following legislative and other historical bonds—to harmonize patent, copyright, and trademark law with one another.<sup>189</sup> It is, therefore, quite logical to consider that the Supreme Court would want courts to extend the doctrine of willful blindness to other areas of law, including, where appropriate, copyright and trademark law.

In particular, willful blindness may be an appropriate standard for courts to apply as a scienter requirement for claims of fraud on the USPTO. In *In re Bose*, the Federal Circuit held that fraud can only be found where a false statement was knowingly made with a “willful intent to deceive” the USPTO.<sup>190</sup> The Supreme Court has clearly stated that willful blindness is a higher standard of scienter than recklessness and should be applied in appropriate contexts,

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<sup>185</sup> See *supra* Part IV.C.

<sup>186</sup> See *In re Seagate Tech. LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc) (adopting objective recklessness as the scienter requirement for willful infringement in patent law). Although this was a patent case, *id.* at 1368, the court looked to copyright law for guidance, *id.* at 1370, further supporting the concept that the three areas of intellectual property law should be aligned.

<sup>187</sup> *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2069 (2011). Note that the Supreme Court in *Global-Tech* did cite to one circuit that has issued a decision admonishing the growing trend of courts issuing conscious disregard or willful blindness instructions. *Id.* at 2070 n.9 (citing *United States v. Alston-Graves*, 435 F.3d 331, 339–41 (D.C. Cir. 2006)). The Court of Appeals for the D.C. Circuit questioned whether the instruction was inappropriate where actual knowledge was evident. See *Alston-Graves*, 435 F.3d at 336–39. The court found the willful blindness instruction to be harmless error. See *id.* at 342. This issue is not relevant in non-jury trials, which includes administrative proceedings at the TTAB.

<sup>188</sup> See *supra* Part I.

<sup>189</sup> See *supra* Part II.

<sup>190</sup> *In re Bose Corp.*, 580 F.3d 1240, 1245–46 (Fed. Cir. 2009).

looking for guidance to regional circuits’ well-developed jurisprudence on this standard of scienter.<sup>191</sup>

In *Global Tech*, the Supreme Court stated that, “[g]iven the long history of willful blindness and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits.”<sup>192</sup> While it is not entirely clear that the Federal Circuit (or other regional circuits applying these claims) would accept willful blindness as meeting the strict standards of *In re Bose*, the Supreme Court noted in *Global-Tech* that one who is willfully blind “can almost be said to have actually known” the facts.<sup>193</sup> The Court also condemningly stated that “[t]he traditional rationale for this doctrine is that defendants who behave in this manner are just as culpable as those who have actual knowledge.”<sup>194</sup> The doctrine has been applied by the Federal Circuit as a standard of knowledge in patent law,<sup>195</sup> as well as by various regional circuits to find knowledge in criminal law,<sup>196</sup> and scienter in certain trademark contexts, with several circuit courts comfortably saying that “willful blindness is equivalent to actual knowledge for purposes of the Lanham Act.”<sup>197</sup> All of this logically indicates that, under the *In re Bose* standard, willful blindness is an appropriate scienter requirement for finding fraud on the USPTO.

## Conclusion

While the Federal Circuit set forth a knowledge requirement for parties alleging fraud on the USPTO in their trademark disputes,<sup>198</sup> there are three viable interpretations of that level of scienter. Looking to other areas of law, it becomes apparent that “knowledge” may be interpreted to mean (1) actual knowledge; (2) recklessness or reckless disregard;<sup>199</sup> or, looking creatively to historically and legally-related patent law, as well as to other applications of

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<sup>191</sup> See *Global-Tech*, 131 S. Ct. at 2070. Certainly, there is a fine distinction between willful blindness and the standard that the Supreme Court displaced, “deliberate indifference to a known risk.” *Id.* at 2065. See *supra* Part V.A for various courts’ definitions of “willful blindness.”

<sup>192</sup> *Global-Tech*, 131 S Ct. at 2069.

<sup>193</sup> *Id.* at 2070–71.

<sup>194</sup> *Id.* at 2069.

<sup>195</sup> See *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.3d 1559, 1581 (Fed. Cir. 1992); see also *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1428–29, (Fed. Cir. 1988). As noted, *supra*, the Federal Circuit has also recently accepted “objective recklessness” as an appropriate scienter requirement for finding “willful” infringement in patent claims. See *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc).

<sup>196</sup> See cases cited *supra* Part V.A.

<sup>197</sup> *Hard Rock Cafe Licensing Corp. v. Concession Servs., Inc.*, 955 F.2d 1143, 1149 (7th Cir. 1992); see also cases cited *supra* Part V.B.

<sup>198</sup> See *In re Bose Corp.*, 580 F.3d 1240, 1245 (Fed. Cir. 2009).

<sup>199</sup> See *supra* Part IV.C.

trademark law, (3) willful blindness.<sup>200</sup> Supreme Court precedent should guide all areas of jurisprudence. The Supreme Court has provided a useful standard in willful blindness.<sup>201</sup> To simply close one's eyes to analogies in related areas of law would be unwise.

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<sup>200</sup> See *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2069 (2011); *Louis Vuitton S.A. v. Lee*, 875 F.2d 584, 590 (7th Cir. 1989).

<sup>201</sup> See *Global-Tech*, 131 S. Ct. at 2063, 2069.

# Striking a Better Compromise: Suggested Revisions to the Agent Orange Act of 1991

Meagan E. Fassinger\*

## Introduction

Thirty-six years have passed since Saigon fell and the last American combat troops left Vietnam. The War's effects on troops, however, continue to be a matter of vigorous debate and investigation. In September 2010, the Senate Committee on Veterans' Affairs held a hearing to discuss the current state of science on the health effects of an herbicide called "Agent Orange."<sup>1</sup> During the war, the U.S. military sprayed mass quantities of Agent Orange over the jungles of Vietnam in an effort to combat the enemy's ability to effortlessly hide in the dense jungle terrain.<sup>2</sup> The herbicide killed the vegetation, leaving the Viet Cong out in the open and reducing the danger to American troops.<sup>3</sup> What the government did not know was that this weapon was itself a danger and would leave U.S. soldiers with lasting health problems.

Upon returning home, Vietnam veterans reported ailments in numbers far higher than veterans of previous wars.<sup>4</sup> However, studies aimed at determining the health effects of Agent Orange exposure were slow to produce results, and the results they did produce were inconclusive.<sup>5</sup> After years of debate, Congress finally passed the Agent Orange Act of 1991 ("Agent Orange Act"

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<sup>1</sup> *VA Disability Compensation: Presumptive Disability Decision-Making: Hearing Before the S. Comm. on Veterans' Affairs*, 111th Cong. 1 (2010) (statement of Sen. Daniel K. Akaka, Chairman, S. Comm. on Veterans' Affairs) [hereinafter *VA Hearing*].

<sup>2</sup> See VIET. VETS. OF AM., THE VVA SELF-HELP GUIDE TO SERVICE-CONNECTED DISABILITY COMPENSATION FOR EXPOSURE TO AGENT ORANGE 3 (2010), available at <http://www.vva.org/Guides/AgentOrangeGuide.pdf>.

<sup>3</sup> See *id.*

<sup>4</sup> Ctrs. for Disease Control, *Health Status of Vietnam Veterans: II. Physical Health*, 259 JAMA 2708, 2708 (1988).

<sup>5</sup> See *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. 740, 787–88 (E.D.N.Y. 1984).



or “the Act”).<sup>6</sup> This legislation eliminated the requirement that veterans show a causal link between their illness and exposure to Agent Orange in order to receive disability benefits,<sup>7</sup> thus making it easier for them to receive these benefits. Since 1991, all a veteran must show to qualify for benefits is that he has one of the illnesses covered and that he served in Vietnam during the war.<sup>8</sup> The Act was an attempt to strike a compromise between the desire to give veterans the aid they deserve and the need to make responsible decisions based on sound, scientific evidence, which was simply not available.

Recently, the U.S. Department of Veterans Affairs (“VA”) added new conditions to the list of presumptive illnesses, including diabetes and ischemic heart disease (“IHD”).<sup>9</sup> Because these illnesses are prevalent among all men in this age group and have a plethora of other known risk factors,<sup>10</sup> the additions give rise to concerns about the breadth of the Agent Orange Act, highlighting its long-standing shortcomings.

Evidence used to associate some of these illnesses with Agent Orange has been lacking. For example, most of the studies on IHD did not control for other known risk factors, such as smoking, high blood pressure, and obesity.<sup>11</sup> As a result, coverage extends to any Vietnam veteran who has the disease, regardless of how many other serious risk factors they may have.<sup>12</sup> No study to date has been able to gauge the long-term effects of Agent Orange exposure.<sup>13</sup> Additionally, because little must be shown to qualify for benefits, the Act covers even those with very weak ties to Vietnam. Not only does this expansive coverage pose the problem of over-extending resources, but many have expressed concern that it could also create doubts about the system’s very legitimacy.<sup>14</sup> If the American public begins to believe the VA benefit process

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<sup>6</sup> Agent Orange Act of 1991, Pub. L. No. 102-4, 105 Stat. 11 (codified as amended in scattered sections of 38 U.S.C.).

<sup>7</sup> *Id.* § 2(a) (codified as amended at 38 U.S.C. § 1116(f) (2006)).

<sup>8</sup> *See id.*

<sup>9</sup> *VA Hearing, supra* note 1, at 17, 22 (statements of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs & Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs).

<sup>10</sup> *See, e.g., id.* at 101 (statement of Dr. Diane Bild, Associate Director, Prevention & Population Sciences Program, National Heart, Lung, and Blood Institute, National Institutes of Health) (“[A]pproximately 80–90% of men aged 60–79 would be expected to have either symptomatic or asymptomatic IHD.”).

<sup>11</sup> *Id.* at 109.

<sup>12</sup> *See id.* at 18 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>13</sup> *See id.* at 52 (statement of Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs).

<sup>14</sup> *See id.* at 53.



is being mismanaged, Congress may begin to doubt it as well and legislative support could wane, negatively affecting veterans with genuine claims.

This Article presents a plan for improving the Agent Orange Act at all three stages—the evidence-gathering stage, the review stage, and the application stage. First, Congress should improve study designs for illnesses it has already deemed to be presumptively caused by Agent Orange, as well as for any new presumptive illnesses it may add. New studies should control for other known risk factors, particularly for diseases prevalent among the general population. To determine whether a presumption is necessary, studies should also compare the number of affected veterans to the number affected in the general population, as opposed to engaging in a case-by-case review. Second, once all studies are complete, the VA's 60-day deadline for determining whether to grant an illness presumptive status<sup>15</sup> should be extended to 120 days. This would allow for a more complete review of all studies and a more calculated decision. Third, a veteran seeking benefits under the Agent Orange Act should, in addition to showing his diagnosis and connection to the service area, be required to submit a medical history report from his own physician. This report should show the presence of any other risk factors associated with the disease for which benefits are being sought. If the applicant's other risk factors are weak or even moderate, the presumption should stand. However, if the applicant has a strong showing of other risk factors, the presumption should be denied, and his case should be individually reviewed to assess his entitlement to benefits. This will ensure that all deserving veterans receive benefits, without unnecessarily over-extending the system.

Part I of this Article discusses the general history of Agent Orange and its negative effects on those veterans who were exposed to it. Part II continues with a description of the lengthy process for obtaining VA benefits when no presumption exists. Part III discusses the legislative history of the Agent Orange Act of 1991 and the motivations behind its passage. Part IV outlines problems with the Act as it currently stands. Finally, Part V presents recommendations for amending the Act to better serve its purpose and ensure the future legitimacy of the benefits system.

## **I. Agent Orange Background**

### **A. Composition & Use in Vietnam**

Agent Orange was an herbicide U.S. forces used during the Vietnam War to defoliate the dense jungle landscape.<sup>16</sup> This terrain provided the Viet Cong with hiding places, produced their food, and prevented U.S. service

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<sup>15</sup> 38 U.S.C. § 1116(c)(1)(A) (2006).

<sup>16</sup> VIET. VETS. OF AM., *supra* note 2, at 3.

members from having a clear line of fire when needed;<sup>17</sup> destroying it was crucial for American forces. Agent Orange was a combination of chlorinated phenoxy acids, the most dangerous of which was 2,3,7,8-tetrachlorodibenzo-paradoxin, the contaminant more commonly known as dioxin.<sup>18</sup> The level of dioxin contained in the herbicide ranged from less than .05 parts per million to almost 50 parts per million.<sup>19</sup>

Sprayed from aircrafts, trucks, and backpacks, Agent Orange was the most extensively used of all chemical combinations in Vietnam, primarily in “Operation Ranch Hand,” an aerial spray program beginning in 1962.<sup>20</sup> The peak year for herbicide spraying was 1967; in that year, 1.57 million acres were sprayed with 3.17 million gallons of Agent Orange.<sup>21</sup> Altogether, the United States sprayed an estimated eleven million gallons in Vietnam during the course of the war.<sup>22</sup> “Some three million veterans served in Southeast Asia and no one knows for sure how many of these veterans were exposed to Agent Orange”<sup>23</sup> or in what quantities.

### **B. Post-War Health Complaints**

Following their service in Vietnam, veterans reported a variety of health problems, including “chloracne, skin lesions, liver damage, loss of sex drive, changes in skin pigmentation and sensitivity to light, numbing or tingling in the extremities, sore joints, cancers, and birth defects in their children.”<sup>24</sup> In the years following the war, the Centers for Disease Control (“CDC”) conducted a “congressionally mandated health study of Vietnam veterans called the Vietnam Experience Study.”<sup>25</sup> Through telephone interviews, the CDC found that Vietnam veterans reported health problems more frequently than non-Vietnam veterans.<sup>26</sup> Additionally, they were nearly twice as likely as other veterans to describe their health as “poor” or “fair.”<sup>27</sup> Subsequent studies have demonstrated a correlation between herbicide exposure and soft-tissue sarcoma, non-Hodgkin’s lymphoma, chronic lymphocytic leukemia, Hodgkin’s

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<sup>17</sup> *Id.* at 1.

<sup>18</sup> *Id.* at 3.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *In re* “Agent Orange” Prod. Liab. Litig., 597 F. Supp. 740, 780 (E.D.N.Y. 1984).

<sup>22</sup> *Id.*

<sup>23</sup> VIET. VETS. OF AM., *supra* note 2, at 3.

<sup>24</sup> *Id.*

<sup>25</sup> Ctrs. for Disease Control, *supra* note 4, at 2708.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at 2709 (19.6 percent of Vietnam veterans described their health as “poor” or “fair,” compared to 11.1 percent of other veterans).

disease, and chloracne, as well as associations with numerous other serious health problems.<sup>28</sup> However, chronic effects of herbicide exposure can be difficult to assess, because exposure usually occurs over a long period of time, and effects are often dormant for a prolonged duration.<sup>29</sup> In some cases, this latency period can make it impossible to assign liability to herbicide exposure.<sup>30</sup>

## II. General Process for Obtaining VA Benefits

### A. Qualification

All veterans who have become disabled in the line of duty as a result of contracting an injury or disease or aggravating a previously existing condition are entitled to compensation from the U.S. government.<sup>31</sup> A veteran seeking compensation is presumed to have been in sound condition when accepted for service, except as noted at that time or where “clear and unmistakable evidence shows” that his service could not have caused the condition.<sup>32</sup> Additionally, qualification is conditioned on the disability not being the result of the veteran’s willful misconduct or abuse of alcohol, drugs, or tobacco products.<sup>33</sup>

### B. Application

The process for obtaining compensation can be lengthy and often frustrating for veterans. The disability application form requires veterans to list the diseases or medical conditions for which they are seeking benefits, the date on which those conditions began, and any facilities at which they have sought treatment.<sup>34</sup> Applicants must also attach any materials that support or explain their claims.<sup>35</sup> To successfully claim benefits, a veteran must show five elements: (1) veteran status; (2) existence of a disability; (3) a service connection; (4) degree of disability; and (5) effective date of disability.<sup>36</sup> Further,

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<sup>28</sup> COMM. TO REVIEW THE HEALTH EFFECTS IN VIET. VETS. OF EXPOSURE TO HERBICIDES, INST. OF MED., VETERANS AND AGENT ORANGE: UPDATE 2008, at 652 (2009) [hereinafter IOM REPORT], available at <http://www.nap.edu/catalog/12662.html>.

<sup>29</sup> Cf. Mary Cabrera, Note, *Legal Remedies for Victims of Pesticide Exposure*, KAN. J.L. & PUB. POL’Y, Summer 1991, at 113, 113 (discussing the chronic effects of pesticide exposure).

<sup>30</sup> Cf. *id.* at 114.

<sup>31</sup> 38 U.S.C. § 1110 (2006).

<sup>32</sup> *Id.* § 1111.

<sup>33</sup> *Id.* §§ 1103, 1110.

<sup>34</sup> U.S. DEP’T OF VETS. AFFAIRS, FORM NO. 21-526, VETERAN’S APPLICATION FOR COMPENSATION AND/OR PENSION 5 (2009).

<sup>35</sup> *Id.* at 1, 3.

<sup>36</sup> *D’Amico v. West*, 209 F.3d 1322, 1326 (Fed. Cir. 2000).

the veteran must establish that his claim is well-grounded, with evidence of the disability, in-service incurrence, and a nexus between an in-service injury or disease and the disability.<sup>37</sup> Generally, establishing this nexus is the most difficult part of seeking disability benefits.<sup>38</sup>

Establishing a nexus requires four key pieces of evidence.<sup>39</sup> First, the veteran must provide credible scientific or medical evidence that an environmental or occupational exposure during service is associated with that illness or injury.<sup>40</sup> A letter from a doctor or a report of a medical examination is sufficient to fulfill this requirement.<sup>41</sup> Second, the veteran must show evidence that the exposure occurred during active military duty.<sup>42</sup> Third, he must demonstrate that the illness or injury was initiated or exacerbated during duty.<sup>43</sup> Finally, the veteran must show that the exposure was at least as likely to have been the specific cause of the illness or injury as any other potential cause.<sup>44</sup> A decision on each veteran's claim for benefits is first made at the local VA office.<sup>45</sup> If there is an "approximate balance of positive and negative evidence" on any material issue, the veteran receives the benefit of the doubt.<sup>46</sup>

### C. Appeals Process

If a veteran's claim for benefits is denied or if the award is less than desired, he may appeal to the Board of Veterans' Appeals ("Board").<sup>47</sup> An applicant begins this process by filing a Notice of Disagreement, stating a desire to appeal.<sup>48</sup> He may then request that a Decision Review Officer review the file again and hold a personal hearing on the claim.<sup>49</sup> A personal hearing is a

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<sup>37</sup> *Shedden v. Principi*, 381 F.3d 1163, 1166–67 (Fed. Cir. 2004).

<sup>38</sup> See Mark Brown, *The Role of Science in Department of Veterans Affairs Disability Compensation Policies for Environmental and Occupational Illnesses and Injuries*, 13 J.L. & POL'Y 593, 595 (2005).

<sup>39</sup> *Id.* at 597.

<sup>40</sup> *Id.*

<sup>41</sup> See 38 U.S.C. § 5125 (2006) (medical examination report); *McCartt v. West*, 12 Vet. App. 164, 167–68 (1999) (doctor letter).

<sup>42</sup> Brown, *supra* note 38, at 597.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> BD. OF VETS. APPEALS, U.S. DEP'T OF VETS. AFFAIRS, PAMPHLET 01-02-02A, HOW DO I APPEAL? 3 (2002).

<sup>46</sup> See 38 U.S.C. § 5107(b) (2006).

<sup>47</sup> BD. OF VETS. APPEALS, *supra* note 45, at 1.

<sup>48</sup> *Id.* at 4.

<sup>49</sup> *Id.*

meeting between the veteran, his representative,<sup>50</sup> and a VA official who will decide the case.<sup>51</sup> Claimants are given a chance to add any new information or discuss any information that they think is important for the Board to hear.<sup>52</sup> A transcript of the hearing is then added to the veteran's claim file.<sup>53</sup> Based on the file review and personal hearing, the Board ultimately makes a decision on the appeal.<sup>54</sup> However, due to the high volume of appeals the Board receives, requesting a personal hearing can significantly prolong a veteran's claim process.<sup>55</sup>

If the veteran is still unhappy with the Board's decision, he may appeal further.<sup>56</sup> There are three means of appealing: a veteran may (1) attempt to reopen the claim at the local VA office based on new information; (2) file a motion asking the Board to reconsider; or (3) file an appeal with the U.S. Court of Appeals for Veterans Claims ("CAVC").<sup>57</sup> The CAVC's jurisdiction is limited to appeals of Board decisions "which are adverse to a claimant."<sup>58</sup> From there, claims may be further appealed to the U.S. Court of Appeals for the Federal Circuit; however, Federal Circuit jurisdiction over CAVC decisions is limited to review of statutes and regulations used in deciding the claim.<sup>59</sup> It has no jurisdiction to review factual determinations or applications of law to facts, unless they present constitutional issues.<sup>60</sup>

Thus, a veteran's attempt to get disability benefits for an illness or injury is a long and complicated process, requiring him to produce significant evidence regarding his service, current illness or injury, and the cause of that condition. Appeals may take many months or even years, and, if a claimant is unable to show a nexus between his service and his condition, he may be altogether denied benefits that he truly deserves. For Vietnam veterans, establishing this nexus can be especially hard, given the lack of firm scientific evidence on veterans' exposure to Agent Orange and the health effects it causes.

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<sup>50</sup> *Id.* at 7. Veterans may receive the assistance of a representative hired from a veterans' service organization (many of which offer free assistance) at any point during the claim process, but may only hire an attorney to represent them after filing a Notice of Disagreement. See VIET. VETS. OF AM., *supra* note 2, at 10–12.

<sup>51</sup> BD. OF VETS. APPEALS, *supra* note 45, at 7.

<sup>52</sup> *Id.* at 9–10.

<sup>53</sup> *Id.* at 10.

<sup>54</sup> *Id.*

<sup>55</sup> See *id.* at 8.

<sup>56</sup> *Id.* at 12.

<sup>57</sup> *Id.*

<sup>58</sup> 38 U.S.C. §§ 7252(a), 7266(a) (2006); see also *Hibbard v. West*, 13 Vet. App. 546, 548 (2000) (per curiam).

<sup>59</sup> *Id.* § 7292(a) (2006); see also *D'Amico v. West*, 209 F.3d 1322, 1325 (Fed. Cir. 2000).

<sup>60</sup> *Id.* § 7292(d)(2); *D'Amico*, 209 F.3d at 1325.

### III. The Agent Orange Act of 1991

#### A. Background

Despite the significant number of health complaints from veterans following the war, few initial studies actually showed a connection between these illnesses and herbicide exposure.<sup>61</sup> In 1984, the only ailment for which Vietnam veterans could receive disability benefits was chloracne, as it was the only disease with a proven connection to Agent Orange.<sup>62</sup> Consequently, some veterans began to feel that the VA “was not giving serious consideration to their legitimate concerns regarding the harmful exposures incurred in their service.”<sup>63</sup> In response, Congress passed the Veterans’ Dioxin and Radiation Exposure Compensation Standards Act, which “directed [the] VA to establish standards and guidelines for deciding [veterans’] claims and to identify the diseases that [the] VA would recognize as being associated with herbicide exposure.”<sup>64</sup> However, as enacted, the bill’s stated purpose was to provide benefits for diseases that were “connected, based on sound scientific and medical evidence,” to Agent Orange exposure.<sup>65</sup> Because chloracne was the only disease for which such evidence was available, the bill essentially did nothing to solve the problems of veterans suffering from other ailments.<sup>66</sup>

One of the biggest issues facing those who supported granting compensation to veterans for other conditions was the lack of evidence establishing the required nexus between these conditions and Agent Orange. In 1987, the CDC halted a mandated study of long-term health effects in Vietnam veterans who may have been exposed to phenoxy herbicides, including Agent Orange, after it determined that a scientifically valid exposure study could not be performed.<sup>67</sup> The VA Department of Medicine and Surgery endorsed the recommendation to cancel the study, agreeing that “no one ha[d] successfully identified a large enough group of Vietnam veterans known to have been exposed to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151.”<sup>68</sup> In a subsequent lawsuit regarding the stoppage, the U.S. District Court for the District of Columbia found that the decision

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<sup>61</sup> See *In re* “Agent Orange” Prod. Liab. Litig., 597 F. Supp. 740, 787–88 (E.D.N.Y. 1984).

<sup>62</sup> See *id.* at 749.

<sup>63</sup> *VA Hearing*, *supra* note 1, at 19–20 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>64</sup> *Id.* at 20.

<sup>65</sup> Veterans’ Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542, § 3, 98 Stat. 2725, 2727 (1984).

<sup>66</sup> See *VA Hearing*, *supra* note 1, at 20.

<sup>67</sup> *Am. Legion v. Derwinski*, 827 F. Supp. 805, 807–08 (D.D.C. 1993).

<sup>68</sup> *Id.* at 808.

to halt the study was not arbitrary or capricious and did not violate the law mandating the study.<sup>69</sup> There was simply no way to study which veterans had been exposed to Agent Orange or in what amounts.<sup>70</sup>

Furthermore, other available research offered little evidence of a nexus between dioxin exposure and health problems. A study in the early 1990s found that, of civilians who regularly worked with dioxins, “only those exposed to massive amounts of dioxin suffered any ill effects, and those effects formed only a modest indictment against the chemical.”<sup>71</sup> There, more than two-thirds of the workers had been exposed to over ninety times the normal level of dioxin exposure but presented no increased risk of cancer and only modest other ill effects.<sup>72</sup> A study of those who had participated in spraying through Operation Ranch Hand produced similar results—these were the veterans who had the most exposure to the chemicals, yet the study found no increased risk of cancer.<sup>73</sup> However, many remained firm in their belief that Agent Orange had resulted in serious negative health consequences for the veterans exposed to it.<sup>74</sup> These conflicting results and beliefs “resulted in verbal and legal warfare between veteran’s [sic] groups and Government agencies.”<sup>75</sup> Some members of Congress began to feel that, in the midst of all this debate over scientific findings, Congress had “lost sight of the real issue—the veterans suffering from debilitating ailments.”<sup>76</sup>

Congress wanted to be fair to these veterans, without frivolously spending taxpayer money or compensating for conditions that were not actually caused by exposure to Agent Orange.<sup>77</sup> Several bills attempting to compensate Vietnam veterans for their disabilities failed to pass both houses of Congress.<sup>78</sup> Decades after the Vietnam War, another bill was introduced—the Agent Orange Act of 1991.<sup>79</sup> The Act was deemed a compromise between the desire to address

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<sup>69</sup> *Id.* at 812–14.

<sup>70</sup> *See id.* at 808.

<sup>71</sup> Malcolm Gladwell, *Extensive Study Finds Reduced Dioxin Danger*, WASH. POST, Jan. 24, 1991, at A3 (discussing Marilyn A. Fingerhut et al., *Cancer Mortality in Workers Exposed to 2,3,7,8-Tetrachlorodibenzo-p-Dioxin*, 324 NEW ENG. J. MED. 212 (1991)), *quoted in* 137 CONG. REC. 2348 (1991) (statement of Rep. Montgomery).

<sup>72</sup> *See id.*

<sup>73</sup> *See* 137 CONG. REC. 2488 (1991) (statement of Sen. Simpson).

<sup>74</sup> *Id.* at 2482 (statement of Sen. Daschle) (“A sizeable and growing body of scientific evidence suggests that exposure to agent orange [sic] is associated with the development of various diseases in Vietnam veterans.”).

<sup>75</sup> *Id.* at 2361 (statement of Rep. McGrath).

<sup>76</sup> *Id.* at 2356 (statement of Rep. Bilirakis).

<sup>77</sup> *See id.* at 2355–56 (statement of Rep. Penny).

<sup>78</sup> *Id.* at 2484.

<sup>79</sup> Agent Orange Act of 1991, Pub. L. No. 102-4, 105 Stat. 11.



legitimate health concerns of veterans and the desire for more concrete scientific evidence connecting those ailments to service in Vietnam.<sup>80</sup>

### **B. Purpose of the Act: A “Compromise” Bill**

The Agent Orange Act of 1991 created a presumption that certain illnesses are caused by exposure to Agent Orange, thereby allowing Vietnam veterans to bypass a large part of the disability claim process.<sup>81</sup> Presumptions are often used when a connection has not yet been shown to be scientifically certain but veterans’ health issues need to be addressed promptly.<sup>82</sup> The Act gives the Secretary of Veterans Affairs the power to declare additional presumptions.<sup>83</sup> Once an illness has been granted presumptive status, a Vietnam veteran must show only two things in order to qualify for disability compensation: (1) service in Vietnam between January 9, 1962 and May 7, 1975; and (2) a current diagnosis of a disease on the list of presumptive illnesses, or residual or secondary conditions from one of these illnesses.<sup>84</sup> In other words, presumptions eliminate the need for a veteran to establish a nexus linking their condition to service in Vietnam.<sup>85</sup> Presumptions facilitate several other goals as well—ensuring that similar claims are given similar treatment, enabling the VA to process claims more quickly, and helping veterans obtain prompt medical assistance for their conditions when they may not otherwise have been eligible.<sup>86</sup>

In addition to compensating afflicted veterans, the Act had several other objectives. First, it was intended to further research into the effects and treatment of exposure to Agent Orange.<sup>87</sup> Second, it established independent review of scientific studies related to Agent Orange and its effects.<sup>88</sup> This provision was included to combat suspicions that the government was trying to conceal the actual effects of Agent Orange.<sup>89</sup> Finally, the ultimate goal of the Act was to ensure that, where evidence remains indeterminate, veterans are given the benefit of the doubt.<sup>90</sup>

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<sup>80</sup> *VA Hearing*, *supra* note 1, at 20 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>81</sup> Agent Orange Act § 2(a) (codified as amended at 38 U.S.C. § 1116(a) (2006)).

<sup>82</sup> *VA Hearing*, *supra* note 1, at 19.

<sup>83</sup> Agent Orange Act § 2(a) (codified as amended at 38 U.S.C. § 1116(b) (2006)).

<sup>84</sup> VIET. VETS. OF AM., *supra* note 2, at 7.

<sup>85</sup> *VA Hearing*, *supra* note 1, at 19.

<sup>86</sup> *Id.*

<sup>87</sup> 137 CONG. REC. 2494 (1991) (statement of Sen. Bradley).

<sup>88</sup> *See id.* at 2353 (statement of Rep. Hammerschmidt).

<sup>89</sup> *See id.* at 2351–52, 2354 (statements of Rep. Edwards, Rep. Stump, & Rep. Weiss).

<sup>90</sup> *See id.* at 2491 (statement of Sen. Biden).



### C. Components of the Final Bill

The main provisions of the Act were twofold: they provided for the establishment of presumptive illnesses and they mandated further research on the effects of Agent Orange. The presumptive illness provision of the enacted law explained that:

[A] *disease specified in paragraph (2)* of this subsection becoming manifest as specified in that paragraph in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era; *and . . . each additional disease (if any) that* (1) the Secretary determines in regulations prescribed under this section warrants a presumption of service-connection by reason of having positive association with exposure to an herbicide agent, and (2) becomes manifest within the period (if any) prescribed in such regulations in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era and while so serving was exposed to that herbicide agent, *shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during the period of such service.*<sup>91</sup>

Originally, only three illnesses were granted presumptive status: non-Hodgkin's lymphoma, soft-tissue sarcoma (other than osteosarcoma, chondrosarcoma, Kaposi's sarcoma, or mesothelioma), and chloracne or other similar acneform diseases.<sup>92</sup> This section of the Act codified the step former Secretary of Veterans Affairs Edward Derwinski had taken two years prior when he granted presumptions for these three illnesses.<sup>93</sup>

As noted in the text of the law, the Secretary is given the power to grant any further presumptions that are warranted.<sup>94</sup> However, these determinations are guided by standards prescribed in the Act.<sup>95</sup> The research provision mandated that the Secretary enter into an agreement with the National Academy of Sciences ("NAS"), an "independent nonprofit scientific organization with appropriate expertise which is not part of the Federal Government," to "review and evaluate the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides."<sup>96</sup> Under this agreement, the NAS would "review and summarize the scientific evidence, and assess the strength thereof, concerning the association between exposure [to Agent Orange] . . . and each disease suspected

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<sup>91</sup> Agent Orange Act of 1991, Pub. L. No. 102-4, § 2(a), 105 Stat. 11, 11 (emphasis added) (codified as amended at 38 U.S.C. § 1116(a)(1) (2006)).

<sup>92</sup> *Id.* (codified as amended at 38 U.S.C. § 1116(a)(2) (2006)).

<sup>93</sup> 137 CONG. REC. 2487, 2492 (1991) (statements of Sen. Simpson & Sen. McCain).

<sup>94</sup> Agent Orange Act § 2(a) (codified as amended at 38 U.S.C. § 1116(a)(1)(B) (2006)).

<sup>95</sup> *See id.* (codified as amended at 38 U.S.C. § 1116(b)–(c) (2006)).

<sup>96</sup> *Id.* § 3(a). If agreement with NAS was not possible, the Secretary was to enter into agreement with another appropriate organization that was independent of the government and operated as a nonprofit. *Id.* § 3(j).

to be associated with such exposure.”<sup>97</sup> It would also determine whether an association existed, whether there was an increased risk of the disease among those exposed to herbicides during service, and whether there was any evidence of a causal relationship.<sup>98</sup> All recommendations are to be transmitted in written reports to the Secretary of Veterans Affairs every two years.<sup>99</sup> The ultimate decision on presumptive service connection diseases is left in the hands of the Secretary.<sup>100</sup> NAS was to “focus on a purely scientific analysis of studies and other information regarding possible links between diseases and exposure to herbicide agents used in Vietnam,” while the Secretary was to make the ultimate determination, based on this association.<sup>101</sup> Congress considered this an “appropriate division of responsibilities.”<sup>102</sup>

The Institute of Medicine (“IOM”), the health policy arm of the NAS, creates these reports and delivers them to the Secretary of Veterans Affairs.<sup>103</sup> The Secretary must take these reports into account, along with all other available sound medical and scientific evidence.<sup>104</sup> He or she should also consider “whether the results are statistically significant, are capable of replication, and withstand peer review.”<sup>105</sup> Further, the Secretary is obliged to declare an illness presumptive if there is a “positive association” between herbicide exposure and the occurrence of the disease.<sup>106</sup> A positive association exists if the “credible evidence for the association is equal to or outweighs the credible evidence against the association.”<sup>107</sup> The Act does not require a causal relationship, merely a correlation between the illness and exposure to herbicides.<sup>108</sup> Finally, the Secretary must make a determination of whether a presumption is warranted no later than sixty days after receiving the reports from the IOM on the current state of evidence.<sup>109</sup>

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<sup>97</sup> *Id.* § 3(c).

<sup>98</sup> *Id.* § 3(d).

<sup>99</sup> *Id.* § 3(g).

<sup>100</sup> See 38 U.S.C. § 1116(b)(1) (2006).

<sup>101</sup> 137 CONG. REC. 1844 (1991) (statement of Sen. Cranston).

<sup>102</sup> *Id.*

<sup>103</sup> See *Veterans and Agent Orange: Update 2010*, INST. OF MED., <http://www.iom.edu/Reports/2011/Veterans-and-Agent-Orange-Update-2010.aspx> (last visited Nov. 8, 2011) (describing IOM’s role in the evaluation of the health effects of Agent Orange pursuant to the Act).

<sup>104</sup> 38 U.S.C. § 1116(b)(2).

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* § 1116(b)(1).

<sup>107</sup> *Id.* § 1116(b)(3).

<sup>108</sup> See *VA Hearing*, *supra* note 1, at 20 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>109</sup> 38 U.S.C. § 1116(c)(1)(A).

Additional provisions of the Act established that the VA is to “compile and analyze, on a continuing basis, all clinical data . . . obtained by the Department of Veterans Affairs in connection with examinations and treatment furnished to veterans by the Department” which is “likely to be scientifically useful in determining the association.”<sup>110</sup> This information is to be published in an annual report.<sup>111</sup> Further, the Act established a system to collect and store blood and tissue samples of Vietnam veterans that were voluntarily donated, so that they could be available for additional research.<sup>112</sup> Finally, it created a program to study the feasibility of conducting additional scientific research on health hazards resulting from exposure to dioxins and other herbicides.<sup>113</sup>

#### **D. Amendments, Updates, and Associated Rules**

As mentioned previously, the VA is under an obligation to give all veterans the benefit of the doubt as to their service connection if the evidence is ambiguous:

It is the defined and consistently applied policy of the Department of Veterans Affairs to administer the law under a broad interpretation, consistent, however, with the facts shown in every case. When . . . a reasonable doubt arises regarding service origin, the degree of disability, or any other point, such *doubt shall be resolved in favor of the claimant*.<sup>114</sup>

“Reasonable doubt” is defined as “an approximate balance of positive and negative evidence which does not satisfactorily prove or disprove the claim.”<sup>115</sup> This benefit of the doubt is applicable even where no official records are available.<sup>116</sup> Since the Act was passed in 1991, the list of presumptive illnesses has been expanded and now also includes Hodgkin’s disease, porphyria cutanea tarda, respiratory cancers (including cancers of the lung, bronchus, larynx, or trachea), multiple myeloma, and diabetes mellitus.<sup>117</sup> Most recently, B-cell (or hairy cell) leukemia, Parkinson’s disease, and ischemic heart disease have been added as well.<sup>118</sup>

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<sup>110</sup> Agent Orange Act of 1991, Pub. L. No. 102-4, § 6(a), 105 Stat. 11, 15.

<sup>111</sup> *Id.* § 6(b).

<sup>112</sup> *Id.* § 7(a).

<sup>113</sup> *Id.* § 8(a).

<sup>114</sup> 38 C.F.R. § 3.102 (2011) (emphasis added).

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> 38 U.S.C. § 1116(a)(2) (2006).

<sup>118</sup> See *VA Hearing*, *supra* note 1, at 17 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs) (discussing the proposal of regulations to establish presumptions of service connection for these diseases).

## IV. Problems with the Act

Despite the passage of the Act, establishing disability benefits for Vietnam veterans remains a contentious issue. Scientific studies used to determine presumptions continue to be both limited and conflicting. The recent addition of more common diseases to the list of presumptive illnesses has reignited the dispute. These common diseases have a wider variety of risk factors, and issues with isolating those factors has made it difficult to determine the strength of herbicide contribution. The uncertainty stemming from these limitations leads to decisions based on degrees of possibility and can result in over-inclusion, compromising the legitimacy of the system and over-extending its resources.

### A. Insufficient Bases for Presumption Decisions

#### 1. Study Limitations

One of the primary reasons the Agent Orange Act continues to be controversial is that the studies underlying presumption decisions are still scientifically limited. Former Secretary of Veterans Affairs Anthony J. Principi testified that it is “difficult, if not impossible, to determine the level of exposure to herbicides” that troops in Vietnam experienced.<sup>119</sup> Consequently, most studies on Agent Orange have been conducted using people who were exposed to herbicides in civilian life or industrial accidents.<sup>120</sup> Further complicating the assessment of Agent Orange’s lasting effects is the fact that there is no way to tell when or where an individual with dioxin in his blood was exposed to the chemical, as all Americans are exposed to some herbicides in their lifetimes.<sup>121</sup> Because an accurate estimation of each Vietnam veteran’s exposure is not considered feasible, studies have instead considered factors such as branch of service, military occupation specialty code, and location of the individual’s unit in Vietnam.<sup>122</sup> The inability to gauge exposure is a primary reason that studies have been unable to establish connections.<sup>123</sup> In its most recent published report to the VA, the IOM specifically noted that “[w]ithout information on the extent of herbicide exposure of Vietnam veterans and

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<sup>119</sup> *Id.* at 52 (statement of Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs).

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *E.g.*, Han K. Kang et al., *Dioxins and Dibenzofurans in Adipose Tissue of US Vietnam Veterans and Controls*, 81 AM. J. PUB. HEALTH 344, 345 (1991).

<sup>123</sup> IOM REPORT, *supra* note 28, at 10.

quantitative information about the dose-time-response relationship for each health outcome in humans, estimation of the risks” is simply not possible.<sup>124</sup>

Additionally, it has been difficult to separate “the potential role of service-related factors in diseases that have multiple causes, particularly as disease rates rise with age.”<sup>125</sup> In fact, the Act explicitly prohibits consideration of other risk factors.<sup>126</sup> It has been noted that former Secretary Principi “desperately wanted clearer scientific evidence to help him sort through confounding lifestyle factors, like diet or smoking, which might contribute to an illness.”<sup>127</sup> Such factors can be particularly important for diseases such as diabetes, cancer, and heart disease.<sup>128</sup> Also unclear is how much risk remains several years after dioxin exposure.<sup>129</sup>

In addition to these generalized limitations on research, certain studies have been criticized for their own specific failings; among these is the Ranch Hand Study, which fell far short of expectations.<sup>130</sup> Begun in 1982, the study was designed to be a comprehensive, “25-year, \$140 million research program to assess the health of 1,300 ranch hands, air and ground crew members who handled and sprayed Agent Orange and other defoliants in Vietnam.”<sup>131</sup> It was expected to generate significant scientific data, enabling the VA to make health care and compensation decisions for Vietnam veterans with precision.<sup>132</sup> In 2000, eighteen years after the study commenced, Congress expressed con-

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<sup>124</sup> *Id.* A “dose-time-response relationship” estimates expected health responses to a substance over a period of time. See Michael Raymond Wessel, *Dose Time Response Modeling of Neurobehavioral Screening Data: Application of Physiologically Relevant Parameters to Describe Dose Dependent Time of Peak Effects 4* (June 1, 2005) (unpublished M.S. thesis, University of South Florida), <http://scholarcommons.usf.edu/etd/911/>.

<sup>125</sup> *VA Hearing, supra* note 1, at 66 (statement of Dr. Jonathan M. Samet, Chair, Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans Institute of Medicine of the National Academies).

<sup>126</sup> *Id.* at 21 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>127</sup> David Rogers, *Panel May Rethink Agent Orange Law*, POLITICO (Sept. 24, 2010, 12:33 AM), <http://www.politico.com/news/stories/0910/42663.html>.

<sup>128</sup> *VA Hearing, supra* note 1, at 57 (statement of Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs).

<sup>129</sup> *Id.* at 109 (statement of Dr. Linda Birnbaum, Director, National Institute of Environmental Health Services, National Institutes of Health & Director, National Toxicology Program, U.S. Department of Health and Human Services).

<sup>130</sup> *Agent Orange: Status of the Air Force Ranch Hand Study: Hearing Before the Subcomm. on Nat'l Sec., Vets. Affairs, & Int'l Relations of the H. Comm. on Gov't Reform*, 106th Cong. 1 (2000) (statement of Rep. Christopher Shays, Chairman, Subcomm. on Nat'l Sec., Vets. Affairs, and Int'l Relations of the H. Comm. on Gov't Reform).

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

cern with several problems—the researchers were “slow to publish findings, unwilling to share data, inconsistent in conveying design limitations, and resistant to congressionally mandated participation by independent parties.”<sup>133</sup>

The many failings of the Ranch Hand Study led to speculation over whether it had been “designed to fail, or manipulated to avoid controversial findings.”<sup>134</sup> Part of this belief was based on the fact that the Air Force, which had conducted the spraying, was also responsible for conducting the research.<sup>135</sup> Aside from such suspicions, the study had two major limitations: the study group was relatively small (including fewer than one thousand veterans), and there was no suitable comparison group.<sup>136</sup>

## ***2. Contradictory Findings***

In addition to these limitations, research surrounding the health effects of Agent Orange has continued to produce a wide array of contradictory findings. A study of U.S. Army Chemical Corps veterans who had sprayed defoliant in Vietnam revealed an increased risk for diabetes, heart disease, hypertension, and chronic respiratory disease.<sup>137</sup> However, the increased risks for both these illnesses, and for heart conditions and hypertension turned out to be statistically insignificant.<sup>138</sup> The study did find that Vietnam veterans faced significantly elevated odds ratios for hepatitis, all cancers, respiratory problems, poor health status, and work limitations.<sup>139</sup> However, the researchers readily admitted that their findings did not accord with other studies.<sup>140</sup> For instance, a National Institute for Occupational Safety and Health study of workers exposed to dioxins found no elevated odds for chronic bronchitis, diabetes, or cardiovascular diseases, but it did find an increased mortality rate from cancers and ischemic heart disease.<sup>141</sup> Indeed, a prior study, conducted in

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<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 2.

<sup>135</sup> *See id.* at 1–2.

<sup>136</sup> Nancy A. Dalager & Han K. Kang, *Mortality Among Army Chemical Corps Vietnam Veterans*, 31 AM. J. INDUS. MED. 719, 720 (1997). Both a reasonably large number of subjects and a control group are vital to the validity of a clinical trial. *See Validity of Clinical Trials*, MEDICALBIostatISTICS.COM 1, 6, <http://www.medicalbiostatistics.com/ValidityOfClinical-Trials.pdf> (last visited Nov. 8, 2011).

<sup>137</sup> Han K. Kang, et al., *Health Status of Army Chemical Corps Vietnam Veterans Who Sprayed Defoliant in Vietnam*, 49 AM. J. INDUS. MED. 875, 875 (2006).

<sup>138</sup> *Id.* at 875, 877.

<sup>139</sup> *Id.* at 877.

<sup>140</sup> *Id.* at 882.

<sup>141</sup> *Id.*

part by one of the Army Chemical Corps study researchers, found that the risk for several site-specific cancers was elevated but not statistically significant.<sup>142</sup>

Veterans' observed risk of Hodgkin's disease also varies among studies. One study published in 1995 showed that service in Vietnam was not associated with any significantly increased risk of Hodgkin's disease.<sup>143</sup> Additionally, the study attempted to measure exposure to Agent Orange. Because no precise estimates were available, the scientists used "surrogate measures" including branch of the military, deployment to a particular region, service in a combat role, duration of time in Vietnam, and presence during the peak spraying years of 1967 to 1969 to serve as alternate measurement devices.<sup>144</sup> These findings stand in stark contrast to a recent NAS report, which concluded there was sufficient evidence to find a positive association between herbicide exposure and Hodgkin's disease.<sup>145</sup>

### 3. *Insufficient Review Time*

Finally, the Agent Orange Act allows the Secretary of Veterans Affairs only sixty days after receiving an IOM report to make a final decision on a presumption.<sup>146</sup> The Secretary also considers advice from a VA working group that has medical, legal, and program expertise.<sup>147</sup> However, the Secretary is ultimately responsible for determining whether the evidence satisfies the positive-association standard.<sup>148</sup> Secretary of Veterans Affairs Eric Shinseki noted in testimony before the Senate Committee on Veterans Affairs that dialogue among all the task forces reviewing this information is important and that he works to ensure that all views, including minority ones, are expressed and considered.<sup>149</sup> The IOM reports reflect a two-year process and are generally over six hundred pages long.<sup>150</sup> Secretary Shinseki admitted that reviewing all of this information, engaging in dialogue with others, and

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<sup>142</sup> Kevin K. Watanabe & Han K. Kang, *Military Service in Vietnam and the Risk of Death from Trauma and Selected Cancers*, 5 ANNALS EPIDEMIOLOGY, 407, 412 (1995).

<sup>143</sup> Nancy A. Dalager et al., *Hodgkin's Disease and Vietnam Service*, 5 ANNALS EPIDEMIOLOGY 400, 405 (1995).

<sup>144</sup> *Id.* at 402.

<sup>145</sup> *Id.* at 403.

<sup>146</sup> 38 U.S.C. § 1116(c)(1)(A) (2006).

<sup>147</sup> *VA Hearing*, *supra* note 1, at 17 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>148</sup> *Id.* at 16.

<sup>149</sup> *Id.* at 37.

<sup>150</sup> *Id.*; see also COMM. TO REVIEW THE HEALTH EFFECTS IN VIET. VETS. OF EXPOSURE TO HERBICIDES, INST. OF MED., VETERANS AND AGENT ORANGE: UPDATE 2006 (2007), available at [http://www.nap.edu/catalog.php?record\\_id=11906](http://www.nap.edu/catalog.php?record_id=11906) (896 pages); COMM. TO REVIEW THE HEALTH EFFECTS IN VIET. VETS. OF EXPOSURE TO HERBICIDES, INST. OF MED., VETER-



coming to a decision within this sixty-day window can be “challenging” and recommended extending the deadline.<sup>151</sup> Former Secretary Principi echoed these sentiments and agreed that, during his time at the VA, the sixty-day period created difficulties.<sup>152</sup> He noted that it may be best to abolish limits on the review period altogether.<sup>153</sup>

### **B. Limitations of the Process**

In addition to the limitations of research studies, the process for declaring illnesses presumptive itself restricts decisionmakers. All reports from the IOM categorize the findings in one of four ways: “illnesses that have sufficient evidence of an association with herbicide exposure; illnesses that have limited or suggestive evidence of an association; illnesses with limited or suggestive evidence of no association; and illnesses with inadequate or insufficient evidence to determine whether an association exists.”<sup>154</sup> It is the category of “limited or suggestive evidence of an association” that presents the most difficulty.<sup>155</sup> Former Secretary Principi testified as to the challenges:

In making this kind of decision, we are talking degrees of possibility; the possibility that veterans were exposed to dangerous herbicides; the possibility that such exposure might lead to illness; and the possibility that the illness in any individual veteran was caused by that exposure—and turning them into certainties with significant consequences for veterans and the American people.<sup>156</sup>

This categorization also means that a single study showing association can place a disease in the “limited or suggestive” category and result in disability benefits, even if numerous other studies show no association.<sup>157</sup> The reverse can occur as well, and it is possible that a disease that is correlated would be found to have no association—for diabetes, just one study showing no correlation

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ANS AND AGENT ORANGE: UPDATE 2004 (2005), *available at* [http://www.nap.edu/catalog.php?record\\_id=11242](http://www.nap.edu/catalog.php?record_id=11242) (650 pages).

<sup>151</sup> *VA Hearing, supra* note 1, at 37 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>152</sup> *Id.* at 50 (statement of Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs).

<sup>153</sup> *Id.* at 59–60.

<sup>154</sup> *Id.* at 52.

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* at 53.

<sup>157</sup> *Id.* at 65 (statement of Dr. Jonathan M. Samet, Chair, Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans, Institute of Medicine of the National Academies).



kept the disease from being placed in the “positive association” category; it was instead listed in the “limited or suggestive” category.<sup>158</sup>

### C. Over-Inclusion

As a consequence of these limitations, the Agent Orange Act qualifies a vast number of veterans for disability benefits. Currently, the Act does not allow the VA to consider the prevalence of a disease among the general population when considering whether to grant presumptive classification.<sup>159</sup> The VA further may not consider the fact that a disease is associated with a number of other known risk factors.<sup>160</sup> Many studies on presumptive illnesses have not even controlled for other risk factors when assessing Vietnam veterans’ risk of disease.<sup>161</sup> This failure to recognize other risk factors means that any Vietnam veteran with a presumptive illness may collect disability benefits, regardless of the prevalence of other risk factors.<sup>162</sup> Such a policy runs the risk of including veterans whose health conditions may have very little, if anything, to do with their exposure to Agent Orange.

The problem is becoming highlighted now that Vietnam veterans are getting older and starting to exhibit illnesses that are more prevalent among an older population. For example, Dr. Diane Bild, a cardiologist for the National Institute of Health, testified that 80 to 90 percent of men aged sixty to seventy-nine can be expected to have either symptomatic or asymptomatic ischemic heart disease.<sup>163</sup> Major causes of ischemic heart disease include smoking, high LDL cholesterol, low HDL cholesterol, high blood pressure, and diabetes.<sup>164</sup> Also thought to contribute are a sedentary lifestyle, poor diet, obesity, and psychosocial factors such as stress and depression.<sup>165</sup> While the IOM has recently found that dioxin exposure is associated with ischemic heart disease, this association is modest and most of the studies cited failed to account for other risk factors.<sup>166</sup> The nine primary studies considered in the review of ischemic

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<sup>158</sup> *Id.* at 53 (statement of Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs).

<sup>159</sup> *Id.* at 21 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 109 (statement of Dr. Linda Birnbaum, Director, National Institute of Environmental Health Services, National Institutes of Health & Director, National Toxicology Program, U.S. Department of Health and Human Services).

<sup>162</sup> *See id.* at 21 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>163</sup> *Id.* at 101 (statement of Dr. Diane Bild, Associate Director, Prevention & Population Sciences Program, National Heart, Lung, and Blood Institute, National Institutes of Health).

<sup>164</sup> *Id.* at 100.

<sup>165</sup> *Id.* at 99.

<sup>166</sup> *Id.* at 100.

heart disease did control for age, but their control for other risk factors varied greatly.<sup>167</sup> Additionally, only two of these studies actually dealt with Vietnam veterans.<sup>168</sup> As a result of these shortcomings, a veteran may receive disability benefits under the Agent Orange Act even if he has every other possible risk factor for ischemic heart disease.

In response to questions at a hearing regarding veteran disability compensation, Secretary Shinseki noted that the presumption for ischemic heart disease could theoretically cover a veteran who has smoked two packs of cigarettes per day for years.<sup>169</sup> He also admitted to hearing of one veteran who allegedly was receiving disability benefits under the Act after spending only eight hours in Vietnam, all of which was spent in the Saigon airport.<sup>170</sup> While Secretary Shinseki admitted to being aware of the prevalence of ischemic heart disease and other risk factors associated with it in the general population, he was bound to consider only whether a positive association existed.<sup>171</sup> “In effect, the VA’s policy compensates a very large number of veterans . . . in order to ensure coverage of the few veterans who may have contracted the disease because of [Agent Orange exposure].”<sup>172</sup>

Such over-inclusion can cause several significant problems. First, it may result in an over-extension of VA resources. The VA is not permitted to consider the potential economic impact of declaring an illness presumptive,<sup>173</sup> and rightfully so—veterans risked their lives to fight for their country, and, if they are in need of benefits, money should not be a factor. However, over-inclusion is likely diverting money to those whose disabilities were not actually caused by exposure to Agent Orange. These resources could be better spent on further studies or on providing more benefits to those whose disabilities are legitimately connected to herbicide exposure.

Second, if the public begins to lose faith in the ability of the VA to distribute veterans’ benefits fairly and accurately, the over-inclusion may threaten the legitimacy of the system. If the public loses confidence in the system, it is possible that their congressional representatives could reflect this skepticism in their votes on funding for such programs. Senator Daniel Akaka, the Chairman of the Senate Committee on Veterans’ Affairs, expressed this concern:

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<sup>167</sup> *Id.* at 17 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>168</sup> *Id.* at 26.

<sup>169</sup> *See id.* at 47–48.

<sup>170</sup> *Id.* at 48.

<sup>171</sup> *Id.* at 17.

<sup>172</sup> Brown, *supra* note 38, at 606.

<sup>173</sup> *VA Hearing, supra* note 1, at 21 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

Issues concerning veterans' benefits have largely survived in this partisan era with bipartisan support, mainly because most members of Congress agree that these benefits are tied to the sacrifices made by those who wear the Nation's uniforms and are deserved.

Maintaining that high level of public and political support depends on a clear and sound decision-making process for any expansion of veterans' benefits. If resources are expended in the name of expanding presumptions for service-connected disabilities, when in fact the disabilities are not due to service, the larger effort to provide care and benefits that veterans and their families urgently need and deserve will suffer.

Congress must fulfill its oversight responsibility . . . .<sup>174</sup>

The government is accountable for making the decisions regarding disability benefits. To ensure continued support of such decisions, they should be based on the soundest scientific advice possible.

Finally, the idea that veterans whose illnesses were not caused by Agent Orange may be receiving disability benefits could serve to undermine both the sacrifices and the health problems of veterans who were legitimately affected by Agent Orange.

## V. Suggested Improvements

### A. Improve Study Designs

Congress must order new research with improved designs to obtain better information on the effects of Agent Orange. Information could be augmented in several key areas. First, many studies have failed to control for other known risk factors.<sup>175</sup> The addition of such controls could provide much clearer data on whether exposure to Agent Orange was a significant contributing factor to these diseases. Dr. Jonathan Samet, of the IOM, recommended such an idea during his testimony before the Senate Committee on Veterans' Affairs.<sup>176</sup> If other risk factors can be controlled for, it may be easier to determine what portion of the disease is attributable to dioxin exposure.<sup>177</sup> This additional information would aid the VA in deciding "whether a presumption should be made for the veteran population in general, for subgroups, or not at all."<sup>178</sup>

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<sup>174</sup> *Chairman Daniel K. Akaka Opening Statement*, U.S. SENATE COMMITTEE ON VETERANS' AFFAIRS (Sept. 22, 2010), [http://veterans.senate.gov/hearings.cfm?action=release.display&release\\_id=55666d2e-3409-45bd-9d2e-d5831b428192](http://veterans.senate.gov/hearings.cfm?action=release.display&release_id=55666d2e-3409-45bd-9d2e-d5831b428192).

<sup>175</sup> *See VA Hearing*, *supra* note 1, at 109 (statement of Dr. Linda Birnbaum, Director, National Institute of Environmental Health Services, National Institutes of Health & Director, National Toxicology Program, U.S. Department of Health and Human Services).

<sup>176</sup> *See id.* at 64 (statement of Dr. Jonathan M. Samet, Chair, Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans Institute of Medicine of the National Academies).

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

Second, establishing the long-term effects of dioxin exposure would provide important information for establishing presumptions. Studies could look at veterans who actually handled Agent Orange through Operation Ranch Hand, comparing them to veterans who either did not handle the chemicals or served only a short time in Vietnam. This could provide a clearer indication of the extent to which dioxin exposure has negative health effects and whether those effects depend on the quantity of the herbicide the person was exposed to.

Additionally, studies could be performed on civilians in Vietnam; these studies may provide more answers on how long dioxins remain in the blood and whether Vietnamese people who lived close to highly sprayed areas report any of the same health concerns as American Vietnam veterans. Senator Sanders mentioned this possibility at the Senate hearing on the issue, and Secretary Shinseki admitted he was not aware of any studies performed on the Vietnamese people.<sup>179</sup> Again, this could more easily show whether the exposure causes certain health problems or if other factors are more likely to blame.

Third, studies should strive to use the general population as a control group. Comparing these studies to studies on Vietnam veterans would aid in determining the service-attributable fraction of the disease, compared to other known risk factors. When the rate of natural occurrence of a condition in the general population is not considered in a clinical trial, research findings can be misinterpreted.<sup>180</sup> Studies have compared Vietnam veterans to both veterans from other arenas and to those who have worked with dioxins in civilian life, but they have not generally included non-veteran civilians who were not regularly exposed to dioxins in their lifetime.<sup>181</sup> A study that looked at all four of these groups (Vietnam veterans, non-Vietnam veterans, civilians who regularly handle dioxins, and civilians who do not regularly handle dioxins) could provide a clearer picture of whether the incidence of such illnesses is elevated among Vietnam veterans, who were presumably exposed to Agent Orange. In other words, it could reveal whether Agent Orange was a significant contributing factor, a slight contributing factor, or if men in this age group are simply prone to such illnesses, independent of exposure. The Vietnam veterans group could conceivably be broken down further into those who participated in Operation Ranch Hand and those who did not. Secretary Principi recommended asking the Institute of Medicine

[T]o estimate the number of Vietnam veterans who might be affected by an illness with limited or suggestive linkage to herbicide exposure. In other words, if 100,000

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<sup>179</sup> *Id.* at 42 (statements of Sen. Bernard Sanders & Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>180</sup> David Sue et al, UNDERSTANDING ABNORMAL BEHAVIOR 106–07 (7th ed. 2003).

<sup>181</sup> See *VA Hearing*, *supra* note 1, at 30–31 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

veterans in the age cohort of Vietnam veterans could be expected to develop a disease, approximately how many more veterans will develop that disease as a result of exposure to herbicides.<sup>182</sup>

Again, this consideration can lead to better determinations of whether an illness needs to be presumptive for all Vietnam veterans, for certain classes of them, or should be left to individual case-by-case review.

Finally, researchers could perform a comparison of all completed studies that contradict each other. The comparison should look at how each test was conducted, what the control group (if any) was, what factors were considered and controlled for, what tests were run, and what statistical formulas were applied to the data. This detailed comparison may help explain why so many studies have contradicted one another. It would also be less costly than conducting some of the studies again to check their accuracy against each other.

### **B. Extend the VA's Decision Deadline from 60 Days to 120 Days**

The IOM studies produce a significant amount of evidence, all of which the VA must review, digest, and make a decision on within sixty days.<sup>183</sup> Secretary Shinseki has noted that this review time is rushed.<sup>184</sup> Congress must strike a better balance between speed and accuracy. Accordingly, the deadline should be extended from 60 to 120 days. Extending the deadline is a very simple change and would allow time for a more thorough analysis at all stages of the review process. A flexible schedule could be set as follows: forty-five days for the Secretary and his working group to review the reports on their own; sixty days for dialogue and discussion among all taskforces; and fifteen days for the Secretary to consider and make his final decision. This schedule is hypothetical, but it shows how the VA could effectively use the additional time.

While this extension would admittedly delay veterans' access to benefits, it would allow for a more accurate determination of which illnesses should be granted presumptive status. Striking this balance between speed and accuracy is similar to the process required for FDA approval of a new drug. There, it is important to allow the public access to the benefits of new drugs as quickly as possible;<sup>185</sup> similarly, with disability benefits, veterans will be aided by presump-

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<sup>182</sup> *Id.* at 53 (statement of Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs).

<sup>183</sup> 38 U.S.C. § 1116(c)(1)(A) (2006).

<sup>184</sup> See *VA Hearing*, *supra* note 1, at 37 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>185</sup> *Cf.*, Austin Winniford, Note, *Expanding Access to Investigational Drugs for Treatment Use: A Policy Analysis and Legislative Proposal*, 19 HEALTH MATRIX 205 (2009) (arguing for increased access to investigational drugs for seriously ill patients because of the potential benefits).

tions being granted as soon as possible. However, it is also important in both situations to ensure that the decisions are made accurately and after careful review of all available information. The FDA's period of review for new drug applications is 180 days; a decision must be made to either approve the drug or grant an opportunity for a hearing by the end of this period.<sup>186</sup> The fact that this review period is three times as long as that given to the Secretary of Veterans Affairs for disability presumption decisions highlights the severity of the sixty-day deadline. However, because the consequences of approving a drug without sufficient information could result in physical harm, the longer FDA review period is warranted. Both situations require a similar balance, but it is not necessary that the review period be equal. In this situation, a period of 120 days would be an appropriate balance, giving the Secretary sufficient review time, while ensuring that veterans receive a prompt answer. This is a very simple change that can greatly improve the accuracy of the process.

### **C. Create an Additional Step to Proving Causation**

Creating an additional, though not overly taxing, step toward showing causation would improve the accuracy of disability benefits and minimize the problem of over-inclusion. Congress could achieve these goals by requiring a medical history report from each applicant's doctor, which shows the veteran's history of other known risk factors for his condition. If the applicant's history of other risk factors is low or moderate, the presumption that Agent Orange was the cause of his condition should stand. If, however, the claimant has a high showing of other proven risk factors for that illness, the presumption should not apply, and his case should be individually reviewed to assess his entitlement to benefits.

The presumptions provided under the Agent Orange Act are rebuttable by contrary evidence—that is, evidence showing that some other factor was the cause of the illness, rather than Agent Orange.<sup>187</sup> Requiring a medical history report would establish a method for properly considering all evidence to the contrary. Because these presumptions are already statutorily rebuttable, this step would not change the entire system; it would merely create a standard for considering evidence that could rebut the presumption. It would also reinforce the statutory exclusion of conditions caused by tobacco or alcohol use,<sup>188</sup> as abuse of these substances is a risk factor for several diseases.<sup>189</sup>

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<sup>186</sup> 21 C.F.R. § 314.101(f)(1) (2008).

<sup>187</sup> 38 U.S.C. § 1113(a) (2006).

<sup>188</sup> *Id.* § 1103.

<sup>189</sup> *See, e.g., VA Hearing, supra* note 1, at 100 (statement of Dr. Diane Bild, Associate Director, Prevention & Population Sciences Program, National Heart, Lung, and Blood Institute, National Institutes of Health) (discussing smoking as a cause of ischemic heart disease).

The veteran would retain the benefit of the doubt, in that the presumption would be upheld for those with even moderate additional risk factors. Even for those with whose other risk factors are significant, the possibility of obtaining benefits is not cut off, as they can still apply through the regular benefits application system. Furthermore, this requirement would not impose much more of a burden on veterans—all they need do is request such a report from their physician. The VA could create a standard form for each presumptive illness, which the applicant's doctor only need fill out based on the patient's medical history. This is far less strenuous than actually proving causation, as is required when no presumption exists at all.<sup>190</sup> The report could also be completed by a VA doctor as well, if the VA has sufficient medical records. In the event of scattered records or a non-cooperating private physician, records could be sent to the VA and a report prepared and confirmed by a VA doctor. It should also be noted that those with higher risk factors would not be kept from receiving healthcare, only the presumption for disability benefits.

Claims processors in local VAs already have discretion to discuss evidence of potential risk factors with veterans' doctors, including whether another risk factor is the more likely cause of an illness than herbicide exposure.<sup>191</sup> Requiring veterans to submit medical history reports would have much the same effect: it would allow the veteran's other risk factors to be considered in determining his eligibility for benefits. However, submitting medical reports would establish a standard procedure for doing so. It would also create a record of all factors considered in the claims decision, unlike a verbal discussion had by a claims processor, aiding in appeals.

Admittedly, this option would result in a delay for some benefits, but, for most applicants, the process would still be significantly shorter than going through the entire application and causation process for non-presumptive illnesses.<sup>192</sup> Additionally, there would be a cost: personnel would have to be hired to review these reports, and a system would need to be established for categorizing the risks as "low," "moderate," or "high." This expense would likely be made up for, though, by eliminating the resources misplaced on claimants whose conditions were not caused by Agent Orange.

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<sup>190</sup> See *supra* Part II.B.

<sup>191</sup> *VA Hearing, supra* note 1, at 47–48 (statement of Thomas J. Pamperin, Associate Deputy Under Secretary for Policy and Program Management, U.S. Department of Veterans Affairs).

If there is clear evidence in the file of risk factors for heart disease—when [the official] request[s a medical] examination [of the veteran], it is appropriate for them to ask the clinician . . . [if it is] as likely as not that the veteran's current disability is due to herbicide exposure[.]

*Id.*

<sup>192</sup> See *supra* Part II.



This step is, once again, a compromise—it keeps presumptions intact but aims to solve the over-inclusion problem. If new studies that control for other risk factors are conducted, as recommended above, this step could potentially be eliminated for conditions *proven* to be caused by Agent Orange. Appropriate research will have to be performed, however, before reaching the point where this step could be eliminated for certain illnesses.

#### **D. Limitations of these Improvements**

These suggested changes will not fix all of the problems with the Agent Orange Act, nor will they make the process of obtaining benefits function perfectly. Because of the way in which the spraying was conducted, it probably will never be possible to determine individual levels of exposure for each veteran, regardless of how many studies are carried out.<sup>193</sup> Further, these suggestions leave in place the Secretary of Veterans Affairs' lack of discretion over whether to deem an illness presumptively caused by Agent Orange—he or she will still be bound by the positive association standard.<sup>194</sup> Finally, these improvements do not solve the problem that arises when a single positive study creates a presumption for an illness, even though numerous other studies have shown no association.<sup>195</sup>

A range of possible other solutions could likely account for the limitations of the suggestions advanced here. One idea is to change the meaning of positive association to a higher preponderance of the evidence standard.<sup>196</sup> Another idea is to eliminate presumptions altogether for illnesses that either have a high number of other known risk factors or are highly prevalent among the general population.<sup>197</sup> This process would operate under the presumption that any diseases that are prevalent or have common risk factors were *not* caused by Agent Orange. Still, it would leave open the possibility that a veteran could go through the application process and, if necessary, the appeals process to prove a service connection. A third suggestion is to require a specified length of time spent in the spray region in order to qualify for disability benefits.<sup>198</sup>

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<sup>193</sup> See *supra* notes 67–70, 119–25, and accompanying text.

<sup>194</sup> See *VA Hearing, supra* note 1, at 21 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>195</sup> See *supra* Part IV.B.

<sup>196</sup> Cf. 38 U.S.C. § 1116(b)(3) (2006) (requiring finding of association when “credible evidence for the association is *equal to* or outweighs the credible evidence against the association” (emphasis added)).

<sup>197</sup> See *supra* Part IV.C.

<sup>198</sup> See *VA Hearing, supra* note 1, at 53 (statement of Anthony J. Principi, former Secretary, U.S. Department of Veterans Affairs) (questioning if it is possible to distinguish between those who received extended exposure to Agent Orange and those who merely had brief exposure).



This assumes that any exposure would need to meet a certain level in order to be a factor in the illness or injury.

These suggestions lean too far toward favoring accuracy and leave benefits out of reach of too many veterans. As previously noted, a balance must be struck between ensuring that veterans are compensated for their service-related illnesses and ensuring that the system is run responsibly and based on the most accurate information possible. This balance was the ultimate goal of the Agent Orange Act of 1991,<sup>199</sup> and it should remain intact through any changes.

First, it should be a priority to uphold a “benefit of the doubt” standard.<sup>200</sup> All of our nation’s veterans have sacrificed enormously in order to defend our country and our belief in personal liberty; this entitles them to the benefit of the doubt in any situation where there is insufficient information to make a determination one way or the other. Changing the positive association to a higher standard would eliminate, or at least significantly deteriorate, this benefit of the doubt. A higher standard would mean that, if researchers were unsure about an association, the veterans would not receive benefits. This would be wrong, because it would still be possible such a veteran’s ailments *were* caused by Agent Orange. The same arguments apply for requiring a specified length of duty.

As long as there remains a possibility . . . that agent orange is a cause of cancer in many veterans, the benefit of the doubt should be given to those who were in the field; those who had to wear agent orange in their clothing; those who had to sleep with agent orange; those who had to eat food, drink water, and breathe air contaminated with agent orange.<sup>201</sup>

It should be of paramount importance that any changes continue to reflect deference to this standard.

Second, the process of obtaining benefits should be as easy as possible for veterans, while still ensuring that they are granted only where it is likely that health problems were caused by Agent Orange. Eliminating presumptions altogether for any illness that is common among the general population would require all veterans with that illness to go through the lengthy claims application and appeals process. This may delay the receipt of benefits to which veterans exposed to Agent Orange are legitimately entitled. A higher number of claims could also clog up the system, delaying benefits for all veterans. Creating an additional step to showing causation and ordering better-designed studies will hopefully solve this issue, without going to extremes.

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<sup>199</sup> *Id.* at 20 (statement of Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs).

<sup>200</sup> *Id.* at 42 (statement of Sen. Sanders).

<sup>201</sup> 137 CONG. REC. 2491 (1991) (statement of Sen. Biden).

## **Conclusion**

The Agent Orange Act of 1991 was a compromise bill, and, while it was necessary to address the health concerns of veterans returning from Vietnam, it is significantly flawed. Ordering further studies with improved designs, creating an extra step to showing causation, and extending the VA's review time from 60 days to 120 days would create more accuracy and legitimacy in the system, while preserving the benefit of the doubt for Vietnam veterans and ensuring them faster claim review time.

# Unjust Imprisonment Claims Before the Court of Federal Claims: The Presentation of a Certificate of Innocence Should Not Be Considered “Jurisdictional”

Lawrence Bluestone\*

## Introduction

Among the more unusual areas of the jurisdiction of the Court of Federal Claims (“COFC”) is its authority to award money damages to individuals who have been unjustly imprisoned by the federal government.<sup>1</sup> The COFC’s authority is divided between two sections of Title 28 of the U.S. Code: § 1495 and § 2513.<sup>2</sup> Section 1495, which waives sovereign immunity, provides: “The United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim for damages by any person unjustly convicted of an offense against the United States and imprisoned.”<sup>3</sup> Section 2513 contains the substantive requirements for asserting such a claim, providing:

(a) Any person suing under section 1495 of this title must allege and prove that:

(1) His conviction has been reversed or set aside on the ground that he is not guilty of the offense of which he was convicted, or on new trial or rehearing he was found not guilty of such offense, as appears from the record or certificate of the court setting aside or reversing such conviction, or that he has been pardoned upon the stated ground of innocence and unjust conviction and

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\* Lawrence Bluestone is an Associate in the Commercial Litigation department at Genova, Burns & Giantomasi in Newark, New Jersey. The idea for this Article can be traced back to 2010, when the Author served as a law clerk to the Honorable George W. Miller at the U.S. Court of Federal Claims. The author would like to thank Judge Miller for his guidance.<sup>1</sup> According to a search of the COFC’s electronic filing system, as of October 5, 2011, there were only two active unjust imprisonment cases both filed by pro se litigations and countered with government motions to dismiss for lack of jurisdiction and failure to state a claim. *See* Defendant’s Motion to Dismiss *Pro Se* Complaint at 6–7, *White v. United States*, No. 11-357C (Fed. Cl. Aug. 3, 2011); Defendant’s Motion to Dismiss at 1–2, *Pulungan v. United States*, No. 11-193C (Fed. Cl. May 24, 2011).

<sup>2</sup> 28 U.S.C. §§ 1495, 2513 (2006).

<sup>3</sup> § 1495.

(2) He did not commit any of the acts charged or his acts, deeds, or omissions in connection with such charge constituted no offense against the United States, or any State, Territory or the District of Columbia, and he did not by misconduct or neglect cause or bring about his own prosecution.

(b) Proof of the requisite facts shall be by a certificate of the court or pardon wherein such facts are alleged to appear, and other evidence thereof shall not be received.

(c) No pardon or certified copy of a pardon shall be considered by the United States Court of Federal Claims unless it contains recitals that the pardon was granted after applicant had exhausted all recourse to the courts and that the time for any court to exercise its jurisdiction had expired.

(d) The Court may permit the plaintiff to prosecute such action in forma pauperis.

(e) The amount of damages awarded shall not exceed \$100,000 for each 12-month period of incarceration for any plaintiff who was unjustly sentenced to death and \$50,000 for each 12-month period of incarceration for any other plaintiff.<sup>4</sup>

The statute allocates tasks between the COFC and the court that “set[] aside or revers[ed] such conviction,” ordinarily the district court or military tribunal that convicted the individual.<sup>5</sup> Under this statute, the court of conviction determines whether to issue a “certificate of innocence” (“COI”), and the COFC then determines the amount of damages, if any, subject to the statutory cap.<sup>6</sup>

This Article discusses one of many open questions about this provision: whether a plaintiff is jurisdictionally required to obtain a COI to proceed in the COFC, or if it is merely a matter of proof.<sup>7</sup> Part I discusses the history of

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<sup>4</sup> § 2513.

<sup>5</sup> § 2513(a)(1). One court of appeals recently declined to issue such a certificate, holding that the district court “is the most appropriate court to issue the certificate.” *United States v. Graham*, 608 F.3d 164, 169 (4th Cir. 2010), *cert. denied*, 131 S. Ct. 998 (2011).

<sup>6</sup> § 2513. The statute permits damages to be awarded if an individual has been pardoned “upon the stated ground of innocence and unjust conviction.” § 2513(a)(1). This Article uses the term “COI” interchangeably for a COI or pardon with the appropriate statutory recitals.

<sup>7</sup> This Article addresses the principal unresolved issue directly involving the COFC’s jurisdiction. Another issue, one that is perhaps of more direct importance to those individuals whose convictions were set aside, is the standard by which the court of conviction determines whether an individual “br[ought] about his own prosecution” through “misconduct or neglect.” § 2513(a)(2). Surprisingly few appellate decisions address this issue. *Graham*, 608 F.3d at 173 n.4 (“In fact, although Congress first enacted a certificate of innocence statute in 1938, this opinion cites to *all* published circuit-court opinions interpreting § 2513 or its predecessors.” (citation omitted)) (citing *United States v. Racing Servs., Inc.*, 580 F.3d 710 (8th Cir. 2009); *Betts v. United States*, 10 F.3d 1278 (7th Cir. 1993); *Osborn v. United States*, 322 F.2d 835 (5th Cir. 1963); *Rigsbee v. United States*, 204 F.2d 70 (D.C. Cir. 1953); *Brunner v. United States*, 200 F.2d 276 (6th Cir. 1953)).

In *United States v. Graham*, 608 F.3d 164 (4th Cir. 2010), *cert. denied*, 131 S. Ct. 998 (2011), the Fourth Circuit appears to have created a circuit split as to the applicable standard specifically addressing this language, departing from the prior reasoning of the Seventh Cir-

the unjust imprisonment statutes and briefly reviews the inconsistent Court of Claims, Federal Circuit, and COFC precedent on whether the filing of a COI at the COFC is jurisdictional. Part II reviews recent Supreme Court precedent analyzing when a statutory provision is jurisdictional. Part III argues that the COI should not be considered a jurisdictional requirement before the COFC, but, rather, a substantive element of plaintiff's claim for relief.

## I. Background of the Unjust Imprisonment Statutes and the Ambiguous Case Law

### A. History of the Unjust Imprisonment Statutes

The call for a statute to compensate individuals who had been erroneously convicted of federal crimes appears to have originated in a 1912 article written by Professor Edwin M. Borchard, the law librarian of Congress at the time, which was presented to the Senate Committee on the Judiciary.<sup>8</sup> Professor Borchard also drafted a bill implementing his proposed statutory language,

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cuit in *Betts v. United States*, 10 F.3d 1278 (7th Cir. 1993), which had interpreted § 2513(a)(2) as follows:

[T]he statute expressly requires a causal connection between the petitioner's conduct and his prosecution; it does not preclude relief simply because the petitioner engaged in misconduct or neglect, period. In a moral sense, perhaps, a person who engages in conduct that a prosecutor or trial court mistakenly believes to constitute a criminal offense might be said to have "brought about" his own prosecution, on the theory that he would not have been charged had he comported himself in a more upstanding fashion. Yet, construing the statute in that way would require courts to assess the virtue of a petitioner's behavior when it does not amount to a criminal offense.

*Id.* at 1285. The Fourth Circuit "reject[ed] this narrow reading of subsection (a)(2) because it effectively reads 'neglect' out of the statute," *Graham*, 608 F.3d at 174, albeit over dissent:

[W]hat the majority fails to recognize in summarily dismissing the reasoning of the one circuit that has specifically interpreted the second clause of § 2513(a)(2) is that *Betts* specifically accounts for both affirmative misconduct and careless omissions. Thus, contrary to the majority's assertion, the Seventh Circuit interpreted the statute in its entirety and gave the statute its most natural reading.

*Id.* at 181–82 (Gregory, J., dissenting) (footnote omitted) (citation omitted). The Supreme Court declined to resolve the issue, denying certiorari. *United States v. Graham*, 131 S. Ct. 998 (2011).

<sup>8</sup> EDWIN M. BORCHARD, STATE INDEMNITY FOR ERRORS OF CRIMINAL JUSTICE, S. DOC. NO. 62-974, at 31–33 (3d Sess. 1912), *quoted in* *United States v. Keegan*, 71 F. Supp. 623, 627–30 (S.D.N.Y. 1947). *Keegan* also quotes extensively from the House and Senate reports that accompanied the eventual passage of unjust imprisonment statutes in 1938, 71 F. Supp. at 630–35, and is often cited as the authoritative source for the statutes' legislative history. *See, e.g., Graham*, 608 F.3d at 171; *Betts*, 10 F.3d at 1284; *Brunner*, 200 F.2d at 279.

which was introduced to Congress but ultimately failed.<sup>9</sup> Notably, in Professor Borchart's original bill, "jurisdiction to try the facts of the applicant's innocence was given to the Court of Claims, the burden of proving his innocence being on the applicant."<sup>10</sup> According to his commentary:

[T]he Court of Claims would, of course, receive the record from the trial court, the appellate court, and the second trial court, in order to determine the justice of relief in the case. They may also call for oral or written testimony whenever desired. This section gives the court full power and opportunity to arrive at the facts.<sup>11</sup>

Professor Borchart considered it important for determinations of actual innocence to be made by the Court of Claims, rather than the "trial court, or the appellate court, or the second trial court (which presumably could judge better of the merits and circumstances of the case) in order to maintain the traditions of American judicial procedure."<sup>12</sup> He further explained:

If the jury or trial court were given the right to pronounce on the propriety of an award in a case of acquittal (as is the case in some of the European countries), it would bring into our law a new kind of acquittal, in which the jury or judge could acquit *with degrees of approval or sympathy*. The distinction would be an odious one to make. While it would be desirable to have the benefit of the special knowledge of the case secured by the trial court or the jury, still it is better to forego this advantage for the sake of conformity with legal custom and leave the establishment of the damage to a new court conforming in its jurisdiction in this case to is jurisdiction in similar cases of claims against the United States.<sup>13</sup>

Congress did not attempt to pass similar legislation for over two decades.<sup>14</sup> Largely reflecting Professor Borchart's version, the Senate bill continued to provide the Court of Claims with authority to determine the actual innocence of the individual.<sup>15</sup> When the bill reached the House, however, it was altered to provide that "innocence must be established by the courts or pardoning authority before a claim for damages is presented in the Court of Claims, which only hears the question of damages."<sup>16</sup>

The House version of the bill was eventually passed to become the original version of the unjust imprisonment statute, and it has survived almost entirely

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<sup>9</sup> *Keegan*, 71 F. Supp. at 627.

<sup>10</sup> S. Doc. No. 62-974, at 32. To prove innocence under Professor Borchart's bill, the claimant was required to "show that the act with which he was charged was not committed at all, or, if it was committed, was not committed by the accused," as well as "that he has not, by his acts or failure to act, either intentionally or by willful misconduct or negligence, contributed to bring about his arrest or conviction." *Keegan*, 71 F. Supp. at 628.

<sup>11</sup> S. Doc. No. 62-974, at 31.

<sup>12</sup> *Id.* at 33.

<sup>13</sup> *Id.*

<sup>14</sup> *Keegan*, 71 F. Supp. at 630.

<sup>15</sup> S. REP. NO. 75-202, at 3 (1937).

<sup>16</sup> H.R. REP. NO. 75-2299, at 2 (1938).

to the present date.<sup>17</sup> Thus, the statute has always denied the Court of Claims' authority to pass upon the guilt or innocence of claimants, a function far afield of the court's ordinary jurisdiction.<sup>18</sup>

However, this principle is expressed not as an issue of the Court of Claims' jurisdiction, but, rather, in terms of the type of evidence the court is competent to receive when judging whether a plaintiff is entitled to compensation. Professor Borchart's 1912 bill and the Senate's 1938 bill "would have the Court of Claims try the *facts*."<sup>19</sup> The enacted statute, on the other hand, provided—and to this day continues to provide in slightly revised language—that "[t]he only *evidence* admissible on the issue of innocence of the plaintiff shall be a certificate of the court in which such a person was adjudged not guilty or a pardon or certified copy of a pardon."<sup>20</sup>

Since its original passage, there have been no major substantive revisions to the unjust imprisonment statute. With the creation of Title 28 in 1948, the statute was split into two parts, and changes to the phraseology were made.<sup>21</sup> With the passage of the Federal Courts Improvement Act of 1982, the statute was revised to transfer authority from the abolished Court of Claims to the newly created U.S. Claims Court, and it was updated again in 1992 to reflect the renaming of the Claims Court as the COFC, with appellate review vested in the Federal Circuit.<sup>22</sup> In 2004, with minimal comment, Congress increased the maximum recovery under the statute from its original \$5,000 to the more realistic "\$50,000 for each 12-month period of incarceration" and, in the case of those "unjustly sentenced to death," to \$100,000 per year of incarceration.<sup>23</sup>

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<sup>17</sup> Act of May 24, 1938, ch. 266, 52 Stat. 438 (codified as amended at 28 U.S.C. §§ 1495, 2513 (2006)).

<sup>18</sup> *Reed v. United States*, 25 F. App'x 903, 904 (Fed. Cir. 2001) (per curiam) ("The Court of Federal Claims does not have jurisdiction to review and overturn criminal convictions.") (citing *Lott v. United States*, 11 Cl. Ct. 852, 853 (1987)).

<sup>19</sup> H.R. REP. NO. 75-2299, at 2 (emphasis added).

<sup>20</sup> 18 U.S.C. § 730 (Supp. IV 1938) (emphasis added) (current version at 28 U.S.C. § 2513(b) (2006)).

<sup>21</sup> Act of June 25, 1948, Pub. L. No. 80-773, §§ 1495, 2513, 62 Stat. 869, 941, 978.

<sup>22</sup> Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, § 133(c)(1), 96 Stat. 25, 40 (replacing "Court of Claims" with "United States Claims Court"); Federal Courts Administration Act of 1992, Pub. L. No. 102-572, § 902(a)(1), 106 Stat. 4506, 4516 (replacing "United States Claims Court" with "United States Court of Federal Claims").

<sup>23</sup> Justice for All Act of 2004, Pub. L. No. 108-405, § 431, 118 Stat. 2260, 2293; *see also* H.R. REP. NO. 108-711, at 8, *reprinted in* 2005 U.S.C.C.A.N. 2274, 2280 (explaining only that "[a]ny such payments would be made from the U.S. Treasury's Judgment Fund and would be considered direct spending. The number of such cases in recent years has been very small, so we do not expect any increase in payments for this purpose to be significant.").



## B. The Case Law is Ambiguous as to Whether a COI is Jurisdictional

Owing perhaps to a lack of frequent use, there are no appellate decisions that explicitly analyze whether the presentation of a COI is a jurisdictional requirement or a matter of proof. Thus, in cases brought by individuals who have been unable to obtain COIs or who have obtained inadequate COIs, the trial decisions vary, dismissing either for lack of subject matter jurisdiction or for failure to state a claim upon which relief can be granted.<sup>24</sup>

In her 2009 decision in *Wood v. United States*,<sup>25</sup> Judge Christine Miller conducted an extensive review of this precedent, concluding that binding authority requires the COFC to treat the presentation of a COI as jurisdictional.<sup>26</sup> Judge Miller's thorough analysis need not be repeated in detail. However, given the contradictory precedent—and cautious of “drive-by jurisdictional rulings”—her conclusion that precedent so clearly favors the view that the COI is a jurisdictional requirement is flawed.

In what appears to be the earliest reported case touching on this issue, *Prisament v. United States*,<sup>27</sup> the Court of Claims presaged the conflict. The petitioner in that case was convicted of bank robbery in 1937 but was eventually pardoned by President Roosevelt.<sup>28</sup> The pardon itself did not contain all of the necessary recitals required by the statute.<sup>29</sup> While it included a statement that petitioner was “innocent of the offense for which he [was] being held,” it did not state that his conduct “did not constitute a crime or offense” in the state in which he was convicted, nor did it declare that he had not “intentionally, or by willful misconduct, or negligence” brought about his own conviction.<sup>30</sup> The government moved to dismiss on jurisdictional grounds, and the court noted that “[n]o objection is made on the ground that a motion to dismiss

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<sup>24</sup> The Supreme Court has observed that “judicial opinions . . . ‘often obscure the issue by stating that the court is dismissing “for lack of jurisdiction” when some threshold fact has not been established, without explicitly considering whether the dismissal should be for lack of subject matter jurisdiction or for failure to state a claim.’” *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 511 (2006) (quoting *Da Silva v. Kinsho Int'l Corp.*, 229 F.3d 358, 361 (2d Cir. 2000)). Such “drive-by jurisdictional rulings” . . . should be accorded no ‘precedential effect’ on the question whether the federal court had authority to adjudicate the claim in suit.” *Id.* (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998)).

<sup>25</sup> 91 Fed. Cl. 569 (2009).

<sup>26</sup> *Id.* at 573–79.

<sup>27</sup> 92 Ct. Cl. 434 (1941).

<sup>28</sup> *Id.* at 434.

<sup>29</sup> *Id.* at 435–36.

<sup>30</sup> *Id.* at 435–37 (quoting Act of May 24, 1938, ch. 266, § 2(b)–(c), 52 Stat. 438, 438 (the original unjust imprisonment statute as passed three years earlier) (current version at 28 U.S.C. § 2513(a)(1)–(2) (2006))).



is filed instead of a demurrer. Either way the objection to the cause of action is made, the result would be the same,” i.e., dismissal, because plaintiff had not presented a pardon with the adequate recitals.<sup>31</sup>

The post-*Prisament* Court of Claims’ cases dealing with the adequacy of a plaintiff’s COI fall into two categories. First, there is a series of cases in which, like *Prisament*, the court did not discuss jurisdiction, but instead ruled on the adequacy of the COI presented to the court as a matter of evidence. Several of these cases resulted in dismissal for failure to allege a cause of action, the court holding that the COI presented was insufficient as a matter of law.<sup>32</sup> However in one case, the court held that the plaintiff had adequately pleaded the requirements of the statute.<sup>33</sup> Second, there are several cases in which the court explicitly treated the COI requirement as jurisdictional and dismissed on the grounds that, because the plaintiff failed to obtain an adequate COI, the court did not possess jurisdiction over the claim.<sup>34</sup>

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<sup>31</sup> *Id.* at 437. Given this disposition, one might consider *Prisament* the quintessential “drive-by jurisdictional ruling” envisioned by the Court in *Arbaugh*.

<sup>32</sup> See *Stout v. United States*, 210 Ct. Cl. 722, 722 (1976) (unpublished table decision) (dismissing for what appears to be failure to state a claim after “plaintiff’s former attorney of record[] made a diligent effort to obtain the necessary certificate but was unable to do so”); *Vincin v. United States*, 468 F.2d 930, 933 (Ct. Cl. 1972) (per curiam) (dismissing case for failure to state a claim when “[p]laintiff . . . neither alleged nor complied with the requirements of the statute and cannot prevail in this case. Without the recitals specified by the statute . . . plaintiff’s pardon creates no cause of action.”); *Brunner v. United States*, 110 F. Supp. 479, 480 (Ct. Cl. 1953) (vacating prior decision granting damages under statute after the Sixth Circuit reversed the district court’s grant of a COI because “there is now no proof in the record to sustain the allegations of plaintiff’s petition in this court”); *Sinclair v. United States*, 109 F. Supp. 529, 531–32 (Ct. Cl. 1953) (granting government’s motion for summary judgment when decision reversing conviction did not state that “plaintiff’s misconduct or neglect did not bring about his prosecution” and thus did not serve as a COI); *Hadley v. United States*, 66 F. Supp. 140, 141–42 (Ct. Cl. 1946) (dismissing complaint for failure to state a claim because plaintiff’s submission did not make the appropriate recitals to be a COI).

<sup>33</sup> *Andolschek v. United States*, 77 F. Supp. 950, 951–52 (Ct. Cl. 1948).

<sup>34</sup> *McMurry v. United States*, 228 Ct. Cl. 897, 898 (1981) (“Plaintiff has furnished us with no such certificate. . . . We therefore have no jurisdiction under this statute.”); *Lucas v. United States*, 228 Ct. Cl. 862, 862 (1981) (“Plaintiff here has not met the requirements of the statute and we have no jurisdiction.”); *Calloway v. United States*, 215 Ct. Cl. 1065, 1066 (1978) (unpublished table decision) (“[W]ithout such statements in the certificate of innocence, plaintiffs cannot prove any claim within the jurisdiction of this court.”); *Viles v. United States*, 95 Ct. Cl. 591, 591–92 (1942) (dismissing “for lack of jurisdiction” where plaintiff’s “pardon does not contain the recitals called for” by the statute).

While the Federal Circuit has ruled on numerous cases addressing this issue, it has never done so in a published opinion.<sup>35</sup> Thus, neither Federal Circuit case law nor those cases from the COFC are binding on future courts considering § 1495 claims.<sup>36</sup> However, these cases generally fall into the same two categories as the Court of Claims' cases, albeit with significantly more falling in the jurisdictional camp. Besides Judge Miller's recent decision in *Wood*, most cases finding the COI to be jurisdictional do so without analysis.<sup>37</sup> Additionally, several of these cases state that dismissal is appropriate for lack of jurisdiction but include phrases that suggest that the case is being dismissed for failure to state a claim.<sup>38</sup> The two cases in which the court found the COI

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<sup>35</sup> *Wood v. United States*, 91 Fed. Cl. 569, 575 & n.1 (2009).

<sup>36</sup> *See id.* (discussing nonbinding nature of unpublished Federal Circuit and COFC decisions); *see also* FED. CIR. R. 32.1(d) ("The [Federal Circuit] . . . will not give one of its own nonprecedential decisions the effect of binding precedent."); *W. Coast Gen. Corp. v. Dalton*, 39 F.3d 312, 315 (Fed. Cir. 1994) ("Court of Federal Claims decisions, while persuasive, do not set binding precedent for separate and distinct cases in that court.").

<sup>37</sup> *See, e.g., Chevalier v. United States*, 329 F. App'x 924, 926 (Fed. Cir. 2009) (per curiam) ("Section 1495 therefore does not provide the Court of Federal Claims with jurisdiction over Chevalier's claims."); *Humphrey v. United States*, 60 F. App'x 292, 295 (Fed. Cir. 2003) (per curiam) (holding that, because the district court's order "did not indicate that Mr. Humphrey did not cause his own prosecution by misconduct or neglect . . . the Court of Federal Claims correctly concluded that Mr. Humphrey did not meet the jurisdictional requirements of § 2513"); *Reed v. United States*, 25 F. App'x 903, 905 (Fed. Cir. 2001) (per curiam) ("The Court of Federal Claims correctly dismissed Mr. Reed's complaint for lack of jurisdiction or failure to state a cognizable claim for relief."); *Dorrrough v. United States*, 13 F. App'x 954, 956 (Fed. Cir. 2001) (per curiam) ("As no other court has overturned Mr. Dorrough's conviction, the Court of Federal Claims has no power to entertain this claim."); *Cochran v. United States*, No. 00-5054, 2000 WL 727785, at \*1 (Fed. Cir. May 19, 2000) (unpublished table decision) ("Cochran ha[s] failed to establish the statutory requirements for jurisdiction over false imprisonment and unjust conviction because Cochran's conviction ha[s] not been overturned . . ."); *Caudle v. United States*, No. 94-5100, 31994 WL 502934, at \*1 (Fed. Cir. Sept. 15, 1994) ("The courts have repeatedly held that the requirements of 28 U.S.C. section 2513 are jurisdictional and that the plaintiff cannot recover under this statute unless he furnishes a certificate of the convicting court that his conviction has been reversed on the grounds of his innocence."); *Burgess v. United States*, 20 Cl. Ct. 701, 705-06 (1990) (dismissing for lack of jurisdiction because of failure to acquire a COI); *Lott v. United States*, 11 Cl. Ct. 852, 853 (1987) ("[T]he court's jurisdiction to entertain a claim for money damages for unjust conviction arises only *after* the challenged conviction has been reversed, on grounds of innocence, by a court of competent jurisdiction or by Presidential pardon.").

<sup>38</sup> *See, e.g., Reed*, 25 F. App'x at 905 (affirming dismissal on jurisdictional grounds as appropriate because of plaintiff's "failure to state a cognizable claim for relief"); *Calloway*, 215 Ct. Cl. at 1067 (dismissing on the grounds that "plaintiffs cannot prove any claim within the jurisdiction of this court"); *Humphrey*, 52 Fed. Cl. at 598 (dismissing for lack

to be non-jurisdictional emphasized that a COI “is merely a *means of proving* the underlying facts.”<sup>39</sup> In one such case, the trial court observed:

Because plaintiff has not submitted an executed certificate alleging the requisite facts, defendant moved to dismiss plaintiff’s complaint on the ground that the court lacks subject-matter jurisdiction. However, *the court plainly has jurisdiction* to adjudicate claims for unjust conviction and imprisonment asserted pursuant to 28 U.S.C. §§ 1495 & 2513 such as that asserted in the complaint.<sup>40</sup>

In the absence of binding precedent from the Federal Circuit, the precedent from the Court of Claims is undoubtedly controlling.<sup>41</sup> But, while Judge Miller was confident that the Court of Claims’ precedent had resulted in the COI being jurisdictional, the case law is not nearly so cut and dry. The later unpublished Federal Circuit and COFC decisions, while not controlling, also evince that the decisions from the Court of Claims do not lead inescapably to the conclusion that the COI is jurisdictional.<sup>42</sup> Moreover, without actual analysis, the Court of Claims’ decisions assuming the question to be jurisdictional are the types of rulings that the Supreme Court has “accorded ‘no precedential effect’ on the question whether the federal court had authority to adjudicate the claim in suit.”<sup>43</sup>

## II. The Presumption that Statutory Limitations are Non-Jurisdictional: Recent Supreme Court Jurisprudence

Oftentimes, the difference between dismissal for lack of jurisdiction and dismissal for failure to state a claim is purely academic. Take the case of an incarcerated prisoner who files a complaint in the COFC arguing, among other theories, that he was unjustly imprisoned by the federal government. The prisoner’s conviction is affirmed and his petitions for habeas relief denied. He sues in the COFC, because the government has purportedly engaged in a massive conspiracy to defraud him and infringe on his rights.<sup>44</sup>

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of jurisdiction because of “plaintiff’s failure to furnish any document reciting the statutory requirements of section 2513”).

<sup>39</sup> *Bolduc v. United States*, 248 F. App’x 162, 164 (Fed. Cir. 2007) (emphasis added); *see also Veltmann v. United States*, 39 Fed. Cl. 426, 428 (1997).

<sup>40</sup> *Veltmann*, 39 Fed. Cl. at 428 (emphasis added).

<sup>41</sup> *Wood*, 91 Fed. Cl. at 576 (citing *Coltec Indus., Inc. v. United States*, 454 F.3d 1340, 1353 (Fed. Cir. 2006)).

<sup>42</sup> *E.g., Veltmann*, 39 Fed. Cl. at 428.

<sup>43</sup> *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 511 (2006).

<sup>44</sup> This scenario is based loosely on *Fort v. United States*, No. 10-181, 2010 WL 2813127, at \*2 (Fed. Cl. July 2, 2010). This Article expresses no opinion on the merits of Mr. Fort’s claims.

The prisoner's claims do not belong in the COFC primarily because they sound in tort, and tort claims are simply not within the COFC's jurisdiction.<sup>45</sup> Moreover, the prisoner's conviction has been upheld, and therefore he has not, and cannot, obtain a COI, at least as the facts presently stand.<sup>46</sup> Whether the prisoner's furnishing of a COI is deemed jurisdictional or evidentiary is in this case irrelevant. He does not have a COI; the case is dismissed without prejudice.<sup>47</sup>

However, there are differences between a dismissal for lack of jurisdiction and one for failure to state a claim, particularly in the court's ability to raise the issue of jurisdiction on its own initiative at any time, and its mandate to hear any jurisdictional arguments the parties make at any time.<sup>48</sup> For example, in *Arbaugh v. Y & H Corp.*,<sup>49</sup> the defendant raised a jurisdictional defense two weeks after having lost at trial.<sup>50</sup> The trial judge, despite concerns that this late-in-the-game motion was unfair, felt obligated to consider the motion, because it implicated the court's jurisdiction.<sup>51</sup> Agreeing with the defendant—and after the plaintiff had already prevailed on the merits—the district judge dismissed the plaintiff's claims.<sup>52</sup> However, because the Supreme Court eventually found that the issue raised by the defendant was not jurisdictional, it

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<sup>45</sup> See 28 U.S.C. § 1491(a)(1) (2006) (“The United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim . . . for liquidated or unliquidated damages *in cases not sounding in tort.*” (emphasis added)).

<sup>46</sup> See *id.* § 2513(a)(1), (b) (2006) (requiring certificate provided to show that the prisoner's “conviction has been reversed or set aside”).

<sup>47</sup> The case is dismissed without prejudice, of course, out of respect for the possibility that future circumstances may exonerate our incarcerated prisoner, and, if he was then able to obtain a COI from the court that convicted him, he would be entitled to bring his claim again. See 18A CHARLES ALAN WRIGHT, ARTHUR R. MILLER & EDWARD H. COOPER, FEDERAL PRACTICE AND PROCEDURE § 4436 (2d ed. 2002) (“[D]ismissal for lack of jurisdiction or improper venue does not operate as an adjudication upon the merits. This provision means only that the dismissal permits a second action on the same claim that corrects the deficiency found in the first action.” (footnote omitted)).

<sup>48</sup> FED. R. CIV. P. 12(h)(3) (“If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.”); R. CT. FED. CL. 12(h)(3) (same); Kontrick v. Ryan, 540 U.S. 443, 455 (2004) (“A litigant generally may raise a court's lack of subject-matter jurisdiction at any time in the same civil action . . . .” (citing *Mansfield, Coldwater & Lake Mich. Ry. Co. v. Swan*, 111 U.S. 379, 382 (1884))); see also Jason Wojciechowski, Note, *An Obscured Expansion of the Commerce Power*, 30 W. NEW ENG. L. REV. 477, 479 n.12 (2008) (explaining practical implications between the jurisdictional-failure to state a claim distinction).

<sup>49</sup> 546 U.S. 500 (2006).

<sup>50</sup> *Id.* at 508.

<sup>51</sup> *Id.* at 504.

<sup>52</sup> *Id.* at 509.

reversed the dismissal, and the defendant's last-ditch effort failed because he had forfeited this defense.<sup>53</sup>

Over the past decade, the Supreme Court has reviewed several cases that laypersons and lawyers alike might view as appealing to only "procedure geeks."<sup>54</sup> These cases, however, have achieved some measure of clarity in a previously clouded area. Specifically, the Court has attempted to delineate when a rule or statutory requirement should be considered jurisdictional, thus subjecting it to all the baggage that jurisdictional rules carry, compared to those provisions which are either purely procedural or matters of the litigant's substantive claim for relief.<sup>55</sup>

In most of these cases, the Court has commented on the vague usage of "jurisdictional" in opinions, declaring it to be a term that has "too many meanings."<sup>56</sup> Distilled to its core, these cases present a number of lessons for the present quest regarding the COI requirement. The first guideline is a bright line rule: the Court has held that a provision, which Congress does not explicitly state to be "jurisdictional," is presumed not to be.<sup>57</sup> The second guideline is less definite: provisions that mandate certain *timely* actions by a party, but that can be "cured" by later *untimely* actions, are generally not jurisdictional.<sup>58</sup> The final "guideline" is rather less of a guideline than an inconsistency to be wary of: provisions delineating the government's waiver of sovereign immunity must, of course, be "strictly construed," but these provisions are not necessarily "jurisdictional."<sup>59</sup>

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<sup>53</sup> *Id.* at 504, 516. This forfeiture has been commonly referred to as "waiver," but as the Supreme Court has observed, "forfeiture" is more accurate when the party's failure to raise an issue was unintentional rather than a deliberate strategic choice. See *Kontrick v. Ryan*, 540 U.S. 443, 458 n.13 (2004). However, this Article uses these terms interchangeably.

<sup>54</sup> See, e.g., Scott Dodson, *Jurisdictionality and Bowles v. Russell*, 102 N.W. U. L. REV. COLLOQUY 42, 42 (2007), <http://www.law.northwestern.edu/lawreview/Colloquy/2007/21/LRColl2007n21Dodson.pdf> ("On June 14, 2007, the Supreme Court decided *Bowles v. Russell*, a case watched primarily by procedure geeks but one which may have enormous impact for courts and litigators." (footnote omitted)).

<sup>55</sup> See *supra* note 48 and accompanying text. Rules characterized as purely procedural or as part of the litigant's claim for relief are not as strictly enforced, but are not necessarily "waivable." See Dodson, *supra* note 54, at 46–48 (describing "mandatory but nonjurisdictional" time limits).

<sup>56</sup> *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 90 (1997), *quoted in* *Bowles v. Russell*, 551 U.S. 205, 215 (2007) (Souter, J., dissenting), *Arbaugh*, 546 U.S. at 510, & *Kontrick*, 540 U.S. at 454.

<sup>57</sup> *Arbaugh*, 546 U.S. at 516.

<sup>58</sup> See *Becker v. Montgomery*, 532 U.S. 757, 765 (2001).

<sup>59</sup> See *Scarborough v. Principi*, 541 U.S. 401, 414 (2004).

### A. The Presumption that Congress Means “Jurisdiction” Only When It Says So Explicitly

The first guideline discernible from the Supreme Court’s recent jurisprudence is an intuitive presumption that has already had a great impact. In *Arbaugh*, the Supreme Court set out to resolve a circuit split over whether the “employee-numerosity” requirement of Title VII is jurisdictional.<sup>60</sup> As described briefly above, the plaintiff in *Arbaugh* won on the merits of her claim.<sup>61</sup> Two weeks after the entry of judgment, the defendant moved to dismiss for lack of subject matter jurisdiction, arguing that it did not employ fifteen or more employees during the relevant period and was, therefore, not an employer for the purposes of Title VII.<sup>62</sup> The district court, bound by the Fifth Circuit’s interpretation that this Title VII requirement is jurisdictional, vacated the judgment and dismissed the case.<sup>63</sup> The Supreme Court reversed, announcing the bright-line rule that:

[i]f the Legislature clearly states that a threshold limitation on a statute’s scope shall count as jurisdictional, then courts and litigants will be duly instructed and will not be left to wrestle with the issue. But when Congress does not rank a statutory limitation on coverage as jurisdictional, courts should treat the restriction as non-jurisdictional in character.<sup>64</sup>

Applied to the employee-numerosity requirement, the Court held that this provision is contained in a separate section than Title VII’s jurisdictional provision and simply “does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts.”<sup>65</sup> Thus, the Court found no indication that Congress intended this provision to be jurisdictional and

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<sup>60</sup> *Arbaugh*, 546 U.S. at 509–10.

<sup>61</sup> *Id.* at 508.

<sup>62</sup> *Id.* Title VII defines an “employer” as “a person engaged in an industry affecting commerce who has fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year, and any agent of such a person.” 42 U.S.C. § 2000e(b) (2006).

<sup>63</sup> *Arbaugh*, 546 U.S. at 509.

<sup>64</sup> *Id.* at 515–16 (footnote omitted) (citation omitted).

<sup>65</sup> *Id.* at 515 (quoting *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 394 (1982)). Title VII’s “jurisdictional provision” is contained in 42 U.S.C. § 2000e-5(f)(3), which provides “[e]ach United States district court and each United States court of a place subject to the jurisdiction of the United States shall have jurisdiction of actions brought under this subchapter.” 42 U.S.C. § 2000e-5(f)(3) (2006). The Court observed that Title VII is also covered by the court’s general federal question jurisdiction, but, when it was passed, the court’s general federal question jurisdiction included a \$10,000 amount in controversy requirement, and Congress wished to provide jurisdiction over smaller claims. *Arbaugh*, 546 U.S. at 505.



defendant's waiting until after entry of judgment affected a waiver on its right to raise this issue.<sup>66</sup>

The *Arbaugh* rule is both simple and profound. Many commentators have observed the dangers inherent in the federal courts' treatment of certain rules as "jurisdictional" when they should not be so treated.<sup>67</sup> Doing so can lead to "unnecessarily unfair results," and "loose application of the term leads to opaque decisions and courts failing adequately to explain why they reach the harsh results they do."<sup>68</sup> The "first principle of federal jurisdiction"<sup>69</sup> is that the court must "dismiss a suit at any stage of the proceedings if subject matter jurisdiction is lacking."<sup>70</sup> Related to this rule is the principle that objections related to subject matter jurisdiction cannot be waived, even when the circumstances are particularly compelling for a finding of waiver.<sup>71</sup> *Arbaugh* reigns in

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<sup>66</sup> See *Arbaugh*, 546 U.S. at 516.

<sup>67</sup> See, e.g., Alex Lees, Note, *The Jurisdictional Label: Use and Misuse*, 58 STAN. L. REV. 1457, 1464 (2006).

<sup>68</sup> *Id.* at 1466.

<sup>69</sup> HENRY M. HART, JR. & HERBERT WECHSLER, *THE FEDERAL COURTS AND THE FEDERAL SYSTEM* 719 (1953).

<sup>70</sup> Michael G. Collins, *Jurisdictional Exceptionalism*, 93 VA. L. REV. 1829, 1830–31 (2007).

<sup>71</sup> See *id.* at 1831. A classic example of this inflexibility is the Supreme Court's refusal to grant certiorari in *Teague v. Regional Commissioner of Customs*, 394 U.S. 977 (1969). The case involved a "highly important question under the First Amendment," *id.* at 977 (Black, J., dissenting from denial of certiorari), but because of "atmospheric events" the petition for certiorari arrived late, *id.* at 984. Justice Black described the circumstances as follows:

The judgments sought to be reviewed were entered on November 14, 1968, and the 90-day period therefore expired on Wednesday, February 12, 1969. The petition for certiorari, along with the required number of copies, was sent from New York City by first-class mail at about noon on Monday, February 10. A severe snowstorm had hit New York City the night before, causing considerable disruption of many services including, as it turned out, the mails. Counsel for petitioners no doubt anticipated that some delay might possibly result from the storm, but since first-class mail from New York normally reaches Washington overnight, they could not have anticipated that it would take more than the remaining two and one-half days for their petition to arrive. In fact, however, the petition took four days to reach Washington and was docketed here on Friday, February 14, 1969.

*Id.* at 981. Because the statute governing petitions for certiorari states that the petition "shall be taken or applied for within ninety days after the entry of judgment," 28 U.S.C. § 2101(c) (2006), six of nine justices refused to grant a measure of flexibility to the petitioner; Justice Douglas concurred with Justice Black's dissent and Justice Harlan would have postponed consideration of the jurisdictional issue to the merits. *Teague*, 394 U.S. at 977, 984 (Black, J., dissenting). Justice Black continued:

[T]he Court's draconic interpretation of the statute is not supported by our prior decisions. Nor does the language of the statute itself dictate the Court's result. The statute does not say explicitly that the time limitation may be inapplicable under certain



the courts' use of the jurisdictional sledgehammer to only those cases where Congress intended such inflexibility.<sup>72</sup>

### B. A Curable Defect is a Non-Jurisdictional Defect

Before creating this presumption, the Supreme Court addressed a situation where a jurisdictional provision suggested that a defect could actually be cured. In *Becker v. Montgomery*,<sup>73</sup> the Sixth Circuit dismissed a pro se petitioner's appeal because "[o]n the line tagged '(Counsel for Appellant),' [petitioner] typed, but did not hand sign, his own name."<sup>74</sup> In all other respects, Becker had correctly completed the government-printed form to appeal an adverse district court judgment.<sup>75</sup> The Supreme Court reversed, as equity clearly dictated, because, as the respondent conceded, there was no "uncertain[t]y about petitioner Becker's intention to pursue an appeal once he filed his timely, though unsigned, notice of appeal in the district court."<sup>76</sup> Of course,

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extenuating circumstances but it also does not say that the time limit must be ruthlessly applied in every conceivable situation, without regard to hardships involved or extenuating circumstances present. The Court therefore must decide what is the more sensible interpretation of the statute. I for one cannot think of any purpose Congress might have had that could possibly be served by holding that a litigant can be defeated solely because of a delay that was entirely beyond his control.

*Id.* at 983. Some commentators have described Black's diatribe as "the most powerful criticism of the doctrine of jurisdictional time limits." Perry Dane, *Jurisdictionality, Time, and the Legal Imagination*, 23 HOFSTRA L. REV. 1, 16 (1994).

<sup>72</sup> See, e.g., *Reed Elsevier, Inc. v. Muchnick*, 130 S. Ct. 1237, 1245 (2010) (holding that the Copyright Act's registration requirement is non-jurisdictional because the statute did not clearly state that it was); *Pittsburgh Mack Sales & Serv., Inc. v. Int'l Union of Operating Eng'rs, Local Union No. 66*, 580 F.3d 185, 189–90 (3d Cir. 2009) (holding that existence of a contract between employer and union under § 301 of the Labor Management Relations Act is not jurisdictional because Congress did not clearly state such was a limit on subject matter jurisdiction); *In re Trusted Net Media Holdings LLC*, 550 F.3d 1035, 1043 (11th Cir. 2008) (holding that § 303(b) of the Bankruptcy Act does not limit the Bankruptcy Court's jurisdiction because of a lack of specific Congressional expression that the requirement is jurisdictional); *Litecubes, LLC v. N. Light Prods., Inc.*, 523 F.3d 1353, 1363 (Fed. Cir. 2008) (holding that the requirement that patent and copyright infringement occurred in the United States is not jurisdictional because the relevant statutes do not clearly state that the territoriality requirement is jurisdictional); *Partington v. Am. Int'l Specialty Lines Ins. Co.*, 443 F.3d 334, 339 (4th Cir. 2006) (holding that purchase of security under the Securities Act of 1933 is non-jurisdictional, entitling plaintiff to default judgment).

<sup>73</sup> 532 U.S. 757 (2001).

<sup>74</sup> *Id.* at 759–60.

<sup>75</sup> *Id.* at 759.

<sup>76</sup> *Id.* at 761–62 (alteration in original) (quoting Brief in Response to the Petition for Certiorari at 5, *Becker v. Montgomery*, 532 U.S. 757 (2001) (No. 00-6374)). With no party

equitable considerations would have no sway if the signature requirement were jurisdictional. But the Supreme Court held that the signature requirement in the Federal Rules of Appellate Procedure, which incorporates the signature requirement of Federal Rule of Civil Procedure 11(a), is not jurisdictional, because it explicitly permits the appellant to correct the defect promptly after it has been called to the attention of the attorney or party.<sup>77</sup>

This proposition seems intuitive enough. Jurisdictional rules may not be waived; and, while lack of jurisdiction may be cured later by allowing the plaintiff to bring a new action,<sup>78</sup> it would be odd that a plaintiff simply could be allowed to proceed after curing a defect that would permit a court to dismiss immediately for lack of jurisdiction.<sup>79</sup>

This rule contrasts with appellate courts' apparent "fetish of their own authority by characterizing timing defects in notices of appeal as 'jurisdictional.'"<sup>80</sup> The Supreme Court reaffirmed this principle in 2007 in *Bowles v. Russell*,<sup>81</sup> a highly criticized five to four decision.<sup>82</sup> The petitioner in *Bowles* applied for an extension of time to file his notice of appeal with the district court.<sup>83</sup> The court granted this extension but inadvertently gave the petitioner an additional seventeen days, instead of the fourteen days allowed by statute.<sup>84</sup> Relying on the district court's order, the petitioner missed the actual deadline by three days.<sup>85</sup>

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defending the judgment below, the Supreme Court appointed an attorney to participate as amicus curiae in support of the Sixth Circuit's position. *Id.* at 762 n.1.

<sup>77</sup> *Id.* at 764–65; see also FED. R. CIV. P. 11(a).

<sup>78</sup> See *supra* note 47.

<sup>79</sup> See *Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 830 (1989) ("The existence of federal jurisdiction ordinarily depends on the facts as they exist when the complaint is filed."). Courts will sometimes permit a plaintiff to cure a jurisdictional defect through the filing of a supplemental pleading. FED. R. CIV. P. 15(d); e.g., *Mathews v. Diaz*, 426 U.S. 67, 75 (1976) (permitting plaintiff to file supplemental pleading to include administrative claim filed with agency after original complaint was filed). However, whether supplemental pleading will be permitted to cure jurisdictional defects depends on the substantive provision at issue. *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 790 (Fed. Cir. 1996); see, e.g., *Cencast Servs., L.P. v. United States*, 94 Fed. Cl. 425, 449–52 (2010) (allowing plaintiff to supplement complaint with new factual allegations, but not a new theory of recovery).

<sup>80</sup> Mark A. Hall, *The Jurisdictional Nature of the Time to Appeal*, 21 GA. L. REV. 399, 399 (1986). Individuals have thirty days—sixty if the United States is a party—to file a notice of appeal. 28 U.S.C. § 2107(a)–(b) (2006); FED. R. APP. P. 4(a)(1)(A)–(B). Under certain circumstances, the district court may extend or reopen this time period for fourteen days. § 2107(c).

<sup>81</sup> 127 S. Ct. 2360 (2007).

<sup>82</sup> See, e.g., *Dodson*, *supra* note 54, at 43–44.

<sup>83</sup> 127 S. Ct. at 2362.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

Because the filing of a notice of appeal is “mandatory and jurisdictional,” the Court was powerless to excuse the late filing as a matter of equity.<sup>86</sup> Beyond the unfairness of this situation,<sup>87</sup> *Bowles* highlights the fact that jurisdictional defects, such as missing a time limit, cannot be cured.

### C. The Curious Case of Waivers of Sovereign Immunity

*Bowles* demonstrates a break from the apparent trend in the Court’s jurisprudence, exemplified by *Becker* and *Arbaugh*, of reducing the number of jurisdictional requirements. The Supreme Court’s recent sovereign immunity jurisprudence, as demonstrated by *Scarborough v. Principi*<sup>88</sup> and *John R. Sand & Gravel Co. v. United States*,<sup>89</sup> indicates the further confusion that litigation with the federal government adds to the equation. These two recent cases suggest that the addition of sovereign immunity to the inquiry renders the question of whether statutory requirements are jurisdictional even less clear.

In *Scarborough*, the Court confronted a requirement in the Equal Access to Justice Act (“EAJA”) that a plaintiff allege that the position of the United States is not “substantially justified.”<sup>90</sup> The plaintiff filed a timely application under the EAJA but neglected to include this allegation.<sup>91</sup> Plaintiff’s counsel then “promptly filed an amendment to the fee application, stating in a new paragraph that ‘the government’s defense of [its] claim was not substantially justified.’”<sup>92</sup> If the thirty-day EAJA deadline is jurisdictional, as the Federal Circuit had held, then the plaintiff could not have amended his defective application after the deadline.<sup>93</sup> The Supreme Court disagreed. Analogizing to the signature requirement in *Becker*, the Court held that failure to include

<sup>86</sup> *Id.* at 2363, 2366.

<sup>87</sup> *See id.* at 2367 (Souter, J., dissenting) (“It is intolerable for the judicial system to treat people this way, and there is not even a technical justification for condoning this bait and switch.”). *Bowles* is a prime example of the inscrutable reasoning cited by some critics of the Court’s treatment of certain requirements as jurisdictional. *See supra* notes 67–68 and accompanying text.

<sup>88</sup> 541 U.S. 401 (2004).

<sup>89</sup> 128 S. Ct. 750 (2008).

<sup>90</sup> 541 U.S. at 407–08. The EAJA provides that:

A party seeking an award of fees and other expenses shall, within thirty days of final judgment in the action, submit to the court an application for fees and other expenses which shows that the party is a prevailing party and is eligible to receive an award under this subsection . . . . The party shall also allege that the position of the United States was not substantially justified.

28 U.S.C. § 2412(d)(1)(B) (2006).

<sup>91</sup> 541 U.S. at 409.

<sup>92</sup> *Id.*

<sup>93</sup> *See id.* at 412.

the substantial justification allegation could be cured and therefore was not a jurisdictional requirement.<sup>94</sup> The Court rejected the government's argument that, because the EAJA effects a partial waiver of sovereign immunity, the time limitation must be interpreted strictly.<sup>95</sup> Quoting two recent decisions, the Court observed that "limitations principles should generally apply to the Government 'in the same way that' they apply to private parties."<sup>96</sup>

However, the Court appeared to retreat from this holding a mere four years later. In *John R. Sand & Gravel*, the government essentially conceded at trial that plaintiff's claims were timely filed and did not raise the issue on appeal.<sup>97</sup> After "an *amicus* brief called the issue to the [Federal Circuit's] attention, [t]he court considered itself obliged to address the limitations issue, and it held that the action was untimely."<sup>98</sup> Relying on two cases from the nineteenth century, the Supreme Court held that the six-year statute of limitations for invoking the Tucker Act is "'jurisdiction[al], . . . not susceptible to judicial 'engraft[ing]' of unlisted disabilities such as 'sickness, surprise, or inevitable accident,' and . . . that 'it [was] the duty of the court to raise the [timeliness] question whether it [was] done by plea or not.'"<sup>99</sup> The Court rejected the theory that cases like *Scarborough* overruled this precedent, which the majority of the Court declined to overturn on *stare decisis* grounds.<sup>100</sup>

Several commentators have analyzed *John R. Sand & Gravel*, both for consistency with precedent and on general policy grounds.<sup>101</sup> For purposes of

<sup>94</sup> See *id.* at 419.

<sup>95</sup> *Id.* at 419–21.

<sup>96</sup> *Id.* at 421 (quoting *Franconia Assocs. v. United States*, 536 U.S. 129, 145 (2002) (quoting *Irwin v. Dep't of Veterans Affairs*, 498 U.S. 89, 95 (1990))).

<sup>97</sup> *John R. Sand & Gravel Co. v. United States*, 128 S. Ct. 750, 753 (2008).

<sup>98</sup> *Id.* (citation omitted).

<sup>99</sup> *Id.* at 754 (alterations in original) (quoting *Kendall v. United States*, 107 U.S. 123, 125–26 (1883)).

<sup>100</sup> *Id.* at 756.

<sup>101</sup> See, e.g., David R. Volosov, Note, *Too Much Time, Too Little Power: Waivers of Sovereign Immunity and Their Statutes of Limitations*, 38 PUB. CONT. L.J. 761, 765 (2009). Volosov opines:

Because of the Supreme Court's inconsistent interpretation of the statutes of limitations contained in congressional waivers of sovereign immunity, both the U.S. Court of Appeals for the Federal Circuit . . . and the U.S. Court of Federal Claims have struggled with the issue of whether these statutes of limitations are affirmative defenses or jurisdictional.

*Id.*; see also Gregory C. Sisk, *The Continuing Drift of Federal Sovereign Immunity Jurisprudence*, 50 WM. & MARY L. REV. 517, 606 (2008) ("Just as federal sovereign immunity jurisprudence was coming safely into the harbor and the anchor was being lowered, however, the Supreme Court's recent decision in *John R. Sand & Gravel Co. v. United States* may have pushed the ship back out into the pitching waves." (footnote omitted)).

determining whether a COI is jurisdictional, these cases urge caution. Specifically, while the precedent may be inconsistent, one must take into account the courts' unwillingness to depart from older cases.

### **III. The Plain Language, Structure, and History of the Unjust Imprisonment Statutes Imply that the COI Requirement is Not Jurisdictional in Nature**

Despite uncertainty in the case law, the plain language, structure, and history of the unjust imprisonment statutes lead to the conclusion that the COI requirement is an element of a plaintiff's substantive claim for relief, not a jurisdictional requirement. Any ambiguity is a vestige of the muddled way courts have treated sovereign-immunity-waiving provisions. Ultimately, given the difficult position of innocent plaintiffs and their already uphill battle to receive compensation, courts should be wary of imposing further jurisdictional requirements.

#### **A. Plain Language, Structural, and Historical Arguments that the COI is Non-Jurisdictional**

With the *Arbaugh* presumption in mind, it is clear that the unjust imprisonment statutes do not contain express requirements that the COFC consider presentation of a COI jurisdictional.<sup>102</sup> Indeed, the language and structure of the statute are evidence that the COI requirement should *not* be considered jurisdictional.

First and foremost, the portion of the statute that limits the COFC to consideration of the COI speaks in terms of the type of *evidence* that the COFC may receive to make its determination and the *facts* that the court must find.<sup>103</sup> Specifically, § 2513(b) provides that “[p]roof of the requisite facts shall be by a certificate of the court or pardon wherein such facts are alleged to appear, and *other evidence thereof shall not be received* [by the COFC].”<sup>104</sup> This language implies that the COFC must receive evidence to determine whether a plaintiff's COI contains the recitals necessary under § 2513(a). This ability to take evidence and determine the adequacy of a plaintiff's COI presupposes that the COFC possesses jurisdiction over the cause of action.

The legislative history of the statutes corroborates this view. Both Professor Borchard's original 1912 bill and the Senate version of the 1938 bill granted the Court of Claims the jurisdiction to try the facts of the plaintiff's

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<sup>102</sup> See 28 U.S.C. § 2513 (2006).

<sup>103</sup> § 2513(b).

<sup>104</sup> *Id.* (emphasis added).

innocence.<sup>105</sup> The requirement that the district court grant the plaintiff a COI (or that the President grant a pardon) originated in Congress's shifting the function of judging guilt to the court of conviction.<sup>106</sup> The COI requirement did not change the underlying grant of jurisdiction to the Court of Claims; it merely changed the role that the court played. The COFC looks to see whether the plaintiff has put forth a COI or pardon and judges whether this document or judgment is adequate under the statutes.<sup>107</sup> Once a plaintiff makes enough nonfrivolous allegations to "raise a right to relief above the speculative level"—specifically, that the plaintiff was pardoned or deemed innocent by a court of conviction—then the COFC possesses jurisdiction.<sup>108</sup> The COI is not a talisman granting or denying the COFC's jurisdiction; rather, the COFC already has jurisdiction, and a plaintiff simply must plead the existence of a COI to invoke it.

The structure of the unjust enrichment statutes also weighs in favor of the non-jurisdictional view. Congress grants jurisdiction to the COFC and waived sovereign immunity in § 1495, a distinct section from the substantive requirements of a claim for relief found in § 2513.<sup>109</sup> As in *Arbaugh*,

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<sup>105</sup> *United States v. Keegan*, 71 F. Supp. 623, 635 (S.D.N.Y. 1947) (discussing Borchard's bill); S. REP. NO. 75-202, at 3 (1937) (discussing Senate bill). See generally *supra* Part I.A (discussing Professor Borchard's policy rationale for vesting such jurisdiction in the Court of Claims).

<sup>106</sup> See H.R. REP. NO. 75-2299, at 2 (1938).

<sup>107</sup> § 2513(a).

<sup>108</sup> *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); see also *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009) ("When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief."). The heightened pleading requirements explained in *Twombly* and *Iqbal* should be adequate to deter frivolous cases. If a plaintiff does not plead that she was granted a COI or something that should be considered a COI, or that she was pardoned, then she has failed to allege an element of his case for compensation, and the complaint will be dismissed under FED. R. CIV. P. 12(b)(6). See, e.g., *In re Plywood Antitrust Litig.*, 655 F.2d 627, 641 (5th Cir. 1981) ("[A] complaint still must contain either direct or inferential allegations respecting all the material elements necessary to sustain a recovery under *some* viable legal theory.").

Even if a plaintiff does plead that she was granted a COI or something that could be considered a COI, but the remainder of the complaint renders this allegation implausible on its face, the complaint will be similarly dismissed under FED. R. CIV. P. 12(b)(6). Dismissal in these circumstances does not suggest that the court is without jurisdiction, but rather that the plaintiff is not entitled to relief on the merits of the complaint. See *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998) ("[T]he absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, *i.e.*, the courts' statutory or constitutional *power* to adjudicate the case."). A court's ability to make such a determination inherently suggests that it possesses jurisdiction over the merits of the case.

<sup>109</sup> See 28 U.S.C. §§ 1495, 2513 (2006).



the substantive provision related to the COI requirement does not speak in jurisdictional terms.<sup>110</sup> Judge Turner recognized this argument in *Veltmann v. United States*,<sup>111</sup> quoted above in Part I.A.<sup>112</sup> Moreover, this structural division is not a product of the 1948 reformatting caused by the creation of Title 28.<sup>113</sup> The original codification of the unjust imprisonment statutes separated the jurisdictional grant from the substantive provisions of the Act.<sup>114</sup>

Finally, like the signature requirement in *Becker*, a plaintiff's failure to plead (and subsequently *prove*) that it received a COI with the appropriate recitals, is a curable defect.<sup>115</sup> For example, in *United States v. Graham*,<sup>116</sup> owing to the strict (jurisdictional) statute of limitations at the COFC, the plaintiff filed a protective complaint with that court pursuant to § 1495.<sup>117</sup> Should plaintiff have prevailed in his litigation in the Fourth Circuit, he would presumably have been entitled to amend his pleadings to attach the COI that he obtained. If, on the other hand, the presence of a COI were jurisdictional, the plaintiff's original complaint (which did not attach this COI) would have to be dismissed. Plaintiff could, of course, refile *curing* the original "jurisdictional" defect.<sup>118</sup> However, given the potential statute of limitations problems, this might not be a viable option.<sup>119</sup>

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<sup>110</sup> *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 515 (2006) ("[T]he 15-employee threshold appears in a separate provision that 'does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts.'" (emphasis added) (quoting *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 394 (1982))).

<sup>111</sup> 39 Fed. Cl. 426, 428 (1997).

<sup>112</sup> See *supra* note 40 and accompanying text.

<sup>113</sup> See *supra* note 21 and accompanying text.

<sup>114</sup> Compare 18 U.S.C. § 729 (Supp. IV 1938) (current version at 28 U.S.C. § 1495 (2006)) (authorizing suit in the Court of Claims against the government "for damages sustained . . . as a result of [unjust] conviction and imprisonment."), with 18 U.S.C. § 730–732 (Supp. IV 1938) (current version at 28 U.S.C. § 2513 (2006)) (limiting evidence to be considered in such suits, requiring exhaustion of all other judicial remedies, and providing for in forma pauperis plaintiffs).

<sup>115</sup> Cf. *Scarborough v. Principi*, 541 U.S. 401, 418–19 (2004) (analogizing a lack of verification or signature to a failure to initially plead a circumstance as statutorily required and holding both to be curable defects).

<sup>116</sup> 608 F.3d 164 (4th Cir. 2010), *cert. denied*, 131 S. Ct. 998 (2011).

<sup>117</sup> See *id.* at 169 (explaining procedural history). In reality, the district court denied Mr. Graham's application for a COI and the Fourth Circuit affirmed. *Id.* at 177, *affg* 595 F.Supp.2d 681 (S.D. W. Va. 2008) The Supreme Court denied Graham's petition for certiorari, ending his suit in the COFC before it could begin. *Graham v. United States*, 131 S. Ct. 998 (2011); see also *supra* note 7 (describing the interesting circuit split Graham's case has led to).

<sup>118</sup> See *supra* note 47.

<sup>119</sup> See *Bolduc v. United States*, 248 F. App'x 162, 164 (Fed. Cir. 2007) (finding that the statute of limitations ran from the time that the court vacated the plaintiff's conviction



In sum, viewed through the lens of the Supreme Court's recent jurisprudence, the plaintiff's presentation of a COI is not a jurisdictional requirement but, rather, a substantive element of plaintiff's claim for relief.

### B. The Effect of Sovereign Immunity

One potential problem in this analysis is the presence of the federal government as the defendant. For a number of years, the Supreme Court retreated from the view that the federal government is in a different position from the ordinary litigant.<sup>120</sup> This trend was halted in *John R. Sand & Gravel*, where the Supreme Court held that, despite the *Arbaugh* presumption, a long history in the case law of a provision being treated as jurisdictional may be enough for the Court to maintain that position as a matter of stare decisis.<sup>121</sup>

It seems doubtful that the case law on point would be considered the type of longstanding precedent that would qualify for such stare decisis treatment. To begin, as discussed above, this case law is far from uniform.<sup>122</sup> Unlike the situation in *John R. Sand & Gravel*,<sup>123</sup> the Supreme Court has not passed on this issue. Additionally, the precedent holding the COI to be a jurisdictional prerequisite has done so with little to no analysis.<sup>124</sup> The Supreme Court has specifically cautioned that such “drive-by jurisdictional rulings’ . . . should be accorded no ‘precedential effect’ on the question whether the federal court had authority to adjudicate the claim in suit.”<sup>125</sup>

More importantly, holding that the COI requirement is jurisdictional would serve no Congressional purpose, merely insulating the government from liability in cases where the statute intended individuals to be compensated. Courts analyzing whether to grant exonerated individuals COIs have observed that Congress was concerned that only those individuals who were *actually* innocent be compensated, not those whose convictions were

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rather than when the COI was granted because “the events [had] occurred which fix[ed] the liability of the Government and entitle[d] [him] to institute an action” (alterations in original) (quoting *Brighton Vill. Assocs. v. United States*, 52 F.3d 1056, 1060 (Fed. Cir. 1995))).

<sup>120</sup> See *Scarborough*, 541 U.S. at 421; *Franconia Assocs. v. United States*, 536 U.S. 129, 145 (2002); *Irwin v. Dep’t of Veterans Affairs*, 498 U.S. 89, 95 (1990); see also *Bowles v. Russell*, 127 S. Ct. 2360, 2367 (2007) (Souter, J., dissenting). See generally *supra* Part II.C.

<sup>121</sup> *John R. Sand & Gravel Co. v. United States*, 128 S. Ct. 750, 756–57 (2008).

<sup>122</sup> See *supra* Part I.B.

<sup>123</sup> See 128 S. Ct. at 754 (quoting precedent from the 1880s).

<sup>124</sup> See *Wood v. United States*, 91 Fed. Cl. 569, 573–76 (2009) (discussing precedent relevant to the jurisdictional issue).

<sup>125</sup> *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 511 (2006) (quoting *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 91 (1998)); see also *supra* note 24.

overturned on procedural technicalities.<sup>126</sup> The fear that the statutes would open the floodgates to compensating individuals who did not deserve it was allayed by the stringent findings that the court of conviction must make in order to grant the COI in the first place.<sup>127</sup>

It is hard to imagine what can be gained by doubling the protection the government already receives by considering the COI to be jurisdictional. The COFC is already mindful in its analyses in § 1495 cases that it does not sit as an appellate court over the criminal judgments of the district courts.<sup>128</sup> The inflexibility that jurisdictional requirements receive would be an added barrier to recovery in a program that already rarely compensates individuals. The COFC should be wary of the potential unfairness that could result, particularly in the case of a remedial statute intended to compensate those who were improperly deprived of their liberty by their government.

## Conclusion

Professor Borchard observed that it was unfair to vehemently defend the property owner's right to compensation for property taken without just compensation, but leave the individual whose liberty was taken without any redress.<sup>129</sup> The right to compensation for a government taking of property is guaranteed by our Constitution, whereas the *limited* right to redress for the

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<sup>126</sup> See, e.g., *United States v. Graham*, 608 F.3d 164, 171 n.2 (4th Cir. 2010) *cert. denied*, 131 S. Ct. 998 (2011). Courts typically cite the letter written by Attorney General Homer Cummings in response to a request from the Senate Judiciary Committee to review the unjust imprisonment compensation bill for this proposition. See, e.g., *id.* General Cummings observed that:

[R]eversals in criminal cases are more frequently had on the ground of insufficiency of proof or on the question as to whether the facts charged and proven constituted an offense under some statute. Consequently, it would be necessary to separate to separate from the group of persons whose convictions have been reversed, those few who are in fact innocent of any offense whatever.

S. REP. NO. 75-202, at 3 (1937), *quoted in* *United States v. Keegan*, 71 F. Supp. 623, 631–32 (S.D.N.Y. 1947).

<sup>127</sup> See S. REP. NO. 75-202, at 3 (“The bill contains a proper safeguard in this respect by providing, in section 4, that the claimant shall have the burden of proving his innocence.”), *quoted in Keegan*, 71 F. Supp. at 632; see also *United States v. Brunner*, 200 F.2d 276, 280 (6th Cir. 1952) (“[T]he phrasing of the Act and its legislative history proclaim the care with which its framers guarded against opening wide the door through which the treasury may be assailed by persons erroneously convicted.”).

<sup>128</sup> See, e.g., *Lott v. United States*, 11 Cl. Ct. 852, 853 (1987) (“[T]he statutory provisions noted do not confer upon the Claims Court the power to review and overturn convictions.”).

<sup>129</sup> EDWIN M. BORCHARD, *STATE INDEMNITY FOR ERRORS OF CRIMINAL JUSTICE*, S. DOC. NO. 62-974, at 6 (3d Sess. 1912). Professor Borchard proclaimed:

deprivation of liberty was only created by Congress in 1938.<sup>130</sup> The resulting statutes set the barrier extremely high and limited compensation to a low level given the magnitude of the wrong.

The COFC should be hesitant to erect further barriers to compensation for those who have cleared the hurdles that Congress already set. The current prevailing view that the COI requirement is a jurisdictional barrier to getting to the COFC is therefore untenable as a matter of both reasoned analysis and policy. Because it is doubtful that this issue will ever reach the limited docket of the Supreme Court, the Federal Circuit should take up the gauntlet and issue a *published* opinion on this issue.<sup>131</sup>

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When property is taken from individuals for the public use our fundamental law prescribes that just compensation must be paid. . . . On the other hand, when in the administration of the criminal law, an equally sovereign right, society takes from the individual his personal liberty, a private right at least equally as sacred as the right of property, it dismisses him from consideration, regardless of the gross injustice inflicted upon an innocent man, without even an apology, much less compensation for the injury.

*Id.* Professor Borchard suggested that this failure of compensation in the United States and England derives from “[t]he general rule of the immunity from civil suit of a judge having jurisdiction for injuries resulting to private individuals from his acts, however malicious or corrupt.” *Id.* at 7.

<sup>130</sup> The current statutory cap on damages is \$50,000 per year of incarceration, or \$100,000 per year of incarceration if the plaintiff was “unjustly sentenced to death.” 28 U.S.C. § 2513(e) (2006). Prior to 2004, the cap was a miniscule \$5,000. 28 U.S.C. § 2513(e) (2000); *see, e.g.*, *Roberson v. United States*, 124 F. Supp. 857, 865 (Ct. Cl. 1954) (recognizing plaintiff suffered damages “in excess of \$5,000,” yet entering judgment for \$5,000 under statutory cap).

<sup>131</sup> As a final observation, it is unclear whether a panel of the Federal Circuit alone, as opposed to the court sitting en banc, could clarify the law given the force of Court of Claims precedent. *See Barclay v. United States*, 443 F.3d 1368, 1373 (Fed. Cir. 2006) (“Panels of this court are bound by previous precedential decisions until overturned by the Supreme Court or by this court *en banc*.”); *S. Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc) (“We hold that the holdings of our predecessor courts, the United States Court of Claims and the United States Court of Customs and Patent Appeals, announced by those courts before the close of business September 30, 1982, shall be binding as precedent in this court.”). Panels of the Federal Circuit have the authority to order a case heard en banc in circumstances where precedent is challenged. *See* FED. CIR. R. 35(a)(1). On the other hand, that panel could simply find that the “drive-by jurisdictional ruling[s]” of the Court of Claims regarding the COI are not precedential on the issue of whether the COI requirement is jurisdictional. *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 91 (1998).



# BING, BANG, BOOM: An Analysis of *In re Vertex Group LLC* and the Struggle for Inherent Distinctiveness in Sound Marks Made During a Product's Normal Course of Operation

Daniel R. Bumpus\*

## Introduction

Sitting in a crowded law library for hours on end among the whispers, coffee sips, and overstressed students, two thoughts always spring to mind. How is it that law students, of a supposedly tech-savvy generation, do not know how to silence their cell phones? And why did Apple program such an annoying default ringtone into the iPhone?

Apple's iPhone ringtone could be used as a mark for Apple. It is unique. No other cell phone manufacturer utilizes the same sound or anything that comes close to resembling it.<sup>1</sup> Every time a person hears the iPhone's default ringtone, there is no mistaking it for the cell phone of another manufacturer. The hearer knows exactly what product and manufacturer the ringtone comes from, meaning that he or she can identify that the sound emanates from an iPhone and that Apple manufactures it.

Through the hundreds of millions of dollars Apple spends in advertising every year<sup>2</sup> and the market share it has acquired through the iPhone's popularity,<sup>3</sup> the company seemingly faces few hurdles in registering the ringtone as a

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<sup>2</sup> APPLE INC., FORM 10-K ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934, at 54 (2010), *available at* <http://www.sec.gov/Archives/edgar/data/320193/000119312510238044/d10k.htm> (stating that Apple spent \$691 million on advertising in 2010, \$501 million in 2009, and \$486 million in 2008).

<sup>3</sup> See Jason Mick, *Android Market Share Reaches 56 Percent; RIM's, Microsoft's Cut in Half*, DAILY TECH (Sept. 28, 2011, 8:01 AM), <http://www.dailytech.com/Android+Market+Share+Reaches+56+Percent+RIMs+Microsofts+Cut+in+Half/article22852.htm> (putting Apple's iPhone market share at 28 percent in July 2011).

sound mark, because it can easily establish in the minds of consumers that the iPhone ringtone is its source indicator.<sup>4</sup> But what were to happen if Apple wanted to register its iPhone ringtone for trademark protection before selling the product, or before unveiling a multi-million dollar marketing campaign that revolved around the ringtone as a mark for Apple?

Traditionally, all sound marks underwent a simple test for registration with the U.S. Patent and Trademark Office (“USPTO”).<sup>5</sup> All sounds were either “unique, different, or distinctive,” or they were “commonplace.”<sup>6</sup> The former group of inherently distinctive sounds required no proof of acquired distinctiveness to be registered on the Principal Register.<sup>7</sup> The latter, however, required proof of acquired distinctiveness.<sup>8</sup> These sounds only became distinctive in the mind of consumers through their use in connection with the manufacturer.<sup>9</sup>

Under the traditional test, Apple’s iPhone ringtone would qualify as an inherently distinctive sound, because it does not “resemble or imitate ‘commonplace’ sounds.”<sup>10</sup> Because the ringtone is an inherently distinctive sound, Apple would not need to show proof of acquired distinctiveness in its application to the USPTO.<sup>11</sup> Under the above hypothetical, where Apple had not yet sold the iPhone or started a marketing campaign centered around the ringtone, proof of acquired distinctiveness would not yet exist. Thus, requiring Apple to establish acquired distinctiveness would have barred the company from protecting its iPhone ringtone until after it had unveiled the sound to the world and could demonstrate acquired distinctiveness.

Last year, the Trademark Trial and Appeal Board (“TTAB” or “Board”) turned the world of sound marks on its head for products that make the relevant sound in their normal course of operation, like the iPhone ringtone.<sup>12</sup> The Board held in *In re Vertex Group LLC*<sup>13</sup> that sounds made by a product during its normal course of operation may only be registered on a showing of acquired distinctiveness.<sup>14</sup> Under this new *Vertex Group* rule, Apple would

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<sup>4</sup> See *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1699 (T.T.A.B. 2009) (noting the standard used for giving sounds trademark protection).

<sup>5</sup> See *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B. 1978) (explaining the general test by which sounds are approved for service marks).

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> See *id.*

<sup>12</sup> See *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1700 (T.T.A.B. 2009).

<sup>13</sup> 89 U.S.P.Q.2d (BNA) 1694 (T.T.A.B. 2009).

<sup>14</sup> *Id.* at 1700.

be forced to set forth proof of acquired distinctiveness: that consumers connected the iPhone ringtone to Apple. As mentioned above, Apple would have faced little problem demonstrating proof of acquired distinctiveness after the iPhone was introduced to the marketplace, but protection would be unavailable before Apple unveiled its product to the world.

*Vertex Group* did away with applying the traditional test to sound marks made by their products in the normal course of operation.<sup>15</sup> The Board failed to provide sufficient justification for deviating from this traditional test and, in the process, created a rule likely to hamper product manufacturers. In order to solve these problems, the Board should abandon the rule or, in the alternative, narrow its applicable scope. In essence, the *Vertex Group* rule should not stand in the way of an inherently distinctive sound receiving trademark protection simply because a company cannot show acquired distinctiveness when the product happens to make the sound in its normal course of operation.

Part I of this Article provides background information on the evolution of sound marks, along with the application of distinctiveness and functionality to this category of marks. Part II analyzes *Vertex Group* and examines the Board's lone decision applying the new rule. Part III discusses the reasons why the *Vertex Group* rule is flawed. Part IV sets forth a solution to the problems created by the rule.

## I. Background Prior to *Vertex Group*

When Congress passed the Lanham Act in 1946,<sup>16</sup> it provided a flexible definition for trade and service marks.<sup>17</sup> The definition of trademark “includes any word, name, symbol, or device, or any combination thereof . . . [used] to identify and distinguish [a person's] goods, including a unique product, from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown.”<sup>18</sup> The Supreme Court determined that the mark's form was nearly irrelevant under the Lanham Act, which based the validity of a mark on its source-identifying abilities.<sup>19</sup> The Court reasoned that

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<sup>15</sup> See *id.*

<sup>16</sup> Act of July 5, 1946, ch. 540, 60 Stat. 427 (1946) (codified as amended at 15 U.S.C. §§ 1051–1127 (2006)).

<sup>17</sup> See *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 162 (1995) (holding the definition of trademarks under the Act to be “not restrictive”); Kevin K. McCormick, “*Ding*” You Are Now Free To Register That Sound, 96 TRADEMARK REP. 1101, 1106 (2006) (finding U.S. trademark law to be quite flexible in that, as long as a mark performs as a source indicator and complies with other statutory requirements, trademark protection should be granted).

<sup>18</sup> 15 U.S.C. § 1127 (2006).

<sup>19</sup> See *Qualitex Co.*, 514 U.S. at 164.



“[i]t is the source-distinguishing ability of a mark—not its ontological status as color, shape, fragrance, word, or sign—that permits it to serve” as a mark.<sup>20</sup>

### A. The Evolution of Sound Marks

The National Broadcasting Company filed the first application for a sound mark in 1947 to protect its iconic chimes,<sup>21</sup> but it was not until 1978 that the TTAB expressly stated that sounds could serve as marks.<sup>22</sup> In *In re General Electric Broadcasting Co.*,<sup>23</sup> the TTAB examined a radio station’s application to register the sound of a periodically ringing ship bell.<sup>24</sup> The Board held that the Lanham Act did not require the mark to be in graphic form and that a sound could serve as a source indicator.<sup>25</sup> It went on to state that:

a sound mark depends upon aural perception of the listener which may be as fleeting as the sound itself unless . . . the sound is so inherently different or distinctive that it attaches to the subliminal mind of the listener to be awakened when heard and to be associated with the source or event with which it is struck.<sup>26</sup>

The ringing ship bell in *General Electric* did not qualify as inherently distinctive, because the TTAB found it to be a commonplace sound that resembled other sounds.<sup>27</sup> Therefore, the applicant needed to show proof of acquired distinctiveness<sup>28</sup> to register the sound as a mark.<sup>29</sup>

At the time of *General Electric*, there were only nine other sound marks registered in the United States.<sup>30</sup> Applications for sound marks picked up in the 1980s, with fourteen more, and the pace exploded in the 1990s and 2000s, due partially to the increased use of technology and personal com-

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<sup>20</sup> *Id.*

<sup>21</sup> Registration No. 523,616 (“The mark composes the musical notes G, E, C played on chimes.”). NBC later registered the chimes for the broadcasting of television programs. See Registration No. 916,522.

<sup>22</sup> See *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B. 1978) (reviewing an application unrelated to the NBC chimes but noting the flexibility of trademark law in allowing NBC to register the sound mark).

<sup>23</sup> 199 U.S.P.Q. (BNA) 560 (T.T.A.B. 1978).

<sup>24</sup> *Id.* at 563.

<sup>25</sup> *Id.*; see also U.S. PATENT & TRADEMARK OFFICE, TRADEMARK MANUAL OF EXAMINING PROCEDURE § 1202.15, at 1200-114 (8th ed. Oct. 2011) [hereinafter TMPEP].

<sup>26</sup> *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. at 563.

<sup>27</sup> *Id.*

<sup>28</sup> “Acquired distinctiveness” is also known as “secondary meaning,” see TMPEP, *supra* note 25, § 1212, at 1200-325, but this Article will use the former term. Proof of distinctiveness is “acquired” from the mark’s use in commerce to identify the source. See *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 851 n.11 (1982).

<sup>29</sup> *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. at 563.

<sup>30</sup> See McCormick, *supra* note 17, at 1104.

puting.<sup>31</sup> Another reason for the increase in sound mark applications was that marketing embraced “multisensory branding” to more effectively connect with consumers.<sup>32</sup> “Sound is the only human sense that causes activity in both hemispheres of the brain, and can influence how people react and behave.”<sup>33</sup> Today there are 463 results in the Trademark Electronic Search System (“TESS”) for applications in which no drawing is possible, which is the designation that includes sound marks.<sup>34</sup> The rise in applications demonstrates that these “nontraditional” marks are gaining in popularity, and there is no indication that the growth will slow.

## B. Trademarks Compared to Other Intellectual Property Protections

By passing the Lanham Act, Congress formed an additional intellectual property protection distinct from copyrights and patents.<sup>35</sup> For example, “patent law, not [trademark] law, is the principal means for providing exclusive rights in useful product features.”<sup>36</sup> “Copyright law protects the artist’s right

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<sup>31</sup> *Id.* at 1104–05 (recognizing, in addition to digital media, “the adoption of several new trademark systems” as the cause of the increased number of applications).

<sup>32</sup> Jerome Gilson & Anne Gilson LaLonde, *Cinnamon Buns, Marching Ducks and Cherry-Scented Racecar Exhaust: Protecting Nontraditional Trademarks*, 95 TRADEMARK REP. 773, 775 (2005) (citing MARTIN LINDSTROM, BRAND SENSE: BUILD POWERFUL BRANDS THROUGH TOUCH, TASTE, SMELL, SIGHT, AND SOUND 139–48, 161 (2005)).

<sup>33</sup> McCormick, *supra* note 17, at 1103 (citing Ruth Mortimer, *Sonic Branding: Branding the Perfect Pitch*, BRAND STRATEGY, Feb. 7, 2005, at 24–25); *see also* Rebecca Tushnet, *Gone In Sixty Milliseconds: Trademark Law and Cognitive Science*, 86 TEX. L. REV. 507, 508, 514 (2008) (finding that exposure to a mark triggers ideas and emotions in the mind of consumers and that consumers transfer feelings about advertising, packaging, and trademarks to the products themselves).

<sup>34</sup> TESS catalogs all trademark applications at the USPTO. *Trademark Electronic Search System*, U.S. PATENT & TRADEMARK OFFICE, <http://tess2.uspto.gov/> (follow “Word and/or Design Mark Search (Structured); enter “6” as Search Term and “Mark Drawing Code” as Field) (last visited Nov. 2, 2011). The number six is the code for “non-visual marks” which do not have traditional drawings. MPEP, *supra* note 25, § 807.18, at 800-107 to -108.

<sup>35</sup> *See* EMI Catalogue P’ship v. Hill, Holliday, Connors, Cosmopolulos Inc., 228 F.3d 56, 63 (2d Cir. 2000) (noting that fundamental differences exist between trademark and other intellectual property protections) (quoting Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 439 n.19 (1984) *superseded by statute*, Digital Millennium Copyright Act, Pub. L. No. 105-304, 112 Stat. 2860).

<sup>36</sup> *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1580 (Fed. Cir. 1995)); *see also* J. Thomas McCarthy, 1 *McCarthy on Trademarks and Unfair Competition* § 7:64 (4th ed. 2011) (explaining that trademark law cannot provide a loophole to avoid the “strict requirements of utility patent law” by giving equivalent rights to exclude”).

in an abstract design or other creative work.”<sup>37</sup> “Trademark law is concerned with protection of the symbols, elements or devices used to identify a product in the marketplace and to prevent confusion as to its source.”<sup>38</sup> Protection under one form of intellectual property does not foreclose protection under the others, provided the required elements of each form are met.<sup>39</sup>

Narrowing the focus to sound marks, the difference in intellectual property protections manifests itself through music.<sup>40</sup> Theoretically, both trademark and copyright protection exist for music, but, in practice, receiving protection under both is nearly impossible, because a song cannot be a trademark for itself.<sup>41</sup> Songs can be trademarks only if they “identify ownership or origin,”<sup>42</sup> and “sound recordings . . . do not indicate the source of the goods; they are the goods.”<sup>43</sup> One artist, attempting to circumvent this argument and show identification of a song’s origin, asked the Second Circuit to recognize trademark protection for a musical artist’s “signature performance.”<sup>44</sup> The court declined to do so, because numerous artists bringing suits against entities that had only paid license fees for the use of the copyrighted work and subsequent unforeseen liabilities would be disruptive to commerce.<sup>45</sup> It is important to note that the Second Circuit did not hold that “signature performances” could not serve to identify the origin of the goods (here, music) but that business concerns trumped the intellectual property interests.<sup>46</sup>

### C. Distinctiveness

Congress passed the Lanham Act in order to promote competition by “secur[ing] to the owner of the mark the goodwill of his business and to pro-

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<sup>37</sup> *EMI Catalogue P’ship*, 228 F.3d at 63.

<sup>38</sup> *Id.*

<sup>39</sup> *See Oliveira v. Frito-Lay, Inc.*, 251 F.3d 56, 61–62 (2d Cir. 2001) (finding that musical compositions protected under copyright law could also be protected under trademark law if the musical compositions served as marks).

<sup>40</sup> *See, e.g., id.* at 58, 62; *EMI Catalogue P’ship*, 228 F.3d at 59, 62; *G.M.L., Inc. v. Mayhew*, 188 F. Supp. 2d 891, 893 (M.D. Tenn. 2002).

<sup>41</sup> *G.M.L., Inc.*, 188 F. Supp. 2d at 897; *see also EMI Catalogue P’ship*, 228 F.3d at 64 (“[T]rademark[s] serve[] to identify [ ] copyrighted music.”).

<sup>42</sup> *G.M.L., Inc.*, 188 F. Supp. 2d at 897.

<sup>43</sup> *Id.* at 896.

<sup>44</sup> *Oliveira*, 251 F.3d at 60 (discussing plaintiff’s request to the court for trademark protection of her signature song “A Girl from Ipanema”).

<sup>45</sup> *Id.* at 62–63.

<sup>46</sup> *Id.* (“We cannot say it would be unthinkable for the trademark law to accord to a performing artist a trademark or service mark in her signature performance.”).

protect the ability of consumers to distinguish among competing producers.”<sup>47</sup> To achieve these ends, any proposed trademark, including those for sound marks, must be distinctive.<sup>48</sup> There are two types of distinctiveness: marks that are inherently distinctive and marks that acquire distinctiveness through use in commerce.<sup>49</sup> To prove acquired distinctiveness, “a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself.”<sup>50</sup> This additional step of proving acquired distinctiveness is no small task,<sup>51</sup> because “[t]o acquire [distinctiveness] in the minds of the buying public, an article of merchandise when shown to a prospective customer must prompt the affirmation, ‘That is the article I want because I know its source.’”<sup>52</sup>

An applicant can prove acquired distinctiveness in three ways.<sup>53</sup> First, the applicant can show “ownership of one or more prior registrations on the Principal Register of the same mark for goods or services that are the same as or related to those named in the pending application.”<sup>54</sup> Second, the applicant can verify a statement “that the mark has become distinctive . . . by reason of substantially exclusive and continuous use in commerce by the applicant for . . . five years.”<sup>55</sup> Third, the applicant can show “[a]ctual evidence of acquired distinctiveness.”<sup>56</sup> In addressing what constitutes actual evidence of acquired distinctiveness, one court provided an illustrative list of items used in the past, including “the length and manner of the term’s use,” “the nature and extent of advertising and promotion,” and any “other efforts at creating

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<sup>47</sup> *Park ’N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 193, 198 (1985) (citing *S. REP. NO. 79-1333*, at 3, 5, 6 (1976)).

<sup>48</sup> *See* 15 U.S.C. § 1052(f) (2006) (providing that, except for a few narrowly constructed exceptions, “nothing . . . shall prevent the registration of a mark used by the applicant which has become *distinctive* of the applicant’s goods in commerce”) (emphasis added); *see also In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B. 1978) (holding the ship’s bell to be a commonplace sound, so it could not be inherently distinctive).

<sup>49</sup> *See Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 210–11 (2000).

<sup>50</sup> *Inwoods Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 851 n.11 (1982) (citing *Kellogg Co. v. Nat’l Biscuit Co.*, 305 U.S. 111, 118 (1938)); *see also* TMEP, *supra* note 25, § 1212, at 1200-325 (defining “acquired distinctiveness” as public knowledge that the product is produced by a particular manufacturer).

<sup>51</sup> *See, e.g., In re Owens-Corning Fiberglas Corp.*, 774 F.2d 1116, 1127 (Fed. Cir. 1985) (discussing how Owens-Corning spent more than \$42 million on its advertising campaign to establish acquired distinctiveness of the color pink with its insulation).

<sup>52</sup> *Esercizio v. Roberts*, 944 F.2d 1235, 1239 (6th Cir. 1991).

<sup>53</sup> TMEP, *supra* note 25, § 1212, at 1200-326.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

a conscious connection in the public's mind between the designation and the [goods or] service.”<sup>57</sup>

The separation between inherently distinctive marks and marks that must acquire distinctiveness applies to traditional and nontraditional trademarks alike through the spectrum of trademark classifications, which sets forth four classes of marks.<sup>58</sup> Marks are classified as (1) generic, (2) descriptive, (3) suggestive, or (4) arbitrary or fanciful.<sup>59</sup> Under this standard, generic marks refer to the “genus of which the particular product is a species”<sup>60</sup> and are not registrable at all, even with a showing of acquired distinctiveness.<sup>61</sup> Descriptive marks “describe[] the qualities or characteristics of a good or service.”<sup>62</sup> Because they are not inherently distinctive, they can be registered only upon a showing of acquired distinctiveness.<sup>63</sup> Suggestive marks “require[] imagination, thought and perception to reach a conclusion as to the nature of goods”<sup>64</sup> and are registrable without any proof of acquired distinctiveness.<sup>65</sup> Arbitrary and fanciful marks enjoy the same luxury as suggestive marks, in that no proof of acquired distinctiveness is required for registration.<sup>66</sup>

### *1. Distinctiveness in Sound Marks*

Distinctiveness continues to play a prominent role in the evolution of sound marks.<sup>67</sup> Traditionally, the Board and courts followed *General Electric* by distinguishing commonplace sounds from ones that are inherently distinctive.<sup>68</sup> Commonplace sounds require proof of acquired distinctiveness, but

<sup>57</sup> *Ride the Ducks LLC v. Duck Boat Tours Inc.*, 75 U.S.P.Q.2d 1269, 1275 (E.D. Pa. 2005).

<sup>58</sup> *Abercrombie & Fitch Co. v. Hunting World, Inc.*, 537 F.2d 4, 9 (2d Cir. 1976).

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985).

<sup>63</sup> 15 U.S.C. § 1052(f) (2006) (marks are not barred from registration if proof that the term has acquired distinctiveness in commerce is shown); *Abercrombie & Fitch Co.*, 537 F.2d at 10.

<sup>64</sup> *Abercrombie & Fitch Co.*, 537 F.2d at 11.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> See *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1700 (T.T.A.B. 2009) (holding that all sounds made in the normal course of operation of a product require proof of acquired distinctiveness).

<sup>68</sup> See, e.g., *Ride the Ducks LLC v. Duck Boat Tours, Inc.*, 75 U.S.P.Q.2d (BNA) 1269, 1274 (E.D. Pa. 2005) (defining “commonplace sounds” as those which “resemble or imitate ‘commonplace sounds’” and sounds that are inherently distinct as “unique, different, or distinctive sounds” (quoting *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B. 1978))); see also TMEP *supra* note 25, § 1202.15, at 1200-114 (defining “commonplace sounds” as “those to which listeners have been exposed under different circumstances”).

inherently distinctive sounds do not require any additional showing.<sup>69</sup> For example, in *Ride the Ducks LLC v. Duck Boat Tours, Inc.*,<sup>70</sup> the court found the quack of a duck to be a commonplace sound, because it was familiar to the general public.<sup>71</sup> As such, the duck quack was not inherently distinctive, and registration as a mark required proof of acquired distinctiveness.<sup>72</sup>

The *Ride the Ducks* court clearly differentiated between sounds that are inherently distinctive and those that are commonplace,<sup>73</sup> but this distinction is not always black and white. The Supreme Court addressed this potential concern by requiring courts deciding close cases to err on the side of caution and require a showing of acquired distinctiveness whenever there is any doubt about the inherent distinctiveness of a mark.<sup>74</sup>

## 2. *Distinctiveness in Other “Nontraditional” Marks*

The Supreme Court, the Federal Circuit, and the TTAB have all prohibited certain categories of nontraditional marks from registration absent a showing of acquired distinctiveness.<sup>75</sup> These decisions, in essence, bar these categories of marks from being inherently distinctive.<sup>76</sup>

In *Qualitex Co. v. Jacobson Products Co.*,<sup>77</sup> the Supreme Court held that color marks can only be registered with a showing of acquired distinctiveness.<sup>78</sup> The Court drew an analogy between color marks and descriptive words on a product.<sup>79</sup> Descriptive words<sup>80</sup> can only be registered on a showing of acquired distinctiveness, so the Court reasoned that color marks should face the same

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<sup>69</sup> See *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B, 1978).

<sup>70</sup> 75 U.S.P.Q.2d (BNA) 1269 (E.D. Pa. 2005).

<sup>71</sup> *Id.* at 1275.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 215 (2000). The Supreme Court’s decision expressly applied to trade dress, but the language of the opinion can be applied to all marks, including sound marks. Julia Anne Matheson & Anna S. Balichina, *If It Quacks Like A Duck . . . It Just Might Be A Trademark*, LANDSLIDE, July/Aug. 2010, at 43.

<sup>75</sup> *Wal-Mart Stores, Inc.*, 529 U.S. at 216 (product design); *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 163 (1995) (color); *In re Etablissements Darty et Fils*, 759 F.2d 15, 17 (Fed. Cir. 1985) (surnames); *In re N.V. Organon*, 79 U.S.P.Q.2d (BNA) 1639, 1650 (T.T.A.B. 2006) (flavor); *In re Clarke*, 17 U.S.P.Q.2d (BNA) 1238, 1239–40 (T.T.A.B. 1990) (scent).

<sup>76</sup> See, e.g., *Wal-Mart Stores, Inc.*, 529 U.S. at 212 (holding that product design, like color, is not inherently distinctive).

<sup>77</sup> 514 U.S. 159 (1995).

<sup>78</sup> *Id.* at 163 (holding that, over time, color may come to indicate a product’s source).

<sup>79</sup> *Id.* (noting that color and descriptive words function in source indication in the same manner).

<sup>80</sup> Descriptive words “describe[] the qualities or characteristics of a good or service,” *Park ‘N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985), or “immediately convey[]



limitation to registration, because color describes the product.<sup>81</sup> Supporting this analogy, the Court added that consumers were not predisposed to identify a color or descriptive word with the source of a product; therefore, it would take time for consumers to mentally build this bridge between the mark and the source.<sup>82</sup>

In *Wal-Mart Stores, Inc. v. Samara Bros.*,<sup>83</sup> the Supreme Court followed the path paved by its earlier decision in *Qualitex* to bar product design marks from registration without proof of acquired distinctiveness.<sup>84</sup> Product design is a subset of a larger category of marks referred to as “trade dress.”<sup>85</sup> Trade dress “is essentially [a product’s] total image and overall appearance.”<sup>86</sup> In *Wal-Mart*, the Court continued to express serious doubts that consumers would connect product design, like color, with source identification.<sup>87</sup> Therefore, *Qualitex* and *Wal-Mart* provided two rationales for requiring proof of acquired distinctiveness to register color or product design marks. The Court held that these categories of marks are descriptive and lack consumer predisposition to view the features as a source identifier.<sup>88</sup>

Scents also require proof of acquired distinctiveness in order to be registered.<sup>89</sup> The TTAB granted the trademark application of one scent used on thread and embroidery yarn for “a high impact, fresh, floral fragrance reminiscent of Plumeria blossoms.”<sup>90</sup> The examining attorney rejected the application on the grounds that customers were “unlikely to regard scent in any product as an indication of exclusive origin in view of their conditioning

knowledge of the ingredients, qualities or characteristics of the product,” *In re Dial-A-Mattress Operating Corp.*, 240 F.3d 1341, 1346 (Fed. Cir. 2001).

<sup>81</sup> *Qualitex Co.*, 514 U.S. at 163 (“trademark law says that the word[,] . . . although not inherently distinctive, has developed [acquired distinctiveness]”).

<sup>82</sup> *Id.*

<sup>83</sup> *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 215 (2000).

<sup>84</sup> *Id.* at 216.

<sup>85</sup> Trade dress is split into two subcategories, product design and product packaging. *Id.* at 215 (citing *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 773 (1992)).

<sup>86</sup> *Blue Bell Bio-Med. v. Cin-Bad, Inc.*, 864 F.2d 1253, 1256 (5th Cir. 1989). The definition of “product design” expanded as of late to include “size, shape, color, texture, and graphics.” Nick Pisarsky, Note, *PoTAYto-PoTAHto-Let’s Call the Whole Thing Off: Trademark Protection of Product Sounds*, 40 CONN. L. REV. 797, 812 (2008) (citing *Wal-Mart Stores, Inc.*, 529 U.S. at 209).

<sup>87</sup> *Wal-Mart Stores, Inc.*, 529 U.S. at 213 (“[W]e think consumer predisposition to equate the feature with the source does not exist”).

<sup>88</sup> *Id.*; *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 163 (1995).

<sup>89</sup> See TMEP, *supra* note 25, § 1202.13, at 1200-13 (“Just as with a scent or fragrance, a flavor can never be inherently distinctive”).

<sup>90</sup> *In re Clarke*, 17 U.S.P.Q.2d (BNA) 1238, 1238-39 (T.T.A.B. 1990).



in the consumer product marketplace.”<sup>91</sup> The Board reversed, finding that the applicant demonstrated proof of acquired distinctiveness.<sup>92</sup>

In *In re N.V. Organon*,<sup>93</sup> the TTAB faced an issue of first impression as to whether flavor could be registered as a mark.<sup>94</sup> The Board held that the non-restrictive language of the Lanham Act theoretically permits flavor to be registered as a mark.<sup>95</sup> However, it denied the application at hand for failing to operate as a mark and on functionality grounds.<sup>96</sup> The Board expressed reservations about the ability of flavor, in general, to serve as a mark, because “a consumer generally has no access to the product’s flavor prior to purchase.”<sup>97</sup> In the end, the Board followed one of the Supreme Court’s rationales for color and product design marks (lack of consumer predisposition to equate the feature with the source) to require proof of acquired distinctiveness before a flavor can be registered for trademark protection.<sup>98</sup>

Finally, the Federal Circuit requires applicants for trademark protection of surnames to produce proof of acquired distinctiveness.<sup>99</sup> The Federal Circuit based this decision on the language of the Lanham Act, which rejects registration of marks that are “primarily merely a surname”<sup>100</sup> unless they have acquired distinctiveness through use in commerce.<sup>101</sup> The court stated that the Lanham Act follows common law, which recognizes that people share surnames and that each of those people may have an interest in using the surname in business.<sup>102</sup>

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<sup>91</sup> *Id.* at 1239.

<sup>92</sup> *Id.* at 1240 (finding based on emphasis of scented feature in advertising and at craft fairs).

<sup>93</sup> 79 U.S.P.Q.2d (BNA) 1639 (T.T.A.B. 2006).

<sup>94</sup> *Id.* at 1644.

<sup>95</sup> *Id.* (noting “the statutory language describes the universe of things that can qualify as a trademark ‘in the broadest of terms’” (quoting *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 162 (1995))).

<sup>96</sup> *Id.* at 1649 (holding that orange flavor holds a utilitarian purpose that would hinder competition if protected, and the applicant provided nothing in the record to demonstrate source indication).

<sup>97</sup> *Id.* at 1650.

<sup>98</sup> *Id.* at 1649 (citing *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205 (2000)).

<sup>99</sup> *In re Etablissements Darty et Fils*, 759 F.2d 15, 17 (Fed. Cir. 1985).

<sup>100</sup> 15 U.S.C. § 1052(e)(4) (2006).

<sup>101</sup> *Id.* § 1052(f).

<sup>102</sup> *In re Etablissements Darty et Fils*, 759 F.2d at 17.

## D. Functionality

An additional requirement for registration of a mark is that it must not be functional.<sup>103</sup> Functionality applies to trade and service marks in two distinct categories: de facto and de jure functionality.<sup>104</sup> De facto functionality means that the feature is either functional in the lay sense of the word or has a utilitarian purpose.<sup>105</sup> De jure functionality demonstrates that the feature is “superior in [its] function . . . or economy of [its] manufacture.”<sup>106</sup> A feature that is de facto functional may be protected as a trademark, because its protection *will not* hinder competition, but a feature that is de jure functional cannot be granted trademark protection, because doing so *will* hinder competition.<sup>107</sup> “[A] product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article.”<sup>108</sup> The Supreme Court enhanced this definition of functionality by summarizing the inquiry as asking “if exclusive use of the feature would put competitors at a significant non-reputation-related disadvantage.”<sup>109</sup> The rationale behind this analysis is that “[t]he Lanham Act does not exist to reward manufacturers for their innovation in creating a particular device; that is the purpose of the patent law and its period of exclusivity.”<sup>110</sup>

Even with the Court’s detailed definition, attempting to determine whether a feature is functional can be a difficult task. In *In re Morton-Norwich Products*,

<sup>103</sup> 15 U.S.C. § 1052(e)(5) (barring registration of a mark that “comprises any matter that, as a whole, is functional”); see also TMEP, *supra* note 25, § 1202.02(b), at 1200-63 (noting that an application may be refused on both distinctiveness and functional grounds independently).

<sup>104</sup> See *In re Morton-Norwich Prods., Inc.*, 671 F.2d 1332, 1337 (C.C.P.A. 1982) (classifying product design, product container and product features as de facto functional).

<sup>105</sup> *Id.*; see also *Valu Eng’g, Inc. v. Rexnord Corp.*, 278 F.3d 1268, 1274 (Fed. Cir. 2002) (“[D]e facto functional means that the design of a product has a function” (quoting *In re R.M. Smith, Inc.*, 734 F.2d 1482, 1484 (Fed. Cir. 1984))).

<sup>106</sup> *In re Morton-Norwich Prods., Inc.*, 671 F.2d at 1339; see also *Valu Eng’g, Inc.*, 278 F.3d at 1274 (“[T]he product has a particular shape ‘because it works better in this shape.’” (quoting *In re R.M. Smith*, 734 F.2d at 1484)).

<sup>107</sup> *In re Morton-Norwich Prods., Inc.*, 671 F.2d at 1337; see also *Park ’N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 193 (1985) (stating that the purpose of the Lanham Act was to promote competition in the marketplace (citing S. REP. NO. 79-1333, at 5-6 (1946))).

<sup>108</sup> *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 850 n.10 (1982); see also *In re Morton-Norwich Prods., Inc.*, 671 F.2d at 1337.

<sup>109</sup> *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 165 (1995) (citing *Inwood Labs, Inc.*, 456 U.S. at 850 n.10). *But see Valu Eng’g, Inc.*, 278 F.3d at 1275 (clarifying that a feature does not have to be a competitive necessity for it to be found functional).

<sup>110</sup> *TraFFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 34 (2001).

*Inc.*,<sup>111</sup> the court developed a set of factors to consider in determining if a feature is functional.<sup>112</sup> These factors include: (1) “the existence of an expired utility patent . . . disclos[ing] the *utilitarian advantage of the design*,”<sup>113</sup> (2) advertising material in which “the originator of the design touts [the design’s] utilitarian advantages,”<sup>114</sup> (3) the availability of alternate designs to competitors,<sup>115</sup> and (4) whether the alternate designs provide competitors with comparatively simple and cheap methods of manufacturing the product.<sup>116</sup>

Functionality’s application to sound marks was evident in *Kawasaki Motors Corp. U.S.A. v. H-D Michigan Inc.*, (hereinafter *Harley-Davidson*)<sup>117</sup> where Kawasaki contested Harley-Davidson’s trademark application for the sound of its motorcycle engine.<sup>118</sup> Harley-Davidson described the mark as “consist[ing] of the exhaust sound of applicant’s motorcycles, produced by V-Twin, common crankpin motorcycle engines when the goods are in use.”<sup>119</sup> The court noted that it must consider whether the claimed sound was just the function of the parts and features of the motor, including the exhaust, something that other manufacturers also claim the right to use.<sup>120</sup> If other manufacturers put together their motors in the same way, the same sound would be emitted.<sup>121</sup> The TTAB did not resolve the functionality question but stated that the issue deserved consideration at trial, because granting trademark protection to Harley-Davidson would foreclose all other motorcycle manufacturers from making their engines in the same manner.<sup>122</sup> In other words, because the sound may have been functional, granting the trademark application could have hampered competition.<sup>123</sup> If the sound was functional, which was to be determined at trial, then it would be unregistrable.<sup>124</sup>

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<sup>111</sup> 671 F.2d 1332 (C.C.P.A. 1982).

<sup>112</sup> *Id.* at 1340–41.

<sup>113</sup> *Id.* (citing *In re Shenango Ceramics, Inc.*, 362 F.2d 287, 291 (C.C.P.A. 1966)).

<sup>114</sup> *Id.* at 1341.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> 43 U.S.P.Q.2d (BNA) 1521 (T.T.A.B. 1997).

<sup>118</sup> *Id.* at 1523.

<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 1525.

<sup>121</sup> *See id.*

<sup>122</sup> *Id.*

<sup>123</sup> *See id.* (denying summary judgment, because the court might need to reconsider whether the sound was the byproduct of the engine’s components).

<sup>124</sup> *See id.* The decision of the court effectively ended Harley-Davidson’s application for registration, as Harley-Davidson abandoned its efforts instead of electing to proceed with the litigation. *See* John O’Dell, *Harley-Davidson Quits Trying to Hog Sound*, L.A. TIMES (June 21, 2000), <http://articles.latimes.com/2000/jun/21/business/fi-43145>.

The Board's *Harley-Davidson* decision is consistent with others examining functionality in nontraditional trademarks.<sup>125</sup> Functionality concerns led the Federal Circuit to affirm a refusal to register a trademark for the color black on an outboard motor.<sup>126</sup> In that case, the court held the color black to be functional, because black is compatible with nearly all colors and makes objects look smaller.<sup>127</sup> Thus, prohibiting competitors from using it would hinder competition.<sup>128</sup> Additionally, the TTAB refused registration of a trademark for the orange flavor of an antidepressant medicine because it would foreclose competitors from using the same flavor to make their tablets more palatable for patients.<sup>129</sup>

## II. Recent TTAB Decisions Regarding Sound Marks

### A. *In re Vertex Group LLC*

The TTAB considered Vertex Group's appeal of the denial of its applications for trademark protection for the sound made by its "AmberWatch."<sup>130</sup> Vertex Group developed the AmberWatch as "a combination watch and personal alarm for children,"<sup>131</sup> designed to help parents protect their children from kidnapping or other wrongdoing.<sup>132</sup> The watch was equipped to emit a 115-decibel signal that Vertex Group claimed could "be heard from over a football field away."<sup>133</sup>

Vertex Group filed two separate applications to register the sound of its alarm as a mark.<sup>134</sup> The first sought trademark protection for goods identified as a "[p]ersonal security alarm in the nature of a child's bracelet to deter and prevent child abductions."<sup>135</sup> The second application identified the goods as "[p]ersonal security alarms."<sup>136</sup> Both applications stated that Vertex Group intended to use the mark in commerce for the identified goods.<sup>137</sup> Both ap-

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<sup>125</sup> See TMER, *supra* note 25, § 1202.02(a)(viii), at 1200-62 to 1200-63 (stating that the functionality doctrine is applied to nontraditional marks).

<sup>126</sup> *Brunswick Corp. v. British Seagull Ltd.*, 35 F.3d 1527, 1529 (Fed. Cir. 1994).

<sup>127</sup> *Id.* at 1531.

<sup>128</sup> *Id.*

<sup>129</sup> *In re N.V. Organon*, 79 U.S.P.Q.2d (BNA) 1639, 1648, 1651 (T.T.A.B. 2006).

<sup>130</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1695-96 (T.T.A.B. 2009).

<sup>131</sup> *Id.* at 1696.

<sup>132</sup> *Id.* at 1695-96.

<sup>133</sup> *Id.* at 1696.

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

plications also described the sound, in an incomprehensible fashion to the layperson, as:

A descending frequency sound pulse (from 2.3kHz to approximately 1.5kHz) that follows an exponential, RC charging curve, wherein said descending frequency sound pulse occurs four to five times per second, and that over a one second period of time, there is alternating sound pulses and silence with each occurring approximately 50% of the time during a one second period of time.<sup>138</sup>

The examining attorney refused both applications for failure to function as a mark and on functionality grounds.<sup>139</sup>

In reviewing the refusal of Vertex Group's applications for a proposed sound mark, the Board returned to first principles of sound marks. After examining the underlying facts, it began its opinion by reaffirming its earlier holdings that sounds can serve as trade or service marks.<sup>140</sup> Next, the Board echoed *General Electric's* distinction between commonplace and inherently distinctive sounds.<sup>141</sup> The Board stated that commonplace sounds "must be shown to have acquired distinctiveness."<sup>142</sup> Inherently distinctive sounds, on the other hand, do not require proof of acquired distinctiveness as long as the sound "indicate[s] . . . that a particular product or service was coming from a particular, even if anonymous, source."<sup>143</sup>

The TTAB's decision then took an unforeseen turn. The Board discussed recent developments in color and product design marks, referring to the Supreme Court's decisions in *Qualitex* and *Wal-Mart*.<sup>144</sup> It cited the Supreme Court's requirement that these two categories of marks demand a showing of acquired distinctiveness, regardless of whether the mark is inherently distinctive or commonplace.<sup>145</sup> The Board then stated that "[t]here is no subsequent case law . . . stating such a rule in regard to sound marks. Nonetheless, we find it appropriate to follow the Supreme Court's rule regarding color and product design, for certain types of sound marks."<sup>146</sup>

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<sup>138</sup> *Id.*

<sup>139</sup> *Id.* at 1695–96.

<sup>140</sup> *Id.* at 1699 (citing *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B. 1978)).

<sup>141</sup> *Id.* at 1699–1700 (citing *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. at 563).

<sup>142</sup> *Id.* at 1700.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.* (citing *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 216 (2000) (product design must show acquired distinctiveness for registration); *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 163 (1995) (color foreclosed from registration without proof of secondary meaning)).

<sup>146</sup> *Id.*

The Board provided its rule and some direction in applying it. “When a sound is proposed for registration as a mark on the Principal Register, for goods that make the sound in their normal course of operation, registration is available only on a showing of acquired distinctiveness.”<sup>147</sup> To further explain the rule, the TTAB set forth an illustrative list of goods governed by the new rule, including “alarm clocks, appliances that include audible alarms or signals, telephones, and the alarm products of applicant.”<sup>148</sup> The Board applied its new rule to Vertex Group’s applications and affirmed the denial, while also justifying the decision on the two grounds applied below (functionality and failure to function as a mark) with a detailed analysis of each.<sup>149</sup>

### **B. Nextel Communications, Inc. v. Motorola, Inc.**

*Nextel Communications Inc. v. Motorola Inc.*<sup>150</sup> remains the Board’s only decision where it applied the *Vertex Group* rule. This decision is examined here in an attempt to gain further insight into the rule.

In April 2003, Motorola filed an application to register its “chirp” as a sound mark.<sup>151</sup> It described the sound as “an electronic chirp consisting of a tone at 1800Hz played at a cadence of 24 milliseconds ON, 24 ms OFF, 24 ms ON, 24 ms OFF, 48 ms ON,” used for “cellular telephones and two-way radios.”<sup>152</sup> Motorola claimed it first used the chirp in April 1996.<sup>153</sup> Nextel opposed the registration on two grounds, claiming that Motorola “ha[d] not used the chirp as a trademark in commerce” and “that the chirp [was] not inherently distinctive and ha[d] not acquired distinctiveness.”<sup>154</sup>

The Board applied the *Vertex Group* rule and affirmed the denial of Motorola’s application.<sup>155</sup> Motorola first maintained that its mark, the chirp, was inherently distinctive.<sup>156</sup> The Board quickly dismissed this assertion, stating: “[N]otwithstanding the Board’s flexibility toward what constitutes a trademark, the Board very recently determined that certain sound marks are not inher-

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<sup>147</sup> *Id.*

<sup>148</sup> *Id.* at 1700, 1700 n.14.

<sup>149</sup> *Id.*

<sup>150</sup> 91 U.S.P.Q.2d (BNA) 1393, 1400 (T.T.A.B. 2009).

<sup>151</sup> *Id.* at 1395.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 1395–96. Additionally, Nextel filed its own application for registration of the same chirp sound that Motorola sought to protect. *Id.* at 1397. Nextel’s “application has been suspended by the [USPTO] based on a potential likelihood of confusion refusal should [Motorola’s] application . . . mature into a registration.” *Id.* at 1397–98.

<sup>155</sup> *Id.* at 1409.

<sup>156</sup> *Id.* at 1400.

ently distinctive.”<sup>157</sup> The Board found that “the chirp, because of the nature of its use, i.e., in connection with cellular telephones, cannot be inherently distinctive.”<sup>158</sup> It went on to expressly restate the *Vertex Group* rule and quoted the same illustrative list of products.<sup>159</sup> In reinforcing its earlier holding, the Board stated “cellular telephones, including those manufactured by applicant that emit the chirp, fall into the category of goods that make sound in their normal course of operation.”<sup>160</sup> Therefore, the sounds that cellular telephones make “cannot be inherently distinctive and may only be registered upon a showing of acquired distinctiveness.”<sup>161</sup>

### III. The *Vertex Group* Rule Is Flawed

The Trademark Trial and Appeal Board’s decision in *Vertex Group* sets forth a flawed rule in many regards: (1) the TTAB followed the Supreme Court’s holdings to require proof of acquired distinctiveness in applications for color and product design marks without providing any reasoning as to why sound marks made by a product in its normal course of operation should follow the same rule; (2) the Board’s application of the new rule lacks specificity; (3) the rule is overbroad in that it denies registration for inherently distinctive sounds that would otherwise be registrable without a showing of acquired distinctiveness; and (4) the rule is unnecessary.

#### A. The TTAB’s Decision Lacks Support as to Why Sound Marks Made by a Product During Its Normal Course of Operation Are Sufficiently Analogous to Color and Product Design Marks

In holding that sound marks made in the normal course of operation of their goods require proof of acquired distinctiveness in order to be registered, the Board acknowledged that “[t]here is *no subsequent case law* . . . stating such a rule in regard to sound marks.”<sup>162</sup> However, the Board held that the *Vertex Group* rule should apply to this subset of sound marks, because the Supreme Court requires color and product design marks to make the same showing.<sup>163</sup> No further rationale for the new rule appears in either *Vertex Group* or the subsequent *Nextel* decision.<sup>164</sup> The Board engaged in no comparison of color

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<sup>157</sup> *Id.* (citing *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694 (T.T.A.B. 2009)).

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* (quoting *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700).

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 1401.

<sup>162</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700 (emphasis added).

<sup>163</sup> *Id.*

<sup>164</sup> See *Nextel Commc’ns Inc.*, 91 U.S.P.Q.2d at 1400–01 (applying the new rule without adding any new justifications for applying the rule to the subset of sound marks at issue); *In*



and product design marks with sound marks.<sup>165</sup> This analysis follows, as does a comparison of sound marks made by a product during its normal course of operation with other categories of marks that require proof of acquired distinctiveness, in order to demonstrate that no underlying rationale of requiring proof of acquired distinctiveness for any category of marks applies.

***1. The Supreme Court's Rationale for Denying Registration of Color and Product Design Marks Without a Showing of Acquired Distinctiveness Does Not Apply to Sound Marks Made by a Product During the Normal Course of Its Operation***

***a. The Supreme Court Rested Its Holdings for Color and Product Design on Descriptiveness and Lack of Consumer Predisposition to View the Product's Feature as an Indication of the Product's Source***

While the Supreme Court's decision in *Qualitex* does not expressly state a rule that color marks cannot be registered absent a showing of acquired distinctiveness,<sup>166</sup> this principle can be easily inferred from the opinion's language that "over time, customers may come to treat a particular color on a product or its packaging . . . as signifying a brand."<sup>167</sup> Five years later, *Wal-Mart* reinforced the interpretation of *Qualitex* to provide a bright-line rule prohibiting color marks from registration without acquired distinctiveness.<sup>168</sup>

The Court based its decision to limit registration of color marks to those demonstrating proof of acquired distinctiveness on the principle that "color is unlike 'fanciful,' 'arbitrary,' or 'suggestive' words or designs, which almost *automatically* tell a customer that they refer to a brand."<sup>169</sup> In so doing, the Court analogized color marks to descriptive marks.<sup>170</sup> Descriptive marks are not inherently distinctive, because they "describe[] the qualities or characteristics

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*re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700 (engaging in no comparison between color and product design marks and sound marks).

<sup>165</sup> See *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

<sup>166</sup> See *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 162–63 (1995) ("[A] product's color is unlike 'fanciful,' 'arbitrary,' or 'suggestive' words or designs, which almost *automatically* tell a customer that they refer to a brand.").

<sup>167</sup> *Id.* at 163.

<sup>168</sup> See *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 211 (2000) ("[W]ith respect to at least one category of mark—colors—we have held that no mark can ever be inherently distinctive."). This rule also fits within pre-*Qualitex* requirements for the registration of color marks. See *In re Owens-Corning Fiberglas Corp.*, 774 F.2d 1116, 1127 (Fed. Cir. 1985) (granting registration based on showing of acquired distinctiveness).

<sup>169</sup> *Qualitex Co.*, 514 U.S. at 162–63.

<sup>170</sup> *Id.* at 163 (stating that color marks and descriptive words on a product come to indicate source in the same manner).

of a [product,]” so there is no inherent connection between the description and source indication.<sup>171</sup>

The Supreme Court likewise held in *Wal-Mart* that product design marks are only eligible for trademark protection upon a showing of acquired distinctiveness.<sup>172</sup> The Supreme Court reached this conclusion by piggybacking off of its previous decision in *Qualitex*, stating that color marks cannot be inherently distinctive.<sup>173</sup> In *Qualitex*, the Court focused its discussion on the spectrum of trademark classification, but *Wal-Mart* de-emphasized the role of this analysis.<sup>174</sup> The Court held in *Wal-Mart* that product design would not be regarded by consumers as source indicating at the time of the feature’s introduction, because “[c]onsumers are aware of the reality that, almost invariably, even the most unusual of product designs—such as a cocktail shaker shaped like a penguin—is intended not to identify the source, but to render the product itself more useful or more appealing.”<sup>175</sup> The Court’s holding in *Wal-Mart* more thoroughly developed the rationales prohibiting registration for color and product design marks without proof of acquired distinctiveness.<sup>176</sup> *Qualitex* stated that color marks are descriptive, and descriptive marks fail to indicate source.<sup>177</sup> *Wal-Mart* stated that product design marks fail to indicate source without classifying them as descriptive.<sup>178</sup>

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<sup>171</sup> *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985).

<sup>172</sup> *Wal-Mart Stores, Inc.*, 529 U.S. at 212 (stating that product design is never inherently distinctive).

<sup>173</sup> *Id.* at 212–13 (holding that “consumer predisposition to equate [color and product design] with the source does not exist”).

<sup>174</sup> *Id.* (going a step further than *Qualitex* in discussing the strength of consumer predisposition to recognize the source of a product with a symbol, which does not exist for descriptive words or color and product design marks).

<sup>175</sup> *Id.* at 213; see also *In re Slokevage*, 441 F.3d 957, 959 (Fed. Cir. 2006) (interpreting *Wal-Mart* to rely predominantly on a product design’s inability to indicate source in the public’s mind).

<sup>176</sup> *Id.* at 212–13 (explaining why descriptive marks fail to indicate source).

<sup>177</sup> *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 162–163 (1995).

<sup>178</sup> *Wal-Mart Stores, Inc.*, 529 U.S. at 213 (holding that “[i]n the case of product design, as in the case of color, . . . consumer predisposition to equate the feature with the source does not exist”). Even though these two underlying rationales for requiring proof of acquired distinctiveness for color and product design marks are related (in that part of the reason why descriptive marks require this showing is that consumers will not view the description as a source identifier), the next two parts treat these rationales as distinct for purposes of the discussion.

***b. Not All Sound Marks Made in a Product's Normal Course of Operation Are Descriptive Marks***

*Qualitex* rested almost completely on the idea that color marks are descriptive of the goods they are applied to, thus proof of acquired distinctiveness is required for registration.<sup>179</sup> Trying to make this rationale conform to sound marks made by a product in its normal course of operation is like putting a square peg into a round hole.

One commentator, Nick Pisarsky, has posited that sounds made in the normal course of a product's operation cannot serve as marks for that product because the sounds are descriptive of the product and, therefore, require proof of acquired distinctiveness in order to serve as marks.<sup>180</sup> In a nutshell, Pisarsky states that these sounds, referred to as "sound products,"<sup>181</sup> are a form of trade dress<sup>182</sup> within the category of product design.<sup>183</sup> He argues that after *Wal-Mart* held that an application for a product design mark always requires proof of acquired distinctiveness, sound products are foreclosed from registration without a showing of acquired distinctiveness.<sup>184</sup> Proof of acquired distinctiveness is appropriate, according to this argument, because "sound products are produced by a particular product configuration, [and] they naturally describe the product from which they originate."<sup>185</sup>

<sup>179</sup> *Qualitex Co.*, 514 U.S. at 1663 (providing that color marks and descriptive words indicate source in the same fashion).

<sup>180</sup> See Pisarsky, *supra* note 86, at 811–17. A year before the Board created this rule in *Vertex Group*, Pisarsky argued that sounds made by a product during its normal course of operation should be required to provide proof of acquired distinctiveness. See *id.* at 811. This section of the Article addresses Pisarsky's argument that all of these sounds are descriptive in an attempt to prove that one of the bases that the Supreme Court relied upon is not appropriate to apply to sound marks made by a product in its normal course of operation. See *id.* at 811–17.

<sup>181</sup> *Id.* at 805. Pisarsky defines "sound products" as sounds "that are generated by the product itself, and, at least in the minds of producers, can serve as source identification for that product." *Id.* at 804–05. This definition is substantially similar, but not identical, to rule set forth in *Vertex Group*. The Board's rule applies to sounds made by a good in its "normal course of operation." *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1700 (T.T.A.B. 2009). Despite the difference between Pisarsky's "generated by the product itself" and *Vertex Group's* "sounds made in the product's normal course of operation," the author of this Article treats these two classifications as indistinguishable for purposes of this discussion, except where stated otherwise.

<sup>182</sup> Pisarsky, *supra* note 86, at 812 (noting that the notion of trade dress is expanding from just appearance to include "size, shape, color, texture, and graphics").

<sup>183</sup> See *id.* at 815.

<sup>184</sup> See *id.* at 816 (citing *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 215 (2000)).

<sup>185</sup> *Id.*

This argument falls flat for several reasons. Sound products are not trade dress, because trade dress refers only to a product's physical appearance.<sup>186</sup> Most of Pisarsky's argument is based on sound products fitting within the growing definition of trade dress.<sup>187</sup> The definition of trade dress is expanding, but it has yet to reach beyond a product's physical appearance.<sup>188</sup> *Wal-Mart* states that trade dress "originally included only the packaging, or 'dressing,' of a product, but in recent years has been expanded . . . to encompass the design of the product."<sup>189</sup> The language "design of the product" would seem to include the sounds that a product makes, as manufacturers *design* their products to make certain sounds, but the meaning of the language has a much narrower definition. Pisarsky even points this out when he provides that "trade dress of a product is essentially its appearance."<sup>190</sup> It is only the definition of the term "appearance" that expanded from a product's packaging to its "size, shape, color, texture, and graphics."<sup>191</sup> All of these elements refer to the product's visual appearance,<sup>192</sup> so the sounds a product makes do not fall within the definition of trade dress and are, therefore, not controlled by *Wal-Mart*.

Pisarsky incorrectly states that sound products "naturally describe the product from which they originate,"<sup>193</sup> because they are "produced by a particular product configuration."<sup>194</sup> This contention assumes that all sounds are produced by a product's specific configuration, but, given the increasing presence of sounds being programmed into products' software, this is no longer true. These sounds are not the byproduct of the product's parts in the same manner as the Harley-Davidson motor.<sup>195</sup>

If a sound is the byproduct of the product's parts, then these sounds are functional, not descriptive. These are two independent inquiries in the trademark registration process, with major differences. A descriptive mark is registrable by showing proof of acquired distinctiveness between the mark

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<sup>186</sup> See *Blue Bell Bio-Med. v. Cin-Bad, Inc.*, 864 F.2d 1253, 1256 (5th Cir. 1989) ("The 'trade dress' of a product is essentially its total image and overall appearance.").

<sup>187</sup> Pisarsky, *supra* note 86, at 812 (surmising that the notion of trade dress is expanding from just appearance to include "size, shape, color, texture, and graphics").

<sup>188</sup> See *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 209 (2000).

<sup>189</sup> *Id.*

<sup>190</sup> Pisarsky, *supra* note 86, at 812.

<sup>191</sup> See *id.*

<sup>192</sup> See *Wal-Mart Stores, Inc.*, 529 U.S. at 209 (citing *Ashley Furniture Indus., Inc. v. Sangiacomo N.A., Ltd.*, 187 F.3d 363 (4th Cir. 1999) (bedroom furniture); *Knitwaves, Inc. v. Lollytogs, Ltd.*, 71 F.3d 996 (2d Cir. 1995) (sweaters); *Stuart Hall Co., Inc. v. Ampad Corp.*, 51 F.3d 780 (8th Cir. 1995) (notebooks)).

<sup>193</sup> See Pisarsky, *supra* note 86, at 816.

<sup>194</sup> See *id.*

<sup>195</sup> See *supra* Part I.D.

and the manufacturer.<sup>196</sup> A functional mark, on the other hand, is not registrable even if it has acquired distinctiveness because of the negative impact trademark protection would have on competition.<sup>197</sup> For instance, *Harley-Davidson* involved an application for trademark protection for a sound that was created merely as a byproduct of the configuration of a motorcycle's engine and exhaust system.<sup>198</sup> The Board held that granting Harley-Davidson's application would inhibit competition, as, if this argument had merit, all other manufacturers would be prohibited from building their engines in the same fashion as Harley-Davidson.<sup>199</sup> As for sound products, if they are emitted because of a particular product configuration, granting trademark protection would foreclose competitors from building the product in the same manner, thus inhibiting competition. As a result, these applications should be denied on functionality grounds, without any consideration of descriptive ability. Denial on functionality grounds completely bars registration of the sound as a mark, while descriptive sounds are registrable with a showing of acquired distinctiveness.<sup>200</sup>

Sound products are also not descriptive because not all sound products describe the products that make them. A descriptive mark, by definition, "describes the qualities or characteristics of a good or service"<sup>201</sup> or "immediately conveys knowledge of the ingredients, qualities or characteristics of the product."<sup>202</sup> Some sounds emitted by products in their normal use would be descriptive. For instance, the alarm on an alarm clock would qualify as a descriptive sound, because the alarm sound is the primary feature of the alarm clock. Not all sounds produced by a product would be descriptive, though, because not every product's function is not to produce a sound.<sup>203</sup> The sound

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<sup>196</sup> 15 U.S.C. § 1052(f) (2006).

<sup>197</sup> See *Brunswick Corp. v. British Seagull Ltd.*, 35 F.3d 1257, 1531 (Fed. Cir. 1994) (upholding the Board's refusal to trademark the use of the color black, because it would hinder competition).

<sup>198</sup> *Kawasaki Motors Corp. U.S.A. v. H-D Mich. Inc.*, 43 U.S.P.Q.2d (BNA) 1521, 1525 (T.T.A.B. 1997).

<sup>199</sup> *Id.*

<sup>200</sup> Compare *id.* (setting the issue of functionality for trial, because, if the sound was functional, it would be barred from registration), with *Ride the Ducks LLC v. Duck Boat Tours, Inc.*, 75 U.S.P.Q.2d (BNA) 1269, 1275 (E.D. Pa. 2005) (allowing registration, as the district court merely held that proof of acquired distinctiveness for the duck quack was required in order to register the sound).

<sup>201</sup> *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985).

<sup>202</sup> *In re Dial-A-Mattress Operating Corp.*, 240 F.3d 1341, 1346 (Fed. Cir. 2001).

<sup>203</sup> See Jordan S. Weinstein, *Annual Review: The Sixty-Second Year of Administration of the U.S. Trademark (Lanham) Act of 1946 Part II. Ex Parte Cases*, 100 TRADEMARK REP. 17, 30 (2010).

a cellular telephone makes when it is powered on is an example of this type of sound, and so is the iPhone ringtone. The iPhone ringtone does not describe the iPhone because it is merely used in one of the many functions of the product<sup>204</sup> without conveying information on the product as a whole.<sup>205</sup> The power-on sound and the iPhone ringtone are closer to arbitrary or suggestive marks, because they convey little information on the characteristics of the product, and the programmers could have replaced them with nearly any other sound.<sup>206</sup>

Sounds that are descriptive are core sounds<sup>207</sup> and sounds that are not core sounds are not descriptive.<sup>208</sup> “Core sounds” describe, or more appropriately are, the dominant characteristic of the product.<sup>209</sup> As such, they easily fit into the definition of a descriptive mark.<sup>210</sup> The alarm buzzer on an alarm clock is a core sound. Not every product has a core sound, however, because products typically make lots of sounds, and only products whose function it is to make them have core sounds. Many of the other sounds a product makes do not describe the qualities or characteristics of a product (e.g., the sound a TiVo emits when scrolling through its menus). Therefore, these sounds fall outside the context of core sounds and are not descriptive of the product.

Not only are none of Pisarsky’s sound products descriptive, but neither are any of *Vertex Group*’s sounds made in the normal course of operation of a product. This is because sound products and sounds made in the normal course of operation are subsets of sounds that contain more than just core sounds.

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<sup>204</sup> The iPhone acts as a phone, web browser, GPS, mp3 player, email client, alarm clock, and camera. *iPhone Built-in Apps*, APPLE INC., <http://www.apple.com/iphone/built-in-apps/> (last visited Nov. 5, 2011). The iPhone’s function is not to make the ringtone sound in the same way as an alarm clock’s function is to make its alarm sound in order to wake people up.

<sup>205</sup> A sound alerting a user to something is not sufficient to describe the function of the product. Otherwise, all ringtones would describe phones even if it is not a commonplace sound.

<sup>206</sup> See *Abercrombie & Fitch Co. v. Hunting World, Inc.*, 537 F.2d 4, 11 (2d Cir. 1976) (“A term is suggestive if it requires imagination, thought and perception to reach a conclusion as to the nature of the goods.”).

<sup>207</sup> “Core sounds” are those sounds made by product’s whose function it is to make that sound. See Weinstein, *supra* note 203, at 30.

<sup>208</sup> See *id.*

<sup>209</sup> See *id.*

<sup>210</sup> See *Park ’N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985) (defining descriptive marks as those marks that “describe[] the qualities or characteristics of a good or service”); *In re Dial-A-Mattress Operating Corp.*, 240 F.3d 1341, 1346 (Fed. Cir. 2001) (explaining that descriptive marks “immediately convey[] knowledge of the ingredients, qualities or characteristics of the product”).



Pisarsky defines “sound products” as “those [sounds] generated by the product itself”<sup>211</sup> or as “sounds that a product emits when it is in use.”<sup>212</sup> This definition allows nearly all sounds a product makes to fall within the jurisdiction of the rule. *Vertex Group* explains the sounds that it applies to, sounds made by a product during its normal course of operation, through an illustrative list of products.<sup>213</sup> This list includes “alarm clocks, appliances that include audible alarms or signals, telephones, and the alarm products of [Vertex Group].”<sup>214</sup> It is easy to see from the illustrative list that *Vertex Group* applies to a much narrower group of potential sound marks than Pisarsky’s sound products;<sup>215</sup> however, *Vertex Group* still includes sounds outside of core sounds.<sup>216</sup> The Board’s dicta in *Nextel* reads the illustrative list provided in *Vertex Group* as allowing all of the sounds a cellular telephone emits to fall within the rule.<sup>217</sup> As discussed, a cellular telephone’s primary function is not to make power-on or ringtone sounds, so these sounds are not descriptive.<sup>218</sup> As such, *Vertex Group*’s application extends beyond descriptive sounds, and the Board’s implicit use of descriptive marks to justify its rule, via the Supreme Court’s decision in *Qualitex*, is inappropriate.

***c. Consumer Predisposition Exists to Equate Sounds Made by a Product During Its Normal Course of Operation with the Product’s Source***

A consumer’s ability to identify sounds made in the normal course of operation of a product as source identifiers is much stronger than it is for other nontraditional marks like color, product design, scent, or flavor. Equating sounds with source indication is easier, regardless of whether they are made during a product’s normal course of operation,<sup>219</sup> because society is inundated

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<sup>211</sup> Pisarsky, *supra* note 86, at 804.

<sup>212</sup> *Id.* at 805.

<sup>213</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1700 (T.T.A.B. 2009).

<sup>214</sup> *Id.*

<sup>215</sup> Pisarsky wrote before the Board decided *Vertex Group*, so one cannot infer that his argument only addresses the narrower category of *Vertex Group* sounds. See Pisarsky, *supra* note 86, at 797.

<sup>216</sup> See *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

<sup>217</sup> See *Nextel Commc’ns Inc. v. Motorola Inc.*, 91 U.S.P.Q.2d (BNA) 1393, 1400–01 (T.T.A.B. 2009) (interpreting the discussion that a cellular telephone makes numerous sounds and alerts to provide that these other sounds would be barred from registration as a mark, like the chirp, without a showing of acquired distinctiveness, because the cellular telephone falls within the ambit of the rule).

<sup>218</sup> See *id.*

<sup>219</sup> Many sound marks are not sounds made in a product’s normal course of operation; they are commercial jingles or other sounds associated with a business. See *e.g.*, Registration



with hundreds of sound marks on a daily basis. Consumers already possess the ability to connect sound marks with source indication, which enables them to connect sounds made by a product in its normal course of operation with the brand name of that product.

Much of today's modern marketing on radio, television, and the Internet is built upon the premise that consumers will identify the source of a good or service from a sound.<sup>220</sup> Try turning on a radio or television without being bombarded by sound marks. Every time the "ding" plays in a Southwest Airlines commercial, consumers connect it to the source it identifies.<sup>221</sup> Consumers subconsciously make these connections from countless sound marks, whether it is the start sound to a Windows-powered computer,<sup>222</sup> the default ringtone of an iPhone, or the jingle of a local business aired during a radio or television ad. Consumers are ingrained to make these connections between sound and source from years of subconsciously doing so.<sup>223</sup> This ability to connect sound with source translates to the context of sounds made during a product's normal course of operation. The same mental process is involved in hearing a sound and connecting it to the source of a product,<sup>224</sup> and there is no proof that consumers will fail to do so.

The counterargument can be made that, even though consumers are predisposed to connect sound marks with sources, they are more likely to view sound marks made by a product during its normal course of operation like they do the product features of color and design, as a way to make the product more appealing. But the product features of color and design have not

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No. 2,927,617 (showing that Southwest Airlines' "ding" followed by the words "you are now free to move about the country" represents a sound mark not made by a product in its normal course of operation). But all sound marks condition the brain to accept that sounds can indicate source. This predisposition is what the Supreme Court held to be lacking in *Wal-Mart*, *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 212–13 (2000), and is what the Board implicitly relied upon in cases for scent and flavor. *See In re N.V. Organon*, 79 U.S.P.Q.2d (BNA) 1639, 1644 (T.T.A.B. 2006) (flavors require proof of acquired distinctiveness for registration as a mark); *In re Clarke*, 17 U.S.P.Q.2d (BNA) 1238, 1240 (T.T.A.B. 1990) (scents).

<sup>220</sup> *See* McCormick, *supra* note 17, at 1103 (citing Ruth Mortimer, *Sonic Branding: Branding the Perfect Pitch*, BRAND STRATEGY, Feb. 7, 2005, at 24–25).

<sup>221</sup> *See* Registration No. 2,927,617 (registering the "ding of an airplane intercom").

<sup>222</sup> Registration No. 2,880,267 (registering the Windows start up sound).

<sup>223</sup> *See* McCormick, *supra* note 17, at 1102–04 (discussing the history of sound marks from the 1920s through modern day).

<sup>224</sup> *See* Ruth Mortimer, *Sonic Branding: Branding the Perfect Pitch*, BRAND STRATEGY, Feb. 7, 2005, at 24, 27.

been used as source identifiers for years and years like sound marks have.<sup>225</sup> Common sense suggests that consumers do not confront nearly as many source-identifying color and product design marks as they do sound marks.<sup>226</sup> Therefore, while the subconscious source-identifying abilities of consumers may be weaker for these other nontraditional marks, they are quite strong for sound marks.<sup>227</sup> Given a lifetime of exposure to sound marks, a consumer's ability to connect sound with source translates to a predisposition to connect the sound a product makes with its brand name.<sup>228</sup>

***2. The Rationales Requiring Proof of Acquired Distinctiveness in Scent, Flavor, and Surname Marks Do Not Apply to Sound Marks Made by a Product During Its Normal Course of Operation***

Color and product design marks are not the only categories required to show proof of acquired distinctiveness for registration on the Principal Register. Proposed marks of scents, flavors, and surnames all categorically require proof of acquired distinctiveness. In these instances, the underlying rationale does not translate to sounds made by a product during the normal course of operation.

***a. Scent***

Scents can never be inherently distinctive<sup>229</sup> because people are not predisposed to utilize scent as an indication of source,<sup>230</sup> and, like flavor as discussed below, scents are merely byproducts of their ingredients.<sup>231</sup> Due to these concerns, a scent mark that is not functional is registrable but only upon a showing of acquired distinctiveness.<sup>232</sup> These reasons do not apply to sounds made during a product's normal course of operation because consumers are predisposed to connect sound with source and not all of these sounds are the byproducts of their components.

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<sup>225</sup> See McCormick, *supra* note 17, at 1101–04 (running through the history from the MGM's Lion Roar in 1924 through the Southwest Airline's "Ding" in present day).

<sup>226</sup> See McCormick, *supra* note 17, at 1102–03 (popularity of sound marks centers on sounds transcending languages and the ability influence people to react and behave).

<sup>227</sup> See *id.* at 24 (noting that sound is processed throughout the whole brain, unlike other senses).

<sup>228</sup> See *id.*

<sup>229</sup> TMEP, *supra* note 25, § 1202.13, at 1200-112.

<sup>230</sup> See *In re Clarke*, 17 U.S.P.Q.2d (BNA) 1238, 1239 (T.T.A.B. 1990) (application rejected by examining attorney on these grounds).

<sup>231</sup> See TMEP, *supra* note 25, § 1202.13, at 1200-112. (citing examples of the scent of a perfume and an air freshener).

<sup>232</sup> See *In re Clarke*, 17 U.S.P.Q.2d at 1240 (granting registration for scent due to proof that customers, dealers, and distributors recognize applicant as source of her scented yarns).

### *b. Flavor*

“Just as with a scent or fragrance, a flavor can never be inherently distinctive.”<sup>233</sup> Therefore, registration of flavor as a trademark is available only upon proof of acquired distinctiveness.<sup>234</sup> In *In re N.V. Organon*, the TTAB held that flavor is merely a characteristic of a good, like a descriptive mark, or the product of the good’s ingredients, thus barring registration on functionality grounds.<sup>235</sup> The Board also expressed serious reservations about how flavor can function as a source indicator, given that “flavor or taste generally performs a utilitarian function and consumers have no access to a product’s flavor or taste prior to purchase.”<sup>236</sup> Even so, the Board held the language of the Lanham Act to be open-ended, so it declined to close the door on flavor ever serving as a mark.<sup>237</sup>

This rationale does not apply to sounds made in a product’s normal course of operation. As discussed above, none of these sounds are either descriptive or functional.<sup>238</sup> Moreover, the Board did not believe that flavor could function as a source indicator because consumers do not have access to a product’s flavor prior to purchasing the product.<sup>239</sup> However, consumers can access a product’s sounds through marketing in a variety of media. Therefore, the underlying rationale for barring registration of flavor absent acquired distinctiveness does not provide an adequate basis to require proof of acquired distinctiveness for the subset of sound marks at issue.

### *c. Surnames*

Sections 1052(f) and 1052(e)(4) of the Lanham Act require acquired distinctiveness<sup>240</sup> for a mark that “is primarily merely a surname” to be registered.<sup>241</sup> This statute’s roots are planted in the common law.<sup>242</sup> “[S]urnames are shared by more than one individual, each of whom may have an interest in using his surname in business, and by the requirement for evidence of distinctive-

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<sup>233</sup> TMER, *supra* note 25, § 1202.13, at 1200-113; *see also In re N.V. Organon*, 79 U.S.P.Q.2d (BNA) 1639, 1650 (T.T.A.B. 2006) (also comparing flavor with color, concluding that there is no inherent distinctiveness).

<sup>234</sup> TMER, *supra* note 25, § 1202.13, at 1200-113. (citing *In re N.V. Organon*, 79 U.S.P.Q.2d 1639 (T.T.A.B. 2006)).

<sup>235</sup> *In re N.V. Organon*, 79 U.S.P.Q.2d at 1649–50.

<sup>236</sup> TMER, *supra* note 25, § 1202.13, at 1200-113. (citing *In re N.V. Organon*, 79 U.S.P.Q.2d at 1650).

<sup>237</sup> *See In re N.V. Organon*, 79 U.S.P.Q.2d at 1644.

<sup>238</sup> *See supra* Part III.A.1.b.

<sup>239</sup> *See In re N.V. Organon*, 79 U.S.P.Q.2d at 1650.

<sup>240</sup> 15 U.S.C. § 1052(f) (“[N]othing . . . shall prevent the registration of a[n] [(e)(4)] mark used by the applicant which has become distinctive of the applicant’s goods in commerce.”).

<sup>241</sup> 15 U.S.C. § 1052(e)(4).

<sup>242</sup> *In re Etablissements Darty et Fils*, 759 F.2d 15, 17 (Fed. Cir. 1985).

ness, in effect, delays appropriation of exclusive rights in the name.”<sup>243</sup> The rationale for surnames to show proof of acquired distinctiveness clearly does not apply to sound marks.

### **B. The TTAB’s Decision Lacks Specificity as to the Exact Contours of the *Vertex Group* Rule**

The Board’s holding leaves open the primary concern of how broadly the *Vertex Group* rule should apply. The rule begs the question of whether it applies to the sounds a product makes or to the product itself. The rule is also unclear on what is meant by a product’s “normal course of operation.”

The *Vertex Group* rule applies a product-driven analysis and does not analyze the individual sounds that the products make. The Board held that “[w]hen a sound is proposed for registration as a mark on the Principal Register, for goods that make the sound in their normal course of operation, registration is available only on a showing of acquired distinctiveness.”<sup>244</sup> To help explain its new *Vertex Group* rule, the Board provided an illustrative list of examples of goods governed by the rule, including “alarm clocks, appliances that include audible alarms or signals, telephones, and the alarm products of [Vertex Group].”<sup>245</sup> From the plain language of this illustrative list, the rule applies to products, not to sounds. Applying the new rule in *Nextel*, the Board reinforced this product-driven approach by holding that a cellular telephone falls within “the category of goods that make sound in their normal course of operation.”<sup>246</sup> This meant that the term “telephones” found on the illustrative list also included cellular telephones, and the Board, therefore, did not analyze the proposed sound, a chirp, in any manner to reach its decision in *Nextel*.<sup>247</sup>

Applying a product-driven analysis raises many problems. To begin with, products make many sounds. A cellular telephone has a ringtone for its phone function, but it also may have different default alerts for text messages, e-mails, voicemails, and low battery warnings. Should all of these sounds be barred from serving as marks for the product? Where should the TTAB draw the line between a product’s many sounds, if it draws a line at all? *Nextel*, the Board’s lone decision applying the rule, indicates that the Board interprets

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<sup>243</sup> *Id.*

<sup>244</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1700 (T.T.A.B. 2009).

<sup>245</sup> *Id.* at 1700, 1700 n.14.

<sup>246</sup> *Nextel Commc’ns Inc. v. Motorola Inc.*, 91 U.S.P.Q.2d (BNA) 1393, 1400 (T.T.A.B. 2009).

<sup>247</sup> *See id.* at 1400–01.

“normal course of operation” loosely to include all sounds that a product makes during its use.<sup>248</sup>

Also problematic is the Board’s break from *General Electric*, denying an application’s examining attorney the opportunity to even assess whether the sound itself is inherently distinctive, because a threshold determination must first be made to establish whether the product that makes the sound falls within the ambit of the rule.<sup>249</sup> By examining the products rather than the sounds, the Board implicitly presumes, notwithstanding the new rule, that all of the products that fall within the rule emit sounds that could not be registered absent a showing of acquired distinctiveness.<sup>250</sup>

Moving forward, there is still plenty of uncertainty as to the exact scope of the *Vertex Group* rule. It is important to keep in mind that the Board has only applied the rule once since creating it,<sup>251</sup> so reading too far into the application should be done with caution. Evidently, the rule applies to a certain set of products, but how broadly does this category extend beyond the examples provided in the illustrative list? Should the language normal course of operation be interpreted as broadly as the Board hinted at in *Nextel*? Only time will tell.

### C. The *Vertex Group* Rule Is Overbroad

The Board’s *Vertex Group* rule is overbroad because it denies registration of many inherently distinctive sounds made by products during their normal course of operation unless the applicant makes a showing of acquired distinctiveness.<sup>252</sup> Under *General Electric*, any inherently distinctive sound can be registered as a mark without having to make such a showing.<sup>253</sup> The *Vertex Group* rule eliminates the *General Electric* consideration of whether a sound is inherently distinctive or commonplace.<sup>254</sup> It does so without properly justifying why sounds made during a product’s normal course of operation cannot be registered absent this showing. It is true that many of these sounds

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<sup>248</sup> *Id.* (holding that registration of a cellular telephone’s chirp was blocked absent proof of acquired distinctiveness, because the cellular telephone is within the realm of product provided on the illustrative list and implicitly stating that all sounds by those products required the additional showing for registration).

<sup>249</sup> *See In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

<sup>250</sup> The Board must make this presumption, because it failed to provide an adequate basis for which it could categorically consider all sounds not to be inherently distinctive. *See supra* Part III.A.

<sup>251</sup> *See Nextel Commc’ns Inc.*, 91 U.S.P.Q.2d at 1400.

<sup>252</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

<sup>253</sup> *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B. 1978).

<sup>254</sup> *See Nextel Commc’ns Inc.*, 91 U.S.P.Q.2d at 1400–01 (applying the *Vertex Group* rule sets forth a product-driven analysis that does not consider the distinctiveness of the sound); *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700 (same).

either would not be registrable at all due to functionality concerns or, if the sounds are commonplace, would require proof of acquired distinctiveness. But, without this rule, not all sounds made by a product during its normal course of operation would be barred from registration absent a showing of acquired distinctiveness. Products make all sorts of inherently distinctive sounds during their normal courses of operation. The USPTO has even registered some of these sounds on the Principal Register.<sup>255</sup> The occurrence of sounds like these will only increase as technology continues to evolve and more sounds made by products become inherently distinctive.

Upon further examination, the *Vertex Group* rule appears to target sounds that are functional and/or commonplace. This conclusion arises from the Board's attempt to narrow the products governed by the rule in an illustrative list.<sup>256</sup> Most of these products contain only functional or commonplace sounds. Unfortunately, the rule goes further than that. It bars *all* sounds made by products like those on the list without a showing of acquired distinctiveness.<sup>257</sup> The inclusion of telephones in this list is not problematic, as a standard telephone's ringer is a commonplace sound. However, *Nextel's* holding that cellular telephones fall within the rule<sup>258</sup> creates overbreadth concerns because of the many functions the phone serves and the many sounds it makes. Every sound a cellular telephone emits, from the power-on sound to the text message alert to the ringtone, are not necessarily functional or commonplace.

By forcing product manufacturers to prove acquired distinctiveness for these sounds, the TTAB places a large burden on a manufacturer that chooses to use a sound that one of its products makes as a mark for itself. Forcing a product manufacturer to prove acquired distinctiveness creates a minimal problem for large multi-national corporations like Apple, with annual marketing budgets in the hundreds of millions of dollars,<sup>259</sup> but it places a much greater burden on the small or medium-sized manufacturers that do not have millions of dollars to spend in marketing.

The process of acquiring distinctiveness is no inexpensive task. Owens-Corning spent \$42.4 million between 1972 and 1981 to acquire distinctiveness in its pink insulation in order to get its application for trademark

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<sup>255</sup> See e.g., Registration No. 2,821,863 (America Online, Inc.'s "You've Got Mail"); Registration No. 2,880,267 (Microsoft Corp.'s Windows start up sound). These marks are registered as service marks but are used in normal course of operation of the products they are associated with, so they could be registered as trademarks.

<sup>256</sup> See *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

<sup>257</sup> *Id.*

<sup>258</sup> See *Nextel Commc'ns Inc.*, 91 U.S.P.Q.2d at 1400-01, 1408.

<sup>259</sup> APPLE INC., *supra* note 2, at 54. Apple spent a total of \$1.687 billion on advertising from 2008-2010 alone. *Id.*

protection approved.<sup>260</sup> Acquiring distinctiveness for all marks should not cost nearly as much, especially because, unlike the proposed color marks in the Owens-Corning example, consumers are predisposed to connect sounds with sources, unlike the proposed color marks.<sup>261</sup> Still, acquiring distinctiveness is no simple task.<sup>262</sup>

Proving acquired distinctiveness places a substantial burden in the path of applicants as well.<sup>263</sup> In *In re Craigmyle*,<sup>264</sup> a manufacturer of horse halters offered sales volumes as proof of acquired distinctiveness for a product design mark, but the Board denied the application because there was no indication that the manufacturer tried to develop recognition of the halter's design and the source of the halter.<sup>265</sup> Therefore, circumstantial evidence can be offered to prove acquired distinctiveness, but the Board prefers direct evidence of source indication.<sup>266</sup>

The burden of acquiring and proving distinctiveness robs many product manufacturers of the ability to utilize trademark protection of sounds made by their products because it requires a substantial amount of time and money to establish and then prove distinctiveness. Simply put, if a product manufacturer does not have protection of the sound it plans to build its brand name around, it will be less apt to market that sound out of fear that trademark protection may never be realized.

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<sup>260</sup> *In re Owens-Corning Fiberglas Corp.*, 774 F.2d 1116, 1125 (Fed. Cir. 1985) (establishing acquired distinctiveness between the color pink and its insulation).

<sup>261</sup> Erik W. Kahn, *On the 'Net, Unusual Marks Gain in Importance*, NAT'L L.J., Oct. 19, 1998, at C13 (stating that sound immediately can convey source, while color requires acquired distinctiveness).

<sup>262</sup> *See, e.g., Kellogg Co. v. Gen. Mills, Inc.*, 82 U.S.P.Q.2d (BNA) 1766, 1768, 1772 (T.T.A.B. 2007) (finding acquired distinctiveness where applicant spent \$46 million on advertising over a five-year period and brought in revenue of \$650 million in sales, but noting that this holding was "the rare case").

<sup>263</sup> *See* Mark P. McKenna, *Trademark Use and the Problem of Source*, 2009 U. ILL. L. REV. 773, 821–23 (2009) (discussing the challenges posed by reliance on consumer awareness in trademark law); *see also In re Clarke*, 17 U.S.P.Q.2d (BNA) 1238, 1240 (T.T.A.B. 1990) (holding that applicant established a prima facie case of acquired distinctiveness through advertisements and other promotions).

<sup>264</sup> 224 U.S.P.Q. (BNA) 791 (T.T.A.B. 1984).

<sup>265</sup> *Id.* at 793.

<sup>266</sup> *Compare In re Clarke*, 17 U.S.P.Q.2d at 1239–40 (finding distinctiveness based on direct evidence of advertisements touting a scented feature), *with In re Craigmyle*, 224 U.S.P.Q. at 793 (concluding that circumstantial evidence of sales number was insufficient to indicate acquired distinctiveness without any direct connection between product design and source indication).



Moreover, the marketing world is changing. Marketing campaigns utilize multiple senses to build strong customer loyalty for products, and sound marks are a large piece of that puzzle.<sup>267</sup> Requiring proof of acquired distinctiveness for sounds made in the normal course of a product's operation inhibits manufacturers from using these sounds as marks, thereby frustrating the development of effective modern marketing plans. Unlike other categories of marks that the Board or courts have held to require proof of acquired distinctiveness, there exists no strong reasoning to require this proof for sound marks made in the normal course of a product's operation. In order to help manufacturers thrive, this impediment should be removed.

#### D. Creating the *Vertex Group* Rule Was Unnecessary

The Board denied Vertex Group's applications under its newly crafted rule, but it also upheld the examining attorney's denial on functionality grounds and for failing to serve as a mark.<sup>268</sup> To say the Board did not need to create the rule to deny the application would be an understatement.

Distinctiveness and functionality are still available to examine all applications for sound marks, and this new rule achieves nothing these underlying tests do not. Since *General Electric*, the Board and the courts have applied that test to sound marks.<sup>269</sup> *General Electric* created the two-prong classification of sounds as either inherently distinctive or commonplace.<sup>270</sup> Classifying a sound into one of these two camps determines whether the applicant needs to prove acquired distinctiveness.<sup>271</sup> This analysis is still in place for sounds other than those made in the normal course of operation of a product<sup>272</sup> and can once again be easily applied to sounds that fall within this category. Furthermore, functionality bars registration when the product feature "is essential to the use or purpose of the article or if it affects the cost or quality of the article."<sup>273</sup> This definition does not require the product feature to be a "competitive necessity" in order to be found to be functional and does not alter the *Morton-Norwich*

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<sup>267</sup> See Gilson & Gilson LaLonde, *supra* note 32, at 775 (noting that marketing is moving toward multisensory branding (citing MARTIN LINDSTROM, BRAND SENSE: BUILD POWERFUL BRANDS THROUGH TOUCH, TASTE, SMELL, SIGHT, AND SOUND 139–48, 161 (2005))).

<sup>268</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1702, 1704 (T.T.A.B. 2009).

<sup>269</sup> See, e.g., *Ride the Ducks LLC v. Duck Boat Tours, Inc.*, 75 U.S.P.Q.2d (BNA) 1269, 1275 (E.D. Pa. 2005) (applying the *General Electric* test to hold that a duck quack was a commonplace sound).

<sup>270</sup> *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. (BNA) 560, 563 (T.T.A.B. 1978).

<sup>271</sup> *Id.*

<sup>272</sup> See *Ride the Ducks LLC*, 75 U.S.P.Q.2d at 1275 (finding a duck quack to be commonplace and, thus, requiring proof of acquired distinctiveness).

<sup>273</sup> *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 850 n.10 (1982).

factors for functionality.<sup>274</sup> There is no change to the functionality inquiry of sounds made in a product's normal course of operation, and functionality still operates to deny registration to proposed marks.<sup>275</sup> Due to the presence of the tests for distinctiveness and functionality, the TTAB did not need to create the *Vertex Group* rule to reach the same end result.

#### IV. How to Solve the Problems Created by the *Vertex Group* Rule

In order to solve the many problems created by *Vertex Group*, the Board should either abandon the rule entirely or narrow its scope to only apply to functional or commonplace sounds. Both approaches allow the Board to return to firm footing, because the current rule is based on faulty assumptions that sounds made by products in their normal course of operation are either descriptive or that consumers are not predisposed to connect them with the manufacturer of the products. Because neither rationale correctly applies to these sounds, the Board should act to rectify its *Vertex Group* rule.

If the Board chooses to abandon the *Vertex Group* rule, it would still be able to rely on the underlying tests of distinctiveness and functionality to determine if an application for trademark protection should be granted. In terms of distinctiveness, abandoning the rule should reaffirm *General Electric* and its distinction between inherently distinctive and commonplace sounds.<sup>276</sup> Before ever arriving at the fork in the road that is the *General Electric* test, the *Vertex Group* rule places a threshold question: whether a product falls within the ambit of the rule.<sup>277</sup> The answer to this question leads to different results than the *General Electric* test would yield, yet there is no solid rationale for creating these differing outcomes. Reverting to *General Electric* embraces a sound-driven approach to this analysis, instead of a product-driven focus, and should eliminate overbreadth concerns. As for functionality, it still bars registration of a mark due to the harm that granting the registration would have on marketplace competition. In the absence of the *Vertex Group* rule, the functionality test would not change.

Should the Board choose not to abandon its rule, narrowing *Vertex Group* could be achieved in one of two ways. The products covered by the rule could be focused in such a way that it would only apply to products that create

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<sup>274</sup> *Valu Eng'g, Inc. v. Rexnord Corp.*, 278 F.3d 1268, 1276 (Fed. Cir. 2002).

<sup>275</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d (BNA) 1694, 1702 (T.T.A.B. 2009) (applying the functionality test to sound).

<sup>276</sup> *See In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. at 563.

<sup>277</sup> *See In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

functional or commonplace sounds.<sup>278</sup> This could be achieved by slimming the illustrative list to include the alarm on an alarm clock, the Vertex Group watch, or the buzzer on a household appliance. The net result would be to eliminate telephones from the illustrative list of products covered by the rule, or to expressly overrule the *Nextel* dicta that cellular telephones fall within its scope. The reason for trimming this list is that not all the sounds a cellular telephone makes in its normal course of operation are functional and/or commonplace. Alternatively, the Board could interpret “normal course of operation”<sup>279</sup> as only applying to functional or commonplace sounds. This avenue embraces a sound-driven focus, so there should be little, if any, overbreadth concern. However, by shifting to a sound-specific approach the Board loses the efficiency that a bright-line product-central rule provides. There would also be little difference between this narrow normal course of operation approach and returning to pre-*Vertex Group* world where the Board considered functionality and distinctiveness in the application process.<sup>280</sup> Embracing this approach leaves no purpose for the rule other than serving as an umbrella under which the functionality and distinctiveness tests stay dry.

The Board must act in some fashion. In *Vertex Group*, it created an imperfect rule that was doomed from the moment of its adoption. The Board held that the Supreme Court’s underlying rationales for requiring proof of acquired distinctiveness in color and product design marks also translated to sound marks for sounds made by products in the normal course of their operation.<sup>281</sup> This is not true. These sounds are not necessarily descriptive of the products that make them. Consumers are much more predisposed to connect these sounds with the sources of the products that make them than other types of marks.<sup>282</sup> Common sense suggests that consumers establish linkages between sounds and the sources they identify every day. Abandoning or narrowing the rule enables the Board to grant trademark protection to all inherently distinctive sounds absent proof of acquired distinctiveness, whether or not these sounds are made during a product’s normal course of operation.

## Conclusion

In *Vertex Group*, the Trademark Trial and Appeal Board announced a new rule for sound marks that are made by products in their normal courses of

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<sup>278</sup> One drawback of staying with a product-driven approach is that it will inherently lead to overbreadth issues. More and more products make multiple sounds, and not every sound a product makes can be classified as functional or commonplace.

<sup>279</sup> *Id.*

<sup>280</sup> See *In re Gen. Elec. Broad. Co.*, 199 U.S.P.Q. at 563.

<sup>281</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

<sup>282</sup> See Kahn, *supra* note 261, at C13.

operation, requiring proof of acquired distinctiveness in order to be registered on the Principal Register.<sup>283</sup> The Board based its new rule on the similarity in consumer predisposition to connect color, product design, and sounds made by a product during its normal course of operation to the source of the product.<sup>284</sup> Secondarily, the Board relied upon this subset of sound marks as being merely descriptive of the product.<sup>285</sup> These assumptions are inaccurate, because consumers are much more predisposed to connect a sound, whether it is made by a product or not, with its source<sup>286</sup> through decades of subconscious experience doing precisely that with other sound marks.<sup>287</sup> Moreover, not all sounds made by a product during its normal course of operation are descriptive of that product. Additionally, the rule does not sufficiently delineate its outer bounds. It applies to products, not sounds, and no bright lines differentiate which sounds are governed by the rule and which are not.<sup>288</sup> Furthermore, the product-driven approach called for by the *Vertex Group* rule is overbroad because it presumes that no sounds made in the normal course of a product's operation are inherently distinctive, able to serve as a source identifier, or not descriptive or functional,<sup>289</sup> when plenty of these sounds exist. Finally, the Board's creation of the *Vertex Group* rule was unnecessary, because it achieved nothing that the underlying tests of distinctiveness and functionality would not.

In closing, the TTAB should abandon its *Vertex Group* rule and return to the tried-and-true tests of distinctiveness and functionality to determine whether to grant registration on the Principal Register to a proposed mark of a sound made by a product during its normal course of operation. In the alternative, the Board should narrow the scope of the rule so that it only requires proof of acquired distinctiveness for commonplace sounds and bars registration for functional sounds. By so doing, the Board would clearly define what falls inside and outside the scope of an otherwise amorphous rule, while allowing inherently distinctive sounds made by products in the normal course of operation to be registered without proof of acquired distinctiveness, as was the case before the rule was created.

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<sup>283</sup> *In re Vertex Grp. LLC*, 89 U.S.P.Q.2d at 1700.

<sup>284</sup> *Id.*

<sup>285</sup> *Id.*

<sup>286</sup> See Kahn, *supra* note 261, at C13.

<sup>287</sup> See McCormick, *supra* note 17, at 1102–04 (noting the presence of sound marks since the 1920s).

<sup>288</sup> See *supra* Part III.B.

<sup>289</sup> See *supra* Part III.C.



# Solving the Confidentiality Designation Problem in Federal Circuit Briefs: A Proposed Amendment to Local Rule 11

Mark Davies\*, Lauren Parker\*\*, and Jennifer Overall\*\*\*

## Introduction

The Federal Circuit recently expressed concern about the excessive use of confidentiality markings in briefs and improper confidentiality designations in materials submitted for review.<sup>1</sup> The court explained that not only does excessive redaction make non-confidential versions of briefs “virtually incomprehensible,” but also the presumptive right of public access to court proceedings and records requires a strong showing of “good cause” to keep filed materials out of public view.<sup>2</sup>

This Article will propose a practical solution to this problem of excessive confidentiality markings. The local Federal Circuit Rules provide that protective orders, whether issued by an agency or a trial court, are preserved on appeal.<sup>3</sup> The Rules also provide a procedure that the parties may utilize to modify prior protective orders.<sup>4</sup> Despite this system, the practical realities of litigation tend to result in little change in protective orders on appeals to the Federal Circuit. This Article will describe the status quo with respect to the issuance of protective and sealing orders in federal courts and agencies. It will also provide a suggestion for modifying current practice in the Federal Circuit to address the court’s concerns of past abuse and litigants’ concerns about efficiency and predictability.

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<sup>1</sup> See *In re Violation of Rule 28(d)*, 635 F.3d 1352, 1354 (Fed. Cir. 2011).

<sup>2</sup> See *id.* at 1357, 1360.

<sup>3</sup> FED. CIR. R. 11(c), 17(e).

<sup>4</sup> FED. CIR. R. 11(d), 17(f).

## I. The Problem

In one case before the court, the Federal Circuit issued sanctions against counsel for “extensive use of improper confidentiality markings” in its brief.<sup>5</sup> The underlying case, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*,<sup>6</sup> was an appeal from a revised consent judgment involving the interpretation of a license agreement and a settlement agreement between the parties for the manufacture and sale of certain pharmaceuticals.<sup>7</sup> During trial, the district court issued a protective order that permitted the parties to designate as confidential “any form of trade secret or other confidential research, development, or commercial information” that was within the meaning of Federal Rule of Civil Procedure 26,<sup>8</sup> additionally providing that:

If any party files [information designated as confidential] . . . in connection with any motion, other written submission, hearing or trial in this action, the filing party shall make such filing under seal and shall simultaneously file a motion to seal such information . . . ; provided, however, that the burden of proving that such information should be sealed . . . shall at all times remain on the party which designated the information [as confidential].<sup>9</sup>

The court noted that this order correctly required the parties to show “good cause” and required the court to rule on the parties’ motions to seal.<sup>10</sup> The parties designated the license and settlement agreements as confidential; that designation was never formally lifted, even though the parties agreed to do so at oral argument on appeal.<sup>11</sup>

The court took the opportunity to discuss its views on the standard required for the issuance of a protective order. The court stated that parties must show “good cause” for the issuance of an order by demonstrating that “specific prejudice or harm will result if no protective order is granted.”<sup>12</sup> This showing is required even where the parties agree that an order should be entered.<sup>13</sup> The

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<sup>5</sup> *In re* Violation of Rule 28(d), 635 F.3d at 1354.

<sup>6</sup> 405 Fed. App’x 493 (Fed. Cir. 2010).

<sup>7</sup> *See In re* Violation of Rule 28(d), 635 F.3d. at 1354–55.

<sup>8</sup> *Id.* at 1359 (quoting Joint Proposed Discovery Confidentiality Order at 7, *Sanofi-Aventis U.S. LLC v. Sun Pharm. Indus., Ltd.*, No. 07-CV-03411 (D.N.J. Dec. 14, 2007)) (internal quotation marks omitted). This protective order mirrors the language of the Federal Rule of Civil Procedure. *See* FED. R. CIV. P. 26(c)(1)(G).

<sup>9</sup> *Id.* (quoting Joint Proposed Discovery Confidentiality Order at 19, *Sanofi-Aventis*, No. 07-CV-03411) (internal quotation marks omitted).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 1357–58 (quoting *Phillips v. Gen. Motors Corp.*, 307 F.3d 1206, 1210–11 (9th Cir. 2002)) (internal quotation marks omitted).

<sup>13</sup> *Id.* at 1358 (quoting *Jepson Inc. v. Makita Elec. Works, Ltd.*, 30 F.3d 854, 858 (7th Cir. 1994)).



court also noted that the basic “good cause” showing is not strong enough to protect materials filed with the court; once introduced at trial, only a compelling showing of prejudice or harm to the individual seeking protection can justify limitations on disclosure through sealing.<sup>14</sup> Finally the court noted that the issuance of broad stipulated protective orders, which allow the parties to designate material as confidential and file it under seal without court approval for “good cause,” violates Rule 26.<sup>15</sup> It is unclear from the court’s opinion how this standard will be applied when it considers protection orders and sealed materials from agencies.

In this case, the Federal Circuit did not take issue with the underlying protective order.<sup>16</sup> Instead, it sanctioned counsel for Sun Pharmaceutical Industries, Ltd. and Caraco Pharmaceutical Laboratories, Ltd. (the defendants-appellants, collectively “Sun”) for improperly marking as confidential citations from published court opinions (the district court injunctive order), case citations, and legal arguments that Sun asserted would reveal the content of other protected materials (namely, the license and settlement agreements).<sup>17</sup> The court stated that its local rule 28(d), which governs the submission of briefs containing material subject to a protective order,<sup>18</sup> implicitly requires that designations conform to the standards of Rule 26, both in content and for good cause shown.<sup>19</sup> The materials marked by Sun, the court explained, could never properly be designated as confidential, given the strong presumption of public access to court proceedings and records.<sup>20</sup>

In making these statements in its opinion, the court demonstrated several concerns with current practice. First, the court appeared concerned with applying the proper level of scrutiny to motions for protective and sealing orders (or, in this case, orders to protect materials filed with the court, which are similar to sealing orders).<sup>21</sup> Second, the Federal Circuit cautioned that trial court orders and the parties themselves must respect the substantive limits contained in Rule 26 of the Federal Rules of Civil Procedure.<sup>22</sup> In other words, the court wished parties to take greater care to only mark as confidential

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<sup>14</sup> *Id.* (quoting *Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 533 (1st Cir. 1993)).

<sup>15</sup> *Id.* (quoting *Procter & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219, 222, 227 (6th Cir. 1996)).

<sup>16</sup> *See id.* at 1359.

<sup>17</sup> *See id.* at 1359–61.

<sup>18</sup> FED. CIR. R. 28(d).

<sup>19</sup> *In re Violation of Rule 28(d)*, 635 F.3d at 1358–59.

<sup>20</sup> *Id.* at 1360.

<sup>21</sup> *See id.* at 1357–58.

<sup>22</sup> *See id.* at 1358.

“trade secret[s] or other confidential research, development, or commercial information,” as stated in the rule.<sup>23</sup>

## II. Confidentiality Designations in Lower Courts and Agencies

To place the Federal Circuit’s concerns in context, it is useful to begin with a description of the confidentiality designation process.

### A. Federal District Courts and Protective Orders

In federal district courts, protective orders circumscribing disclosure of trade secrets and confidential business information during discovery are issued under Rule 26(c)(1) of the Federal Rules of Civil Procedure.<sup>24</sup> Generally, the rule comes into play in response to one or more parties’ discovery requests.<sup>25</sup> Rule 26(c)(1) states that:

The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense including . . .

. . . .

(G) requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way . . .<sup>26</sup>

Frequently, adverse parties agree to the scope of a requested protective order to facilitate broad discovery going forward.<sup>27</sup> Even when the parties are in agreement, they must still demonstrate good cause for the issuance of the order.<sup>28</sup>

In practice, the level of scrutiny a court applies to a request for a protective order varies widely across the circuits; so, too, varies the scope and structure of the issued orders themselves.<sup>29</sup> Generally, courts require a particularized

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<sup>23</sup> *Id.* at 1357 (quoting FED. R. CIV. P. 26(c)(1)(G)) (internal quotation marks omitted).

<sup>24</sup> *Id.* (citing FED. R. CIV. P. 26(c)(1)).

<sup>25</sup> FED. R. CIV. P. 26(c)(1).

<sup>26</sup> *Id.*

<sup>27</sup> See *In re Violation of Rule 28(d)*, 635 F.3d at 1358.

<sup>28</sup> See, e.g., *Procter & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219, 227 (6th Cir. 1996) (finding that a protection order in which the parties were allowed to determine which documents were protected without showing good cause was invalid under Rule 26(c)). *But see Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 532 (1st Cir. 1993) (emphasizing a judge’s discretion to “frame and administer” the orders after an initial showing of good cause, and upholding an order that allowed a party to designate further confidential material, subject to objection by the other party).

<sup>29</sup> For an excellent overview of the law of each of the U.S. Circuit Courts of Appeal, see ANDREA KUPERMAN, COMM. ON RULES OF PRACTICE & PROCEDURE, CASE LAW ON ENTERING PROTECTIVE ORDERS, ENTERING SEALING ORDERS, AND MODIFYING PROTECTIVE ORDERS 1

showing of good cause to protect the documents at issue, but the strength of the required showing differs.<sup>30</sup> After the initial showing of good cause has been made, some circuits permit the issuance of orders granting broad discretion to the parties to determine which material should be designated as confidential.<sup>31</sup>

Protective orders generally apply to materials exchanged between the parties in discovery.<sup>32</sup> Discovery materials are presumptively public,<sup>33</sup> and, over the years, as the scope of discovery grew and filing requirements associated with discovered materials shrunk, parties began to increasingly utilize protective orders to preserve confidentiality where good cause can be demonstrated.<sup>34</sup> However, these orders do not automatically protect material filed with the court. To be protected, a filed document, or any document that enters court records, must be sealed.<sup>35</sup> The standard for sealing is discussed below in Part II.C.

In new lawsuits, courts also frequently address requests from third parties who seek to modify previously entered protective orders in order to gain access to discovery relevant to their suits; however, the standards that courts have developed to respond to these requests for modification are not relevant here.<sup>36</sup>

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(2010), [http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Caselaw\\_Study\\_of\\_Discovery\\_Protective\\_Orders.pdf](http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Caselaw_Study_of_Discovery_Protective_Orders.pdf).

<sup>30</sup> See, e.g., *In re Terra Int'l, Inc.*, 134 F.3d 302, 306 (5th Cir. 1998) (per curiam) (stating that the burden on the movant to establish the need for the order requires a “particular and specific demonstration of fact as distinguished from stereotyped and conclusory statements” (quoting *United States v. Garrett*, 571 F.2d 1323, 1326 n.3 (5th Cir. 1983) (internal quotation marks omitted))).

<sup>31</sup> See, e.g., *Citizens First Nat'l Bank of Princeton v. Cincinnati Ins. Co.*, 178 F.3d 943, 946 (7th Cir. 1999) (stating that, while a court will not allow the parties to seal whatever they want, good cause need not be determined on a document-by-document basis so long as (1) the initial demonstration is made; (2) the parties are aware of what qualifies for protection and are acting in good faith; and (3) the opposing party has a opportunity to object to the designation).

<sup>32</sup> See Giles T. Cohen, Comment, *Protective Orders, Property Interests and Prior Restraints: Can the Courts Prevent Media Nonparties from Publishing Court-Protected Discovery Materials?*, 144 U. PA. L. REV. 2463, 2463 n.2 (1996) (noting that “[p]rotective orders generally impose confidentiality on materials exchanged during discovery”); see also FED. R. CIV. P. 26(c).

<sup>33</sup> See *Citizens First Nat'l Bank of Princeton*, 178 F.3d at 946 (noting that most cases recognize a presumption of public access to discovery materials).

<sup>34</sup> See Arthur R. Miller, *Confidentiality, Protective Orders, and Public Access to the Courts*, 105 HARV. L. REV. 427, 466, 476 (1991) (noting the unparalleled scope of information available through discovery and explaining how parties use protective orders to manage confidentiality issues).

<sup>35</sup> See *In re N.Y. Times Co.*, 828 F.2d 110, 116 (2d Cir. 1987).

<sup>36</sup> See KUPERMAN, *supra* note 29, at 30, 59–60, 66.

## **B. Federal Agency Protective Orders: The International Trade Commission**

Federal agencies may also issue protective orders in the course of administrative investigations or enforcement actions.<sup>37</sup> For purposes of illustration, this Article will address the regulations that govern practice at the International Trade Commission (“ITC” or “Commission”).

19 C.F.R. § 201.6(a) defines “confidential business information,” for the purposes of the regulations that follow it, as:

information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization or other information of commercial value, the disclosure of which is likely to have the effect of either impairing the Commission’s ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained . . .<sup>38</sup>

This definition is broader than that invoked by the Federal Rules of Civil Procedure.

In order to protect material in an investigation or in a proceeding before an administrative law judge (“ALJ”), the parties must request an order from an ALJ.<sup>39</sup> This order dictates the procedures for identification of confidential material, submission of confidential material to the ALJ, and the exchange of confidential material between the parties.<sup>40</sup> Section 210.5(e) contains no explicit requirement that the parties show good cause for their designations, nor is the ALJ required to limit the parties’ discretion in any way beyond applying the regulatory definition.<sup>41</sup> Therefore, in ITC proceedings, a protective order issued by an ALJ is all that is necessary to prevent disclosure of filed documents. No additional request or motion to seal is required.

## **C. District Courts and Sealing Filed Documents**

While protective orders issued under Rule 26 prevent parties from disclosing the contents of discovery documents to all but a select set of individuals, they do not automatically protect filings with the court.<sup>42</sup> This distinction has become increasingly important since the amendment of Rule 5(d) of the

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<sup>37</sup> See, e.g., 19 C.F.R. § 210.5(e) (2011).

<sup>38</sup> 19 C.F.R. § 201.6(a) (2011).

<sup>39</sup> 19 C.F.R. § 210.5(e).

<sup>40</sup> *Id.*

<sup>41</sup> See *id.*

<sup>42</sup> See *Nault’s Auto. Sales, Inc. v. Am. Honda Motor Co.*, 148 F.R.D. 25, 44 (D.N.H. 1993).

Federal Rules of Civil Procedure in 2000, which eliminated the requirement that discovery documents be filed with trial courts.<sup>43</sup> In most districts, when a party files a motion with the court and wants to attach a protected discovery document or disclose protected information in that filing, testimony, or other evidence, it must make a separate motion to the court to *seal* the record or the filing.<sup>44</sup> Generally, only filed documents or testimony presented to the court becomes part of the district court record, and therefore the U.S. courts of appeals generally only confront confidential material in the form of sealed filings and records.<sup>45</sup> This is reflected in the local rules of the circuit courts, discussed more thoroughly in Table 1 below.

Sealing a part of the record precludes all public access to it.<sup>46</sup> Most courts require that the parties demonstrate a strong showing of need to protect the document before sealing the filing, even if the parties relied on a protective order when they produced the material.<sup>47</sup> The Federal Circuit does not differentiate between protective and sealing orders in its rules for handling confidential material on appeal.<sup>48</sup> This is likely due to the unique jurisdiction of the court, a point discussed further in Part III below. However, recent case law suggests that the court does require a stronger showing of good cause or need to protect documents filed with the court, analogous to the standards for sealing applied in other circuits.<sup>49</sup>

When considering sealing motions for filed materials, most courts recognize a presumption of public access to judicial documents.<sup>50</sup> This presumption, depending on the weight a particular circuit applies, may be overcome by a

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<sup>43</sup> FED. R. CIV. P. 5 2000 amendment committee note.

<sup>44</sup> *See, e.g., In re N.Y. Times Co.*, 828 F.2d 110, 116 (2d Cir. 1987) (“[D]ocuments may be sealed if ‘specific, on the record findings are made demonstrating that closure is essential to preserve higher values and is narrowly tailored to serve that interest.’” (quoting *Press-Enter. Co. v. Superior Court*, 478 U.S. 1, 13–14 (1986))).

<sup>45</sup> *See, e.g.*, 1ST CIR. R. 11.0(c)(1).

<sup>46</sup> *Phillips v. Gen. Motors Corp.*, 307 F.3d 1206, 1213 (9th Cir. 2002).

<sup>47</sup> *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 125–26 (2d Cir. 2006).

<sup>48</sup> *See* FED. CIR. R. 11(c), 17(e).

<sup>49</sup> *In re Violation of Rule 28(d)*, 635 F.3d 1352, 1357–58 (Fed. Cir. 2011).

<sup>50</sup> *See, e.g., Chi. Tribune Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304, 1311 (11th Cir. 2001) (stating that, when discovery materials are filed in connection with pretrial motions that require judicial resolution of the merits, the material is subject to a common law right of public access and requires a very strong showing to receive protection); *SEC v. Van Waeyenberghe*, 990 F.2d 845, 848 (5th Cir. 1993) (stating that courts recognize the public’s common law right to inspect and copy judicial records, and this interest must be balanced against interests favoring non-disclosure when a party seeks to seal records).

compelling showing of need to justify sealing.<sup>51</sup> In addition, the role that a document plays in a proceeding—whether attached to a dispositive or non-dispositive motion—may influence the court’s perspective on the necessity of sealing it.<sup>52</sup> For example, the Ninth Circuit applies a strict standard to justify sealing of information included in dispositive motions, requiring a party to show “compelling reasons supported by specific factual findings”<sup>53</sup> that outweigh the “history of access and the public policies favoring disclosure.”<sup>54</sup>

### III. The Cause of Over-Designation at the Federal Circuit

The Federal Circuit’s present rules do not provide an efficient way to modify prior orders. As discussed further below, the Federal Circuit’s approach to managing disclosure of confidential business information included in the record on appeal is unique among the circuits. The court’s rules do not distinguish sealed filings from material subject to protective orders, though the court itself has stated that it supports using a stricter standard for the former.<sup>55</sup> It is likely that the court’s policy was crafted in response its unique jurisdiction.<sup>56</sup> The chart below provides a summary of the cases filed with the Federal Circuit in 2010 by their category or type.

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<sup>51</sup> See KUPERMAN, *supra* note 29 (providing a detailed discussion of the standard applied by each court).

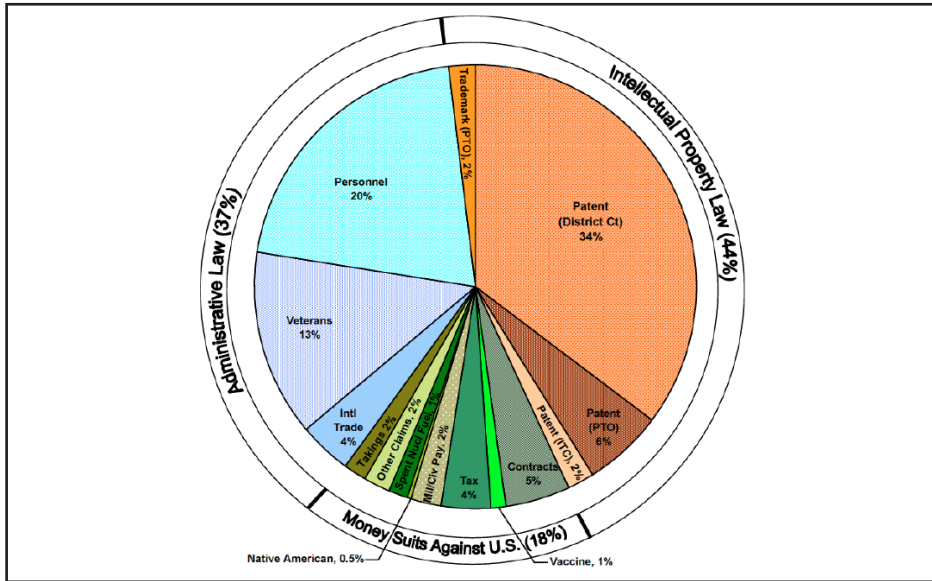
<sup>52</sup> See, e.g., *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003) (stating that, in light of the weaker public interest in non-dispositive materials, the court applies the “good cause” standard to requests for sealing).

<sup>53</sup> *Id.*

<sup>54</sup> *Kamakana v. Honolulu*, 447 F.3d 1172, 1178–79 (9th Cir. 2006).

<sup>55</sup> *In re Violation of Rule 28(d)*, 635 F.3d 1352, 1358 (Fed. Cir. 2011).

<sup>56</sup> See Sean M. McEldowney, Comment, *The “Essential Relationship” Spectrum: A Framework for Addressing Choice of Procedural Law in the Federal Circuit*, 153 U. PA. L. REV. 1639, 1639, 1642 (2005).

**Figure 1. Federal Circuit Appeals Filed by Category, Fiscal Year 2010<sup>57</sup>**

The jurisdiction of the court discloses several motivations for the current policy. First, the United States and its administrative bodies are frequently parties appearing before the court.<sup>58</sup> As the ITC regulations demonstrate, agencies may not clearly distinguish sealed filings from materials subject to protective orders.<sup>59</sup> In addition, the United States as a litigant may make use of protective orders to preserve national security interests<sup>60</sup> or to protect the privacy of third parties.<sup>61</sup> Second, the largest portion of the court's docket comes from patent cases that often involve significant amounts of confidential information, and adverse parties are likely to have a unified interest in preventing disclosure of the information.<sup>62</sup>

<sup>57</sup> *Appeals Filed, by Category, FY2010*, U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT, [http://www.cafc.uscourts.gov/images/stories/the-court/statistics/Caseload\\_by\\_Category\\_Appeals\\_Filed\\_2010.pdf](http://www.cafc.uscourts.gov/images/stories/the-court/statistics/Caseload_by_Category_Appeals_Filed_2010.pdf) (last visited Oct. 10, 2011).

<sup>58</sup> *Id.* (indicating that money suits against the United States and cases relating to administrative law comprised approximately 55 percent of those heard by the court in Fiscal Year 2010).

<sup>59</sup> See 19 C.F.R. § 210.5(e) (2011).

<sup>60</sup> See, e.g., *United States v. Reynolds*, 345 U.S. 1, 6–7 (1953) (finding that the privilege against revealing military secrets is “a privilege which is well established in the law of evidence”).

<sup>61</sup> *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 35 (1984) (noting a substantial governmental interest in protecting the privacy interests of litigants and third parties during discovery).

<sup>62</sup> See *supra* Figure 1. See also James Juo & David J. Pitman, *A Prosecution Bar in Patent Litigation Should Be the Exception Rather Than the Rule*, 15 VA. J.L. & TECH. 43, 44 (2010) (noting confidential information may be disclosed to opposing parties absent a protective



The Federal Circuit Rules provide parallel systems for protective orders issued by courts,<sup>63</sup> and those issued by agencies.<sup>64</sup> The substance of the rules is identical, irrespective of the rule governing an order. Rule 17 states, in relevant part:

(e) *Preserving a Protective Order on Appeal.* Any portion of the record that was subject to a protective order in an agency remains subject to that order unless otherwise ordered.

(f) *Agreement by Parties to Modify Protective Order; Certificate of Compliance.* . . . [E]ach party must promptly review the record to determine whether protected portions need to remain protected on appeal. If a party determines that some portions no longer need to be protected, that party must seek an agreement with the other party. Any agreement that is reached must be promptly presented to the agency, which may issue an appropriate order. Whether or not an agreement is reached, each party must file a certificate of compliance within 45 days of docketing stating it complied with this rule.

(g) *Motion to Modify the Protective Order.* A party may move at any time in this court to modify a protective order to remove protection from some material or to include another person within its terms. This court may decide the motion or may remand the case to the agency. This court, sua sponte, may direct the parties to show cause why a protective order should not be modified.<sup>65</sup>

Thus, the rules preserve on appeal all protective and sealing orders of the fact-finding entity, whether that be an agency or a district court.<sup>66</sup> The rules also require that the parties confer in order to determine whether and how a prior order might be modified, placing the onus on the parties to return to the agency or district court if modifications are agreed upon.<sup>67</sup> It is important to note that some cases arriving at the court from an agency bring with them agency protective orders promulgated under a different standard than Rule 26.<sup>68</sup> Such orders may not require the parties to show “good cause” for the issuance of confidentiality designations or sealing materials contained in

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order and that disclosure of information during litigation even to patent attorneys may result in misuse if that attorney also prosecutes patents).

<sup>63</sup> FED. CIR. R. 11(c)–(e).

<sup>64</sup> FED. CIR. R. 17(e)–(g).

<sup>65</sup> *Id.*

<sup>66</sup> FED. CIR. R. 11(e), 17(e).

<sup>67</sup> FED. CIR. R. 11(d); 17(f). Rule 11(e) allows parties to move in the Federal Circuit for a modification to a prior protection order, but also stipulates that the Federal Circuit has the *option* of deciding the motion itself or remanding it to the district court for a ruling. FED. CIR. R. 11(e). Because a district court retains the power to modify protective orders that it enters, *see, e.g., Biovail Labs., Inc. v. Anchen Pharms., Inc.*, 463 F. Supp. 2d 1073, 1079 (C.D. Cal. 2006), the Federal Circuit is likely to defer to that authority in the absence of other factors, *see id.* at 1085 (ruling on the parties motion to modify a protective order and authorizing future motions to modify in the Federal Circuit pursuant to Rule 11(e) of the Federal Circuit Rules).

<sup>68</sup> *See discussion supra* Part II.A.

the record.<sup>69</sup> Nevertheless, the Federal Circuit's local rules relating to agency protective orders are the same as the local rules for district court protective orders.<sup>70</sup> The Federal Circuit Rules makes explicit the court's intent to apply its procedural standards uniformly in all cases, without regard to their origin, in Federal Circuit Rule 1.<sup>71</sup>

In short, the rules provide a procedure for reducing the amount of confidential information, but it can be cumbersome. During the hurried briefing period that follows the filing of an appeal,<sup>72</sup> few attorneys may wish to return to the trial court or agency body to file a motion for modification of a protective order as contemplated by Federal Circuit' Rules. Even if the parties agree that certain material may no longer require protection—such as a currently public patent application or an outdated corporate policy—composing, filing, and arguing a motion before another court during that short time frame may be entirely out of the question for the litigants. For simplicity's sake, parties may choose to abide by the status quo and let prior designations stand throughout the appeal.

Many attorneys may also sympathize with Sun's counsel's decision, discussed above in Part I, to mark as confidential information that it believed *might* violate a prior court order and upset a prior settlement agreement.<sup>73</sup> When faced with the choice of under- versus over-designation of confidential material, attorneys may over-designate to protect their client and their litigation position with the other party. Thus, despite complications caused by procedure, litigants have a strong interest in preserving the strength and validity of protective and sealing orders.<sup>74</sup>

#### IV. Suggestions for Modification

In proposing a revision of the Federal Circuit's designation rules, it is worth considering the rules of other courts of appeals.

Some circuits have local rules that address the treatment of sealed or protected material when included in an appellate record or cited in a brief. Table

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<sup>69</sup> See, e.g. 19 C.F.R. § 210.5(e) (2011) (giving the ITC ALJs discretion over a confidentiality determinations).

<sup>70</sup> Compare FED. CIR. R. 11(c) (governing the preservation of trial court protective orders), with FED. CIR. R. 17(e) (governing the preservation of agency protective orders).

<sup>71</sup> FED. CIR. R. 1(b)(1) (stating that references in the Federal Circuit Rules to the Federal Rules of Civil Procedure encompass all analogous rules of the Court of International Trade and the Court of Federal Claims).

<sup>72</sup> See FED. CIR. R. 31(a) (allowing sixty days after docketing for the filing of the appellant's brief and requiring the appellee's brief to be filed forty days after the appellant's brief).

<sup>73</sup> See *In re Violation of Rule 28(d)*, 635 F.3d 1352, 1356 (Fed. Cir. 2011).

<sup>74</sup> See generally Miller, *supra* note 34.

I below compares provisions contained in the local rules of the various circuits and general practices gleaned from case law where no rule governs. Circuits listed in the table below with an asterisk have rules that may provide some support for the amended Federal Circuit Rule proposed below.

**Table 1. Circuit Rule and Practice Summary**

Circuit	Relevant Rules	Summary of Treatment
1st*	1ST CIR. R. 11.0(c)–(d), 28.0(c), 28.1.	Lower court’s sealing order remains in place for the record. <sup>a</sup>  For briefs, litigants are instructed to attempt to make arguments relating to sealed material in a separate brief that may be sealed so that the main brief need not be. <sup>b</sup>  A motion must be made to the court of appeals to seal a brief, and references to prior sealed material will not automatically qualify the brief to be sealed. <sup>c</sup>
2d*	No relevant rules.	Issues liberal protective orders in discovery, but once material is filed with the court, the presumption of public access applies, which requires a strong showing to allow filing under seal on appeal, even when the documents have been subject to a previous protection order. <sup>d</sup>
3d	3D CIR. R. 30.3(b).	Records sealed by the district court and not unsealed are not to be included in the paper appendix but must be filed separately. <sup>e</sup>  Case law indicates that the Third Circuit recognizes a presumption of public access to judicial documents filed with the court and will only seal in limited circumstances where the interest in secrecy outweighs the presumption; case law also indicates that sealing orders are intended to be temporary and should be lifted as soon as the reasons for sealing no longer exist. <sup>f</sup>
4th	4TH CIR. R. 25(c)(1), 25(c)(3).	The district court’s or agency’s protection orders remain in place. <sup>g</sup>  Rules appear to equate sealed documents with documents subject to a confidentiality order. <sup>h</sup>  Requires that the party file a “certificate of confidentiality” with any document containing such materials. <sup>i</sup>  Appendices and briefs containing confidential and sealed materials are filed in two versions. <sup>j</sup>

<sup>a</sup> 1ST CIR. R. 11.0(c)–(d).

<sup>b</sup> 1ST CIR. R. 28.1.

<sup>c</sup> 1ST CIR. R. 11.0(c)(2).

<sup>d</sup> See *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 126 (2d Cir. 2006).

<sup>e</sup> 3D CIR. R. 30.3(b).

<sup>f</sup> *In re Cendant Corp. v. Forbes*, 260 F.3d 183, 192–96 (3d Cir. 2001).

<sup>g</sup> 4TH CIR. R. 25(c)(1).

<sup>h</sup> See 4TH CIR. R. 25(c)(1), 25(c)(3).

<sup>i</sup> 4TH CIR. R. 25(c)(1).

<sup>j</sup> 4TH CIR. R. 25(c)(3).

**Table 1. Circuit Rule and Practice Summary (Continued)**

Circuit	Relevant Rules	Summary of Treatment
5th	No relevant rules.	Recognizes a presumption of public access to judicial records and will only seal judicial documents after a showing that interests in favor of sealing outweigh the presumption. <sup>k</sup>  No case law indicates how such materials are treated on appeal.
6th	6TH CIR. R. 11(d), 25(j)(2), 28(g).	Records sealed by the district court remain sealed and may be filed with the Sixth Circuit under seal unless the lower court or the court of appeals modifies the order. <sup>l</sup>  Briefs that refer to information filed under seal are not automatically placed under seal; instead, counsel must make a specific and timely motion to seal. <sup>m</sup>
7th*	No relevant rules.	Information transmitted to the Seventh Circuit is presumptively public. <sup>n</sup>  Discovery orders are not appropriate to protect appellate documents. <sup>o</sup>  Any claim of secrecy (trade secrets or bona fide long-term confidentiality) must be reviewed independently by the appellate court. <sup>p</sup>
8th	No relevant rules.	The case law does not indicate a clear standard for how the Eighth Circuit handles documents filed under seal at the district court.
9th	No relevant rules.	The case law indicates that prior orders to seal or protective orders for discovery documents are not automatically enforced in the Ninth Circuit. <sup>q</sup>  If protected documents or sealed filings relate to a motion that was dispositive in the case, compelling reasons must be given for sealing in the court of appeals. <sup>r</sup>  If protected documents or sealed filings relate to non-dispositive motions, then only “good cause” is required. <sup>s</sup>
10th	10TH CIR. R. 11.3(d), 30.1(c)(4).	Materials sealed by the district court remain sealed with the court of appeals. <sup>t</sup>  Sealed materials in the appendix must be separately assembled and filed under seal. <sup>u</sup>

<sup>k</sup> SEC v. Van Waeyenberghe, 990 F.2d 845, 848 (5th Cir. 1993).

<sup>l</sup> 6TH CIR. R. 11(d), 25(j)(2).

<sup>m</sup> 6TH CIR. R. 28(g).

<sup>n</sup> Baxter Int’l Inc. v. Abbott Labs., 297 F.3d 544, 545 (7th Cir. 2002).

<sup>o</sup> *Id.*

<sup>p</sup> *Id.* at 545–46.

<sup>q</sup> Foltz v. State Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1135 (9th Cir. 2003).

<sup>r</sup> *Id.*

<sup>s</sup> *Id.* at 1135–36.

<sup>t</sup> 10TH CIR. R. 11.3(d).

<sup>u</sup> 10TH CIR. R. 30.1(c)(4).

**Table 1. Circuit Rule and Practice Summary (Continued)**

Circuit	Relevant Rules	Summary of Treatment
11th	No relevant rules.	<p>Only requires a showing of “good cause” to seal documents that are attached to dispositive motions.<sup>v</sup></p> <p>Applies a lenient standard for granting protective orders during discovery.<sup>w</sup></p> <p>Case law is unclear on whether sealing orders automatically remain in place on appeal.</p>
D.C.	D.C. CIR. R. 47.1.	<p>Any portion of the record placed under seal by the district court or an agency remains under seal at the D.C. Circuit.<sup>x</sup></p> <p>Parties must individually review the record and seek an agreement on the unsealing to present to the district court or agency for the appropriate order.<sup>y</sup></p> <p>Parties may move to unseal any part of the record, a motion that will usually be referred to the district court but may be decided by the court of appeals.<sup>z</sup></p>
Fed. Cir.	FED. CIR. R. 11(c)–(e), 17(e)–(g).	<p>Protective order of lower court or agency remains in force unless otherwise ordered.<sup>aa</sup></p> <p>Parties are required to conference regarding continuing confidentiality of material and certify, within forty-five days of docketing, that the parties agree that material marked as confidential requires continued protection.<sup>bb</sup></p> <p>A party may move to modify the order, and the Federal Circuit may remand to district court or decide the motion.<sup>cc</sup></p>

<sup>v</sup> See *Chi. Tribune Co. v. Bridgestone/Firestone, Inc.* 263 F.3d 1304 (10th Cir. 2011).

<sup>w</sup> See *id.*

<sup>x</sup> D.C. CIR. R. 47.1(a).

<sup>y</sup> D.C. CIR. R. 47.1(b).

<sup>z</sup> D.C. CIR. R. 47.1(c).

<sup>aa</sup> FED. CIR. R. 11(c), 17(e).

<sup>bb</sup> FED. CIR. R. 11(d), 17(f).

<sup>cc</sup> FED. CIR. R. 11(e), 17(g).

Currently, Federal Circuit Rules 11 and 17 automatically validate protective orders (and, by implication, sealing orders) of district courts and agencies without further review.<sup>75</sup> When combined with provisions that require modification through motions to the district court or agency body that issued the prior protective orders, this provision may incentivize parties to maintain the status quo on appeal. The current rule also fails to appropriately address inherent differences between district court sealing, on the one hand, and

<sup>75</sup> FED. CIR. R. 11(c), 17(e).

protective and agency issued orders, on the other. Any amendment to current practice should consider the following factors:

1. The administrative burden it will place on courts and on litigants;
2. Litigants' interests in maintaining protection for validly confidential material;
3. Litigants' interests in releasing from protection information that unnecessarily adds to their administrative burden, as well as the court's interest in doing so in order to reduce the scope of the non-public judicial record;
4. The court's interest in appropriately applying the relevant standard of review to confidential material on appeal; and
5. All parties' interests in reducing litigant uncertainty regarding a prior order's validity, therefore promoting efficient compliance.

One suggestion for reform, with the proposed amendments labeled to correspond to the existing sections of Federal Circuit Rule 11 to be replaced, is amending the court's rules as follows:

*(c) **Status of a Protective Order on Appeal.** Any portion of the record that was subject to a protective order in the trial court remains subject to that order for a period of 45 days after docketing. Material exchanged between the parties in discovery – and not part of the record on appeal – that is subject to a protective order in the trial court remains subject to that protective order unless otherwise ordered by the trial court.*

*(d) **Preserving a Protective Order on Appeal.** Within 30 days of docketing, the parties must each file with the court a certificate that:*

1. Lists all material that is part of the record and was designated by that party as confidential under a protective order in the trial court;
2. Identifies the material in subsection (d)(1) that the party determines, for good cause, should remain subject to a protective order on appeal; and
3. Attaches a copy of the motion granted by the trial court that demonstrates good cause for the protection of the relevant material.

*Within 45 days of docketing, the court, subject to its determination of good cause, will issue an order vacating the protection order of the trial court with respect to the material listed in subsection (d)(1) and will issue a new order protecting the material identified in subsection (d)(2). The parties may, at their discretion, choose to file the required certification jointly. If necessary to show continuing good cause for protection, the parties may also attach a short statement of no more than 500 words to the certification.*

This amendment aligns with the current filing schedule for appeals to the Federal Circuit<sup>76</sup> and would not require significant alterations to any other local rules. An appellant in the Federal Circuit must file its brief within sixty days after docketing.<sup>77</sup> Inside this time frame, parties are also required to as-

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<sup>76</sup> See FED. R. CIV. P. 31(a)(1).

<sup>77</sup> FED. CIR. R. 31(a)(1)(A)–(B).

semble and file their appendices, which may contain confidential material.<sup>78</sup> Therefore, it is appropriate that a determination about confidential material should be made during this window. All other rules that relate to confidential material, such as Rule 28(d), addressing confidential material in briefs,<sup>79</sup> and Rule 30(h) which discusses confidential material in the appendices<sup>80</sup> would only have to be altered to acknowledge that, with respect to confidential material, the parties will be bound by the Federal Circuit's order rather than that of the trial court or agency.<sup>81</sup>

The administrative burden placed on the parties by this amendment is not significantly different from the current status quo. Currently, parties are required to confer about the list of protected material and file a certification.<sup>82</sup> This amendment would still require a certification and examination of protected material, but not significantly more.<sup>83</sup> The burden is also similar to the one that might be placed on parties if the rule were amended to allow prior protective orders to be modified by the parties filing a letter of agreement with the district court or agency. However, unlike filing with a trial court or agency, the suggested procedure also addresses the Federal Circuit's concerns that good cause for confidential treatment be demonstrated.<sup>84</sup> This is particularly important for litigants appealing from agency decisions where they may not have been required to show good cause previously. In so doing, the amendment eliminates a good deal of present uncertainty for litigants about their compliance with court standards as they cite to confidential material going forward.

The rule also preserves the prior protection order until a new order can be entered by the court, protecting the parties' interests as they proceed, and it preserves all orders with respect to discovery materials not included in the

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<sup>78</sup> See FED. CIR. R. 30(a)(4), 30(h)(1).

<sup>79</sup> FED. CIR. R. 28(d).

<sup>80</sup> FED. CIR. R. 30(h)(1).

<sup>81</sup> For example, Rule 28(d) currently reads: "If a party refers in a brief to material subject to confidentiality mandated by statute or to a judicial or administrative protective order, two sets of briefs must be filed." FED. CIR. R. 28(d). The same language appears elsewhere in the rules with respect to confidential material. See, e.g., FED. CIR. R. 27(m)(1) (addressing confidential material discussed in motions). This language could simply be amended to conform to the proposed rule by stating: "*If a party refers . . . to material subject to confidentiality mandated by statute or to an order of this court . . .*"

<sup>82</sup> FED. CIR. R. 11(d), 17(f).

<sup>83</sup> In fact, this rule is significantly less onerous on litigants than some circuit's present rules. In the Fourth Circuit, parties are required to file an individual certificate of confidentiality with each document they wish to remain subject to a sealing order. See *supra* Table 1.

<sup>84</sup> *In re Violation of Rule 28(d)*, 635 F.3d 1352, 1357–58 (Fed. Cir. 2011) (quoting *Phillips v. Gen. Motors Corp.*, 307 F.3d 1206, 1210–11 (9th Cir. 2002)).



record. Most other circuits have adopted rules that preserve sealing orders on appeal in a manner similar to the Federal Circuit's method of preserving all protective orders.<sup>85</sup> Sealing orders are generally less extensive than protective orders, and their impact on the record on appeal is, therefore, generally smaller.<sup>86</sup> Because of the potential for both uncertainty and over-use of confidentiality markings in the Federal Circuit, issuing protective orders on appeal that are narrowly tailored to protect litigants and leave the public record intact makes the most practical sense. Some other circuits have taken care to note that, although they intend to observe a lower court sealing or protective order, they do not intend to automatically extend its protection to briefs or other materials filed on appeal.<sup>87</sup> If the Federal Circuit adopted the proposed rule, its position would be much like these other circuits, while also offering litigants some added level of protection and certainty about procedure.

## Conclusion

Although the Federal Circuit's current rules formally provide a procedure for reducing the amount of information designated as confidential, the procedure requires attorneys to return to the trial court or agency body to modify the protective order. As a practical matter, in the hurried briefing period that follows the filing of an appeal, few attorneys do so. This Article proposes an amendment to the Federal Rules that makes it possible for parties to revise the amount of material designated as confidential without returning to the lower adjudicative body. Instead, the Federal Circuit itself, with assistance from both parties, can reduce the amount of material that is designated as confidential. In this fashion, the Federal Circuit briefing process would improve as more material is made available to the public.

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<sup>85</sup> See *supra* Table 1.

<sup>86</sup> See *supra* Part II.C.

<sup>87</sup> See circuit courts marked with asterisks *supra* Table 1.



# Why Plaintiffs Shouldn't Have It Their Way—Revisiting Concurrent Jurisdiction of Autism Claims Against Thimerosal Manufacturers

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## Introduction

The National Childhood Vaccine Injury Act (“the Act”) was Congress’s attempt to solve the problems plaguing vaccine manufacturers and, in turn, the health and safety of the American people.<sup>1</sup> The Act is designed to promote vaccination, while creating a no-fault compensation scheme for those individuals who are injured or die as a result of receiving a vaccine.<sup>2</sup>

The Act sought to eliminate the not-so-remote possibility of exorbitantly priced vaccines, or, worse, no vaccines at all, by creating a forum colloquially known as “vaccine court.”<sup>3</sup> The vaccine court is where people with vaccine-related injuries can receive compensation without exposing vaccine manufacturers to inconsistent judgments and damage awards, thereby protecting the nation’s vaccine supply from a shortage or increased costs caused by litigation.<sup>4</sup>

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<sup>1</sup> See National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, tit. III, 100 Stat. 3743, 3755–3815, (codified as amended in at 42 U.S.C. § 300aa-1 to aa-34 (2006)).

<sup>2</sup> See 42 U.S.C. § 300aa-10(a) (2006); *National Vaccine Injury Compensation Program*, HEALTH RESOURCES AND SERVICES ADMINISTRATION, <http://www.hrsa.gov/vaccinecompensation/index.html> (last visited Oct. 20, 2011). A very important facet of this no-fault compensation scheme, while not entirely germane to this discussion, is that attorneys have an ethical obligation to inform clients of the scheme’s availability. See 42 U.S.C. § 300aa-10(b).

<sup>3</sup> See 42 U.S.C. §§ 300aa-2, -12; Robert Lowes, *Vaccine Critics Claim Court Paid for Autism Cases*, MEDSCAPE MEDICAL NEWS (May 10, 2011), <http://www.medscape.com/viewarticle/74247> (noting the Vaccine Injury Compensation Program’s popular reference as federal “vaccine court”).

<sup>4</sup> See 42 U.S.C. § 300aa-11(a)(2)(A); see also H.R. REP. NO. 99-908, at 3–7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6344–48.

Congress wanted the National Childhood Vaccine Injury Act to be attractive to potential claimants, but it was unwilling to foreclose plaintiffs completely from traditional state remedies.<sup>5</sup> Because the Act still allows the traditional remedy of filing in state court, Congress tried to entice plaintiffs into the vaccine court by creating a process that promised quicker, faster, and fair results, and by establishing certain procedural requirements that plaintiffs must meet before filing certain claims against specific defendants outside of the vaccine court.<sup>6</sup>

The Act requires plaintiffs seeking damages against a vaccine administrator or manufacturer<sup>7</sup> for a vaccine-related injury or death<sup>8</sup> to follow a set procedure. A plaintiff must file a petition for compensation under the National Vaccine Injury Compensation Program (“the Program”) in the U.S. Court of Federal Claims before filing suit in any state or federal court seeking state law remedies.<sup>9</sup> Any suit that does not comply with this requirement (and has been improperly filed outside of the U.S. Court of Federal Claims) must be dismissed.<sup>10</sup>

On the face of the Act, it appeared that Congress had achieved the impossible by allowing vaccine victims to have both a no-fault scheme and state law remedies. The problem was that Congress tried to please too many people. Realistically, Congress must have foreseen that concurrent jurisdiction may result in disparate treatment of similar cases. However, Congress likely did not realize this disparate treatment would have such pervasive consequences, as became evident after the passage of the Act.

In the years after the Act was passed, evidence began to suggest a link between autism and vaccines. Specifically, Thimerosal, a vaccine component used as a preservative, appeared to act as a potential environmental trigger for autism.<sup>11</sup>

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<sup>5</sup> See 42 U.S.C. § 300aa-11(a)(2)(A) (allowing petitioners to bring state court actions only after certain qualifications have been met); see also H.R. REP. NO. 99-908, at 3, 12, reprinted in 1986 U.S.C.C.A.N. 6344, 6344, 6353.

<sup>6</sup> See 42 U.S.C. § 300aa-11(a)(2)(A); see also H.R. REP. NO. 99-908, at 12–13, reprinted in 1986 U.S.C.C.A.N. at 6353–54.

<sup>7</sup> “Vaccine manufacturer” is statutorily defined as “any corporation, organization, or institution, . . . which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table.” 42 U.S.C. § 300aa-33(3).

<sup>8</sup> “Vaccine-related injury or death” is statutorily defined as “an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.” *Id.* § 300aa-33(5).

<sup>9</sup> 42 U.S.C. §§ 300aa-11(a)(2)(A), -11(a)(3).

<sup>10</sup> *Id.* § 300aa-11(a)(2)(B).

<sup>11</sup> See Bartholomew C. Wacek, Comment, *Taking Sides in the Vaccine/Autism Legal Battle*, 8 DEPAUL J. HEALTH CARE L. 305, 308–09 (2004).

The issue repeatedly arose of whether Thimerosal claims would be included as one of those particular claims subject to the procedural requirements of the National Childhood Vaccine Injury Act.<sup>12</sup> If Thimerosal were excluded, plaintiffs would be able to outright sue Thimerosal manufacturers outside of the vaccine court, where, based on state law causes of action, damages could potentially be exponentially higher.

The vaccine court, U.S. Court of Federal Claims, and the U.S. Court of Appeals for the Federal Circuit have heard Thimerosal claims under the National Childhood Vaccine Injury Act.<sup>13</sup> However, other courts across the United States have split on whether they will defer to these courts in this area, with some allowing Thimerosal claims to be brought outside of the Act.<sup>14</sup> This split between courts showing deference and those that do not has resulted in two completely different treatments of Thimerosal claims.<sup>15</sup> Additionally, the installation of a new vaccine court procedure specifically targeting these claims—the Omnibus Autism Proceedings—exacerbated the disparate treatment of litigants bringing cases under the Act and through traditional tort claims.<sup>16</sup>

Concurrent jurisdiction is now more problematic because, in addition to all the traditional reasons, the choice of forum creates a real difference between whether one is summarily precluded from even attempting to recover and, if recovery is allowed, the amount a plaintiff may be awarded. There is no sound reason for any court except the vaccine court to have original jurisdiction over claims against Thimerosal manufacturers for injuries, such as autism, that allegedly result from the administration of vaccines.<sup>17</sup>

This Article has three parts. Part I discusses the National Childhood Vaccine Injury Act, addressing its legislative history, structure, and intended functionality. Part I also introduces autism, Thimerosal, the purported correlation between the two, and the suggested jurisdiction for claims against

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<sup>12</sup> See *id.* at 306–07.

<sup>13</sup> See *id.* at 313–15.

<sup>14</sup> See *id.* at 318–20; see also Brandon Watson, *Vaccination Incapacitation—Structuring Successful Products Liability Claims Against Vaccine Manufacturers in the Face of the Vaccine Act, and the United States Court of Federal Claims’ Cedillo Holding*, Note, 9 WHITTIER J. CHILD & FAM. ADVOC. 405, 414–15 (2010).

<sup>15</sup> See Watson, *supra* note 14, at 414–15.

<sup>16</sup> See Elizabeth C. Scott, Note, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 357, 361 (2001).

<sup>17</sup> This Article addresses the issue of initial jurisdiction to hear the claim. It does not suggest any change to the appellate jurisdiction of the U.S. Court of Federal Claims or the U.S. Court of Appeals for the Federal Circuit is needed.

manufacturers of vaccine components, including Thimerosal,<sup>18</sup> as evident in the Act and subsequent congressional amendments. Part I concludes with an examination of the treatment of Thimerosal claims by the vaccine court and other courts across the United States.

Part II of the Article discusses how the concurrent jurisdiction over Thimerosal claims is problematic: concurrent jurisdiction is (1) unfair because it allows the potential of large recovery for some plaintiffs at the risk of jeopardizing the nation's vaccine supply; (2) inefficient because it requires plaintiffs to fulfill the procedural requirements of the Act in order to dodge its application and file their complaints elsewhere; and (3) inaccurate because it is contrary to Congress's intent, interpretations by the Secretary of Health and Human Services, and decisions by the U.S. Court of Federal Claims and the U.S. Court of Appeals for the Federal Circuit.

Finally, Part II discusses how congressional action could remedy the situation by statutorily mandating that the vaccine court have exclusive original jurisdiction over vaccine component manufacturers. This proposed solution would necessarily promote judicial goals of fairness, efficiency, and accuracy. The Omnibus Autism Proceeding provides a fair, efficient, and consistent result under current evidence and standards, and ensures that plaintiffs get what they deserve as intended by Congress, while promoting the continued availability of vaccines for the American people. Therefore, all plaintiffs alleging that Thimerosal caused autism or other vaccine-related injuries should be required to exhaust the Omnibus Autism Proceeding before having the option to file a complaint in state court.

## **I. Background Information on Vaccines, the National Childhood Vaccine Injury Act, and Autism Claims Under the Act**

### **A. Overview of Vaccines**

Vaccines help prevent the spread and onset of diseases once thought untreatable.<sup>19</sup> They were first discovered by Edward Jenner, whose observation that milkmaids exposed to cowpox did not subsequently develop smallpox caused him to hypothesize that controlled exposure may prevent the development of a disease upon re-exposure.<sup>20</sup> A vaccine is the intentional introduction of a

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<sup>18</sup> Claims against Thimerosal manufacturers are hereinafter sometimes referred to as "Thimerosal claims."

<sup>19</sup> Scott, *supra* note 16, at 352.

<sup>20</sup> *Id.*

prepared “weakened or killed pathogenic bacteria or virus known to cause a particular disease” to create “antibodies or cellular immunity to the disease.”<sup>21</sup>

Vaccines dramatically decreased the prevalence of certain diseases.<sup>22</sup> This benefit has caused the medical community to widely accept their use<sup>23</sup> and Congress to mandate that anyone desiring to benefit from public school, day care, or federal financial assistance in the United States get all required vaccinations.<sup>24</sup> Children generally receive fourteen different vaccinations.<sup>25</sup> This number has increased since the National Childhood Vaccine Injury Act was passed in 1986, at which time children received eleven doses of vaccines to be protected from eight common infectious diseases.<sup>26</sup> While vaccines are a routine occurrence in most American children’s lives, “no vaccine is 100 percent safe or 100 percent effective.”<sup>27</sup> As some vaccines are the intended introduction of disease-causing microbes, they can have serious side effects, including death.<sup>28</sup> These drawbacks are considered acceptable risks because “the percent of the population expected to suffer adverse effects from vaccination is statistically insignificant compared to the percent that will benefit from vaccination.”<sup>29</sup>

## B. Overview of the National Childhood Vaccine Injury Act

Before the enactment of the National Childhood Vaccine Injury Act, a person seeking relief for a vaccine-related injury would file a state tort claim.<sup>30</sup> Before 1986, vaccines were generally considered unavoidably unsafe products, and, therefore, any manufacturer that properly made and gave adequate

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<sup>21</sup> Helia Garrido Hull, *Induced Autism: The Legal and Ethical Implications of Inoculating Vaccine Manufacturers from Liability*, 34 CAP. U. L. REV. 1, 8 (2005).

<sup>22</sup> Scott, *supra* note 16, at 352. (“Smallpox was eradicated officially in 1977, polio caused by wild-type viruses has been eliminated from the Western Hemisphere, and measles reached a record-low 89 cases in 1998.”).

<sup>23</sup> *Id.* at 353.

<sup>24</sup> Hull, *supra* note 21, at 8.

<sup>25</sup> Watson, *supra* note 14, at 417–18. There has been debate over whether it is appropriate for children to receive this many shots. For further discussion, see Cynthia E.S. Staats & Joel M. Hamme, *The Greater Good: Rethinking Risks and Benefits of Childhood Vaccination Programs*, 3 J. HEALTH & LIFE SCI. L. 164 (2009).

<sup>26</sup> Mary Jo Kennedy & Lanny Foster, *Overview of Immunization*, in 8 ATTORNEYS’ TEXT-BOOK OF MEDICINE ¶ 47.31 (Roscoe N. Gray et al. eds., 3d ed. 2000).

<sup>27</sup> *Id.* ¶ 47.60.

<sup>28</sup> See Hull, *supra* note 21, at 8.

<sup>29</sup> *Id.*

<sup>30</sup> See Scott, *supra* note 16, at 353–54.



warnings about the vaccine was not liable in the United States for damages.<sup>31</sup> However, this legal standard was not the rule in all states.<sup>32</sup>

Plaintiffs' use of state tort law to try to recover damages from vaccine component manufacturers for vaccine-related injuries was undesirable for several reasons. First, state tort law was unsatisfactory to plaintiffs, according to Congress, because it was slow, costly, and only compensated a few.<sup>33</sup> Second, it was unsatisfactory to vaccine manufacturers because the inconsistent verdicts and state tort laws made their own risk to exposure unpredictable.<sup>34</sup> This uncertainty caused many vaccine manufacturers to leave the market completely, and those who remained increased their prices.<sup>35</sup> Thus, in order to minimize the onset and spread of preventable disease, Congress felt that it had to act to prevent a vaccine shortage and to ensure that childhood vaccinations remained routine.<sup>36</sup>

Congress attempted to solve the impending vaccine crisis by enacting the National Childhood Vaccine Injury Act.<sup>37</sup> The Act was passed on November 14, 1986, and went into complete effect two years later.<sup>38</sup> It established the National Vaccine Injury Compensation Program, administered by the Secretary of Health and Human Services.<sup>39</sup>

There are important nuances to the Act's petition filing requirement. First, the Act itself only applies to claims by either the person who sustained the

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<sup>31</sup> *Id.* at 354 (noting that, while the adequate warning was interpreted initially to apply to the recipient of the vaccine, courts later held that the duty to warn only extended to the administering physician).

<sup>32</sup> *See id.*

<sup>33</sup> 133 CONG. REC. 29,215 (1987) (statement of Rep. Norman F. Lent).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* At the time that the National Childhood Vaccine Injury Act was enacted, there existed only one manufacturer of the polio and the Measles-Mumps-Rubella vaccines, two manufacturers of the Diphtheria-Pertussis-Tetanus vaccine, and two states produced their own Diphtheria-Pertussis-Tetanus vaccines. H.R. REP. NO. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6444, 6348. Further, federal vaccine stockpiles were well short of the Centers for Disease Control and Prevention's recommended supply levels. *Id.*

<sup>36</sup> *See* 133 Cong. Rec. 29,215. Some people believe that Congress overstepped its bounds because vaccine liability, as a matter of product liability, should have been left to state tort law. For a more complete discussion of this point, see Victor E. Schwartz & Liberty Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 389 (1987).

<sup>37</sup> *See* Scott, *supra* note 16, at 351.

<sup>38</sup> Deborah F. Buckman, Annotation, *Construction and Application of Preemption Provisions of National Childhood Vaccine Injury Compensation Act of 1986 ("Vaccine Act")*, 42 U.S.C.A. §§ 300aa-1 *et seq.*, 39 A.L.R. FED. 2d 155, 165-66 (2010).

<sup>39</sup> 42 U.S.C. § 300aa-10(a) (2006).

vaccine-related injury or, if the vaccine allegedly caused death, the recipient's estate.<sup>40</sup> Second, it only applies to vaccines listed in the Vaccine Injury Table or, for claimants who did not receive a listed vaccine, to those who contracted polio directly or indirectly from another who received an oral polio vaccine.<sup>41</sup>

A claim of harm stemming from a vaccine listed in the Vaccine Injury Table is made by filing a petition with the U.S. Court of Federal Claims.<sup>42</sup> The petition is then assigned to a special master for adjudication.<sup>43</sup> The role of the special master is another facet of the Act's intentional design to be more attractive than a state tort suit. The special master can recommend different rules to ensure that the process is "less-adversarial, expeditious, and informal."<sup>44</sup> For example, a special master may avoid strict application of the federal rules regarding evidence and discovery.<sup>45</sup> The special master determines whether and how much compensation is appropriate.<sup>46</sup>

Under the Act, there are two ways that a petitioner may be entitled to compensation: (1) by credibly demonstrating a recognized injury listed in the table ("table injury"); or (2) by establishing a preponderance of credible evidence that a vaccine caused an injury not listed in the table ("non-table injury").<sup>47</sup> For a table injury, a petitioner may show, by a preponderance of the evidence, that the injury was incurred during a set time frame, established by the Vaccine Table.<sup>48</sup> This table establishes a grid for different injuries recognized as associated with listed vaccines.<sup>49</sup> If the petitioner opts for this route and can show a specified injury for a listed vaccine, then he or she is entitled to a rebuttable presumption<sup>50</sup> that the vaccine caused the injury (i.e., the petitioner does not have to prove causation).<sup>51</sup>

However, this avenue is unavailable to petitioners alleging that a vaccine caused the onset of autism because autism is not included in the Vaccine Ta-

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<sup>40</sup> 42 U.S.C. § 300aa-11(b)(1)(A). Additionally, if the injured person is a minor or is disabled, their legal representative may bring a claim. *Id.*

<sup>41</sup> *Id.* § 300aa-11(c)(1)(A).

<sup>42</sup> *Id.* § 300aa-11(a)(1).

<sup>43</sup> *Id.* § 300aa-12(d)(1).

<sup>44</sup> *Id.* § 300aa-12(d)(2).

<sup>45</sup> *Id.* §§ 300aa-12(d)(2)(B), -12(d)(2)(E).

<sup>46</sup> *Id.* § 300aa-12(d)(3)(A).

<sup>47</sup> *Id.* §§ 300aa-11(c)(1)(C), -13(a)(1)(A).

<sup>48</sup> *Id.* § 300aa-11(c)(1)(C)(i), -13(a)(1)(A).

<sup>49</sup> *Id.* § 300aa-14(a).

<sup>50</sup> The Secretary of Health and Human Services may rebut this presumption by showing, by a preponderance of the evidence, that the alleged vaccine-related injury or death was caused by other unrelated factors. *See id.* § 300aa-13(a)(1)(B); *see also* Hull, *supra* note 21, at 27.

<sup>51</sup> Hull, *supra* note 21, at 26–27.

ble.<sup>52</sup> Therefore, plaintiffs with autism claims, as well as any other petitioner with a non-table injury, must prove, by a preponderance of the evidence, that the vaccine caused the alleged harm.<sup>53</sup>

The Act entitles a successful petitioner to reasonable attorney's fees and compensation for actual and future damages for reasonably necessary medical, living, and education expenses.<sup>54</sup> If the action was for a vaccine-related death, then the estate is entitled to an additional \$250,000.<sup>55</sup> If the action was for a vaccine-related injury, the petitioner is also entitled to lost wages (actual and projected) and an award for pain and suffering not to exceed \$250,000.<sup>56</sup> The Act strictly prohibits punitive damages.<sup>57</sup> As of 2002, the average award for claims filed pursuant to the Act was \$824,463.<sup>58</sup>

Following the Special Master's judgment, dissatisfied parties have thirty days to seek review in the U.S. Court of Federal Claims.<sup>59</sup> Once the U.S. Court of Federal Claims decides the case, dissatisfied parties have sixty days to appeal to the U.S. Court of Appeal for the Federal Circuit.<sup>60</sup> A petitioner can bring suit alleging a state tort claim in state or federal court only after the U.S. Court of Federal Claims has issued a judgment on the matter and he or she expressly elects to reject that judgment within ninety days.<sup>61</sup>

State tort claims duly filed pursuant to the Act are subject to a presumption of adequate and proper warnings if the vaccine manufacturer complied with the Federal Food, Drug, and Cosmetic Act.<sup>62</sup> This presumption may be

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<sup>52</sup> See 42 U.S.C. § 300aa-14.

<sup>53</sup> See *Watson*, *supra* note 14, at 410–11.

<sup>54</sup> 42 U.S.C. §§ 300aa-15(a)(1), -15(e)(1). There is no ceiling on the amount of compensation that may be awarded for actual and projected costs for these items. See *id.* § 300aa-15. Further, there is no distinction between whether the compensation is being used to treat physical or mental handicaps. *Kleinert v. Sec'y of the Dep't of Health & Human Servs.*, 25 Cl. Ct. 173, 176 (1992). Therefore, petitioner may be awarded any amount, so long as it is for reasonably necessary expenses. *Id.*

<sup>55</sup> 42 U.S.C. § 300aa-15(a)(2).

<sup>56</sup> *Id.* §§ 300aa-15(a)(3)(A), -15(a)(4). If the person who sustained the vaccine-related injury is a minor, the amount of lost wages is based off of the average earnings of a private, non-farm sector worker. See *id.* § 300aa-15(a)(3)(B).

<sup>57</sup> *Id.* § 300aa-15(d)(1).

<sup>58</sup> *Hull*, *supra* note 21, at 27.

<sup>59</sup> 42 U.S.C. § 300aa-12(e)(1).

<sup>60</sup> *Id.* § 300aa-12(f).

<sup>61</sup> *Id.* § 300aa-21(a).

<sup>62</sup> See *Scott*, *supra* note 16, at 356. Before the passage of the National Childhood Vaccine Injury Act, a plaintiff could recover if he or she was able to show that the vaccine did not have adequate warnings. See *Schwartz & Mahshigian*, *supra* note 36, at 392–93. This presumption effectively precludes a plaintiff from recovering on this avenue unless the exception applies. *Id.*

rebutted by clear and convincing evidence that the vaccine manufacturer did not exercise due care or that it engaged in fraud, misrepresentation, or other illegal activity.<sup>63</sup> Second, the Act precludes plaintiffs from asserting that there was a failure to directly warn them of the vaccine's risks.<sup>64</sup> Third, absent a showing of fraud or other malice, the Act bars recovery of punitive damages if the vaccine complies with the Federal Food, Drug, and Cosmetic Act.<sup>65</sup>

The vaccine court was designed to be an attractive alternative to traditional tort litigation for a table injury as a quick, no-fault, and non-adversarial system with a relatively certain payout of any and all reasonable costs associated with injuries.<sup>66</sup> However, the vaccine court soon became awash with petitions, leading plaintiffs to wait years for relief and even longer for payment of compensation awards.<sup>67</sup> Further, despite being touted as less adversarial than traditional litigation, the U.S. Department of Justice assigned more than a dozen veteran litigators to zealously defend the government's coffers.<sup>68</sup>

The vaccine court remains an alternative to tort litigation, and one that must be pursued to some extent before filing a state tort claim for an alleged vaccine-related injury or death. But it is uncertain how attractive the Program remains, considering it caps recovery for pain and suffering, does not allow punitive damages, and only allows reasonable attorney's fees.<sup>69</sup>

## **C. Overview of Claims Alleging Thimerosal, a Vaccine Component, Caused Autism**

### ***1. What is Autism?***

Autism is defined in legal literature as a developmental delay that affects normal brain development and function, resulting in reduced social interaction and minimally effective interpersonal communication.<sup>70</sup> Typically, persons with

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<sup>63</sup> Scott, *supra* note 16, at 356.

<sup>64</sup> 42 U.S.C. § 300aa-22(c).

<sup>65</sup> See Schwartz & Mahshigian, *supra* note 36, at 393.

<sup>66</sup> See *id.* at 390–92.

<sup>67</sup> See Scott, *supra* note 16, at 358.

<sup>68</sup> *Id.*

<sup>69</sup> See Schwartz & Mahshigian, *supra* note 36, at 391, 395 (suggesting that attorneys may be more drawn to state tort actions for higher contingency fees).

<sup>70</sup> See Katherine Marie Bulfer, *Childhood Vaccinations and Autism: Does the National Childhood Vaccine Injury Act Leave Parents of Children with Autism Out in the Cold with Nowhere to Go?*, 27 CAMPBELL L. REV. 91, 92 (2004). It is considered a developmental delay because it typically manifests after birth but before the age of three, at a time when the child is undergoing important physical, mental, and social growth. *Id.* There are marked differences between the brain structure and function of autistic and non-autistic children. Hull, *supra* note 21, at 4.

autism engage in repetitive mannerisms (i.e., repeating words or movements) or compulsive behaviors (i.e., following a rigid schedule),<sup>71</sup> which may also be coupled with sensory and motor issues or trouble processing thoughts.<sup>72</sup> The degree of severity depends on each individual, ranging from mild to severe.<sup>73</sup> Autism is generally thought to be a permanent disorder.<sup>74</sup> There is no conclusive cause of autism,<sup>75</sup> but many believe that both genetic predisposition and environmental triggers are responsible.<sup>76</sup> Regardless of its cause, autism usually manifests when a child is a toddler.<sup>77</sup> There is no strict diagnostic test;<sup>78</sup> rather, a trained professional will determine whether they believe that the child fits a certain profile and displays particular characteristics.<sup>79</sup> After diagnosis, there is no cure or set medical treatment for a person with autism.<sup>80</sup> Management can vary in individual cases, from the use of prescription drugs to treat certain facets and manifestations of the disorder<sup>81</sup> to modifying the autistic individual's environment and lifestyle.<sup>82</sup>

Reported cases of autism have risen dramatically over the last sixty years.<sup>83</sup> In the mid-1980s, one in 2,500 children was diagnosed with the disorder in the United States.<sup>84</sup> By the mid-2000s, that number had risen to nearly one in 250 children.<sup>85</sup> Some studies suggest that this number will continue to increase by 10 to 17 percent annually.<sup>86</sup> At that rate, in the next ten years, nearly four million Americans will be diagnosed with some form of autism.<sup>87</sup>

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<sup>71</sup> Joelle A. Moreno, *It's Just a Shot Away: MMR Vaccines and Autism and the End of the Daubertista Revolution*, 35 WM. MITCHELL L. REV. 1511, 1518 (2009); see also Bulfer, *supra* note 70, at 92.

<sup>72</sup> Bulfer, *supra* note 70, at 92.

<sup>73</sup> Hull, *supra* note 21, at 4; Watson, *supra* note 14, at 415.

<sup>74</sup> Bulfer, *supra* note 70, at 92.

<sup>75</sup> Hull, *supra* note 21, at 4.

<sup>76</sup> *Id.*; Bulfer, *supra* note 70, at 93.

<sup>77</sup> Bulfer, *supra* note 70, at 92.

<sup>78</sup> Watson, *supra* note 14, at 416.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* at 416–17.

<sup>81</sup> *Id.*

<sup>82</sup> See NAT'L INST. OF MENTAL HEALTH, NIH PUB. NO. 08-5511, AUTISM SPECTRUM DISORDERS 18–22 (2008), available at <http://www.nimh.nih.gov/health/publications/autism/nimhautismspectrum.pdf>.

<sup>83</sup> Bulfer, *supra* note 70, at 93.

<sup>84</sup> Wacek, *supra* note 11, at 305.

<sup>85</sup> Hull, *supra* note 21, at 5.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

The exact reason for this increase in incidence is unknown.<sup>88</sup> Some autism experts hypothesize that it is due to a heightened understanding and awareness of autism, creating better methods of detection and allowing more professionals to diagnose it.<sup>89</sup> Others acknowledge that this has had some role but believe that there are other factors involved, strongly noting that the increase in incidence rate has coincided with the advent of mandatory vaccination.<sup>90</sup>

## ***2. What is Thimerosal?***

Vaccines are often packaged in multi-dose vials to reduce costs and increase availability.<sup>91</sup> These multi-dose vials run the risk of contamination.<sup>92</sup> Therefore, a preservative is added to ensure the quality of the vaccine.<sup>93</sup> From the early 1930s until 2001, the preservative added to most multi-dose vaccines was Thimerosal, chosen for its effectiveness at killing bacteria.<sup>94</sup>

Thimerosal is an organic mercury compound.<sup>95</sup> When introduced to the body, it produces ethyl mercury.<sup>96</sup> While there have been many studies about the effect of methyl mercury on humans, there are not as many or as conclusive studies on the effects of ethyl mercury.<sup>97</sup> Accordingly, it is unclear exactly what effect Thimerosal has on the human body.<sup>98</sup>

Generally, all vaccines once contained a small level of Thimerosal.<sup>99</sup> Its prevalence, combined with a rapid increase in the number of required and administered childhood vaccinations, created the possibility that “a child might theoretically have mercury levels that slightly exceed the United States Environmental Protection Agency (EPA) guidelines.”<sup>100</sup> In 1999, the Academy of Pediatrics and the U.S. Public Health Service issued a recommendation that the use of Thimerosal in childhood vaccines be discontinued.<sup>101</sup> By 2001,

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<sup>88</sup> *See id.*

<sup>89</sup> Moreno, *supra* note 71, at 1519.

<sup>90</sup> Hull, *supra* note 21, at 5, 9, 15.

<sup>91</sup> *Id.* at 15, 49.

<sup>92</sup> *Id.* at 15.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 16; Bulfer, *supra* note 70, at 96.

<sup>95</sup> *See* Watson, *supra* note 14, at 419.

<sup>96</sup> *See* Bulfer, *supra* note 70, at 96.

<sup>97</sup> *Id.* at 96–97. For a more complete discussion of the scientific studies on the effects of ethyl mercury, see Staats & Hamme, *supra* note 25.

<sup>98</sup> *See* Bulfer, *supra* note 70, at 97.

<sup>99</sup> Hull, *supra* note 21, at 15; Wacek, *supra* note 11, at 305.

<sup>100</sup> *See* Wacek, *supra* note 11, at 305.

<sup>101</sup> *Id.* at 306.

childhood vaccines contained no or only trace amounts.<sup>102</sup> However, vaccine manufacturers removed Thimerosal voluntarily, and no law prohibits its reintroduction into childhood vaccines.<sup>103</sup>

### ***3. Suggested Correlations Between Autism and Thimerosal***

The potential link between vaccines, Thimerosal, and autism is murky at best. There are many conflicting studies that allegedly support or deny causation or correlation among the three.<sup>104</sup> In 1998, a British medical journal called *The Lancet* published a study by Dr. Andrew Wakefield, stating that experiments had shown the Measles-Mumps-Rubella vaccine (“MMR vaccine”) given to infants to be a trigger for autism.<sup>105</sup> Since its publication, the Wakefield study has been largely discredited, causing *The Lancet* to retract it in February 2010.<sup>106</sup>

The Wakefield study spawned a wave of new claims about autism, vaccines, and Thimerosal. While it pointed to the MMR vaccine as a cause of autism, some said that Thimerosal in the vaccine was the actual trigger, due to the body’s alleged inability to process ethyl mercury.<sup>107</sup> However, no study regarding this latter claim has been conclusive or widely accepted.<sup>108</sup>

While it is unclear for now whether Thimerosal or vaccines or a combination of the two have any role in triggering autism, the U.S. Department of Health and Human Services determined that, as a precaution, as much Thimerosal as possible should be removed from childhood vaccines.<sup>109</sup>

By January 2009, over 5,500 cases alleging autism as a vaccine-related injury had been filed against the U.S. Department of Health and Human Services pursuant to the National Childhood Vaccine Injury Act.<sup>110</sup> Out of those cases,

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<sup>102</sup> Hull, *supra* note 21, at 16. Flu vaccines administered to other groups, including pregnant women and the elderly, still contain Thimerosal. *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> This Article does not set out to resolve the disputes between the conflicting studies and, as such, an in depth discussion is beyond the scope of this paper.

<sup>105</sup> Andrew J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637, 637 (1998), available at <http://briandeer.com/mmr/lancet-paper.pdf>; see also Moreno, *supra* note 71, at 1520.

<sup>106</sup> *Retraction—Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 375 LANCET 445, 445 (2010).

<sup>107</sup> For a more complete discussion on how ethyl mercury arguably triggers autism, see Hull, *supra* note 21, at 9–23 and Moreno, *supra* note 71, at 1525.

<sup>108</sup> See Wacek, *supra* note 11, at 308. For a more complete discussion on all of the conflicting scientific studies regarding whether Thimerosal or vaccines are triggers for autism, see Wacek, *supra* note 11, at 308–11.

<sup>109</sup> Bulfer, *supra* note 70, at 97.

<sup>110</sup> Moreno, *supra* note 71, at 1513.



only one person alleging autism as a vaccine-related injury has been awarded compensation.<sup>111</sup> However, even in that case, it was clear that compensation was awarded based the petitioner's regressive encephalopathy (to which the autism was related), and not because of the autism itself.<sup>112</sup>

## II. Statutory Ambiguity Has Caused Inconsistent Judicial Treatment of Claims Against Vaccine Component (Thimerosal) Manufacturers

### A. The National Childhood Vaccine Injury Act Is Ambiguous Regarding Whether Vaccine Component (Thimerosal) Manufacturers Are Included

The National Childhood Vaccine Injury Act does not define "vaccine,"<sup>113</sup> so it is unclear if the Act exclusively governs claims concerning Thimerosal, an ingredient of pre-2001 childhood vaccines. Under the Act, a petitioner must first file a petition in the vaccine court before filing suit for state tort remedies.<sup>114</sup> However, this requirement only applies to suits brought against a vaccine manufacturer or administrator for a vaccine-related injury.<sup>115</sup> The statute defines a "vaccine manufacturer" and a "vaccine-related injury," but it does not define a "vaccine."<sup>116</sup> Therefore, a suit alleging that autism was caused by Thimerosal, used as a vaccine preservative, may or may not be subject to the Act's filing requirement, depending on whether the definition of "vaccine" includes all the component parts or merely the finished product.

Some courts addressing this issue have used principles of statutory construction to determine whether Thimerosal was intended to be included in the definition of the word "vaccine."<sup>117</sup> One widely accepted, though not universal, position is that the term "vaccine" does not cover Thimerosal because "its status as a vaccine component no more makes Thimerosal a 'vaccine' than does the inclusion of a piston under the hood of an automobile make that object an 'engine.'"<sup>118</sup>

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<sup>111</sup> See *Poling v. Sec'y of Health & Human Servs.*, No. 02-1466V (Fed. Cl. Apr. 10, 2008), available at <http://www.uscfc.uscourts.gov/sites/default/files/CAMPBELL-SMITH.POLING041008.pdf>.

<sup>112</sup> *Id.*; see also *Watson*, *supra* note 14, at 423.

<sup>113</sup> See 42 U.S.C. § 300aa-33 (2006).

<sup>114</sup> See *id.* § 300aa-11(a)(2)(A)–(B).

<sup>115</sup> *Id.* § 300aa-11(a)(2)(A).

<sup>116</sup> *Id.* § 300aa-33.

<sup>117</sup> See, e.g., *Moss v. Merck & Co.*, 381 F.3d 501, 503 (5th Cir. 2004).

<sup>118</sup> *Id.* at 504.

In 2002, Congress passed the Homeland Security Act, which included a last-minute rider amending the National Childhood Vaccine Injury Act in three significant ways.<sup>119</sup> First, the Homeland Security Act amended the definition of “vaccine manufacturers” to include manufacturers of a component or an ingredient used in a vaccine (e.g., Thimerosal).<sup>120</sup> Second, it redefined “vaccine”:

The term ‘vaccine’ means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body’s immune response to a disease or diseases and *includes all components and ingredients* listed in the vaccine’s product license application and product label.<sup>121</sup>

This amended definition clearly included within the meaning of “vaccine” both the finished product and any ingredient or component listed on the label.<sup>122</sup> Third, it explicitly stated that any component or ingredient of a vaccine was not a contaminant, eliminating a position plaintiffs had been using to get into state court.<sup>123</sup> The Homeland Security Act was effective immediately and applied to all pending and future actions.<sup>124</sup> Accordingly, it resolved the inherent ambiguity in the National Vaccine Injury Compensation Program concerning Thimerosal manufacturers, effectively requiring all such claims against those and other vaccine component manufacturers to be filed first in the vaccine court, before seeking state tort remedies.

Just a year later, the 2002 amendments to the National Childhood Vaccine Injury Compensation Act were repealed.<sup>125</sup> Three Republican Senators spearheaded the removal.<sup>126</sup> They contended that the change had been hidden in the Homeland Security Act and had not been discussed before passage.<sup>127</sup> However, there was no debate during the repeal about whether Thimerosal manufacturers should be covered by the Act under the definition of “vaccine

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<sup>119</sup> Homeland Security Act of 2002, Pub. L. No. 107-296, §§ 1714–16, 116 Stat. 2135, 2320–21 (repealed 2003); *see also* Wacek, *supra* note 11, at 322–23.

<sup>120</sup> § 1714, 116 Stat. at 2320.

<sup>121</sup> § 1716, 116 Stat. at 2321 (emphasis added).

<sup>122</sup> *Id.*

<sup>123</sup> *See id.* § 1715, 116 Stat. at 2321.

<sup>124</sup> *Id.* § 1717, 116 Stat. at 2321.

<sup>125</sup> *See* Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding And What Families Should Know Before Rushing Out Of Vaccine Court*, 58 AM. U. L. REV. 459, 484–86 (2008); Wacek, *supra* note 11, at 323.

<sup>126</sup> Wacek, *supra* note 11, at 323 (noting that Senators Olympia Snowe and Susan Collins of Maine, and Lincoln Chafee of Rhode Island were responsible for the removal of the amendments).

<sup>127</sup> *Id.*

manufacturers.”<sup>128</sup> Thus, it is unclear whether Congress disapproved of both the content and method of passing the 2002 amendments, or only the method.<sup>129</sup>

The 2002 Homeland Security Act amendments had significant implications for cases brought against Thimerosal manufacturers for vaccine-related injury. During its short life, the amendment vested initial exclusive jurisdiction of Thimerosal claims in the vaccine court.<sup>130</sup> The effect of the relevant provisions of the Homeland Security Act is best illustrated through two cases, decided within a year of each other, in the U.S. District Court for the Eastern District of Texas.

*Botter v. Aventis Pasteur, Inc.*,<sup>131</sup> decided after the Homeland Security Act’s enactment but before its repeal, held that a plaintiff seeking a claim against a Thimerosal manufacturer must first file a petition under the National Vaccine Injury Compensation Program before being allowed to seek state tort remedies.<sup>132</sup> The court found that Thimerosal clearly fell within the amended definition of “vaccine.”<sup>133</sup> It was necessarily a component or ingredient now covered under the meaning of “vaccine,” because “the FDA had apparently widely approved the use of [T]himerosal as a vaccine preservative since the 1930’s, and required that preservatives be added to vaccines distributed in multi-use vials.”<sup>134</sup> Therefore, the court found that Thimerosal manufacturers were to be considered “vaccine manufacturers” and, as such, were covered by the National Childhood Vaccine Injury Act.<sup>135</sup>

After both the *Botter* decision and the repeal of the pertinent provisions of the Homeland Security Act, the Eastern District of Texas reversed its position. In *Easter v. Aventis Pasteur, Inc.*,<sup>136</sup> the court held that plaintiffs could sue Thimerosal manufacturers without first going through the vaccine court.<sup>137</sup> The repeal specifically stated that courts were not to interpret the existence or repeal of the amendments as having any effect on the status of the law.<sup>138</sup> Therefore, the *Easter* court looked to precedent set by the Federal Circuit

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<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> See *Wax v. Aventis Pasteur, Inc.*, 240 F. Supp. 2d 191, 195 (E.D.N.Y. 2002) (reviewing the newly enacted Homeland Security Act and holding that the action should be stayed pending petition in the vaccine court).

<sup>131</sup> No. 9:02CV181, 2003 U.S. Dist. LEXIS 26197 (E.D. Tex. Jan. 13, 2003).

<sup>132</sup> See *id.* at \*8, \*14–16.

<sup>133</sup> *Id.* at \*14.

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at \*16.

<sup>136</sup> No. 5:03CV141(TJW), 2004 U.S. Dist. LEXIS 26527 (E.D. Tex. Feb. 10, 2004).

<sup>137</sup> *Id.* at \*28–29.

<sup>138</sup> Consolidated Appropriations Resolution, 2003, Division L—Homeland Security Act of 2002 Amendments, Pub. L. No. 108-7, § 102, 117 Stat. 11, 528.

establishing that the National Vaccine Injury Compensation Act applied only to vaccine manufacturers and administrators and, therefore, did not apply to Thimerosal manufacturers.<sup>139</sup>

While the court in *Easter* clearly attempted to return to the status of the law before the passage of the Homeland Security Act, the opinion's constant focus on that legislation suggests that the passage and repeal of its pertinent provisions has done nothing but muddy already murky waters. Additionally, Congress's failure to further address the issue has been interpreted elsewhere as evidence that Thimerosal manufacturers are not "vaccine manufacturers" under the National Childhood Vaccine Injury Act.<sup>140</sup> Therefore, courts have had to resort to statutory construction to determine whether Congress intended the definition to include Thimerosal manufacturers.<sup>141</sup> Quite often, courts faced with this issue give themselves jurisdiction to hear the case.<sup>142</sup>

### **B. Treatment of Autism Claims by the U.S. Federal Circuit and the U.S. Court of Federal Claims**

Prior to the 2002 creation of the Autism Omnibus Proceeding, the U.S. Court of Appeals for the Federal Circuit heard and decided the issue of whether the National Childhood Vaccine Injury Act required a claim against a vaccine component manufacturer to be first filed in the U.S. Court of Federal Claims.<sup>143</sup> The Federal Circuit held that "Congress did not intend to bar civil actions against any party other than a vaccine [administrator or] manufacturer and . . . Congress did not intend the Vaccine Act to bar civil actions against any party other than a vaccine administrator or manufacturer."<sup>144</sup> Therefore, a civil suit against a Thimerosal manufacturer could proceed in state court without first filing a petition in the U.S. Court of Federal Claims.<sup>145</sup>

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<sup>139</sup> *Easter*, 2004 U.S. Dist. LEXIS 26527, at \*28–29 (citing *Schumacher v. Sec'y of the Dep't of Health & Human Servs.*, 2 F.3d 1128, 1133 (Fed Cir. 1993)).

<sup>140</sup> *See Reilly v. Wyeth*, 876 N.E.2d 740, 751 (Ill. App. Ct. 2007).

<sup>141</sup> *See, e.g., id.* (relying on the plain meaning of the statute to hold that Thimerosal manufacturers are not "vaccine manufacturers"); *Easter*, 2004 U.S. Dist. LEXIS, at \*28–29 (interpreting congressional intent to hold that Thimerosal manufacturers are not "vaccine manufacturers" under the statute).

<sup>142</sup> *See, e.g., Reilly*, 876 N.E.2d at 751.

<sup>143</sup> *See Schumacher v. Sec'y of the Dept. of Health & Human Servs.*, 2 F.3d 1128, 1131 (Fed. Cir. 1993).

<sup>144</sup> *Id.* at 1133.

<sup>145</sup> *Id.* at 1134. Additionally, the Federal Circuit held that this state suit would have no effect on the plaintiffs' current petition in the vaccine court against vaccine manufacturers, alleging that the vaccine had exacerbated the injuries. *Id.*

In 2002, the U.S. Court of Federal Claims experienced an exponential increase in petitions alleging a link between vaccines and the onset of autism.<sup>146</sup> Faced with the prospect of thousands more similar petitions being filed in the next several months and lacking the necessary resources to handle the influx, the U.S. Court of Federal Claims convened with representatives of current and potential Program claimants, representatives of the Secretary of Health and Human Services, and the special masters.<sup>147</sup> The result was the U.S. Court of Federal Claims' issuance of Autism General Order #1, which created the Omnibus Autism Proceeding.<sup>148</sup>

The Omnibus Autism Proceeding had two general functions.<sup>149</sup> First, theories regarding the causal link between autism and vaccines would be presented to a special master, who would then rule on each causation theory.<sup>150</sup> Then, the special masters' conclusions would be applied to individual cases.<sup>151</sup> The court intended that this new procedure would provide a quick and expeditious resolution of an unprecedented number of claims, in accordance with the way Congress intended the National Vaccine Injury Compensation Program to function.<sup>152</sup>

A team of plaintiffs' representatives was to present a general causation theory to a special master, using discovery, evidentiary hearings, and expert testimony.<sup>153</sup> When discovery started in the Omnibus Autism Proceeding, it was unclear exactly how many general theories of causation were at issue.<sup>154</sup> Eventually, three different theories of causation clearly emerged: (1) the MMR vaccine causes autism; (2) Thimerosal causes autism; and (3) Thimerosal and the MMR vaccine in conjunction cause autism.<sup>155</sup>

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<sup>146</sup> See Autism General Order #1, *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Autism Master File, slip op. at 2 (Fed. Cl. July 3, 2002), available at <http://www.usfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf> [hereinafter *Autism General Order #1*] (noting that, at the time of the Order, over 400 such petitions had been filed, more than 300 of which were filed in the preceding six months).

<sup>147</sup> *Id.*

<sup>148</sup> *Id.* at 2–4; see also Bulfer, *supra* note 70, at 104.

<sup>149</sup> *Autism General Order #1*, *supra* note 146, at 3–4.

<sup>150</sup> *Id.*

<sup>151</sup> *Id.* at 4.

<sup>152</sup> *Id.* at 5–6.

<sup>153</sup> *Id.* at 4.

<sup>154</sup> *Id.* at 6.

<sup>155</sup> *Id.* As a result, the U.S. Court of Federal Claims appointed two more special masters (for a total of three). Shemin, *supra* note 125, at 483 & n.127.

Three test cases<sup>156</sup> were selected to challenge each theory of general causation.<sup>157</sup> Because these theories all presented non-table injury claims, plaintiffs had to prove causation by a preponderance of evidence.<sup>158</sup> Thus, the plaintiffs had to show “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.”<sup>159</sup> The special masters found that none of the plaintiffs in the three test cases established causation between autism and either the vaccine or Thimerosal.<sup>160</sup> One special master said that, to accept that vaccines, Thimerosal, or a combination caused autism, “an objective observer would have to emulate Lewis Carroll’s White Queen and be able to believe six impossible (or, at least, highly improbable) things before breakfast.”<sup>161</sup>

The finding of no causation in the three test cases was a setback for other claimants, but it was not insurmountable. Had causation been found in any of the test cases, that finding would have been applied to individual cases.<sup>162</sup> Therefore, had the test cases come out differently, plaintiffs filing a petition under the Program would not have to prove causation between autism and the vaccine, transforming the process into one similar to that used for table

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<sup>156</sup> *Cedillo v. Sec’y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec’y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), *aff’d*, 88 Fed. Cl. 473 (2009), *aff’d*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec’y of the Dep’t of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *motion for review denied*, 88 Fed. Cl. 706 (2009).

<sup>157</sup> *See* Moreno, *supra* note 71, at 1513 n.6.

<sup>158</sup> *See, e.g.*, *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d at 1335, 1338 (Fed. Cir. 2010).

<sup>159</sup> *Id.* (quoting *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). The Federal Circuit has ruled that *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005), should apply to determine the validity of the medical theory asserted. *Id.* Therefore, so long as the method of the medical theory is valid, the court should not refuse the conclusions, even if they are not widely accepted in the medical community at large. *See id.* at 1338–39. However, the court need not accept a conclusion if it finds that the data does not plausibly support the asserted conclusion. *See id.*

<sup>160</sup> *See* Moreno, *supra* note 71, at 1513–14.

<sup>161</sup> *Snyder*, 2009 WL 332044, at \*198.

<sup>162</sup> *Autism General Order #1*, *supra* note 146, at 6–7. These individual cases consisted of plaintiffs who opted into the Omnibus Autism Proceeding by filing short form petitions and stating that they were alleging specific causation theories and that their cases met certain set criteria. *Id.* at 5.

injuries.<sup>163</sup> Instead, the findings of no causation are not binding upon the individual cases—any plaintiff is free to introduce case-specific evidence and medical testimony to prove causation by a preponderance of evidence or voluntarily dismiss the petition.<sup>164</sup> It seems reasonable to infer that, in light of the special masters' adverse holdings regarding the three general causation theories and subsequent affirmation by both the U.S. Court of Federal Claims and (for two of the three theories) the U.S. Court of Appeals for the Federal Circuit, plaintiffs who participated in the Omnibus Autism Proceeding will choose one of these two avenues.<sup>165</sup>

### C. Treatment of Autism Claims by State Courts and Other Federal Courts

Potential claimants under the Act may prefer to file civil suits seeking traditional state tort remedies because of the Act's statutory bar on punitive damages and caps on other damages, including those for pain and suffering.<sup>166</sup> Considering the rumored allure of civil juries awarding millions in medical injury cases, these limits on recovery make the Program particularly undesirable.<sup>167</sup>

Plaintiffs typically use several theories to circumvent the Act's requirements.<sup>168</sup> The primary theory is that (1) the injury was caused by Thimerosal; (2) Thimerosal is an adulterant or contaminant; and (3) the Act does not apply to injuries caused by adulterants or contaminants in vaccines.<sup>169</sup> Another theory is that vaccines containing Thimerosal are defectively designed and accompanied by insufficient warnings.<sup>170</sup> Less common theories include propositions that the Act cannot constitutionally apply to autism claims and that, because autism takes so long to manifest in children, they are not proper

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<sup>163</sup> *Id.* at 6–7.

<sup>164</sup> *See id.* at 7.

<sup>165</sup> *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1334 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, 604 F.3d 1343, 1345 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 708 (2009) (sustaining the ruling of the special master). This is because the test cases have made it very unlikely for any petitioner to recover for vaccine-induced autism under the National Vaccine Injury Compensation Program. *See Watson*, *supra* note 14, at 429.

<sup>166</sup> *See* 42 U.S.C. §§ 300aa-15(a)(2), -15(a)(4), -15(d) (2006); *Wacek*, *supra* note 11, 312–13.

<sup>167</sup> *Wacek*, *supra* note 11, at 306.

<sup>168</sup> *Hull*, *supra* note 21, at 29.

<sup>169</sup> *Id.* The Act does not apply to injuries or death caused by adulterants or contaminants. *Id.*

<sup>170</sup> *Id.*



petitioners.<sup>171</sup> Plaintiffs also structure their claims in certain ways to avoid the Act's filing requirements (e.g., the Vaccine Act does not apply to loss of consortium and other third party claims),<sup>172</sup> so litigants are free to seek state tort remedies. This section will explore how state and federal courts (other than the U.S. Court of Federal Claims) tend to resolve the issues that arise under these claims.

State and federal courts generally hold that claims asserted against vaccine component manufacturers are not covered by the National Childhood Vaccine Injury Act.<sup>173</sup> These courts do not interpret the term "vaccine manufacturer" to include manufacturers of vaccine components, such as Thimerosal.<sup>174</sup> Under this reasoning, plaintiffs are not bound by the exhaustion requirement of the Act (i.e., first filing a petition under the Program).<sup>175</sup> Therefore, they can file civil suits against vaccine component manufacturers in any proper forum.

This theory was discussed and applied in *Moss v. Merck & Co.*<sup>176</sup> In *Moss*, the Fifth Circuit held that the National Childhood Vaccine Injury Act only applies to vaccine-related lawsuits brought against a vaccine administrator or manufacturer.<sup>177</sup> Thus, whether the Act precluded civil suit against Thimerosal manufacturers would turn on the definition of "vaccine manufacturer."<sup>178</sup> The court noted that the Act defines "vaccine manufacturer" as "any corporation, organization, or institution . . . which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table."<sup>179</sup> However, this definition relies on the meaning of "vaccine," which the Act does not define.<sup>180</sup> In this context, the Fifth Circuit used the plain meaning principle of statutory construction to determine the meaning of "vaccine."<sup>181</sup> The court held that Thimerosal manufacturers were not "vaccine manufacturers" under the Act.<sup>182</sup> *Moss* held that the Act was only intended to apply to manufacturers of completed vaccines, not to manufacturers of vaccine components.<sup>183</sup> The court reasoned that Thimerosal was not a "vaccine," because it

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<sup>171</sup> *Id.* at 29, 35.

<sup>172</sup> *Id.* at 29.

<sup>173</sup> *See, e.g.,* Watson, *supra* note 14, at 430–32, (discussing cases in the Fifth Circuit and Appellate Court of Illinois).

<sup>174</sup> *See id.* at 430.

<sup>175</sup> *See id.* at 432.

<sup>176</sup> 381 F.3d 501, 503–04 (5th Cir. 2004).

<sup>177</sup> *Id.* at 503.

<sup>178</sup> *Id.* at 503–04.

<sup>179</sup> *Id.* at 503 (quoting 42 U.S.C. § 300aa-33(3) (2006)).

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> *Id.* at 503–04.

<sup>183</sup> *Id.* at 504.

was only a preservative used in vaccines.<sup>184</sup> As such, Thimerosal manufacturers could only be vaccine component manufacturers.<sup>185</sup> Accordingly, because Thimerosal is “part of the finished product,” but “not the finished product itself,” the Act did not preclude civil suit against Thimerosal manufacturers for vaccine injury or death.<sup>186</sup>

This theory also prevailed in an Illinois state court, although for slightly different reasons.<sup>187</sup> In *Reilly v. Wyeth*,<sup>188</sup> the court held that the National Childhood Vaccine Injury Act did not preclude suits involving Thimerosal manufacturers because Congress did not intend vaccine component manufacturers to be covered by the protections of the Act.<sup>189</sup> The court stated that, when the Act was initially passed, “Congress explicitly stated that . . . the Vaccine Act was targeted to protect the manufacturers of vaccines.”<sup>190</sup> The court also held that the provisions of the Homeland Security Act, which specifically included vaccine component manufacturers under the definition of “vaccine manufacturers,” had no effect on Congress’s explicit intent because these amendments were repealed within four months.<sup>191</sup> Because the court is “not to make any inferences from the amendment and subsequent repeal . . . and [because] Congress has not spoken further on the issue,” the *Reilly* court held that Thimerosal manufacturers are not “vaccine manufacturers” under the Act.<sup>192</sup> Accordingly, plaintiffs are free to bring civil suits in Illinois state courts against vaccine component manufacturers outside of the Program, without first exhausting the requirements of the Act.<sup>193</sup>

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<sup>184</sup> *Id.* at 503–04.

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* at 504; *see also* *Holder v. Abbott Labs., Inc.*, 444 F.3d 383, 388–89 (5th Cir. 2006); *Troxclair v. Aventis Pasteur, Inc.*, 864 A.2d 1147, 1153–55 (N.J. Super. Ct. App. Div. 2005) (holding that, because the Vaccine Act precludes civil suit against only a vaccine administrator or manufacturer, summary judgment was inappropriate against a Thimerosal manufacturer).

<sup>187</sup> *See Reilly v. Wyeth*, 876 N.E.2d 740, 749–50 (Ill. App. Ct. 2007).

<sup>188</sup> 876 N.E.2d 740 (Ill. App. Ct. 2007).

<sup>189</sup> *Id.* at 748–51.

<sup>190</sup> *Id.* at 750 (citing H.R. REP. NO. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344).

<sup>191</sup> *Id.* (citing Consolidated Appropriations Resolution, 2003, Division L—Homeland Security Act of 2002 Amendments, Pub. L. No. 108-7, § 102, 117 Stat. 11, 528; Homeland Security Act of 2002, Pub. L. No. 107-296, § 1714, 116 Stat. 2135, 2320 (repealed 2003)).

<sup>192</sup> *Id.* at 751.

<sup>193</sup> *Id.*

### **III. Congress Should Act to Require All Thimerosal Suits Be Brought in the Vaccine Court Because Current Concurrent Jurisdiction over Vaccine Component Manufacturers Does Not Promote Policy Goals**

#### **A. Current Division Allowing Concurrent Jurisdiction Does Not Promote Judicial Goals**

##### ***1. Concurrent Jurisdiction over Vaccine Injury Claims Asserted Against Vaccine Component Manufacturers Does Not Promote Fairness***

A plaintiff currently has the choice of either filing and proving a petition in accordance with the National Vaccine Injury Compensation Program, thereby receiving compensation for actual and expected injuries, or pursuing a civil suit against the vaccine component manufacturer for the vaccine-related injury, potentially collecting greater damages.<sup>194</sup> This choice is patently unfair because it allows for a wide range of compensation for people who suffer substantially the same injury. Plaintiffs who file petitions under the Program are subject to statutory limits on the amount of compensation they can receive.<sup>195</sup> Such claimants may recover only reasonable actual and expected expenses related to the vaccine-related injury or death, plus up to \$250,000 for pain and suffering or death.<sup>196</sup> Additionally, the Program explicitly precludes any punitive damages.<sup>197</sup> However, successful civil suits filed outside of the Program are not subject to these same caps and are eligible for greater damages.<sup>198</sup>

It is possible to assert, however, that this discrepancy is fair because individual plaintiffs who file outside of the Program face a higher standard of proof and more formal proceedings, thus entitling them to potentially higher recovery.<sup>199</sup> Under the Program, a plaintiff who asserts a table injury (i.e., a recognized vaccine-related injury or death) is entitled to a presumption of causation.<sup>200</sup> A civil suit is not entitled to this presumption.<sup>201</sup> Thus, this trade-off does not produce any real unfairness.

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<sup>194</sup> See Wacek, *supra* note 11, at 306–07.

<sup>195</sup> 42 U.S.C. § 300aa-15(a) (2006).

<sup>196</sup> *Id.*

<sup>197</sup> *Id.* § 300aa-15(d).

<sup>198</sup> Wacek, *supra* note 11, at 306.

<sup>199</sup> See Schwartz & Mahshigian, *supra* note 36, at 390–92.

<sup>200</sup> Hull, *supra* note 21, at 26–27.

<sup>201</sup> See Schwartz & Mahshigian, *supra* note 36, at 392.

Even assuming that there is no unfairness to individual plaintiffs, concurrent jurisdiction is also unfair to society as a whole. Granting a plaintiff the ability to file a claim in state court seeking compensatory and punitive damages in excess of the statutory caps imposed by the National Childhood Vaccine Injury Act undercuts the purpose of the Act (i.e., to assure a sufficient, available vaccine supply, thereby decreasing the likelihood of an epidemic or pandemic).<sup>202</sup> Congress passed the Act in response to a dwindling supply, as large legal defense costs forced vaccine manufacturers to flee the market.<sup>203</sup> Therefore, concurrent jurisdiction is unfair because it endangers the many (by potentially decreasing vaccine availability) to benefit the few.

## ***2. Concurrent Jurisdiction over Vaccine Injury Claims Asserted Against Vaccine Component Manufacturers Does Not Promote Efficiency***

Concurrent jurisdiction is inefficient. It allows a plaintiff to file in both the vaccine court, against the vaccine administrators and/or manufacturers, and elsewhere, against the vaccine component manufacturer, for the same injury arising out of the same fact pattern.<sup>204</sup> The case of *Doe v. Bayer Corporation*<sup>205</sup> best illustrates this problem. There, the plaintiffs filed a failure to warn suit against a Thimerosal manufacturer in federal district court, alleging that Thimerosal caused their child to suffer neurological damage.<sup>206</sup> When the complaint was filed, the plaintiffs also had a petition pending in the vaccine court, alleging that the vaccinations had significantly aggravated the child's neurological damage.<sup>207</sup> The *Doe* court allowed the failure to warn suit to proceed because "each forum allows Plaintiffs to split their claims in this way."<sup>208</sup> Because the plaintiffs had framed their claim in federal court against the Thimerosal manufacturer, the court held that they would be unable to bring that claim under the National Vaccine Injury Compensation Program.<sup>209</sup> Moreover, the court could not consolidate the actions and require both to be brought in the federal district court proceeding because the Program demands that the vaccine court have exclusive jurisdiction over vaccine injury claims against vaccine manufacturers.<sup>210</sup> Therefore, even though the court explicitly recognized that "[m]ultiple actions arising out of the same series of events

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<sup>202</sup> *See id.* at 389.

<sup>203</sup> *Id.* at 388–89.

<sup>204</sup> *See, e.g., Doe v. Bayer Corp.*, 367 F. Supp. 2d 904, 911–12 (M.D.N.C. 2005).

<sup>205</sup> 367 F. Supp. 2d 904 (M.D.N.C. 2005).

<sup>206</sup> *Id.* at 907.

<sup>207</sup> *Id.*

<sup>208</sup> *Id.* at 912.

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

can be expensive and wasteful of judicial resources,”<sup>211</sup> it allowed the action because “it would be unfair for th[e] court to refuse to hear it.”<sup>212</sup>

Concurrent jurisdiction is inefficient because the vaccine court has developed particular expertise and knowledge in adjudicating vaccine claims that are not necessarily present in other courts. Specifically, the Omnibus Autism Proceeding created an efficient manner of resolving these particular claims. Under it, plaintiffs enjoy the benefit of using the evidence collected through the general causation proceedings and applying that evidence to substantiate their individual claims.<sup>213</sup> Plaintiffs are then able to supplement that evidence with case-specific information, like medical testimony.<sup>214</sup> Claims brought outside of the Program do not have this benefit. Therefore, plaintiffs bringing civil suits in state and federal courts must independently establish this general information, requiring lengthy and costly expert testimony. This necessarily lengthens trials, usurps judicial resources, and drains the funds of both plaintiffs and defendant vaccine component manufacturers.

### ***3. Concurrent Jurisdiction over Vaccine Injury Claims Asserted Against Vaccine Component Manufacturers Does Not Promote Consistency***

Allowing a plaintiff the choice of filing a petition under the National Childhood Vaccine Injury Act or pursuing a civil suit for vaccine-related injuries against a vaccine component manufacturer promotes inconsistent results. First, concurrent jurisdiction allows the potential for different recoveries.<sup>215</sup> Second, the Secretary of the U.S. Department of Health and Human Services has issued statements that consistently express a preference for having these claims brought in accordance with the Act.<sup>216</sup> However, some courts do not grant due deference to the Secretary’s policy because it is a non-binding agency interpretation of a statute,<sup>217</sup> instead arriving at their own conclusions by interpreting the express language of the statute.<sup>218</sup>

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<sup>211</sup> *Id.* at 913.

<sup>212</sup> *Id.* at 914.

<sup>213</sup> *See Autism General Order #1, supra* note 146, at 3–4.

<sup>214</sup> *See id.* at 7.

<sup>215</sup> *See supra* Part III.A.1.

<sup>216</sup> *Wax v. Aventis Pasteur, Inc.*, 240 F. Supp. 2d 191, 194 (E.D.N.Y. 2002) (“[The Department of Health and Human Services], through ‘statements of interest’ and publications, has expressed the consistent position that injuries caused by thimerosal in vaccines are, ‘vaccine-related’ for purposes of the Program.”).

<sup>217</sup> *Id.*

<sup>218</sup> *See, e.g., Holder v. Abbott Labs., Inc.*, 444 F.3d 383, 388–89 (5th Cir. 2006); *Moss v. Merck & Co.*, 381 F.3d 501, 503 (5th Cir. 2004); *Reilly v. Wyeth*, 876 N.E.2d 740, 749 (Ill. App. Ct. 2007).

Most notably, in *Wax v. Aventis Pasteur, Inc.*,<sup>219</sup> the court held that claims brought against Thimerosal manufacturers ought to be brought under the National Vaccine Injury Compensation Program.<sup>220</sup> In *Wax*, the district court afforded great weight to statements of interest issued by the Secretary of Health and Human Services, which “expressed the consistent position that injuries caused by [T]himerosal in vaccines are ‘vaccine-related’ for purposes of the Program.”<sup>221</sup> While other courts had ignored these policy statements in favor of their own statutory interpretations,<sup>222</sup> the agency’s interpretation persuaded the *Wax* court that the expertise of the Office of Special Masters in resolving complex scientific arguments gave credence to the policy statements and, accordingly, that the claims against Thimerosal manufacturers were more appropriately brought under the confines of the Program.<sup>223</sup>

Concurrent jurisdiction is clearly inconsistent. In those courts that allow plaintiffs to proceed in their civil actions, recovery is uncertain. More importantly, and as *Wax* illustrates, there is an inherent inconsistency in the way courts treat the issue of whether claimants can try to recover outside of the Program’s requirements or if plaintiffs must first seek recovery against Thimerosal manufacturers in the vaccine court.

## **B. Congressional Action Could Eliminate the Fairness, Efficiency, and Consistency Problems Posed by Concurrent Jurisdiction**

### ***1. Congress Should Include Vaccine Components as Part of the Definition of Vaccine in the Statute to Force Component Manufacturers Within the Court’s Exclusive Jurisdiction***

Similar to the repealed Homeland Security Act, Congress should statutorily include vaccine component manufacturers under the National Childhood Vaccine Injury Act. The Homeland Security Act amended the National Childhood Vaccine Injury Act to extend the Program’s exclusive jurisdiction to vaccine component manufacturers.<sup>224</sup> It did so by redefining “vaccine manufacturers” to include both manufacturers of the completed vaccine and manufacturers of vaccine ingredients, like Thimerosal.<sup>225</sup>

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<sup>219</sup> 240 F. Supp. 2d 191 (E.D.N.Y. 2002).

<sup>220</sup> *Id.* at 194–95.

<sup>221</sup> *Id.*

<sup>222</sup> See cases cited *supra* note 218.

<sup>223</sup> *Wax*, 240 F. Supp. 2d at 194–95.

<sup>224</sup> Homeland Security Act of 2002, Pub. L. No. 107-296, § 1714, 116 Stat. 2135, 2320 (repealed 2003).

<sup>225</sup> *Id.*

During the repeal proceedings, Congress never suggested that Homeland Security Act's amended definition of "vaccine manufacturers," which included vaccine component manufacturers, was undesirable.<sup>226</sup> The Senators who spearheaded the amendments' repeal said that they objected to the fact that these provisions had mysteriously appeared without comment or debate.<sup>227</sup> There was no mention that Congress or any individual members objected to the substance of the amendments, in addition to the method used to enact them.<sup>228</sup>

Amending the definition of "vaccine manufacturer" to include vaccine component manufacturers would ensure that these claims are initially filed in accordance with the National Childhood Vaccine Injury Act. There would still be no presumption of causation for claimants alleging that Thimerosal or vaccines caused autism because autism would continue to be a non-table injury. However, it would ensure that all vaccine injury claims are subject to the same procedure and that plaintiffs cannot simply circumvent the Program's procedural requirements by framing their claims as exclusively against vaccine component manufacturers.

***2. Congressional Action to Include Autism Claims in the Vaccine Injury Table Is Unsatisfactory Because Autism Claims Do Not Currently Deserve a Presumption of Causation***

There are other ways Congress could act in response to claims that Thimerosal causes autism. However, these solutions suffer from serious deficiencies that would not resolve the issues of fairness, efficiency, and consistency. One suggested alternative is for Congress to include autism in the Vaccine Injury Table, thus establishing autism as a table injury.<sup>229</sup> Congress would have to amend the National Childhood Vaccine Injury Act to list autism as a recognized vaccine injury. Thereafter, plaintiffs who file a timely claim under the Act alleging that a vaccine caused autism would be entitled to a presumption of causation.<sup>230</sup> Despite at least one commentator advocating for this solution,<sup>231</sup> it will not work. Unlike other injuries listed on the Vaccine Injury Table, it is not yet clear that either Thimerosal or vaccines cause autism. Supported only by controversial scientific evidence,<sup>232</sup> including autism on the Vaccine Injury Table would be presumptuous.

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<sup>226</sup> Wacek, *supra* note 11, at 323.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> Autism currently is not listed on the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14 (2006).

<sup>230</sup> *See* Hull, *supra* note 21, at 26–27.

<sup>231</sup> *Id.* at 46–47.

<sup>232</sup> *See* discussion *supra* Part I.C.3.



Amending the Vaccine Injury Table to include autism also is undesirable because the National Childhood Vaccine Injury Act is already designed to account for contested claims.<sup>233</sup> These claims are not supposed to receive the benefit of the presumption of causation merely because petitioners claim that vaccines caused the injuries. Rather, the Act allows claimants to receive compensation for non-table injuries if they prove causation.<sup>234</sup> This alternative route grants claimants an avenue to compensation if causation exists, without subjecting the Program to mandatory payments if there is no causation. The presence of this alternative route built into the National Childhood Vaccine Injury Act counsels against amending the Vaccine Injury Table to include autism as a table injury.

### **C. Including Thimerosal Manufacturers in the Statutory Definition of “Vaccine Manufacturers” Would Promote Judicial Goals**

#### ***1. Including Vaccine Component Manufacturers in the Statutory Definition of “Vaccine Manufacturers” Would Promote Fairness***

Including vaccine component manufacturers in the statutory definition of “vaccine manufacturers” would promote fairness because, quite frankly, it would solve more problems than it would create. First, the inclusion would still allow plaintiffs to pursue state law claims for vaccine-related injury or death, subject to the procedural requirements of the National Childhood Vaccine Injury Act that Congress intended to apply to such claims. Second, amending the definition of vaccine manufacturer to include vaccine component manufacturers would be fair because plaintiffs must still prove causation.<sup>235</sup> Plaintiffs asserting a non-table injury against a vaccine component manufacturer who prove causation would then fall within the provisions of the Program, entitling them to compensation for all reasonable costs arising from vaccine-related injury or death, including medical expenses, living expenses, actual and expected lost wages, and reasonable attorneys’ fees.<sup>236</sup>

A potential counterargument is that the National Vaccine Injury Compensation Program is unfair to claimants because it caps the payments on pain and suffering and precludes any recovery of punitive damages. The Act does impose statutory limits to recovery that may not be present in proceedings

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<sup>233</sup> See 42 U.S.C. § 300aa-11(c)(1)(c)(ii).

<sup>234</sup> *Id.* § 300aa-13(c)(1).

<sup>235</sup> Again, this is still a hotly contested issue. See *supra* Part I.C.3 for a discussion on the alleged connection between autism and Thimerosal.

<sup>236</sup> See 42 U.S.C. § 300aa-15.

outside of the vaccine court.<sup>237</sup> However, the Act's caps on damages are fair to plaintiffs. First, plaintiffs bear a lower standard of proof under the Act. There is no need to show any breach of a duty of care like negligence, and a plaintiff is only required to prove causation if asserting a non-table injury.<sup>238</sup> Because there is a lower burden on plaintiffs, it seems fair that there should be less recovery available. Additionally, the caps only affect non-compensatory damages.<sup>239</sup> A claimant can receive payment for any reasonable expenses attributable to the injury.<sup>240</sup> This seems fair because the Act still allows claimants to be made whole.

Some scholars have argued that the National Childhood Vaccine Injury Act is unfair because claimants are not receiving the compensation that they deserve.<sup>241</sup> The rate of compensation of claimants has dropped dramatically, from 87 percent of claimants obtaining compensation in the initial years of the Program to only 25 percent in recent years.<sup>242</sup> Some commentators argue that the dramatic drop in recovery means deserving plaintiffs are being denied compensation.<sup>243</sup> The Program would be unfair if petitioners were being denied the money they were entitled to because "society is feeding a fund that is not being spent, and injured plaintiffs are paying for their injuries."<sup>244</sup> However, this argument discounts the fact that there is another valid explanation for the dramatic decrease—more people are filing petitions who do not deserve any recovery.<sup>245</sup> Further, denial of compensation under the program does not necessarily require people to bear the financial burden of vaccine-related injury or death. Such claimants still have access to the recourse of subsequent civil suits against vaccine administrators, vaccine manufacturers, or vaccine component manufacturers.<sup>246</sup>

## ***2. Including Vaccine Component Manufacturers in the Statutory Definition of "Vaccine Manufacturers" Would Promote Efficiency***

Including vaccine component manufacturers in the statutory definition of "vaccine manufacturers" would promote efficiency because it would require

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<sup>237</sup> See *id.* § 300aa-15(a).

<sup>238</sup> See 42 U.S.C. § 300aa-13(a)(1); see also Wacek, *supra* note 11, at 312.

<sup>239</sup> 42 U.S.C. §§ 300aa-15(a)(2), -15(a)(4).

<sup>240</sup> See *id.* § 300aa-15(a).

<sup>241</sup> See Scott, *supra* note 16, at 358–60.

<sup>242</sup> *Id.* at 359.

<sup>243</sup> See *e.g.*, *id.*

<sup>244</sup> *Id.* at 360.

<sup>245</sup> See *id.* at 359 (recognizing, but not discussing, that this could be attributable to the possibility "that people should not be recovering for injuries under the [National Childhood Vaccine Injury Act]").

<sup>246</sup> See 42 U.S.C. § 300aa-21(a) (2006).

all vaccine-related injury or death claims to comply with the Program's procedural requirements, particularly the Omnibus Autism Proceeding, before plaintiffs could bring these claims in other forums. The Omnibus Autism Proceeding requires a plaintiff to file an even shorter petition for recovery than usually required by the Program.<sup>247</sup> It allows for claims to be resolved more quickly because a petitioner uses the evidence established in the general causation proceedings, supplemented by any case-specific evidence.<sup>248</sup> Finally, the presentation of any case-specific evidence would be efficient because the Act specifically provides for speedy discovery.<sup>249</sup> Discovery under the Act is more lenient than traditional federal rules.<sup>250</sup> This efficiency is particularly desirable because the National Childhood Vaccine Injury Act was designed with the goal of quickly resolving these sorts of claims.<sup>251</sup>

For those who argue that the Program itself is inefficient,<sup>252</sup> amending the statutory definition of "vaccine manufacturer" to include vaccine component manufacturers would only increase the inefficiency. True, the sheer volume of cases recently filed has caused a backlog and consequent delay in claimants receiving compensation, even after a judgment has been filed.<sup>253</sup> However, any delay incurred due to the Program is comparable to, if not better than, the delay that plaintiffs would incur in the traditional state civil tort system.<sup>254</sup> Therefore, while the Program may not provide claimants with immediate relief, statutorily requiring claims against vaccine component manufacturers to be brought in the vaccine court would promote a more efficient resolution of those claims.

### ***3. Including Vaccine Component Manufacturers in the Statutory Definition of "Vaccine Manufacturers" Would Promote Consistency***

Including vaccine component manufacturers in the statutory definition of "vaccine manufacturers" would promote consistency because all similarly

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<sup>247</sup> See *Autism General Order #1*, *supra* note 146, Exhibit B. The shorter petition does not require petitioners to file any medical evidence with their petitions, which is usually required under the National Childhood Vaccine Injury Act. See *id.* at 7.

<sup>248</sup> See *id.* at 6–7.

<sup>249</sup> See 42 U.S.C. § 300aa-12(d)(3)(A).

<sup>250</sup> See *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1341–42 (Fed. Cir. 2010).

<sup>251</sup> See *Schwartz & Mahshigian*, *supra* note 36, at 394.

<sup>252</sup> See *Scott*, *supra* note 16, at 358.

<sup>253</sup> See *id.* In 2001, claimants were waiting three to five years to receive compensation after being awarded a judgment. *Id.*

<sup>254</sup> See *id.* Plaintiffs may wait six to eight years to even bring their case in a state tort suit outside of the vaccine court. See *id.*

situated plaintiffs would receive like treatment. Under the current Autism Omnibus Proceeding, all cases alleging a particular general causation theory are treated as having the same basic evidence presented.<sup>255</sup> While each claimant is able to introduce case-specific evidence in his or her individual case, the majority of the evidence will be the same.<sup>256</sup> This enhances the likelihood that similar cases will receive consistent procedural treatment and comparable outcomes. Therefore, the Omnibus Autism Proceeding is an improvement over the current system, in which some courts allow civil suits outside of the Program and other courts do not.<sup>257</sup>

Amending the definition of “vaccine manufacturer” to include vaccine component manufacturers is also consistent with the congressional purpose behind enacting the National Childhood Vaccine Injury Act in the first place. It would provide predictability to vaccine and vaccine component manufacturers. Predictability would ensure an adequate and dependable vaccine supply, which is undermined when plaintiffs are allowed to file claims against vaccine component manufacturers in state courts.<sup>258</sup> All vaccine and vaccine component manufacturers would know that claims filed against them must first be treated under the National Vaccine Compensation Program.<sup>259</sup>

One potential counterargument is that Congress did not intend this in passing the Act. Arguably, Congress was solely concerned with vaccine manufacturers’ liability and not that of vaccine component manufacturers. This counterargument fails for one simple reason: Congress enacted the National Childhood Vaccine Injury Act to ensure that the U.S. population had a readily accessible vaccine supply.<sup>260</sup> This necessarily implies that vaccine component manufacturers must receive similar protections under the Act. If vaccine component manufacturers are subject to state tort liability, they may be less likely to engage in the business for the same reason that vaccine manufacturers dropped out of the market in the 1980s when faced with similar liability.<sup>261</sup> Loss of any vaccine component manufacturer would likely cause either a decrease in the number of vaccine manufacturers or an increase in the cost of vaccines. Either possibility would reduce the availability of vaccines, which would contradict congressional intent. It would appear

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<sup>255</sup> *Autism General Order #1*, *supra* note 146, at 6–7.

<sup>256</sup> *Id.*

<sup>257</sup> See discussion *supra* Part II.C.

<sup>258</sup> See Schwartz & Mahshigian, *supra* note 36, at 394.

<sup>259</sup> See *id.* Predictability will only exist if “the no-fault compensation program becomes the primary means of redress for vaccine-related injuries, meaning that the majority of claims that otherwise would be resolved in the tort system are resolved in the compensation system.” *Id.*

<sup>260</sup> See *id.*

<sup>261</sup> See *id.*

that a necessary implication of the National Childhood Vaccine Injury Act is that it should apply to vaccine component manufacturers in the same way it applies to vaccine manufacturers.

## Conclusion

Currently, plaintiffs alleging that Thimerosal or a combination of Thimerosal and vaccines caused autism have a choice: they can either pursue compensation under the National Childhood Vaccine Injury Act or they can file a civil suit in a state court against the Thimerosal manufacturer.<sup>262</sup> Regardless of whether any plaintiff will actually be successful in alleging causation between Thimerosal and autism, allowing claims in state court circumvents the Program's requirements and contradicts the goals of the National Childhood Vaccine Injury Act. The threat of recovery against a vaccine component manufacturer could decrease the nation's vaccine supply. Making fewer vaccines available to the public could decrease herd immunity and increase deaths from preventable disease. The best way to combat the unfairness, inefficiency, and inconsistency inherent in allowing such a choice is for Congress to amend the National Childhood Vaccine Injury Act's definition of "vaccine manufacturers" to statutorily include vaccine component manufacturers. This solution would force similar treatment of all vaccine-related injury and death claims, which would promote the availability of vaccines to all.

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<sup>262</sup> See discussion *supra* Part III.A.2.