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## A SNAPSHOT OF AN INDUSTRY: THE BIOTECHNOLOGY SECTOR AND THE JUDICIAL MISGIVINGS OF A GENERAL COURT

Mike Rothwell\*

### Introduction

The development of biotechnology and pharmaceutical-based remedies has historically received careful legislative and judicial supervision since the early nineteenth century.<sup>1</sup> The traditional application of patent law to this important sector sought to strike a delicate balance between the needs of a burgeoning industry and the important legal bounds of fundamental protection afforded to the holder of a patent.<sup>2</sup> Throughout the maturation of America's patent law system, this often-oscillating balance underwent a series of seemingly perpetual tweaks, shifts, and re-definitions.<sup>3</sup> In 1984, Congress, in response to a Federal Circuit decision that essentially established a de facto extension of the patent term on a patent held by a brand-name drug \*142

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<sup>1</sup> See *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (holding that the manufacture of a patented machine for profit is a breach of a patent right).

<sup>2</sup> Justice Story remarked, in dictum, that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Id.* Story's dictum effectively established the common law "research use defense" doctrine by which a patent infringer could assert that a patent-protected invention was being utilized for purely research related-purposes and thus avoid liability entirely. *Id.*

<sup>3</sup> See *Merck KGaA v. Integra Lifesciences I, Ltd. (Merck II)*, 545 U.S. 193, 206-07 (2005) (holding that drugs not ultimately the subject of an FDA submission are covered by § 271(e)(1)); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 674 (1990) (holding that research related to the production of medical devices fell under the 271(e) (1) exception); *Madey v. Duke Univ. (Madey II)*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (holding that issues of fact existed as to the applicability of the experimental use exception); *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997) (holding that § 271(e)(1) is applicable to Class II Medical devices); *Teletronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992) (holding that the data generated by the use of patented drugs can permissibly be used for business purposes); *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (holding generic drug producers could not begin FDA testing until the patent held by the principal had expired).

manufacturer,<sup>4</sup> enacted 35 U.S.C. § 271(e)(1) to create an explicit and unmistakable safe harbor by which research activities reasonably related to the FDA approval process would be immune to charges of patent infringement.<sup>5</sup> Specifically, 35 U.S.C. § 271(e)(1) grants, “[i]t shall not be an act of infringement to make, use, offer to sell within the United States or import into the United States any 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 or veterinary biological products” (emphasis added). As with most legislative enactments devised to correct judiciary misgivings, substantial ambiguities exist within the terms of the corrective measure; the broad statutory language leaves ample room for debate and it remains unclear, even in the wake of extensive litigation before the nation’s highest courts, how far the safe harbor provision of 35 U.S.C. § 271(e)(1) truly extends.<sup>6</sup>

Given the lack of directional clarity built into the relatively short § 271(e)(1) amendment, both the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court have been left with considerable maneuvering room to mold the metes and bounds of the safe harbor provision around the presumptive legislative intent. There has undoubtedly been an expansion of the safe harbor guaranteed to drug developers by § 271(e)(1) at both the Federal Circuit and Supreme Court levels.<sup>7</sup> Despite the judicially-driven expansion of the safe harbor provision, ambiguities

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<sup>4</sup> *Roche*, 733 F.2d at 863-64 (holding that a manufacturer of generic drugs could not begin its FDA testing until the patent for the brand name drug had expired—which essentially resulted in an extension of the patent term for the brand name manufacturer as the producer of generic medications could not begin its research and testing phase, which often takes years, until the original patent itself had expired).

<sup>5</sup> 35 U.S.C. § 271(e)(1).

<sup>6</sup> See *Merck II*, 545 U.S. at 205 (exemplifying the vague nature of the amendment) (“We ... do not express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of ‘research tools’ in the development of information for the regulatory process.”).

<sup>7</sup> *Eli Lilly*, 496 U.S. at 674 (expanding coverage to medical devices); *Telectronics*, 982 F.2d at 1525; *AbTox*, 122 F.3d at 1029; *Merck II*, 545 U.S. at 206-07.

pertaining to the scope of the coverage persist.<sup>8</sup> It remains unclear how far an otherwise would-be infringer utilizing patented technology can extend a safe harbor defense into the research and development process and still remain liability free.<sup>9</sup> In light of the relatively consistent expansion of the safe harbor provision, there is a general presumption that the protections afforded to the FDA research-based infringer will only become larger. Owners of highly specific biotechnology products can now warily look forward to the potential foreclosure of their protective patents, should the courts effectuate a further exception to infringement that would encompass the entire research and development process. This result, while initially lowering drug-development costs for universities and pharmaceutical companies by enabling virtually cost-free access to patented technologies, is ultimately undesirable as it will inevitably stifle an important segment of the American Biotechnology sector: that of research tool developers.

Perhaps somewhat paradoxically, large-scale developers of market-capturing drugs have only been able to maintain successful development of viable products through a steady reliance upon a readily available supply of research tools.<sup>10</sup> Without expeditious access to such tools of the trade, it is difficult to surmise how a drug developer, without redirecting large allocations of capital for in-house development of such tools, would expect to maintain the same rate of innovation experienced under previous patent paradigms. This note will argue that, although a further expansion of the § 271(e)(1) provision to incorporate research tools into the envelope of protection afforded by the safe harbor will make certain research-orientated technologies more accessible to researchers in the immediate short term, it will have the eventual negative consequence of stifling the development of the exact

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<sup>8</sup> See *Merck II*, 545 U.S. at 205 (not addressing whether or not research tools are covered by § 271(e)(1)).

<sup>9</sup> *Id.*

<sup>10</sup> See Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 2002 FED. RES. BANK DALLAS CONF. ON SCI. & CENTS: EXPLORING ECON. BIOTECHNOLOGY 87, 90, available at <http://www.dallasfed.org/research/pubs/science/grabowski.pdf> (“The mapping of the genome, and related advances in fields like proteomics and bioinformatics, has led to an abundance of new disease targets. Nevertheless, some industry analysts have hypothesized that these developments may actually cause R&D costs to rise in the short run. The basic reason is that these new technologies require substantial up-front investments, and to date they have generated many disease targets that are not yet well understood. Eventually this expansion in the scientific knowledge base should lead to substantial efficiencies in the R&D process for new pharmaceuticals.”).

technologies that drug producers depend upon. If the courts carelessly expand the bounds of access to infringers too broadly, they will encourage the precise type of free-for-all rush on otherwise protected technologies that patent law was devised to prevent.<sup>11</sup> This will result in the unfortunate and inefficient outcome of independent research tool developers being pushed from the market. In order to fully develop this argument, a comprehensive analysis is necessary of not only the law that has set the stage for this development, but also of the economic forces that both shape and drive the biotechnology and pharmaceutical industries. With this analysis as the backdrop, the note will then demonstrate that any further broadening of § 271(e)(1) to include research tools will effectuate not only a violation of the legislative intent that clearly drove the formulation of § 271(e)(1), but also some of the more fundamental precepts of patent law that a high tech industry must invariably rely upon.

## I. The Creation and Expansion of § 271(e)(1)

### A. *The History*

The presumptive goal of patent law is to strike a harmonious balance between the needs of an inventor and the public's right to access. The general theory is that an inventor, without an obtainable level of enforceable, meaningful protection for the financial value of the invention, will be disinclined to both disclose the invention to the public and continue further inventive activities.<sup>12</sup> Continued innovation, of course, is the mainstay by which a progressive society improves the lot of its citizenry. As such, the courts have thus been apt to both recognize and \*145 enforce a patent, in light of potentially infringing activities, for the duration of its term once the foundational requirements of the United States Patent and Trademark office have been met.<sup>13</sup>

However, the application of rigorous, primary inventor-friendly jurisprudence in the realm of

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<sup>11</sup> See *e.g.*, *Zacchini v. Scripps-Howard Broad. Co.*, 433 U.S. 562, 573 (1977) (“[T]he State’s interest is closely analogous to the goals of patent and copyright law, focusing on the right of the individual to reap the reward of his endeavors.”).

<sup>12</sup> See U.S. Patent Act, 35 U.S.C.S. §§ 1-376 (LexisNexis 2000).

<sup>13</sup> See *generally* *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995) (holding that the anti-tumor compound covered by the patent entailed sufficient utility to survive challenges by the PTO).

inventor-on-inventor type infringement quickly fell into a state of merged anonymity and desuetude.<sup>14</sup> This somewhat errant incantation of patent law found its inception in the words of Justice Story, who remarked, in dictum, that “it could never have been the intention of the legislature to punish a man, who constructed [a patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine.”<sup>15</sup> Utilizing this “research use defense” doctrine, a defendant in an infringement suit could assert that the patented invention was utilized for purposes related to research only, and thus potentially could avoid liability.<sup>16</sup> This defense lingered in modest application, in conjunction with the safe harbor established by § 271(e)(1) for drug developers, until 2002, when the Federal Circuit exacted a substantial limitation upon the doctrine in *Madey v. Duke University (Madey II)*.<sup>17</sup>

### ***B. The Death of a Common Law Doctrine***

Until the *Madey*<sup>18</sup> decision in 2002, a commercially-based developer of technologies could expect to find protection against infringement claims within the confines of the common law research use defense doctrine. The Federal Circuit, in carefully crafting its limitation to the lingering doctrine, declared in its *Madey* decision that only experimental uses relating to one of three exceptions, “[1] amusement ... [2] idle curiosity ... [and 3] strictly philosophical inquiry” \*146 could now reasonably expect to find shelter in the much-narrowed confines of the now-anemic research use common law defense.<sup>19</sup> On remand, the Federal Circuit ordered the district court to apply the new and significantly narrower application of the experimental use defense.<sup>20</sup> The correct focus for the district court, as instructed by the Federal Circuit,

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<sup>14</sup> See *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

<sup>15</sup> *Id.*

<sup>16</sup> See *Madey v. Duke Univ. (Madey I)*, 266 F. Supp. 2d 420, 428 (M.D.N.C. 2001), *aff'd in part, rev'd in part*, 307 F.3d at 1362 (holding that statements made by university that it intended to use certain elements of its lab for commercial uses were insufficient to preclude the application of the research use defense).

<sup>17</sup> *Madey II*, 307 F.3d at 1362 (holding that the common law research use defense now only applied to only experimental uses relating to “amusement ... idle curiosity ... [and] strictly philosophical inquiry”).

<sup>18</sup> 307 F.3d 1351 (Fed. Cir. 2002).

<sup>19</sup> *Id.* at 1362.

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

was not to be placed on the non-profit status of the defendant, but instead on the legitimate business use of the patented invention by the defendant and whether such use fell within the parameters of the three exemptions.<sup>21</sup> With the common law defense thus limited, it no longer remains a viable defense for infringers except in the most restricted of circumstances.<sup>22</sup>

### *C. The New Research Use Defense: § 271(e)(1)*

Interestingly, the virtual eradication of the common law defense doctrine only came after a prolonged § 271-based judicial redefinition of the rights of patent holders.<sup>23</sup> Though no substantive explanation was provided in the Federal Circuit's decision in *Madey II* for its limiting maneuver, one can only surmise that the court was concerned with leaving a loop hole (established by the expansion of § 271(e)(1) and the sufficiently vague language of the common law research-use defense) so broad that any infringing use relating, in at least some capacity, to a form of a research and development application would be able to find protection under the two prongs of potential exemption.<sup>24</sup> It is also plausible, however, that the court removed the somewhat outdated common law ancestor with an eye towards a future, more contemporary rendition anchored in statutory language--thus ensuring researchers a more rigid and predictable \*147 avenue of defense against infringement claims. It has been suggested that the U.S. Supreme Court, in its recent *Merck KGaA v. Integra Lifesciences I, Ltd.*<sup>25</sup> decision, recreated a surrogate form of the experimental use defense, this time finding its legal foundation in § 271(e)(1).<sup>26</sup>

### *D. The Application of Section 271(e)(1)*

Enacted by Congress in response to the *Roche Products v. Bolar Pharmaceutical Co.*<sup>27</sup> decision, 35

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<sup>21</sup> *Id.* The exceptions being: 1) amusement, 2) idle curiosity, and 3) strictly philosophical inquiry.

<sup>22</sup> *Madey v. Duke Univ. (Madey III)*, 336 F. Supp. 2d 583, 591 (M.D.N.C. 2004). The restricted circumstances being the three applicable exceptions described in the *Madey II* decision.

<sup>23</sup> *Merck KGaA v. Integra Lifesciences I, Ltd. (Merck II)*, 545 U.S. 193 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *AbTox, Inc., v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997); *Teletronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

<sup>24</sup> *Madey II*, 307 F.3d at 1362-63. The two prongs being: 1) either the common law doctrine after *Madey II*, or 2) the § 271(e)(1) safe harbor.

<sup>25</sup> 545 U.S. 193 (2005).

<sup>26</sup> Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921, 939 (2006).

<sup>27</sup> 733 F.2d 858 (Fed. Cir. 1984) (holding that a manufacturer of generic drugs could not begin its FDA testing until

U.S.C. § 271(e)(1), has proven to be a force for erosion of patent holders' rights.<sup>28</sup> The apparent end product, as indicated by the U.S. Supreme Court, is a shape-shifting brand of jurisprudence dedicated to the expansion of the safe harbor.<sup>29</sup> This judicial mobility has found its spur in the ambiguous language of § 271(e)(1), which reads in pertinent part, that “[i]t shall not be an act of infringement to ... use . . . a patented invention ... solely for uses reasonably related to the development ... of drugs or veterinary biological products.”<sup>30</sup> This reasonably related “safe harbor” provision has been the impetus for much judicial activism. Even now, despite extensive litigation on the matter, it remains unclear how far this safe harbor actually extends.<sup>31</sup>

**\*148** The ubiquitous trend is unmistakable.<sup>32</sup> In its first interaction with the new statutory provision, the Supreme Court was quick to eradicate any apprehension that they would impute a restrictive interpretation on the vague statutory language of § 271(e)(1).<sup>33</sup> Instead, the Court in *Eli Lilly & Co. v. Medtronic, Inc.*, in a unanimous opinion authored by Justice Scalia in 1990, went on the offensive and expressed no qualms about expeditiously expanding the scope of the safe harbor to medical devices, a biotechnology subset not expressly addressed by the statute.<sup>34</sup> In the eyes of the Court, § 271(e)(1) was

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the patent for the brand name drug had expired).

<sup>28</sup> *Id.* at 863. Congress passed 35 U.S.C. 271(e)(1) in 1984 to respond to this decision as it essentially resulted in a de facto extension of a patent term for the brand name manufacturer, as the producer of generic medications could not begin its research and testing phase (which often takes years) until the original patent itself had expired. Congress declared that the statutory definition of patent infringement did not include any experimental activity “reasonably related” to submitting information to the FDA. H.R. Rep. No. 857, at 8. Drug manufacturers, under the auspices of this statute, were then able to begin the testing phases of their generic medications while the patent held by brand name producer was still valid. Given this “head start,” these producers were able to have their generics on the market shortly after the expiration of the patent held by the principal.

<sup>29</sup> *See Merck II*, 545 U.S. 193.

<sup>30</sup> 35 U.S.C. § 271(e)(1) (2003).

<sup>31</sup> *Merck II*, 545 U.S. at 205 (“We ... do not express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of ‘research tools’ in the development of information for the regulatory process.”).

<sup>32</sup> *See Teletronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992) (holding that the data generated by the use of patented drugs could be used for business purposes, i.e. the recruitment of potential investors, share-holders, etc.); *accord AbTox Inc. v. Exitron Corp.* 122 F.3d 1019, 1028 (Fed. Cir. 1997)(extending the scope of the Hatch-Waxman act to Class II devices, which, and unlike Class III devices, can be marketed without FDA approval).

<sup>33</sup> *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990).

<sup>34</sup> Justice Scalia, for the Court, wrote that “the core of the present controversy is that petitioner interprets the statutory phrase, ‘a Federal law which regulates the manufacture, use, or sale of drugs,’ to refer only to those individual provisions of federal law that regulate drugs, whereas respondent interprets it to refer to the entirety of any Act (including, of course, the FDCA) at least some of whose provisions regulate drugs. If petitioner is correct, only such provisions ... governing premarket approval of new drugs, are covered by § 271(e)(1), and respondent’s

created with the legislative intention of applying the safe harbor provision to any Federal Act, as long as some portion of that act, no matter how de minimis, regulated or contributed to the drug approval process.<sup>35</sup> Using this rationale, the Court in *Eli Lilly*.<sup>36</sup> held that because the FDCA is implicated in the regulation of both medical devices and drugs, the § 271(e)(1) safe harbor is appropriately applied to medical devices.<sup>37</sup> Such a broad application of the statute undoubtedly has had a substantial negative impact upon the value of certain patents.<sup>38</sup>

## \*149 II. A War of Words: Merck v. Integra and Competing Ideologies

### *A. Judge Rader and the Thoughts of an Expert Court*<sup>39</sup>

In *Integra Lifesciences I, Ltd. v. Merck KGaA (Merck I)*, the steady progression towards open-range access to patented biotechnologies encountered its first noticeable bump in the road in 2003 when the Court of Appeals for the Federal Circuit, headed by Judge Rader, issued an unambiguous decree

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submission ... [regarding] medical devices, would not be a noninfringing use.” *Eli Lilly*, 496 U.S. at 666. At the very outset, Justice Scalia makes the expansive intentions of the Court clear: “the phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone.” *Id.*

<sup>35</sup> Justice Scalia explains that “[t]he phrase ‘a Federal law’ can be used to refer to an isolated statutory section ... [t]he phrase is also used, however, to refer to an entire Act.” *Id.* Justice Scalia then backs this assertion with a contextual analysis of the statute, arguing that “[t]his latter usage, which is probably the more common one, seems also the more natural in the present context.” *Id.* at 667.

<sup>36</sup> 496 U.S. 661 (1990).

<sup>37</sup> *Id.* at 673.

<sup>38</sup> Petitioners, in an attempt to caution the Court about the travails of an over-expansive policy, argue “that there was good reason for Congress to establish an infringement exemption with respect to drugs but not devices, since testing of the latter does much greater economic harm to the patentee. Devices, petitioner contends, are much more expensive than drugs (\$17,000 each for respondent’s allegedly infringing defibrillators); and many have only a small number of potential customers, who will purchase only a single device each, so that depleting the market through testing may do substantial harm. These concerns, however, apply with respect to certain drugs as well.” *Id.* The justification that “these concerns ... apply ... to certain drugs as well” is woefully ill-equipped to address the underlying reality sitting at the heart of the petitioner’s complaint. *Id.* It is insufficient to claim that because Congress intended the safe harbor to apply to certain high-cost, large-market drugs, the eradication of the profitability of an entire subset of the biotechnology sector is justified. Certainly the Congressional intent in establishing the § 271(e)(1) safe harbor was to encourage the advent of low-cost pharmaceuticals. Is this goal best served by the destruction of biotechnology micro-markets dependent upon drug-developing customers? The Court seems to impute little weight to this concern, an indication that it does not recognize the full economic ramifications of the matter. *Id.*

<sup>39</sup> United States Courts of Appeals for the Federal Circuit Homepage, <http://www/cafc.uscourts.gov/about.html> (last visited Aug. 29, 2008)(The Federal Circuit ... has nationwide jurisdiction in ... patents”).

effectively limiting the otherwise broad scope of § 271(e)(1).<sup>40</sup> Such a limitation, as enacted and described by the Federal Circuit, was not anchored by an analysis of the context and potential meaning of statutory language, but instead was directly tied to a pragmatic evaluation of the legislative intent underlying the enactment of § 271(e)(1).<sup>41</sup> More revealingly, Judge Rader quoted from the language of the House Committee Report, which explains that the safe harbor of § 271(e)(1) was to only be applied to “a limited amount of testing so that generic manufactures can establish the bioequivalency of a generic substitute.”<sup>42</sup> The \*150 House Committee Report on § 271(e)(1) goes on, stating in clear language that intended consequences for patent holders after § 271(e)(1) were to be micro in scale, noting that “all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is de minimis.”<sup>43</sup>

By comparison, in the *Merck I* case, the experimental processes before the court did not present the issue of direct drug information submission to the FDA.<sup>44</sup> Instead, the case dealt with a pre-FDA submission stage and an experimental screening process by which patented compounds were used to screen for potential would-be drug candidates.<sup>45</sup> The experimental use of patented compounds in pre-submission type experiments is not one of the stated legislative goals underlying § 271(e)(1). As such, this use was

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<sup>40</sup> 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 545 U.S. 193 (2005).

<sup>41</sup> Judge Rader, in describing the rationale behind the Congressional enactment of § 271(e)(1), states that § 271(e)(1) had two purposes. “In the first place, the 1984 Act sought to restore patent term to pharmaceutical inventions to compensate for the often-length period of pre-market testing pending regulatory approval to sell a new drug. The second reason for the 1984 Act responded to ... *Roche* ... to ensure that a patentee’s rights did not *de facto* extend past the expiration of the patent term because a generic competitor also could not enter a market without regulator approval.” *Id.* at 865. The Federal Circuit, having addressed the issue previously, stated that “[s]ection 271(e) permits premarket approval activity conducted for the *sole purposes* of sales after patent expiration.” *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 763 (Fed. Cir. 1997).

<sup>42</sup> H.R. REP. NO. 857, at 8 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2692. This language lends itself directly to the two-pronged assertion made by Judge Rader that the intended purpose of § 271(e)(1) was, in its bare application, to prevent the *de facto* extension of the patent term held by the brand-name drug manufacturer. *Hoechst-Roussel Pharms.*, 109 F.3d at 763. Certainly this Congressional “loop hole” has a valid purpose in that it encourages the production and sale of generic medications upon the exact moment of the expiration of the principal’s patent. Why Justice Scalia decided to overlook this unambiguous legislative language in his *Eli Lilly* opinion remains unclear. 496 U.S. at 667.

<sup>43</sup> H.R. REP. NO. 857, at 8. Any result that then might enact some sort of greater-than-de minimus type effect on a particular subset of the biotechnology market would not be appropriate under the language of the report (as the use then falls outside the realm of the congressionally-intended consequences of § 271(e)(1)).

<sup>44</sup> *Merck I*, 331 F.3d at 863.

<sup>45</sup> *Id.*

not appropriately within the safe harbor.

More specifically, the § 271(e)(1) exception was adopted in response to the *Roche* decision which resulted in a de facto extension for the principal's patent term--a result that Congress felt required realignment.<sup>46</sup> Congress created its safe harbor with the intention of guaranteeing immediate public access to generic medications upon expiration of a patent.<sup>47</sup> As the House Committee Report contemplated only a de minimis impact, it appears ambitious to construe a safe harbor that applies to any activity, as long as it retains some relation to drug \*151 discovery.<sup>48</sup> Such an approach places a heavy toll upon the holders of certain biotechnology patents as it essentially precludes access to a market, which, in some circumstances, constitutes the entirety of the consumer base. Certainly such an effect is not de minimis, and strikes a dissonant chord with the overall themes underlying the Congressional enactment of § 271(e)(1).<sup>49</sup>

Section 271(e)(1) was enacted to allow de minimis access to patented technologies so that a manufacturer of generic drugs would be able to have its product ready for public access as early as legally permissible. It was not created with the intention of enabling a legal free-for-all on the now transparent rights of patent holders, as long as there remained some sort of potential connection to a mystery process that might, at some unknown date, produce a drug somewhere in the pipeline. Such a result, in its real world application, essentially revokes the full value of many biotechnology products, rendering the underlying patent more or less meaningless.

### ***B. A Contrasting Viewpoint: The Supreme Court Weighs In***

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<sup>46</sup> H.R. REP. NO. 857, at 8.

<sup>47</sup> Judge Rader correctly asserts that “[t]he meaning of the phrase ‘reasonably related to the development and submission of information’ as set forth in § 271(e)(1) is clear in the context of the role of the 1984 Act in facilitating expedited approval of a generic version of a drug” ... and that “[t]he FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval.” *Merck I*, 331 F.3d at 866 (emphasis added). Judge Rader also restates, in clear terms, that “the express objective of the 1984 Act was to facilitate the immediate entry of safe, effective generic drugs into the marketplace.” *Id.* at 866-67. In light of the circumstances of *Roche*, and the language found in the House Committee Report, this seems to be the only plausible conclusion.

<sup>48</sup> *Merck I*, 331 F.3d at 867 (holding that the patented peptides at issue were not sufficiently related to the production of a pharmaceutical compound and thus not covered under the safe harbor of § 271(e)(1)).

<sup>49</sup> H.R. REP. NO. 857, at 8.

The U.S. Supreme Court in *Merck KGaA v. Integra Lifesciences I, Ltd. (Merck II)*, in a unanimous decision written by Justice Scalia in 2005, issued an opinion effectively aimed at undoing the entirety of the Federal Circuit's limitation on § 271(e)(1).<sup>50</sup> Instead of assuming a cautionary role, the Court went on the offensive, declaring that safe harbor now applied to "all uses of patented inventions that are reasonably related to the ... submission of *any* information under the FDCA"--effectively extending the bounds of the safe harbor to their broadest possible application.<sup>51</sup> The justification for such expansion is sparse.<sup>52</sup> Curiously, and maybe somewhat **\*152** revealingly, Justice Scalia complains that "to construe § 271(e)(1), as the Court of Appeals did ... is effectively to limit assurance of exemption to the activities necessary to seek approval of a generic drug ... [and] [t]he statutory text does not require such a result."<sup>53</sup> Yet such a limitation, as previously discussed, is not only directly in line with the language found in the House Committee Report, but also correlates directly with the judicial circumstances that precipitated the formation of § 271(e)(1) in the first place.<sup>54</sup> Instead of addressing the intent-based arguments given by the Federal Circuit for limiting § 271(e)(1), Justice Scalia ignores the majority of Judge Rader's reasoning, while devoting the virtual entirety of his opinion to detailing, in express terms, the full extent to which an accused infringer may seek coverage in § 271(e)(1)'s newly expanded harbor.<sup>55</sup> In an otherwise nebulous opinion, the Court does not once address the concerns of Congress, as evidenced by the House Committee Report, nor does it attempt to make its holding comport with the overriding

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<sup>50</sup> 545 U.S. 193, 194 (2005).

<sup>51</sup> *Id.* at 202. This statement creates a safe harbor that engulfs the more limited version crafted by the Federal Circuit by several orders of magnitude. The justification that Justice Scalia provides for the creation of such an expansive boundary has its substance grounded in these few words: "[a]s an initial matter, we think it apparent from the statutory text that § 271(e)(1)'s exemption infringement extends to all uses ..." *Id.* The apparentness for the need of such a massive safe harbor provision is clear to Justice Scalia--but was it equally apparent to Congress when it created § 271(e)(1)? The House Committee Report and the responsive nature (to *Roche*) of the legislation clearly suggests otherwise. H.R. REP. NO. 857.

<sup>52</sup> *Merck II*, 545 U.S. at 201 ("[T]he statutory text makes clear that it provides a wide berth .... [W]e think it apparent .... There is simply no room in the statute for excluding certain information from the exemption."). These statements are perplexing and strain credulity. The language of the § 271(e)(1) statute hardly provides anything that even approaches the degree of certainty that Justice Scalia purportedly sees in its midst. Instead, the statute is ambiguous and leaves room for interpretation (hence the resulting litigation). In light of such ambiguity, analysis of the surrounding circumstances and the legislative intent is required. It is therefore interesting to note that Justice Scalia declined to mention both the House Committee Report and the circumstances that gave rise to *Roche* in his opinion.

<sup>53</sup> *Id.* at 206.

<sup>54</sup> See H.R. REP. NO. 857, at 8; *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

<sup>55</sup> *Merck II*, 545 U.S. at 206 ("As to the first proposition, it disregards ... reality."). Justice Scalia went on declare that § 271(e)(1) does not require that the use of patented compounds produces results that are ultimately submitted to the FDA to qualify for protection. *Id.* Justice Scalia also crafted jury instructions to be used by the lower tribunals. *Id.* at 208.

considerations presented by the fact that the Congressional enactment of § 271(e)(1) was directly responsive to the ruling in *Roche*.<sup>56</sup> Instead, Justice Scalia demands that the statute be interpreted on its face only. In matters so complex, such a superficial mode of interpretation results in the creation of legal constructs that are **\*153** completely disengaged from the real-world undercurrents that drove the formation of the statute in the first place. Not only have the fundamental tenants of patent law been violated by the U.S. Supreme Court's course of action, but so has the clear Congressional intent laid bare by the House Committee Report.

### *C. The Safe Harbor and Research Tools*

Substantial controversy and debate has been sparked by the language in the *Merck II* opinion regarding the application of the safe harbor to research tools. The Court declined to address the matter as it saw the study of a patented research tool to be sufficiently different from the actual use of the same research tool. In line with this reasoning, the matter was therefore not correctly presented before the Court.<sup>57</sup> Regardless of how delineated this distinction may or may not be, there is a general presumption amongst research tool developers that when the U.S. Supreme Court revisits the issue, given its already somewhat ambitious expansion of § 271(e)(1), research tools will soon too be engulfed by the safe harbor. No matter how altruistic the motives for such a potential action would undoubtedly be, the deleterious outcome is unmistakable: certain "research tools" producers will be forced from the market.

### *D. The Amici Rally to Merck*

The *Merck II* decision drew the attention of many interested parties. The Respondents, who were arguing that the Federal Circuit's more limited version of § 271(e)(1) was the correct application, garnered the support of numerous biotechnology producers. Amongst the amici for respondents are some of the largest names in the industry.<sup>58</sup> The amici for **\*154** respondents, almost uniformly, expressed a concern

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<sup>56</sup> See *id.* at 206.

<sup>57</sup> *Id.* at 205.

<sup>58</sup> The following institutions submitted briefs of amicus curiae for respondents: Benitec Australia Ltd., Wisconsin

that a further judicial broadening of the § 271(e)(1) safe harbor would effectively vitiate the economic value of the average biotechnology patent.<sup>59</sup> The amici, like the Federal Circuit, also expressed a concern that any further expansion of § 271(e)(1) would work to counteract the overriding congressional intent driving the formation of the statute.<sup>60</sup> These concerns, coupled with numerous others, \*155 acted

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Alumni Research Foundation, The American Council on Education, Boston University, The Regents of the University of California, Research Corporation Technologies, The Salk Institute for Biological Studies, University of Alberta, University of Oklahoma, Applera Corporation, Isis Pharmaceuticals, Inc., Vaccinex, Inc., Invitrogen Corporation, Analytical & Life Science Systems Association, Biocom, Affymetrix, Inc., Diversa Corporation, Quantum Dot Corporation, Sangamo Biosciences, Inc., and Symyx Technologies, Inc. See Brief of Amicus Curiae, Benitec Australia Ltd. in Support of Integra Lifesciences I, Ltd. and The Burnham Institute, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682092; Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682088; Brief of Amici Curiae Applera Corporation and Isis Pharmaceuticals, Inc. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682090; Brief of Amicus Curiae Vaccinex, Inc. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682091; Brief for Invitrogen Corporation et al. as Amici Curiae in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682093.

<sup>59</sup> See Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682088, at \*16 (“[A] statutory construction that reads the word “solely” out of section 271(e)(1) would effectively neuter all research patents issued in the United States .... Such a construction would be inconsistent with the plain language of section 271(e)(1) ... and would violate the intent of Congress that any effect on the rights of patentees resulting from the enactment of section 271(e)(1) be de minimis.”); *id.* at \*17 (“In the event that the safe harbor of section 271(e)(1) is unduly expanded ... [there will be a] whittling away at the value of pharmaceutical research patents until nothing is left.”); *id.* at \*18 (“[T]here [is] no use other than drug research for such [biotechnology] patents. Should the safe harbor of section 271(e)(1) be expanded to include general pharmaceutical research, it is inconceivable that such research patents will have any value left.”). *Accord* Brief for Invitrogen Corporation et al. as Amici Curiae in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682093, at \*3-4 (“If patents on such [research] tools can be readily infringed in the course of developing information for submission to the Food and Drug Administration (FDA), the economic value of the patents will be essentially lost and the incentives crucial to support creation of new and better tools in the future will be slowed, if not completely eliminated.”); *id.* at \*4 (“[T]ool patents would lose essentially all economic value if their infringement is allowed during drug research and development.”); *id.* at \*12-13 (“Without patent protection, capital markets would not invest in innovative small companies with ground-breaking new technology. Instead, the technology would either languish with limited capitalization from federal grants or would be developed and maintained within the confines of well-funded research organizations such as pharmaceutical companies that would have to protect their investment as a trade secret and limit its dissemination. By contrast, the patent system provides a means to encourage investment in innovative new and unproven technologies and, when those technologies prove successful, encourages their wide commercial availability and licensing as a means of recouping that investment.”). *Accord* Brief of Amici Curiae Applera Corporation and Isis Pharmaceuticals, Inc. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682090, at \*6 (“The potential cost of ignoring the term “solely” [in 271(e)(1)] is staggering. The engine for modern drug discovery is the biotech industry. The biotech industry has provided an increasingly rich set of tools that are used for basic research, drug discovery, and drug development. Yet, if Section 271(e) is construed as the drug companies would like, the patents on such tools could be infringed cost-free. The patents protecting those innovations would lose their value and the incentive to create new tools would diminish dramatically.”).

<sup>60</sup> Brief of Amici Curiae Applera Corporation and Isis Pharmaceuticals, Inc. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682090, at \*5 (commentating on the purpose of § 271(e)(1)) (“Although the terms of the statute are not limited to immunizing infringement in the generic drug approval process, the exemption fits that circumstance like a glove. Because a generic drug is a copy of an existing product, there is no drug discovery necessary. What is necessary is to have a generic drug approved by the FDA by the time the patent on the proprietary version of the drug expires. This simply requires immunity from infringement for the development and submission of information to the FDA for regulatory approval to establish the generic copy is what it is supposed to be.”); Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682088, at \*2 (commentating on the purpose of § 271(e)(1)) (“To expand the safe harbor of 35 U.S.C. § 271(e)(1) beyond the limits set forth in the statute’s plain meaning and identified by the court of appeals below would have an adverse effect on the research community as a whole, and the university research community

as the impetus that helped form a virtual consensus amongst leading research institutions and commercial biotechnology producers that any further indelicate judicial manipulation of § 271(e)(1) could produce severe consequences for the industry.<sup>61</sup>

Instead of addressing the real-world concerns voiced in the numerous amicus briefs, the U.S. Supreme Court, instead decided to rely holistically upon a surface level analysis of the basic language found in the statute itself, and very little more.<sup>62</sup> The result is a hugely expanded safe harbor, with little deference given to the underlying industry--leaving many biotechnology patent holders with very little confidence that the high court would enforce their legal rights in the event of further litigation.

### III. A Snap Shot of an Industry

The biotechnology sector is a robust industry that actively contributes to the stability of the American economy while simultaneously producing significant quality-of-life gains for the global population.<sup>63</sup> These gains, however, neither come cheaply nor quickly. On average, it takes \$800 million dollars, over the course of a 10-12 year developmental period, to produce a \*156 new biological compound.<sup>64</sup> Despite

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in particular .... [As a result] there would be a lessened interest within the private sector to support university-related research functions.”); *id.* at \*16 (arguing that the petitioner’s formulation of the statute is substantially overbroad, as virtually any use of a patented agent is, within some capacity, related to the process of FDA approval) (“[A]ny research activity relates, at least in some remote fashion, to the submission of information to the FDA for approval.”); Brief for Invitrogen Corporation et al. as Amici Curiae in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682093, at \*6 (commentating on the purpose of § 271(e)(1)) (“[The elimination of future tools] would substantially frustrate the purpose of Congress to ensure the continued development of new drugs for treatment of human disease. It also would undermine Congress’s intent to minimize the taking of the economic value of patents.”).

<sup>61</sup> See, e.g., Brief of Amici Curiae Wisconsin Alumni Research Foundation et al. in Support of Respondents, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 682088.

<sup>62</sup> See *Merck II*, 545 U.S. 193, 202-07.

<sup>63</sup> Biotechnology products target more than 200 diseases, including “various cancers, Alzheimer’s disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis.” BIO: Biotechnology Industry Organization, Biotechnology Industry Facts, <http://www.bio.org/speeches/pubs/er/statistics.asp>. Furthermore, the biotechnology sector actively contributes to the advent of sophisticated medical diagnosis tests, cleaner industrial processes, better environmental maintenance and cleaning techniques, and enhanced food items. See *id.*

<sup>64</sup> S. Sivakumar, *The Economics of Biotechnology*, REDIFF, Sept. 8, 2003,

<http://www.rediff.com/money/2003/sep/08guest2.htm>. The culmination of all of this it to produce “lower overall medical costs, higher productivity, and increased longevity.” John v. Duca & Mine K. Yücel, *Exploring the Economics of Biotechnology: An Overview*, 2002 FED. RES. BANK DALLAS CONF. ON SCI. & CENTS: EXPLORING ECON. BIOTECHNOLOGY 3, 4, available at <http://www.dallasfed.org/research/pubs/science/intro.pdf>.

The Biotechnology industry also has the potential to stimulate growth in other industries as well; “[Rice University President Malcolm] Gillis noted that the development of

these staggering costs and lengthy developmental periods, only 22% of the compounds that undergo clinical trials ever achieve FDA approval.<sup>65</sup>

The biotechnology sector is large, and at the end of 2003, there were 1,473 biotechnology companies within the United States.<sup>66</sup> Of those 1,473 companies, only 314 were publicly held.<sup>67</sup> In 2003, the American biotech industry generated over \$39 billion dollars in total revenue.<sup>68</sup> In 1992, this revenue sum was only \$8 billion dollars --a revenue increase of some \$31 billion dollars in an eleven year time span.<sup>69</sup> The expansion of the industry has been dramatic. The biotech industry is also an important destination for investors' capital, and as of early 2005, the total value of publicly traded biotech companies equaled \$311 billion dollars.<sup>70</sup> The industry also provides employment for some 200,000 Americans.<sup>71</sup> It is clear that the biotechnology industry remains upwardly mobile at this early stage of its development.

Given the large costs, lengthy periods, and low success rates associated with the development of biologics, biotechnology producers place tremendous importance upon the patentability of a potential technology. In fact, a survey of biotech firms reveals that the possibility for obtaining a patent on a particular item is one of the key considerations affecting \*157 research and development decisions.<sup>72</sup> It is clear that given the requisite investment for biotechnological development, ambiguities in patent protection (thus affecting potential obtainable revenue) will weigh heavily upon the direction of development in the biotechnology sector.

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biotech will help accelerate growth in dozens of other industries, thereby fostering overall economic growth. Biotech innovations are generally the outcome of the interplay of a collection of discoveries in different fields over a long period. In particular, Gillis stressed how biotech progress is propelled by a synthesis of new technologies, not only from the biosciences but also from other sciences, such as information technology and nanotechnology." *Id.*

<sup>65</sup> Sivakumar, *supra* note 64.

<sup>66</sup> BIO: Biotechnology Industry Organization, *supra* note 63.

<sup>67</sup> *Id.*

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

<sup>69</sup> *Id.*

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

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

<sup>72</sup> Duca & Yücel, *supra* note 64, at 6.

Much of what remains profitable in the biotech sector is not found in direct product development, but instead in the development of techniques and tools to be utilized in the research and development process.<sup>73</sup> Traditionally, various forms of licensing agreements have maintained the financial incentive for further development of otherwise unmarketable compounds.<sup>74</sup> Until recently, however, developers have not had reason to doubt the vitality of their patents, and the portion of the market devoted to the creation of biological compounds for use in research & development has remained profitable. In light of recent judicial adjustments however, the patentability of these items has been thrown into stark question.<sup>75</sup> Leaders of the industry have made clear that market incentives must remain stable in order to justify the risk of pursuing further innovation.

#### IV. Good Ideas, IPOs, and Venture Capital

Venture capital plays an important role in buttressing the mainstay of America's biotechnology corporations. Traditionally, biotech firms have sought to procure additional revenue by making an initial public offering ("IPO"). In more recent years, biotechs have seen a shift away from the reliance on initial public offerings for the creation of funds to the incorporation of wealthy venture capitalists.<sup>76</sup> The private, independent investor is generally not \*158 as bullish as the prototypical venture capitalist. Instead, investors are now demanding more than just useful ideas--they want products that are complete and immediately profitable. Research companies still in the R&D stage with only unproven ideas to sell generally obtain low selling prices from their IPOs.<sup>77</sup> To generate the requisite financial resources to continue research, these smaller biotechnology companies with unproven intellectual property have developed a working relationship with risk-savvy venture capitalists. This enables companies with

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<sup>73</sup> *Id.*

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

<sup>75</sup> See *Merck KGaA v. Integra Lifesciences I, Ltd. (Merck II)*, 545 U.S. 193, 205 (2005).

<sup>76</sup> Peter Benesh, *In Tight IPO Market, Cash-Needy Biotechs Weigh Their Options*, INVESTOR'S BUS. DAILY, Nov. 13, 2006, available at <http://www.investors.com/ibdarchives/artshow.asp?atn=248264645905504> (remarking that the number of IPOs in fell from 73 in 2000 to 7 in 2001 and 6 in 2002).

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

unproven IP to procure substantial investment from outside sources while still being involved in the R&D phase of their product. Without access to investment funds from such venture capitalists, it is unclear whether an alternative source of investment would be obtainable in the modern market.<sup>78</sup>

By all accounts, the biotechnology sector's economic vital signs are strong. The industry tends to attract investors and venture capitalists alike during periods of more generalized economic downturn. This is largely due to the fact that investors tend to believe that the technology component of the business isolates it from the susceptibilities that plague the more generalized elements of the American economy.<sup>79</sup> The fact that investors view certain life sciences technologies as essential in terms of their applicability to modern medicine, etc. leads some to believe that they have "little defensive posture" with regards to their investments.<sup>80</sup>

The biotechnology industry itself is still relatively young. Many of the pioneering technologies are only now realizing their full potential. Innovation in this sector is robust, and the technological boundaries of the industry are still expanding. As a result, venture capitalists are lured to the industry by the prospect of large gains from the development of new and \*159 profitable technologies.<sup>81</sup> In a financial world where the bounds are new and relatively unknown, the stream of investment capital is not in short supply. Yet the profitability of whatever new technology that happens to hit the market next rests upon the strength of its patent. If patents are weakened, it is possible that the venture capitalists will go elsewhere<sup>82</sup>

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<sup>78</sup> See *Id.* (suggesting that traditional investors have become too skittish with regards to developing life science technologies and thus biotechs have developed a symbiotic reliance on the venture capitalists who seem more willing to gamble on the risks inherent to any new developing technology).

<sup>79</sup> Donald H. Gold, *Biotech Gains Ground Amid Economic Fears*, INVESTOR'S BUS. DAILY, Oct. 25, 2006, available at <http://www.investors.com/ibdarchives/artshow.asp?atn=246622620210615>.

<sup>80</sup> *Id.*

<sup>81</sup> Peter Benesh, *Health Industry Sees Green In Gray*, INVESTOR'S BUS. DAILY, Jan. 3, 2006, available at <http://www.investors.com/ibdarchives/ArtShow.asp?atn=220961820440440> ("It's a good time to be a venture capitalist seeking biotech inroads," says Nick Galakatos, managing director of newly formed Clarus Ventures. "It's an exciting time to invest in this sector for a variety of scientific as well as market reasons," he said. With the human genome completed, "science is expanding our knowledge of the molecular basis for disease, and that gives us new mechanisms for targeting disease."").

<sup>82</sup> It is acknowledged that the economic forces that dictate the flow of venture capital to various markets are complex. One could point to any number of current economic predictors and declare that the biotechnology industry is currently as robust and as healthy as it has ever been. Though the economic signs generally show this to be true, the idea that a healthy industry such as America's biotech can withstand any degree of judicial tampering without

## V. Biologic Generics

Traditionally, generics only existed within the realm of the pharmaceutical compound. Pharmaceuticals, with their defined and illustrated chemical structures and formulas, were readily amenable to reproduction by generic manufacturers once the patent term of the principal expired. Now, mainly due to advances in technology within the biotech sector, generics of biologics are beginning to make their way to market prior to the expiration of their patented counterparts.<sup>83</sup> With the advent of these generics, there has been confusion at the Food and Drug Administration (“FDA”).<sup>84</sup> The FDA is unsure how to classify competing generics, mainly **\*160** because biological drugs are composed of proteins, which, when placed in a complex biological system such as a human body, can have a broad range of effects. These results lie in contrast to those produced by the more predictable chemical compounds found in pharmaceuticals. As a result of the confusion created by the complexity inherent to biological drugs, the fate of generic biologics has been uncertain.<sup>85</sup>

Senator Waxman, D-Calif., the co-author of the § 271(e)(1) provision that created the original safe harbor for pharmaceutical generics, recently took notice of the problem facing biologic generics. He expressed concern that the ambiguity surrounding the nature of biologics was hindering the development and production of reasonable generic substitutes.<sup>86</sup> As a result, Waxman, operating in conjunction with

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experiencing some sort of significant consequence is fictitious. It is too early in the process to say whether or not *Merck* has already had a negative effect upon the industry--the court itself declared that it was not yet in a position to comment upon the applicability of § 271(e)(1)'s safe harbor to research tools--and not much time has passed since the decision. Still, it almost goes without saying that the strength of the American patent as pioneered by Thomas Jefferson has been the mainstay from which the United States has derived its status as a chief innovator amongst the world's powers. The significance of the patent system cannot be overlooked or underestimated, even in light of robust economic figures as presented by the biotechnology industry. Without secure and predictable patents, it is unclear that venture capitalists will continue to find “safe harbor” in the biotech industry.

<sup>83</sup> The term “biologics” is defined as “commercial products derived from biotechnology.” See Dictionary.com, Biologics Definition, <http://dictionary.reference.com/search?r=2&q=Biologics>.

<sup>84</sup> Peter Benesh, *Generic Threat Puts Biologic Firms on the Defensive*, INVESTOR'S BUS. DAILY, Oct. 16, 2006, available at <http://www.investors.com/ibdarchives/ArtShow.asp?atn=245844266106805> (pointing out that the confusion arises due to the “FDA’s inability to determine whether a biological drug is identical in all respects to the original drug.”) (“‘Biological molecules are more complex (than chemical-based drugs),’ said Joseph Reisman, a biotech attorney ... ‘They can react differently with cells and receptors on cells. Their presence in the bloodstream can’t be tracked in any linear way to their efficacy.’”).

<sup>85</sup> See *id.*

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

Senators Hillary Clinton and Charles Schumer, introduced a bill to update the existing law so that the FDA would be permitted to approve generic biologics without being mired in the current state of ambiguity and confusion.<sup>87</sup> In a recent statement, Waxman declared that,

“[g]eneric versions of brand-name drugs have long been an essential way for patients to get the medicine they need at a price they can afford .... [t]his bill will use competition to make biological drugs - which are often prohibitively expensive - available to those who suffer from diseases like cancer, diabetes and AIDS.”<sup>88</sup>

\***161** If the bill is successful, generic versions of biological commercial products will pass through the FDA approval process more quickly--thus allowing the consumer to purchase biologics at a price bred from market competition.

#### *A. Biologic Generics and § 271(e)(1)*

The advent of biologic generics is not something new. Since December of 2005, the European Medicines Agency (“EMA”) has been establishing guidelines by which a biologic generic may win approval in the European system.<sup>89</sup> Though the European system is new, it is possible to now move ahead as a

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<sup>87</sup> To amend the Public Health Service Act to provide for the licensing of comparable and interchangeable biological products, and for other purposes of 2007, H.R. 1038, 110th Cong. (2007) (proposed act) (previously the Access to Life-Saving Medicine Act of 2006, H.R. 6257, 109th Cong. (2006)). The problem arises from the fact that even small changes within the protein structure of a “biosimilar” product can enact fairly tremendous changes regarding the operation of the compound within the body. Given that seemingly-negligible changes can produce far from negligible results, the FDA has thus far been generally unwilling to view biosimilar compounds as generics of a preexisting compound. This distinction lies in stark contrast with what is seen in the pharmaceutical arena, where the predictable nature of near-identical chemical compounds has led to a fluid approval process.

<sup>88</sup> Benesh, *supra* note 84. This statement is particularly important as it sheds light on what Sen. Waxman intended when he initiated the enactment of the 1984 bill that created the safe harbor for generic pharmaceuticals. *Id.* This modern incantation of the legislative history surrounding the creation of § 271(e)(1) shows an unequivocal intent to create a regulatory pathway from which generic biologics may be placed on the market (after the patent term has expired, of course) so that the burdensome costs of current biologics may be lowered by competition. *Id.* Waxman’s statements do not aim to create a nebulous safe harbor by which one biotechnology company may utilize the patented technologies of another as long as there is some sort of drawn-out relation to the common law research defense doctrine. Instead, the language specifies a desire to allow generics to enter the market as soon as possible. Senator Clinton, fellow advocate for the current bill, declared in a statement that “[t]his bill comes in response to years of recognition of the need for a new statutory pathway for approval of generic versions of biotech drugs. These products are not subject to the 1984 law that first authorized FDA to approve generic drugs.” Press Release from Senator Hillary Rodham Clinton, Waxman, Schumer, Clinton Introduce “Access to Life-Saving Medicines Act” (Sept. 29, 2006), <http://clinton.senate.gov/news/statements/details.cfm?id=264152>. Not only does this statement make direct reference to the 1984 provision, but it expressly declares that § 271(e)(1) does not apply to biologics. In light of the Supreme Court’s recent findings in *Merck II*, this statement seems to be somewhat inconsistent with the Court’s view on the matter.

<sup>89</sup> Sarah Houlton, *Global Report: Moving Towards Generic Biologics: EMA opens the door a crack. Generic biologics push for minimal testing*, PHARMACEUTICAL EXECUTIVE MAG., Feb. 1, 2006, available at <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=301751>.

producer of biologic generics in the European arena.<sup>90</sup> This regulatory framework, as crafted by the EMEA, gives Europe a huge advantage in the biosimilar products industry.<sup>91</sup> Several important biologics have already seen generic analogues win approval under the European system, and the developmental capital required for the production of such generics has been forthcoming. This change, when finally enacted by the United States, will undoubtedly alter the commercial scenery faced by the American Biotechnology Corporation.

When the change does occur, monopolies that once existed on patent-expired biologics will cease to exist, as the market incentive to enter competition with a grossly overpriced biologic will be high. From the standpoint of the American consumer, this is an advantageous **\*162** result. Correspondingly, it spells difficulty ahead for the biotechnology sector. The industry will undoubtedly change to adjust for the new economic conditions, and though it will easily survive the shift, the reality is that the biotech industry will not be quite as profitable for developers as it once was.<sup>92</sup>

Senator Waxman has recently again stepped forward in the name of securing the rights of generic producers against developers after patent term expiration. In doing so now, as he did previously in 1984, Senator Waxman is again making express reference to the need for generic substitutes to be on the market. As made clear in his statement regarding this issue, his concern lies with securing a quick and predictable mechanism for winning FDA approval of generic biologics. This concern, and the overriding topic of generics generally, does not necessitate the creation of a broad-range safe harbor by which any use of a patented item, no matter how attenuated to the FDA approval process (if even at all, see *AbTox*),

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<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> This is not a bad result, and patent law dictates that the advent of generic biologics is completely permissible upon the expiration of the patent term. Instead, the point is to show that the industry isn't as financially stable as the general perception seems to have it. Generally speaking, when a court is confronted with a question of interpretation, it is sufficient to rely upon the wording of the statute for clarification. In this instance, however, the industry behind the statute is a highly specialized and delicate one, and thus requires a higher degree of economic cognizance than what the current court would give it. It seems insufficient to rely on a short series of relatively imprecise words to craft the bounds of a safe harbor that implicates a finely-balanced high-tech industry when other more reliable considerations are available (such as the foundational principles of patent law or the legislative history behind the enactment of § 271(e)(1) or the recent statements from Senator Waxman, etc.). In other words, there seems to be a disconnect between the current jurisprudence as it relates to the biotechnology sector and the underlying realities of the industry itself.

may be legally justified as somehow relating to research and development.<sup>93</sup> The legislative mandate for such a provision simply does not exist: it cannot be found in the legislative history behind the creation of § 271(e)(1); it cannot be justified by the need to enforce the safe harbor provision as it applies to the production of pharma-generics; it is not present in the current (and overridingly similar) language now coming again from Senator Waxman; it is not even mandated by the hypothetical \*163 needs of an apparent-generic biologics producer should the bill pass.<sup>94</sup> Simply stated, the mandate for the expansion of the § 271(e)(1) safe harbor to uses not related to the production of generic pharmaceuticals upon patent expiration cannot, in any tangible form outside of the hazy language of the statute itself, be found in any meaningful capacity.

#### **VI. Competing Ideologies in Statutory Interpretation of § 271(e)(1): The Arguments Revisited**

Justice Scalia, writing for a unanimous Supreme Court in the *Merck II* decision, relies on established principles of statutory interpretation.<sup>95</sup> Though helpful, these canons of statutory interpretation are to be used as suggestive guideposts, and the Supreme Court itself has declared that they are not mandatory.<sup>96</sup> Regardless, the Court, in its *Eli Lilly* decision, decided that the phrase “patented invention” found in the language of § 271(e)(1) more appropriately applied to all inventions generally, and was not limited to drug-related inventions alone.<sup>97</sup> The opinion did not include a discussion of either policy or legislative intent. Instead, the Court relied wholly on the absence of a modifier in a short statutory provision to

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<sup>93</sup> *AbTox Inc. v. Exitron Corp.* 122 F.3d 1019 (Fed. Cir. 1997).

<sup>94</sup> The potential counter argument that, “if they had really intended that result, they would have made the statute more clear” fails to acknowledge the pitfalls inherent to statutory interpretation. Only very rarely does the legislature succeed at crafting a statute that, on its face, is capable of only one reasonable interpretation. § 271(e)(1) simply cannot be seen as one of those statutes. It is insufficient to rely upon the superficial wording of a very short statute to take broad judicial strokes aimed at expanding a safe harbor provision beyond that was clearly *intended* by the legislature (as evidenced by the House Committee Report). It is not abnormal for the court to rely upon legislative intent in discerning the meaning from confusing or unclear statutes--why the court unanimously decided against doing so here is unclear, and serves an injustice not only upon the underlying industry, but also patent law generally.

<sup>95</sup> See *Merck KGaA v. Integra Lifesciences I, Ltd. (Merck II)*, 545 U.S. 193 (2005).

<sup>96</sup> See *Chickasaw Nation v. United States*, 534 U.S. 84, 91 (2001) (declaring, *inter alia*, that the normal rules of statutory interpretation are guideposts--not mandatory rules to which a court must adhere. The Court also remarked that the legislative intent is also important with regards to fashioning the meaning of a statute).

<sup>97</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990).

buttress a decision with far-ranging ramifications.<sup>98</sup>

15 years later in the *Merck II* decision, the Court took a further step toward expansion, applying the safe harbor provision to “all uses of patented inventions that are reasonably related \*164 to the ... submission of any information under the FDCA.”<sup>99</sup> In order to justify this interpretation, the Court, in a short opinion, seems to rely on its own clout for substantiation.<sup>100</sup> The opinion broadly proclaims that “we think it apparent from the statutory text that § 271(e)(1) exemption infringement extends to all uses” and that “[t]here is simply no room in the statute for excluding certain information from the exemption.”<sup>101</sup> These arguments, admittedly, are not without their merit. As a collective matter, they rely upon a strict judicial tradition that requires a court, when dealing with an unambiguous statute, to interpret it in accordance with the predictable meaning of the offered text. Justice Scalia, who states that “the statutory text makes clear that it provides a wide berth,” is undoubtedly adhering to such doctrine.<sup>102</sup> But the reliance on this formalistic doctrine in the present case is misguided, especially when viewed in light of the overriding goals of patent law and corresponding legislative history shadowing the formulation of § 271(e)(1).

The Federal Circuit’s opinion in *Merck I* represents the functional counterpoint to the Supreme Court’s application of traditional methods of statutory interpretation in the realm of patent law. Judge Rader’s chief argument that § 271(e)(1) was intended to pertain only to the production of generic pharmaceuticals finds its strongest anchor in the unambiguous language of the House Committee Report. This report declares, for reasons presumably related to clarification, that § 271(e)(1) pertains to “a limited amount of testing so that generic manufacturers can establish the bio equivalency of a generic substitute.”<sup>103</sup> This language is more or less unequivocal in its meaning--it says, in terms that cannot be

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<sup>98</sup> *Id.*

<sup>99</sup> *Merck II*, 545 U.S. at 201.

<sup>100</sup> *See Id.*

<sup>101</sup> *Id.*

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

<sup>103</sup> H.R. REP. NO. 857, at 8 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2692.

confused, that the safe harbor guaranteed by § 271(e)(1) applies to the producers of generic pharmaceuticals--and \*165 nothing more. Judge Rader's discussions of patent law and similarly situated constituent decisions are all grounded in this statement of legislative intent. The judicial divide is clear. On the one hand, there is a unanimous Supreme Court relying upon traditional mechanisms of statutory interpretation, and on the other a specialized expert court relying upon the fundamental norms of patent law and the unmistakable declaration of legislative intent.

#### *A. A Correct Interpretation?*

As an initial matter, the Supreme Court is right. The Supreme Court, by virtue of being the highest court in the land, is the controlling law until it reverses itself. Yet the Supreme Court was also right when it spent a good deal of the twentieth century handing down antitrust decisions, usually to the chagrin of advising economists, that were predicated solely upon traditional judicial canons.<sup>104</sup> Only later, after much damage, was credence given to controlling market place considerations by the judiciary.<sup>105</sup> The Court's history indicates that when presented with dualistic breeds of law (antitrust and patent, specifically) it seems apt to over-rely on judicial constructions when the nature of the issue calls for a broader point of view.<sup>106</sup> Judicially right and functionally right, therefore, are not always mutually inclusive concepts.

It is thus clear what the two sides of this coin amount to: on the one hand, there is the unanimous Supreme Court choosing to rely upon the straightforward yet simplistic language of the statute itself, and on the other, a specialized court relying, inter alia, upon considerations such as legislative intent, patent law norms, and, at least presumably, the needs of the scientist. It is \*166 foundationally true that without

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<sup>104</sup> See, e.g., U.S. v. Topco Associates, Inc. 405 U.S. 596, 608 (1972)(applying the per se rule to invalidate a pro-competitive practice).

<sup>105</sup> See Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 52-56 (1977) (holding that geographic restrictions are not per se illegal, relying upon economics literature to formulate the economic efficiency rationale); See State Oil Co. v. Khan, 522 U.S. 3, 15 (1997) (holding that vertical maximum price fixing is not per se illegal, relying upon economic writings in reconsidering their precedents).

<sup>106</sup> Dualistic in the sense that antitrust and patent law both represent a combination of skill sets: for antitrust, the blending of economics and the law; for patent law, the blending of biology, chemistry, engineering, computer science, etc. with the law.

an innovator there cannot be innovation. Dr. Uwe Munster of Bayer Healthcare Pharmaceuticals believes that “[a] patent means that an idea or any matter that results from a certain idea is the property of the person who had the idea.”<sup>107</sup> This is a notion that is firmly anchored in the scientific community. Without such protection, the incentive to disclose inventions to the public at large decreases. Such inventions do not come easily, and generally speaking, a significant upfront financial investment is required. There must exist in the minds of the scientific community at large a notion that their ideas will be protected by the patent laws that presume to protect them.

Recent judicial expansion of § 271(e)(1) by the Supreme Court does little to reassure them. It is now plausible that ideas are being suppressed out of fear that they may be taken without traditional compensation under the expanded scope of the new safe harbor. Certainly, in an industry as fundamental to basic human wants as that of the biotechnology sector, the consumers’ interests are inexorably tied to those of the scientist. Without the continued innovation of potentially life-saving biological technology, the consumer loses out no matter what form the corresponding legal paradigm might take. With such a vital and complex sector as the backdrop to the *Merck II* litigation, it is difficult to believe that the Supreme Court’s text-based formulation of § 271(e)(1) rises to challenges inherent to the industry.

### *B. The Future of the Safe Harbor*

\*167 With the aforementioned issues already decided, the focus now lies on the issue of research tools. In light of the Court’s decisions thus far, it seems appropriate to assume that the Court will once again rely upon the vague language of § 271(e)(1) to apply the safe harbor provision of the statute to the research tools developed by biotechnology companies. For the many reasons that have been espoused,

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<sup>107</sup> Interview with Dr. Uwe Munster, Laboratory Head of Analytical Development, Bayer-Schering Pharma, in Wuppertal, Germany. Dr. Munster went on further to say that, “Given that inventions are usually achieved by the scientist’s drive to improve the quality of life for mankind in sectors such as those of healthcare, energy, transportation, material science, and the like, it is of high importance that an invention receives patent protection. In order to let society fully participate in the advantages of an invention, large sums of investment capital need to be first obtained before that invention can potentially be made available to billions of people (as there are costs relating to production facilities, marketing, infrastructure, stores, etc.). Of course, no company would produce these inventions if there were no assurances that the money invested would one day return by sales of the product.”

this simply cannot be the result. The Supreme Court must adhere to some semblance of patent law norms and draw the line in the sand somewhere. Without a clearly defined boundary, the ambiguity and concern will only mount. The ultimate effect will be the suppression of technologies until legal conditions become more favorable. It is true that biotechnology firms could adjust--technology could be incorporated into a machine thus gaining additional patent protection, or contracts could be formed specifying the release of a technology to a customer predicated upon a secrecy order--such routes would ensure the survival of the industry.

But are such changes advantageous? As discussed previously, the biotechnology sector is as robust now, economically, as it ever has been. Investors and venture capitalists alike favor the industry during periods of economic downturn due to the relative fiscal buoyancy of the technology component. As the venture capitalists go, the innovators and, correspondingly, the consumers go. Without concrete patentability, both investors and the venture capitalists alike head towards markets with more favorable and predictable controlling variables. If they leave, the supply of capital dries, and the rate of innovation correspondingly slows.

It is not unreasonable to impute decent intentions to the Supreme Court with their formulation of § 271(e)(1). It at once appears logical that an immediate reduction in the development costs for big pharmaceutical companies permanently equates to cheaper drugs for consumers. But the issue is not so simple. Judge Rader, writing for an expert court and relying \*168 upon the language of a well-informed legislature, highlights some of the more important complexities, and they are hard to ignore. As the safe harbor grows larger, investors naturally become more skittish, scientists lock down their current innovations, and the industry circles its wagons until conditions become more favorable. This is a result that is clearly not inline with the Court's controlling intent.

### **Conclusion**

The solution to the current problem could take several forms. The legislature could intervene and

redefine the ambiguous terms of § 271(e)(1), thus sparing the Supreme Court the difficulty of defining rules for an esoteric brand of law with complex financial underpinnings. Conversely, more attention could be paid to the expertise of the Court of Appeals for the Federal Circuit. Whatever the remedy, it is imperative that the scope of the safe harbor is not extended to include research tools. Such a move would represent a dangerous and somewhat unprecedented action against the traditional sanctity of the American patent. Given both the unpredictability of the resulting fallout, whatever shape or form it might take, and the inherent importance of the industry to the American consumer, the decision that inevitably touches on the issue of research tools must be one, with all relevant considerations in mind, that shows the appropriate measure of judicial restraint.