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## Sparse Patent Protection for Research Tools: Expansion of the Safe Harbor Has Changed the Rules

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# **SPARSE PATENT PROTECTION FOR RESEARCH TOOLS: EXPANSION OF THE SAFE HARBOR HAS CHANGED THE RULES**

## **ABSTRACT**

*The protection provided by patent rights benefits society by encouraging inventors to disclose their inventions, but these same rights can be wielded against competitors through infringement suits, causing a chilling effect on later innovation. In the field of pharmaceutical innovation, the Hatch-Waxman Act's safe harbor has provided a defense against infringement, allowing generic manufacturers to quickly bring low-cost drugs to the public while trespassing minimally on the patent holder's rights. The Act's delicate balance of benefits and burdens has been threatened by recent judicial interpretations of the provision's scope. The scope of the safe harbor has been expanded to the point that it reduces the value of patent protection for laboratory tools and methods, and in turn threatens the patent system's role in encouraging innovation in these areas.*

*This Comment proposes limits to the safe harbor's scope by (1) specifying the types of inventions that are subject to the safe harbor and (2) permitting those patents to be infringed only until FDA approval has been granted. This proposed scope is supported by the legislative history, which referred extensively to the FDA approval process and repeatedly assured drug manufacturers that the purpose of the safe harbor was to reduce delays caused by the FDA approval process. In addition, this scope comports with the broader themes of patent law in that it promotes certainty in the law and provides parties with notice of their rights. However, because the language used in the safe harbor provision is expansive, textualist interpretations of the provision alone tend to worsen rather than solve the problem. For this reason, this Comment advocates legislative action to produce limits on the scope of the safe harbor that will protect and encourage innovation while promoting early access to generic drugs.*

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## INTRODUCTION

Inventors with groundbreaking ideas have the capacity to change the way society operates—even improve others’ quality of life—simply by sharing these ideas with the public. When the idea has been shared, however, nothing prevents the public from using the idea without compensating the inventor absent some law to the contrary. Inventors will not have an incentive to disclose their inventions to the public if they cannot expect to receive anything in return for their work. The framers of the U.S. Constitution understood this quandary and granted Congress the power to issue exclusive rights to inventors to practice their inventions “[t]o promote the Progress of . . . useful Arts.”<sup>1</sup> Congress defined the exclusive patent rights broadly in the Patent Act of 1952, securing for the inventor the exclusive rights to use, make, sell, or offer to sell the patented invention.<sup>2</sup> These exclusive rights create a form of monopoly power, which allows an inventor to recoup the cost of innovation and incentivizes further invention and research by the inventor and others. Certain areas of innovation, such as pharmaceutical development, rely heavily on patent protection due to the high cost of research. In addition, pharmaceutical products are regulated by the Food and Drug Administration (FDA), which must approve all drugs before they can be sold to the public. Because the FDA approval process for drugs requires clinical testing, the approval process for a generic version of a drug involves “making” and “using” the drug. If the drug is still covered by a patent, then these acts are infringing acts<sup>3</sup>: the generic manufacturer simply cannot begin seeking FDA approval until the patent expires.

This overlapping federal regulation in the area of pharmaceutical products provided layers of monopoly protection for the holders of drug patents, to the detriment of consumers. In 1984, Congress created a statutory experimental use exception to patent infringement—the Hatch-Waxman “safe harbor”<sup>4</sup>—to expedite the entry of generic drugs into the market. This exception involved a delicate balancing of interests between patent owners and generic manufacturers and made it possible for generic drugs to begin the FDA approval process before the patents on the drugs expired. The safe harbor

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<sup>1</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>2</sup> 35 U.S.C. § 271(a) (2006) (creating an action for infringement against parties who “make[], use[], offer[] to sell, or sell[]” the patented invention).

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

<sup>4</sup> Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (current version at 35 U.S.C. § 271(e)(1)).

created an exception to infringement permitting anyone to use a patented invention, so long as the purpose of that use was related to submission of information to the FDA.<sup>5</sup> The scope of the safe harbor was long understood to mean that *patented drugs and medical devices* could be used and experimented with for purposes of *seeking FDA approval*,<sup>6</sup> but that scope has been expanded by the courts.

With its recent holding in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*,<sup>7</sup> the Court of Appeals for the Federal Circuit has expanded the scope of the safe harbor exception such that it now covers far more than just drugs for which FDA approval is being sought.<sup>8</sup> The safe harbor now covers all uses of every sort of patented invention, and exempts these uses from infringement suits so long as the use is related to information *that could ever be requested* by the FDA.<sup>9</sup> This expansion decreases the protection available to patents on drug-related inventions, such as laboratory tools and manufacturing methods (collectively, “research tools”), and consequently reduces the inventor’s incentive to disclose these inventions through seeking patent protection.<sup>10</sup> This Comment argues that the scope of the Hatch-Waxman safe harbor should be limited to cover only (1) patents on inventions regulated by the FDA<sup>11</sup> and (2) infringing actions leading up to FDA approval.<sup>12</sup> The first limitation is needed because allowing the safe harbor to cover the use of research tools for their ordinary purpose creates the very distortion the safe harbor was designed to correct. The second limitation is necessary to prevent too great a reduction of patentees’ rights. Part I of this Comment examines the factors Congress considered when enacting the safe harbor exception, and how the courts have interpreted the provision. Part II formulates a revised scope of the safe harbor by balancing congressional intent with interpretation of the text of the safe harbor and overarching policy concerns unique to patent

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<sup>5</sup> See 35 U.S.C. § 271(e)(1).

<sup>6</sup> See, e.g., *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

<sup>7</sup> 686 F.3d 1348 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 2854 (2013).

<sup>8</sup> Applying the Federal Circuit’s interpretation of the safe harbor exception from *Momenta*, the safe harbor could cover the construction and launch of a patented satellite, if the satellite is used to submit information to the FDA.

<sup>9</sup> *Momenta*, 686 F.3d at 1359.

<sup>10</sup> The quid pro quo of patent protection is disclosure of the invention to the public. Allowing the safe harbor to cover research tools will decrease inventors’ reliance on patent protection for these inventions, which are typically used only in the laboratory and thus amenable to trade secret protection.

<sup>11</sup> Specifically, the safe harbor should cover only those inventions for which the Hatch-Waxman Act granted patent term extensions. See 35 U.S.C. § 156 (2006 & Supp. V 2011).

<sup>12</sup> This limitation comports with Justice Scalia’s view in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206–07 (2005) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 674 (1990)).

jurisprudence. Finally, Part III of this Comment addresses the viability of this revised scope and possible pathways for its induction into law.

## I. HOW THE HATCH-WAXMAN SAFE HARBOR EXCEPTION DEVOLVED INTO THE RULE

The safe harbor provision of the Hatch-Waxman Act began as the keystone of a delicate congressional compromise but has since been expanded through judicial interpretation into a one-size-fits-all defense to infringement in pharmaceutical patent litigation.<sup>13</sup> Because the safe harbor involves the highly lucrative field of pharmaceutical products, the scope of the safe harbor has been the subject of intense litigation. This Part first illustrates the factors that influenced Congress's deliberations regarding the Hatch-Waxman Act, then discusses the relevant interpretations of the Act by the courts, and concludes by analyzing the split of authority at the Court of Appeals for the Federal Circuit. But before considering the scope of the Hatch-Waxman Act, it is important to understand the factors that contributed to its passage.

### A. *Factors That Influenced Congress to Enact the Hatch-Waxman Act*

Congress's power to promote inventive activity is granted by the Constitution.<sup>14</sup> All of patent law hinges on this grant, and Congress has chosen to exercise its power to both establish statutory regimes that protect inventions and to update those statutes over time.<sup>15</sup> Due to the high costs associated with research and development, the pharmaceutical industry relies heavily on patent protection and the limited monopoly it provides as a method of securing a return on investment.<sup>16</sup> Pharmaceutical products are also subject to strict federal regulation by the FDA. These regulations and the protection provided by patent law affected the market for pharmaceutical products in a unique way.

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<sup>13</sup> For cases interpreting the safe harbor provision, see, for example, *Eli Lilly*, 496 U.S. 661; *Momenta*, 686 F.3d 1348; and *Classen Immunotherapies, Inc., v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011), *cert. denied*, 133 S. Ct. 973 (2013).

<sup>14</sup> U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

<sup>15</sup> See, e.g., *Leahy-Smith America Invents Act*, Pub. L. No. 112-29, sec. 3(b)(1), § 102, 125 Stat. 284, 285 (2011) (amending 35 U.S.C. § 102).

<sup>16</sup> In 2011, the pharmaceutical industry watched as patents expired on blockbuster drugs, leading to a loss of monopoly profits close to \$50 billion per year. See Duff Wilson, *Patent Woes Threatening Drug Firms*, N.Y. TIMES, Mar. 7, 2011, at A1, available at <http://www.nytimes.com/2011/03/07/business/07drug.html>.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in response to two inequities caused by overlapping FDA and Patent and Trademark Office regulations on drugs.<sup>17</sup> The first inequity addressed by the Hatch-Waxman Act was that drug patents were mostly worthless for a portion of the patent term—until the FDA approves a drug, it cannot be sold to the public.<sup>18</sup> Any time between the patent issuing and FDA approval was time lost to the patentee. The Hatch-Waxman Act solved this issue by creating an extension of patent terms for time lost during regulatory approval.<sup>19</sup>

The second inequity the Hatch-Waxman Act addressed was a prolongation of protection for patented drugs.<sup>20</sup> Because the Patent Act gave patentees the right to stop others from making or using the patented invention,<sup>21</sup> a generic drug manufacturer would have to wait for the patent to expire before beginning to seek FDA approval. The period of time between the patent's expiration and FDA approval effectively extended the patent monopoly. Consequently, this delay in the release of generic drugs also resulted in higher prices charged for patented drugs.<sup>22</sup> Because the testing done for FDA approval is similar to basic scientific research, it could be argued that this laboratory use should be classified as "experimental use" under the common law, which permits uses that are "philosophical" in nature rather than commercial.<sup>23</sup> However, while Congress was debating the Hatch-Waxman Act, the Federal Circuit held in

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<sup>17</sup> See Hatch-Waxman Act, Pub. L. No. 98-417, §§ 201–202, 98 Stat. 1585, 1598–1603 (1984) (current version at 35 U.S.C. §§ 156, 271(e) (2006 & Supp. V 2011)) (extending patent terms for inventors and permitting the experimental use exception for generic producers).

<sup>18</sup> 21 U.S.C. § 355(a) (2012).

<sup>19</sup> 35 U.S.C. § 156.

<sup>20</sup> *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before the S. Comm. on Labor & Human Res.*, 98th Cong. 1 (1984) [hereinafter *Senate Hearing*] (statement of Sen. Orrin Hatch, Chairman, S. Comm. on Labor & Human Res.) (“[O]ur people are paying too much for drugs whose patents have expired.”).

<sup>21</sup> See 35 U.S.C. § 271(a) (defining infringement).

<sup>22</sup> This is not to say that higher prices are not the just reward for the hard labor and costs involved in bringing a new drug to market, rather, that the public has paid the price long enough to compensate the inventor for his investment. See *Senate Hearing*, *supra* note 20, at 54 (statement of William F. Haddad, President & CEO, Generic Pharmaceutical Industry Association) (noting the availability of a generic alternative for metronidazole cut the price of a dose by more than half, saving the Department of Defense \$1.1 million in one year (in 1983 U.S. dollars)).

<sup>23</sup> See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (“[U]nlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention.”), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified at 35 U.S.C. § 271(e)(1)), *as recognized in* *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 977 F.2d 558 (Fed. Cir. 1992).

*Roche Products, Inc. v. Bolar Pharmaceutical Co.* that the common law experimental use exception did not apply to research done in the course of seeking FDA approval.<sup>24</sup> Congress implicitly overruled the Federal Circuit by creating its own exception to patent infringement in the Hatch-Waxman Act: “It shall not be an act of infringement to make, use, offer to sell, or sell . . . 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 . . . .”<sup>25</sup> In addition, the Hatch-Waxman Act created an artificial form of infringement—triggered by submitting an Abbreviated New Drug Application (ANDA) to the FDA—with limited remedies for the patentee, to speed the entry of generics into the market.<sup>26</sup> The language of this statute, however, is not a model of clarity.<sup>27</sup> As a result, the courts have been burdened with interpreting and clarifying the meaning and scope of this provision.

### B. Textualist Interpretations of the Safe Harbor by the Supreme Court

Section 202 of the Hatch-Waxman Act, also known as the safe harbor provision, contains several unclear phrases that have been the source of intense litigation.<sup>28</sup> In the Supreme Court’s first consideration of the safe harbor provision in *Eli Lilly & Co. v. Medtronic, Inc.*, it addressed the question of whether medical devices are included within the definition of “drugs” for the purposes of the safe harbor exception.<sup>29</sup> Although medical devices are not “drugs” (i.e., pharmaceutical products), Justice Scalia pointed to section 201 of the Act, which gives patent term extensions to both medical devices and pharmaceuticals.<sup>30</sup> Justice Scalia analyzed the Hatch-Waxman Act as a whole, and although medical devices are not listed in section 202, he found that limiting the safe harbor to only drugs would cause an imbalance in the

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<sup>24</sup> See *id.*

<sup>25</sup> 35 U.S.C. § 271(e)(1). Congress recognized it was overturning the Federal Circuit’s holding in *Roche* with this legislation. See H.R. REP. NO. 98-857, pt. 2, at 60 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2719–21, 1984 WL 37417.

<sup>26</sup> See 35 U.S.C. §§ 271(e)(2)–(4) (2006 & Supp. V 2011).

<sup>27</sup> Justice Scalia pronounced the text of the safe harbor provision “not plainly comprehensible.” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990).

<sup>28</sup> See, e.g., *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206–07 (2005) (interpreting the phrase “reasonably related”); *Eli Lilly*, 496 U.S. at 665–66 (considering which “Federal law” is included in the exemption).

<sup>29</sup> See *Eli Lilly*, 496 U.S. at 669–74.

<sup>30</sup> *Id.* at 670–71 (citing 35 U.S.C. § 156(f)).

regulatory scheme.<sup>31</sup> To counter this imbalance, the Court held all of the inventions granted patent term extensions in section 201 were covered by the safe harbor because they are all regulated by the same federal law.<sup>32</sup> By broadening the scope of the safe harbor, the Court maintained the “structural” integrity of the statute.<sup>33</sup>

Fifteen years later, the Court again interpreted the safe harbor provision to determine if the accused infringer must actually submit information to the FDA to receive protection under the safe harbor.<sup>34</sup> The patented compound in *Merck KGaA v. Integra Lifesciences I, Ltd.* was studied as a potential cancer therapy drug, and the accused infringer, Merck, kept records of its preclinical experiments.<sup>35</sup> Merck decided to file for FDA approval several months after the infringement suit was filed.<sup>36</sup> Justice Scalia considered the implications of requiring a researcher to predict whether a drug would work prior to conducting preclinical trials.<sup>37</sup> Justice Scalia also noted that “[b]asic scientific research” with no eye toward developing a particular drug does not qualify as “‘reasonably related to the development and submission of information’ to the FDA.”<sup>38</sup> Balancing these concerns, the Court held that the safe harbor should cover research related to drug development, even when no FDA approval has been sought:

Congress did not limit § 271(e)(1)’s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug. Rather, it exempted from infringement *all* uses of patented compounds “reasonably related” to the process of developing information for submission under *any*

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<sup>31</sup> See *id.* at 669–74.

<sup>32</sup> See *id.*

<sup>33</sup> Justice Scalia did not consider the “purpose” to be served by the statute, but his decision protected that as well. See *id.* at 673–74 (noting the “perfect ‘product’ fit between the two sections” of the Hatch-Waxman Act).

<sup>34</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

<sup>35</sup> *Id.* at 198–200.

<sup>36</sup> *Id.* at 199–200.

<sup>37</sup> See *id.* at 206 (“One can know at the outset that a particular compound will be the subject of an eventual application the FDA *only if* the active ingredient in the drug being tested is identical to that in a drug that has already been approved.” (emphasis added)).

<sup>38</sup> *Id.* at 205–06. It is also important to note that Congress considered the phrase “directly related,” but the final bill contained “reasonably related,” implying Congress intended a broader scope. See H.R. REP. NO. 98-857, pt. 2, at 60 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2720, 1984 WL 37417.

federal law regulating the manufacture, use, or distribution of drugs.<sup>39</sup>

The Court further articulated that the standard for measuring whether an infringer's actions were "reasonably related" enough to trigger section 202 is based on the infringer's reasonable belief:

At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law."<sup>40</sup>

Thus, the applicability of the safe harbor exception is predicated on a reasonableness standard.<sup>41</sup> Justice Scalia noted the unresolved question of whether the safe harbor applies to "research tools"—inventions primarily designed for use in a laboratory setting—but refrained from addressing the question directly.<sup>42</sup>

### C. Early Federal Circuit Interpretation of the Safe Harbor

The Federal Circuit has also been active in interpreting the Hatch-Waxman safe harbor. The Federal Circuit is an "expert court" and serves as the appellate court for all patent-related cases, and its holdings have an immediate impact on federal district courts across the nation.<sup>43</sup> Relying on the Supreme Court's reasoning in *Eli Lilly*, it has extended the safe harbor to all medical products, even those not granted patent term extensions.<sup>44</sup> This broadening was necessary to avoid inconsistency: if "Federal law" means an entire regulatory

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<sup>39</sup> *Merck*, 545 U.S. at 206 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 674 (1990)).

<sup>40</sup> *Id.* at 207 (omission in original) (quoting 35 U.S.C. § 271(e)(1) (2006)).

<sup>41</sup> It is unsurprising that an exception to infringement would operate unlike the infringement provision itself, which is based on strict liability and not on reasonableness. See 35 U.S.C. § 271(a) (defining infringement without mentioning scienter).

<sup>42</sup> The question regarding "research tools" was not before the Court, but the Court's rationale could suggest that the safe harbor would not apply because a researcher would not seek FDA approval for the tool itself. See *Merck*, 545 U.S. at 205 n.7.

<sup>43</sup> One of Congress's purposes in establishing the Court of Appeals for the Federal Circuit was "to improve the administration of the patent law by centralizing appeals in patent cases." S. REP. NO. 97-275, at 2 (1981), reprinted in 1982 U.S.C.C.A.N. 11, 12, 1981 WL 21373.

<sup>44</sup> See *Eli Lilly*, 496 U.S. at 669-74; *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997), amended by 131 F.3d 1009 (Fed. Cir. 1997).

scheme, e.g., the Federal Food, Drug, and Cosmetic Act,<sup>45</sup> then the safe harbor's coverage cannot be limited to only those products given patent term extensions, which are the drugs and devices requiring premarket FDA approval.<sup>46</sup> In extending the scope of applicable patented inventions, the Federal Circuit retained the limitation that the "use" of the invention be the type of use required for FDA approval.<sup>47</sup>

The Federal Circuit later qualified this broad scope in *Proveris Scientific Corp. v. Innovasystems, Inc.*, which involved the use of a patented device in laboratory experiments.<sup>48</sup> The court held that the infringer's use of a patented invention to develop information for the FDA did not qualify for the safe harbor when the invention was not subject to FDA approval itself.<sup>49</sup> Neither the patented invention nor the infringing application of the invention in *Proveris* was submitted to the FDA for approval as a medical device.<sup>50</sup> Instead, the accused infringer made and sold a research tool that applied the patented invention—a tool that would be useful in developing new medical products.<sup>51</sup> The court held that because FDA approval would not be sought for the infringing device, making and selling the device were actions not covered by the safe harbor.<sup>52</sup> In addition, the court noted that the patent was directed to an invention that would not suffer from time lost during FDA approval, and thus it was not a "patented invention" that the safe harbor should cover.<sup>53</sup>

#### *D. Discord at the Federal Circuit: Classen and Momenta*

More recently, the Federal Circuit has addressed the question of whether "routine reporting" to the FDA of information, unrelated to an application for approval of a medical product, counts as "reasonably related" for the purposes

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<sup>45</sup> See 21 U.S.C. §§ 301–399 (2012).

<sup>46</sup> *AbTox*, 122 F.3d at 1027–29.

<sup>47</sup> *Id.* at 1030 (equating the "use" of the invention with "activities" performed with the invention).

<sup>48</sup> 536 F.3d 1256, 1265–66 (Fed. Cir. 2008).

<sup>49</sup> *See id.*

<sup>50</sup> *See id.*

<sup>51</sup> The classic example of a "research tool" is a microscope: it is an invention worth patenting but is useful only in its ability to aid in further research. *See id.*; *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1351 (Fed. Cir. 2007) (Rader, J., dissenting in part and concurring in part) (comparing "research tools" to microscopes).

<sup>52</sup> *See Proveris*, 536 F.3d at 1265–66.

<sup>53</sup> *Id.* The reasoning here is parallel to that of Justice Scalia in *Eli Lilly*—that the structure of the Hatch-Waxman Act implies this relationship between patent term extensions and the safe harbor exception. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669–74 (1990).

of the safe harbor exception.<sup>54</sup> The patented invention in *Classen Immunotherapies, Inc. v. Biogen IDEC* consisted of a method for evaluating and improving the safety of immunization schedules.<sup>55</sup> The accused infringer kept a record of negative relationships between vaccines and reported this information to the FDA in conformance with FDA regulations.<sup>56</sup> The panel's majority surveyed the relevant legislative history of the Hatch-Waxman Act and noted that the purpose and intent of Congress in enacting the Act was to create an exception for drug testing "in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent."<sup>57</sup> The majority applied the Supreme Court's analysis from *Merck* and *Eli Lilly*, which was that the safe harbor exception "leaves adequate space for experimentation and failure on the road to regulatory approval"<sup>58</sup> and "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval."<sup>59</sup> Based on these phrases, the majority in *Classen* concluded that the safe harbor should cover only activities leading up to FDA approval.<sup>60</sup> The majority further recognized and dismissed Judge Moore's dissenting view that the submission of "any" information to the FDA triggers the safe harbor exception.<sup>61</sup> Specifically, the majority held that the routine submission of post-approval drug reactions did not fall within the safe harbor exception.<sup>62</sup>

Judge Moore authored the dissent in *Classen*, which was later adopted by the Federal Circuit in *Momenta*,<sup>63</sup> relying on the text of § 271(e)(1) itself, along with other views expressed in *Merck*, to support a holding that the safe harbor is a broad exception to infringement:

[T]he statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory

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<sup>54</sup> See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011) ("The statute does not apply to information that may be routinely reported to the FDA . . ."), *cert. denied*, 133 S. Ct. 973 (2013).

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

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

<sup>57</sup> *Id.* at 1071 (quoting H.R. REP. No. 98-857, pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648, 1984 WL 37416) (internal quotation mark omitted).

<sup>58</sup> *Id.* (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005)).

<sup>59</sup> *Id.* (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990)) (internal quotation mark omitted).

<sup>60</sup> *Id.* at 1072.

<sup>61</sup> *Id.* at 1072 n.4.

<sup>62</sup> *Id.* at 1072.

<sup>63</sup> See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 2854 (2013).

process. As an initial matter, we think it is apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.<sup>64</sup>

Applying this reasoning, the dissent also determined that the safe harbor should not apply, but only because the infringing administration of the drug was distinct from reporting adverse drug reactions to the FDA—thus the activity was not “solely” related to submission of this information.<sup>65</sup>

The most recent Federal Circuit case involving the safe harbor exception—with Judge Moore writing for the majority and Chief Judge Rader dissenting—expanded the safe harbor along the lines of Judge Moore's dissent in *Classen*.<sup>66</sup> The patented invention in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* was a method for determining the purity of a batch of a particular drug.<sup>67</sup> The accused infringer produced batches of the drug, measured the purity using the patented method, and submitted the results in an ANDA to the FDA.<sup>68</sup> After obtaining FDA approval of the drug, the accused infringer produced larger quantities of the drug in preparation for sale to the public, analyzing the purity of each batch using the patented method.<sup>69</sup> Applying the reasoning from *Classen*, the district court found that the uses of the patented method prior to FDA approval were covered by the safe harbor, while later uses for production in preparation for sale were not covered.<sup>70</sup>

The Federal Circuit majority in *Momenta* analyzed the safe harbor exception anew, starting with a textualist approach.<sup>71</sup> Comparing the broad language of § 271(e)(1) with the much more specific language in the very next

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<sup>64</sup> *Classen*, 659 F.3d at 1083 (Moore, J., dissenting) (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005)).

<sup>65</sup> *See id.* at 1084.

<sup>66</sup> *Compare Momenta*, 686 F.3d 1348, with *Classen*, 659 F.3d at 1075–76, 1084.

<sup>67</sup> *Momenta*, 686 F.3d at 1351.

<sup>68</sup> The major benefit of an ANDA is that the new drug must simply be the bioequivalent of the approved drug, and extensive clinical trials are not required. *See* 21 U.S.C. § 355(j) (2012) (establishing the requirements of an ANDA); *Momenta*, 686 F.3d at 1351.

<sup>69</sup> There were methods for testing purity other than the patented method. *See Momenta*, 686 F.3d at 1353 (alleging that the existence of other methods meant the patented method was not required by the FDA, and thus not covered by the safe harbor).

<sup>70</sup> Information regarding the purity of each batch of the drug must be submitted to the FDA—exactly the sort of routine, post-approval activity *Classen* held as beyond the scope of the safe harbor. *See Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 882 F. Supp. 2d 184, 196 (D. Mass. 2011) (citing *Classen*, 659 F.3d at 1071), *vacated*, 686 F.3d 1348 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 2854 (2013).

<sup>71</sup> *Momenta*, 686 F.3d at 1353–54.

provision, § 271(e)(2), the court found it clear that Congress intended the safe harbor to be broadly construed.<sup>72</sup> The court confirmed this analysis by reference to the broad language in *Eli Lilly* and *Merck*.<sup>73</sup> The court then addressed the issues of whether the information was “developed and submitted” as required by the safe harbor, and whether the information was “routine,” and thus not covered according to *Classen*.<sup>74</sup> The FDA required that the drug manufacturer produce and keep this information for continued marketing approval, and thus the court was able to distinguish these records from the records kept in *Classen*, which were maintained but not required by the FDA on a regular basis.<sup>75</sup> The court compared the drug purity information to the records made in *Merck*, which were records of laboratory test results, and found that the recordkeeping satisfied the “submission” requirement in both cases—thus finding that developing submission-worthy records counts as a “submission,” regardless of whether the records are ever submitted.<sup>76</sup> The court held that because the information obtained by using the patented method was the kind of information required by the FDA for continued approval of the drug, the infringement came within the safe harbor exception.<sup>77</sup> Issues that did not factor in the court’s reasoning were whether alternative methods were available,<sup>78</sup> and the need to maintain statutory equilibrium.<sup>79</sup>

In his dissent, Chief Judge Rader disagreed strongly with the majority’s interpretation of the safe harbor’s text.<sup>80</sup> Beginning with an analysis of the legislative history,<sup>81</sup> the dissent looked to the problem Congress intended to solve through the Hatch-Waxman Act.<sup>82</sup> In so doing, the dissent was unable to find any indication that the safe harbor provision was intended to cover

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<sup>72</sup> See *id.* at 1354–55.

<sup>73</sup> See *id.* at 1355–56 (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990)).

<sup>74</sup> *Momenta*, 686 F.3d at 1357–58; see *Classen*, 659 F.3d at 1071–72.

<sup>75</sup> See *Momenta*, 686 F.3d at 1358; *Classen*, 659 F.3d at 1071–72.

<sup>76</sup> See *Momenta*, 686 F.3d at 1357 (citing *Merck*, 545 U.S. at 208).

<sup>77</sup> *Id.* at 1359.

<sup>78</sup> See *id.* (“The safe harbor’s protection is not limited to the dire situation where the patented invention is the only way to develop and submit the information.”).

<sup>79</sup> *Id.* at 1361 (“The Supreme Court in *Eli Lilly* noted that equilibrium was not always achieved.” (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671–72 (1990))).

<sup>80</sup> See *id.* at 1361–62 (Rader, C.J., dissenting).

<sup>81</sup> It is worth noting that in 1984, Chief Judge Rader was serving as Chief Counsel to the Senate Judiciary Committee, which produced an early version of the Hatch-Waxman Act. See *Randall R. Rader, Chief Judge*, U.S. CT. APPEALS FOR FED. CIRCUIT, <http://www.cafc.uscourts.gov/judges/randall-r-rader-chief-judge.html> (last visited Jan. 12, 2014).

<sup>82</sup> *Momenta*, 686 F.3d at 1362–66 (Rader, C.J., dissenting) (citing to and quoting from multiple congressional reports).

anything other than preapproval submissions of information to the FDA to speed the entry of generic medical products to the market.<sup>83</sup> The dissent also took issue with the majority's construction of the terms "solely" and "submission," and predicted that this broader interpretation would render patents on research tools worthless.<sup>84</sup> Additionally, the dissent disagreed with the majority's interpretation of binding precedent, noting several quotations from *Eli Lilly* and *Merck* that were taken out of context to support the broadened view of the statute.<sup>85</sup>

The Federal Circuit's decisions in *Classen* and *Momenta* are in significant tension with one another, if not wholly irreconcilable. This is a form of intra-circuit split not uncommon at the Federal Circuit.<sup>86</sup> Inconsistencies in interpretation such as this further the view of the Federal Circuit as a panel-dependent institution.<sup>87</sup> Unfortunately, the Supreme Court has declined to review these two cases, leaving the law in a state of disarray.

## II. ADVOCATING FOR AN APPROPRIATE SCOPE OF THE SAFE HARBOR

This Comment seeks both to develop an appropriate scope for applying the Hatch-Waxman Act's safe harbor and to measure this scope against the Federal Circuit's most recent interpretation of the safe harbor in *Momenta*.<sup>88</sup> Because statutory construction does not occur in a vacuum, within the broader concept of the safe harbor's "scope" this Comment focuses on two aspects of the safe harbor. The first is the time during which the safe harbor should apply, and the second is the subject matter—types of patents—that the safe harbor ought to cover.

### A. *Frames of Reference for Fixing the Safe Harbor's Scope*

The conflicting holdings of cases addressing the safe harbor statute center around the phrase "solely for uses reasonably related to the development and

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<sup>83</sup> *Id.* at 1366.

<sup>84</sup> *Id.* at 1367–69.

<sup>85</sup> *Id.* at 1372–74 (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 205–07 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990)).

<sup>86</sup> See Timothy R. Holbrook, *Explaining the Supreme Court's Interest in Patent Law*, 3 IP THEORY 62, 69 (2013), <http://www.repository.law.indiana.edu/ipt/vol3/iss2/1>.

<sup>87</sup> See R. Polk Wagner & Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. PA. L. REV. 1105, 1112 (2004) (finding that the Federal Circuit's decisions on claim construction are panel dependent).

<sup>88</sup> *Momenta*, 686 F.3d 1348.

submission of information” to the FDA.<sup>89</sup> To properly construe this portion of the safe harbor provision, this Comment analyzes the legislative history, looks to the text and structure of the statute, and considers the implications of a broad versus a narrow reading of the statute.

### 1. *Survey of the Act’s Legislative History*

Because the Hatch-Waxman Act involved significant changes to the regulatory scheme both in the Patent and Trademark Office and in the Food and Drug Administration, several prominent representatives of the drug industry participated in the congressional hearings that shaped the Act.<sup>90</sup> Congress understood the realities of the diminished protection for experimental use,<sup>91</sup> and members of Congress had heard from their constituents, many of whom were in dire straits due to high drug costs.<sup>92</sup> The goal of the legislation was to provide a balanced solution to unique problems experienced by pharmaceutical companies because of overlapping governmental regulatory schemes.<sup>93</sup> The Act struck this balance by providing patent term extensions for innovations delayed by FDA approval,<sup>94</sup> by creating an experimental use exception,<sup>95</sup> and by creating a new form of drug application for generic drugs to speed their entry into the market.<sup>96</sup> Both manufacturers of patented drugs and manufacturers of generic drugs testified to their understanding that the

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<sup>89</sup> See, e.g., *Momenta*, 686 F.3d at 1354 (italics removed) (quoting 35 U.S.C. § 271(e)(1) (2006)); *Classen Immunotherapies, Inc., v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011) (quoting 35 U.S.C. § 271(e)(1)), *cert. denied*, 133 S. Ct. 973 (2013).

<sup>90</sup> *Drug Legislation: Hearing on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health & the Env’t of the H. Comm. on Energy & Commerce*, 98th Cong. 42–45 (1983) [hereinafter *House Hearing*] (statement of Kenneth N. Larsen, Chairman, Generic Pharmaceutical Industry Association); *Senate Hearing*, *supra* note 20, at 65–66 (statement of Robert A. Ingram, Vice President for Public Affairs, Merrell Dow Pharmaceuticals, Inc.).

<sup>91</sup> While the Hatch-Waxman Act was being debated, the Court of Appeals for the Federal Circuit held that the affirmative defense of experimental use did not extend to drug manufacturing, which it found was a commercial activity. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified at 35 U.S.C. § 271(e)(1) (2006)), *as recognized in* *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 977 F.2d 558 (Fed. Cir. 1992); *see also* text accompanying note 23.

<sup>92</sup> See *Senate Hearing*, *supra* note 20, at 104 (statement of Sen. Paula Hawkins).

<sup>93</sup> See *id.* at 1–2 (statement of Sen. Orrin Hatch, Chairman, S. Comm. on Labor & Human Resources) (“First, our people are paying too much for drugs whose patents have expired. Second, the domestic drug industry is gradually losing its once-unchallenged prominence in pharmaceutical innovation . . .”).

<sup>94</sup> Extending the patent term increases the benefit provided by a patent, thereby increasing the incentive to innovate. See 35 U.S.C. § 156 (2006 & Supp. V 2011).

<sup>95</sup> *Id.* § 271(e)(1). Congress expressly intended to overturn *Roche*. See, e.g., H.R. REP. NO. 98-857, pt. 2, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711, 1984 WL 37417.

<sup>96</sup> 35 U.S.C. § 156.

Hatch-Waxman Act would allow for generics to begin the approval process prior to expiration of the patented drug, with marketing and sale to follow only after the patent expires.<sup>97</sup>

The congressional record is replete with statements from consumer advocates, pharmaceutical companies, and lawmakers all affirming that the Hatch-Waxman Act represents a well-crafted compromise to the benefit of all parties involved.<sup>98</sup> Some pharmaceutical manufacturers did not approve of the experimental-use aspect of the compromise, arguing that it represented an unconstitutional “taking” of their right to exclude others from making and using their patented inventions in violation of the Fifth Amendment.<sup>99</sup> Without conceding that a “taking” would occur, Congress addressed these concerns by noting that it was balancing the loss of right for these inventions by creating an extension of the patent term, effectively granting additional rights.<sup>100</sup> Congress further emphasized that “[t]he information which can be developed under [the safe harbor] provision is the type which is required to obtain approval of the drug,”<sup>101</sup> and that “the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.”<sup>102</sup>

When the congressional record is considered as a whole, it becomes clear that the Hatch-Waxman Act was tailored to achieve several purposes, and that while all parties involved supported the bill, all parties also made concessions.<sup>103</sup> No party involved in the discussion viewed the safe harbor

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<sup>97</sup> See *Senate Hearing*, *supra* note 20, at 104–05 (statement of Lewis Engman, President, Pharmaceutical Manufacturers Association) (noting that the experimental use exception was a point on which manufacturers of patented drugs compromised to secure their patent term extensions).

<sup>98</sup> See, e.g., *id.* at 221–22 (statement of Dan Saphire, American Association of Retired Persons) (noting that the Act is beneficial in his view—despite extending the patent monopoly—because of the concessions made to expedite generic drugs).

<sup>99</sup> Though patent rights are impermanent, they are analogous to property rights and possibly subject to a taking by the government—and arguably should be given heightened protection because they are time limited. See U.S. CONST. amend. V; see also, e.g., *Senate Hearing*, *supra* note 20, at 147 (excerpts from statement by John R. Stafford, President, American Home Products, before the House Judiciary Committee on H.R. 3605, as amended, June 27, 1984).

<sup>100</sup> See H.R. REP. NO. 98-857, pt. 2, at 30 n.20, *reprinted in* 1984 U.S.C.C.A.N. at 2714 n.20.

<sup>101</sup> H.R. REP. NO. 98-857, pt. 1, at 45 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678, 1984 WL 37416.

<sup>102</sup> H.R. REP. NO. 98-857, pt. 2, at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692 (rejecting amendments that would limit infringing activity to the last year of the patent term).

<sup>103</sup> Consumers and generic drug manufacturers approved the ANDA and safe harbor provisions but disliked the patent term extension, while patented drug manufacturers only supported the bill because of the patent term extension provision. See *Senate Hearing*, *supra* note 20.

provision as anything more than an abrogation of *Roche Products v. Bolar Pharmaceuticals*,<sup>104</sup> and a quid pro quo for the patent term extension provision.<sup>105</sup>

Reading the phrase “solely for uses reasonably related to the development and submission of information” in light of the legislative record, it appears Congress was establishing limitations on the safe harbor.<sup>106</sup> Congress was aware of the potential for an overly broad exception to raise the issue of an unconstitutional “taking,” and thus limited the acceptable uses to those “solely . . . reasonably related to the submission of information” to the FDA.<sup>107</sup> By requiring that the uses be “solely” for development of information, Congress intended to preclude uses that were purely commercial in nature. The “reasonable relation” requirement is a recognition of how laboratory testing is done—not every test will generate the necessary information, and some tests will merely indicate that further testing is required. These requirements show Congress intended for the safe harbor to cover drug development activities leading up to FDA approval, and not beyond. Marketing approval by the FDA should serve as an outermost boundary of the safe harbor exception. Thus, a generic manufacturer’s actions (e.g., making, using, and testing) leading up to FDA approval should be excused, but the same actions taken after FDA approval would constitute actionable infringement.

While Congress spent much time debating the proper balance of interests between patented and generic pharmaceutical manufacturers, Congress did not address whether medical devices or “research tool” patents were covered by the safe harbor. The FDA regulates medical devices, and they were included in the types of patents granted term extensions by the Hatch-Waxman Act.<sup>108</sup> “Research tool,” however, is a relatively new judicial classification for patents

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<sup>104</sup> 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified at 35 U.S.C. § 271(e)(1) (2006)), *as recognized in* W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc., 977 F.2d 558 (Fed. Cir. 1992).

<sup>105</sup> *See, e.g.*, H.R. REP. NO. 98-857, pt. 1, at 45, *reprinted in* 1984 U.S.C.C.A.N. at 2678 (“The purpose of section[] 271(e)(1) . . . is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.”).

<sup>106</sup> *See* 35 U.S.C. § 271(e)(1). Congress did consider an amendment that would have altered this portion by replacing the word “reasonably” with “directly,” but the difference between the two was not debated and the amendment was rejected on other grounds. *See* H.R. REP. NO. 98-857, pt. 2, at 60, *reprinted in* 1984 U.S.C.C.A.N. at 2719–20 (the Moorhead amendment).

<sup>107</sup> *See* 35 U.S.C. § 271(e)(1); H.R. REP. NO. 98-857, pt. 2, at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692.

<sup>108</sup> 35 U.S.C. § 156(a), (f)(1)(B).

whose primary use is within a laboratory.<sup>109</sup> A research tool can be any invention useful in conducting further investigation, and encompasses both traditional laboratory equipment such as microscopes and new innovations such as the use of an “expressed sequence tag” to isolate specific molecules.<sup>110</sup> Because the FDA does not regulate research tools per se, they were not included in Hatch-Waxman’s grant of patent term extensions. If Congress intended to balance Hatch-Waxman’s benefits and burdens by providing safe harbor protection *only for* those patents subject to patent term extensions, then research tool patents should not qualify for the safe harbor.

Considering only the intent of Congress as expressed in legislative reports and hearings, the scope of the safe harbor intended by Congress is limited to a narrow set of patented inventions and for a narrow purpose. The set of patented inventions eligible for the safe harbor are those “harmed” by time lost during FDA approval, such as medical devices and pharmaceutical products. The purpose of this exception is to save taxpayer money, and the purpose is fulfilled when a generic version of a patented drug is approved for sale. By permitting FDA approval to issue prior to the drug patent’s expiration, Congress permitted free-market competition to begin as soon as the patent expired. Any infringing actions taken after FDA approval are merely treading on the patentee’s rights and raise the serious constitutional question of whether a taking has occurred. Though the intent of Congress suggests a narrow interpretation is most suitable given the delicate balancing of interests, the text of the Hatch-Waxman Act is phrased in more expansive language.<sup>111</sup>

## 2. *Textual Analysis of the Statute*

Textual analysis of the Hatch-Waxman safe harbor begins by taking the text of the statute at face value and interpreting any unclear terms through reference to other portions of the statute.<sup>112</sup> The Supreme Court has analyzed the safe harbor provision’s text on two occasions, with both opinions written by Justice Scalia.<sup>113</sup> In *Eli Lilly & Co. v. Medtronic, Inc.*, despite finding that

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<sup>109</sup> See, e.g., *In re Fisher*, 421 F.3d 1365, 1379 (Fed. Cir. 2005) (Rader, J., dissenting) (defending the utility of research tools).

<sup>110</sup> See *id.* at 1379–80.

<sup>111</sup> See 35 U.S.C. § 271(e)(1).

<sup>112</sup> This is the approach used by Justice Scalia in *Eli Lilly* and *Merck*, and later used by Judge Moore in *Momenta*. See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 2854 (2013).

<sup>113</sup> *Merck*, 545 U.S. 193; *Eli Lilly*, 496 U.S. 661.

the relevant text was “not plainly comprehensible,” Justice Scalia looked to the structure of the statute to interpret the scope of the “Federal law which regulates . . . drugs.”<sup>114</sup> He found that to achieve a structural balance between patent term extensions and the safe harbor exception to infringement, the “law” referenced by the statute should be understood to be the regulatory scheme that regulated all devices for which patent term extensions were granted.<sup>115</sup> Later, when interpreting the phrase “reasonably related,” Justice Scalia construed the term “reasonably” to indicate that while the infringing use had to be of the sort that would generate information for the FDA, the information produced did not have to actually be included in submissions to the FDA.<sup>116</sup> Justice Scalia did not offer any guidance on whether “research tools” are protected by the safe harbor exception.<sup>117</sup>

On its face, the statute does not indicate what sorts of patents are or are not covered by the exception, but rather couches the exception in terms of how the patented inventions are used.<sup>118</sup> Every sort of infringing activity—making, using, selling, offering to sell, and importing—is covered by the exception.<sup>119</sup> Thus the limiting language of the safe harbor is that the infringement of the patent must be “solely for uses reasonably related to the development and submission of information” to the FDA.<sup>120</sup> As discussed and analyzed below, this language fails to provide a significant limitation on the scope of the safe harbor.

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<sup>114</sup> *Eli Lilly*, 496 U.S. at 669, 673–74 (internal quotation mark omitted). Justice Scalia determined that saying a “law which regulates the manufacture, use, or sale of drugs” was a form of congressional shorthand for the Federal Food, Drug, and Cosmetic Act—the less plausible alternative was to find that Congress, with this broad phrase, was singling out individual statutes regulating drugs, rather than the whole statutory scheme. *Id.* (internal quotation mark omitted).

<sup>115</sup> The Court considered the implication of interpreting this provision more narrowly—as applying to only those specific statutes that regulated drugs—but rejected the narrow interpretations because medical devices would be given patent term extensions and not be subject to the safe harbor. *See id.* at 669, 672–74.

<sup>116</sup> *Merck*, 545 U.S. at 206–07.

<sup>117</sup> Justice Scalia noted that although the issue was mentioned on appeal, it was not argued by either party, and so he did not need to address it. *See id.* at 205 n.7.

<sup>118</sup> Uses must be “reasonably related” to development and submission of information to the FDA. *See* 35 U.S.C. § 271(e)(1) (2006).

<sup>119</sup> This language parallels the definition of infringement, given in subsection (a) of the same section. *See id.* § 271(a), (e)(1).

<sup>120</sup> *Id.* § 271(e)(1); *see also* Brief of Amicus Curiae Classen Immunotherapies, Inc. in Support of the Petition for Rehearing En Banc at 4–5, *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012) (Nos. 2012-1062, -1103, -1104), 2012 WL 4762489 (supporting en banc review of *Momenta* to read “solely” and “submission” back into the statute).

a. *Does “Solely” Mean Only?*

The dictionary defines “solely” as “not involving anyone or anything else; only,”<sup>121</sup> indicating that the infringing use must not be any use other than one that is “reasonably related to the development and submission of information” to the FDA.<sup>122</sup> “Solely” is used elsewhere in Title 35, and in each case the statute applies this dictionary definition.<sup>123</sup> As it is used here, “solely” could mean either of two things: (1) that the use of the patented invention must be *only* for purposes of submitting information to the FDA, or (2) that the use of the patented invention must be *primarily* for research purposes related to FDA approval. This first possibility is incongruous with practical experience: some uses may have more than one purpose. For example, experiments that determine drug efficacy as required by the FDA may also help researchers decide whether the drug is a viable candidate for further development.<sup>124</sup> Requiring each “use” to be “solely” for submitting information to the FDA, to the exclusion of any other purpose, could cause generic manufacturers to over-disclose information.<sup>125</sup> This is likely too strict of a definition for “solely,” because it is modified by “reasonably related,” suggesting that an appropriate use may have more than one purpose.<sup>126</sup>

The second definition of “solely” raises a new problem: if “solely” does not mean “only,” then can there be more than one purpose? The difficulty introduced by this possibility of dual purposes is that it raises the question of whether the “use” that is reasonably related must be the *primary* use. And if not, to what degree are secondary uses permitted? This question would not pose as great a difficulty if the statute stated that “only patents on FDA-regulated inventions” qualified for the safe harbor.

If only FDA-regulated inventions were covered by the safe harbor, at least some uses of these inventions would be mandated by the FDA—testing for efficacy, bioequivalency, and purity, for example.<sup>127</sup> It is almost tautological to

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<sup>121</sup> NEW OXFORD AMERICAN DICTIONARY (3d ed. 2010).

<sup>122</sup> 35 U.S.C. § 271(e)(1).

<sup>123</sup> See, e.g., *id.* §§ 156(e), 273(g), 299(b) (2006 & Supp. V 2011) (using the word “solely” in apparent agreement with its dictionary definition).

<sup>124</sup> See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005).

<sup>125</sup> For example, applying this strict definition of “solely” could mean that data from a failed experiment on a patented drug must be submitted to the FDA for the safe harbor to apply to the infringing acts which constituted the experiment.

<sup>126</sup> For a use to be “reasonably related” to any one purpose, it must also have another purpose—if there is no secondary purpose, then it is “entirely related” to the first purpose and not merely “reasonably related.”

<sup>127</sup> See 21 U.S.C. § 355(a) (2012) (requiring that the manufacturer establish bioequivalency).

say that an FDA-mandated test bears a strong relation to an FDA submission, and thus even though these uses may serve other purposes,<sup>128</sup> they should be covered by the safe harbor.

When considering inventions that are not regulated by the FDA, however, the number of possible uses unrelated to FDA submissions is necessarily higher, increasing the chance that any given use does not chiefly relate to an FDA submission. A key justification for allowing infringing activities within the safe harbor rests on the assumption that developing and submitting information to the FDA is not the primary purpose of a patented invention.<sup>129</sup> If Congress created an exception to infringement that divested patentees of their chief benefit, that would be a compensable taking of property—therefore the use Congress intended the safe harbor to cover must have been one that would not greatly affect the patentee.<sup>130</sup> Uses that lead up to FDA marketing approval do not greatly affect the patentee unless they are uses of a patented invention that is a research tool.

Research tools and FDA-regulated inventions perform different roles in the pharmaceutical industry. For example, an advanced microscope—an archetype for research tools<sup>131</sup>—would be sold to laboratories for their use in furthering research on drugs, while the drugs themselves are mass-manufactured for distribution to the public. The microscope fulfills its main purpose in the laboratory setting, while the drug does not bring in revenue until it is sold. Allowing an infringer to continually use a patented microscope *for its intended purpose* serves to divest the patentee of all rights. Drugs and devices regulated

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<sup>128</sup> See *supra* text accompanying note 126.

<sup>129</sup> The roots of this argument are found in the common law experimental use defense, which presumes that activities that are “strictly philosophical” in nature are not detrimental to the patentees’ rights. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified at 35 U.S.C. § 271(e)(1) (2006)), *as recognized in* *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 977 F.2d 558 (Fed. Cir. 1992). Inventions that present obvious exceptions to this assertion are research tools, whose primary use is actually to develop new information—a means to an end rather than an end in themselves. Microscopes are a simple example of research tools, but elaborate methods—such as those used for separating and sequencing DNA—may also be considered tools in that their usefulness is in what they produce rather than the methods themselves. See *In re Fisher*, 421 F.3d 1365, 1379–80 (Fed. Cir. 2005) (Rader, J., dissenting).

<sup>130</sup> This is an application of the constitutional avoidance canon, where, presented with two interpretations, the court should choose the one that does not raise a question of constitutionality. See, e.g., Ernest A. Young, *Constitutional Avoidance, Resistance Norms, and the Preservation of Judicial Review*, 78 TEX. L. REV. 1549, 1574 (2000) (citing *Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 345 (1936) (Brandeis, J., concurring)) (critically analyzing the avoidance canon and its uses).

<sup>131</sup> See *In re Fisher*, 421 F.3d at 1379–80 (Rader, J., dissenting) (relying on microscopes as prime examples of research tools).

by the FDA do not suffer from this problem, because their intended purpose is not for developing other drugs. Thus research tools should not qualify for the safe harbor exception, because their primary “use” might only be for conducting research that would be used in pharmaceutical development.

*b. How Reasonable Is “Reasonably Related”?*

The closing portion of the safe harbor provision requires that the submission be reasonably related to “the development and submission of information” to the FDA.<sup>132</sup> As analyzed below, this limitation on the safe harbor’s scope bars only uses that are entirely unrelated to FDA submissions. In an earlier version of the statute, to qualify for the safe harbor the information had to be submitted “under a federal law which regulates the approval of drugs,”<sup>133</sup> but as enacted, the federal law only must “regulate[] the manufacture, use, or sale of drugs.”<sup>134</sup> This shift in language suggests a broadening of the types of FDA submissions that qualify as valid grounds for safe harbor protection. Despite being used in combination with the limitation that the protected uses are “solely . . . reasonably related”<sup>135</sup> to the development of this information, requiring that the information be developed for submission to the FDA is not a strong limitation. Many types of data are required by the FDA through the various stages of the drug and medical device approval process—from safety and efficacy to bioequivalence and adverse reactions.<sup>136</sup> During the drug approval process, information is actually submitted to the FDA, while in later phases the information may simply be compiled and never reported.<sup>137</sup>

The statute states that uses reasonably related to the “development and submission” of information are exempted from infringement.<sup>138</sup> This “and” could be read conjunctively to mean that both development of information and submission of information are required for the safe harbor exception to apply.

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<sup>132</sup> 35 U.S.C. § 271(e)(1) (2006).

<sup>133</sup> See H.R. REP. NO. 98-857, pt. 2, at 26 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2710, 1984 WL 37417 (emphasis added).

<sup>134</sup> 35 U.S.C. § 271(e)(1).

<sup>135</sup> *Id.*

<sup>136</sup> See, e.g., 21 U.S.C. § 355(a) (2012) (requiring that a new drug be bioequivalent to the prior approved drug for purposes of filing an ANDA).

<sup>137</sup> For example, information on adverse drug reactions is compiled but not submitted to the FDA, except in response to an FDA request. See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070–72 (Fed. Cir. 2011), cert. denied, 133 S. Ct. 973 (2013).

<sup>138</sup> 35 U.S.C. § 271(e)(1).

Though “and” is typically used conjunctively, context suggests that this is improper in this case, both because of an impossibility<sup>139</sup> and because of a practical consideration.<sup>140</sup> Therefore the “and” should be read disjunctively to cover the actions of developing and submitting independently.

Taken together, the provision that the use must simply be “reasonably related” to the “development and submission” of information under the FDCA provides no significant limitation on what qualifies as a use under the safe harbor. Only those uses that do not bear a reasonable relation to the development of any information that the FDA could ever require are disqualified.<sup>141</sup>

### 3. *Policy Concerns Unique to Patent Law*

In addition to considering the text of the safe harbor and intent of Congress regarding the Hatch-Waxman Act, courts should also weigh the purposes served by the Patent Act generally.<sup>142</sup> Patent infringement is a strict liability offense, and the application of the law tends to center around the themes of *notice* and *certainty*.<sup>143</sup> To fulfill the notice function of patent law, the rights granted by a patent must mark off the metes and bounds of the patentee’s property.<sup>144</sup> By providing an exception to infringement, Congress created incentives for manufacturers to quickly introduce generic drugs into the marketplace without fear of the danger of an infringement suit.<sup>145</sup> This safe harbor must be limited to the minimum scope needed to achieve its purpose—because it is an exception to the rule—and it must be grounded in the realities

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<sup>139</sup> It is impossible to submit information that has not been developed.

<sup>140</sup> Not all information developed should be submitted, such as the data resulting from a failed experiment.

<sup>141</sup> “Any information” being any information that the FDA could conceivably request, and, as stated earlier, this is a very large category of information. See *supra* note 64 and accompanying text.

<sup>142</sup> The Patent Act grants inventors the right to exclude others from practicing their inventions in exchange for the inventors fully disclosing how their inventions work. See 35 U.S.C. §§ 101–103, 112, 271(a) (2006 & Supp. V 2011).

<sup>143</sup> See, e.g., Craig Allen Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH. 1, 15 (2000) (“The importance of the notice function of the patent claim has always been appreciated, or at least understood by judges on the Federal Circuit . . .”).

<sup>144</sup> See Christopher A. Cotropia, *Patent Claim Interpretation Methodologies and Their Claim Scope Paradigms*, 47 WM. & MARY L. REV. 49, 62–64 (2005) (“A patent claim seeks to inform the public of the subject matter over which the patent provides exclusivity.” (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996))).

<sup>145</sup> The Hatch-Waxman Act also created an “artificial” form of infringement triggered by filing an ANDA, where the damages are limited to essentially preventing the generic from entering the marketplace. See 35 U.S.C. § 271(e)(2), (4).

of the FDA approval process and laboratory research methods to ensure that it gives the incentive Congress intended without overly encroaching on the patent holder's property rights.<sup>146</sup>

The certainty function of patent law requires that parties be subject to rules that yield a predictable and repeatable result.<sup>147</sup> Rules that require factor balancing do not serve this function as well as bright-line rules. If an otherwise infringing use of a patented invention could be exempted under the safe harbor by labeling the use as “developing information for submission to the FDA,”<sup>148</sup> then the certainty function of patent law has been subverted. The scope of safe harbor protection would then depend on the at-trial arguments and characterizations made by skilled attorneys and experts. On the other hand, if only patents subject to FDA regulation were covered by the safe harbor, the outcome of a safe harbor defense would be more certain.

In addition, applying the safe harbor to cover inventions regulated by the FDA logically follows from the structure of the Hatch-Waxman Act.<sup>149</sup> The safe harbor and patent term extension provisions were created by the Hatch-Waxman Act in tandem, to correct for distortions caused by time lost during FDA approval at either end of the patent term.<sup>150</sup> However, allowing the safe harbor to cover inventions not given patent term extensions in the Act creates a new distortion in patent protection, and this distortion can affect patents entirely unrelated to drugs. An additional benefit of restricting safe harbor protection to the inventions regulated by the FDA is that the question of whether the use is “reasonable” or “solely” for the purpose of submitting information becomes easier to address.<sup>151</sup>

Considering the broader themes of patent law—notice and certainty—and the structure of the Hatch-Waxman Act itself, it is clear that the safe harbor

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<sup>146</sup> See H.R. REP. NO. 98-857, pt. 2, at 27–30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711–14, 1984 WL 37417.

<sup>147</sup> See Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759, 763 (1999) (“A patent system, like any rights-based system, should seek to provide the players operating within the system clearly defined guidance as to what is and is not acceptable behavior.”).

<sup>148</sup> 35 U.S.C. § 271(e)(1) (2006).

<sup>149</sup> See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005).

<sup>150</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669–70 (1990).

<sup>151</sup> If the inventions' primary purpose is for laboratory use, then it is hard to draw a line between “reasonably related” use in submitting information to the FDA (for an unrelated drug) and use that is unrelated to submitting information to the FDA. See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1353–60 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 2854 (2013).

must be subject to some limits to avoid creating additional distortions in patent protection.

#### 4. *Proposed Scope of the Safe Harbor*

The above analysis indicates that while a textual analysis of the language of the safe harbor leads to a conclusion that the safe harbor is exceedingly broad, this interpretation may yield results that are inapposite with the statute's legislative history and may raise constitutional questions.<sup>152</sup> A proper scope of the safe harbor statute would suffer from neither of these problems while adhering to Supreme Court precedent. This Comment proposes a scope of the safe harbor that is limited in time to those infringing acts occurring before FDA marketing approval, and limited in subject to those patented inventions that were granted patent term extensions by the Hatch-Waxman Act.<sup>153</sup> This scope adheres to Supreme Court precedent from *Eli Lilly* in extending the safe harbor to all inventions given patent term extensions by the Hatch-Waxman Act,<sup>154</sup> but stops short of destroying the equilibrium intended by Congress that would occur if all patents were covered.<sup>155</sup> In addition, by covering only those infringing activities prior to receiving FDA approval, this scope meshes with the remainder of section 202 of the Hatch-Waxman Act, which concerns infringement in the context of applications for FDA approval for sale prior to the expiry of a patent.<sup>156</sup> This temporal limitation would also provide the bright-line certainty typically favored by the Federal Circuit.<sup>157</sup>

#### B. *Divergence of this Scope from the Scope in Momenta*

The scope of the safe harbor proposed by this Comment differs from that applied by the Federal Circuit in *Momenta Pharmaceuticals, Inc. v. Amphastar*

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<sup>152</sup> See *supra* text accompanying note 130.

<sup>153</sup> See 35 U.S.C. § 156 (2006 & Supp. V 2011).

<sup>154</sup> See *Eli Lilly*, 496 U.S. at 669–74.

<sup>155</sup> See, e.g., H.R. REP. NO. 98-857, pt. 2, at 8 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2692, 1984 WL 37417 (couching discussion of the subject matter exempted through the safe harbor in terms of generic drugs and bioequivalency tests).

<sup>156</sup> Various subsections deal with infringement based on the category a given patent falls in, and the remedies available differ based on whether or not the approval for sale is being sought prior to patent expiration or afterwards. See 35 U.S.C. § 271(e)(2), (4).

<sup>157</sup> See, e.g., Timothy R. Holbrook, *The Supreme Court's Complicity in Federal Circuit Formalism*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 2–4 (2003) (providing several illustrations of the Federal Circuit's bent toward certainty and formalism).

*Pharmaceuticals, Inc.* in two ways.<sup>158</sup> First, the majority in *Momenta* would permit the safe harbor to cover activities conducted after FDA approval has been granted,<sup>159</sup> while the scope this Comment proposes would use FDA approval as the cutoff point. Second, the *Momenta* majority would extend the safe harbor to all patented inventions, including those for which no FDA approval is required.<sup>160</sup> The scope this Comment proposes would restrict the safe harbor to only those inventions granted patent term extensions by the Hatch-Waxman Act.<sup>161</sup>

Based on these two differences, a court applying this Comment's proposed scope would find that the infringing acts in *Momenta* would not qualify for the safe harbor.<sup>162</sup> The first basis for this holding would be that the safe harbor is inapplicable to this type of patent. The patent infringed in *Momenta* was for a method of determining the purity of a substance, and this type of patent is not qualified for a patent term extension.<sup>163</sup> Because it is ineligible for a patent term extension, infringement of this patent would be ineligible for safe harbor protection as proposed by this Comment.<sup>164</sup> In addition, a holding that the safe harbor does not apply to the infringer's actions could also be based on the time the actions occurred relative to FDA marketing approval.<sup>165</sup> The infringer in *Momenta* had already received FDA approval to sell the drug, but continued to use the patented testing method as it produced batches of the drug for sale to the public.<sup>166</sup> While the preapproval uses were necessary to develop bioequivalency data, the later uses were chiefly for producing marketable quantities of the drug.<sup>167</sup> According to the scope proposed by this Comment, these later uses would not qualify for the safe harbor.<sup>168</sup>

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<sup>158</sup> See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1359 (Fed. Cir. 2012), cert. denied, 133 S. Ct. 2854 (2013) (expanding the scope of the safe harbor to cover infringing acts performed both (1) with any sort of invention and (2) after FDA approval was granted).

<sup>159</sup> *Id.*

<sup>160</sup> See *id.*

<sup>161</sup> See 35 U.S.C. § 156.

<sup>162</sup> See *Momenta*, 686 F.3d at 1351–52.

<sup>163</sup> See *id.*

<sup>164</sup> See *supra* Part II.A.4.

<sup>165</sup> See *Momenta*, 686 F.3d at 1351–52.

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

<sup>167</sup> See *id.*

<sup>168</sup> See *supra* text accompanying note 153.

### III. BROADER IMPLICATIONS OF THE SCOPE OF THE SAFE HARBOR

Aside from the two cases decided by the Supreme Court,<sup>169</sup> most of the interpretation of the safe harbor provision has been accomplished through the decisions of the Federal Circuit.<sup>170</sup> Through the broad language employed in its decision in *Momenta*,<sup>171</sup> the Federal Circuit has threatened the value of an entire field of patents and has implicitly overturned portions of its precedent.<sup>172</sup>

#### A. *Future Impacts the Broad Holding in Momenta Will Have for Patent Holders and Inventors*

The broad scope given to the safe harbor by *Momenta* will likely change the actions of generic pharmaceutical manufacturers, who will adopt aggressive business strategies to take advantage of the reduced enforcement power of patentees.<sup>173</sup> The topic of research tools has been an open question since Justice Scalia raised the issue in *Merck*.<sup>174</sup> Though the Federal Circuit has previously held that they should not be covered by the safe harbor,<sup>175</sup> the tenor of *Momenta* is to the contrary.<sup>176</sup> This shift moves the balance struck in the Hatch-Waxman Act strongly toward the side of the generic manufacturers.<sup>177</sup> Now manufacturers may begin using patented research tools

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<sup>169</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

<sup>170</sup> See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070–73 (Fed. Cir. 2011), *cert. denied*, 133 S. Ct. 973 (2013); *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008); *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997), *amended by* 131 F.3d 1009 (Fed. Cir. 1997).

<sup>171</sup> *Momenta*, 686 F.3d at 1354–56.

<sup>172</sup> Compare *Proveris*, 536 F.3d at 1264–66 (holding that “research tools” are not covered by the safe harbor because they are not subject to FDA regulation), with *Momenta*, 686 F.3d at 1359 (holding that the safe harbor may cover any patented invention).

<sup>173</sup> See *Momenta*, 686 F.3d at 1359.

<sup>174</sup> See *Merck*, 545 U.S. at 205 n.7 (“We therefore need not—and 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>175</sup> See *Proveris*, 536 F.3d at 1264–66 (holding that “research tools” are not covered by the safe harbor because they are not subject to FDA regulation).

<sup>176</sup> See *Momenta*, 686 F.3d at 1359 (holding that the determinative factor was whether use of the patented invention was “reasonably related” to an FDA submission).

<sup>177</sup> See, e.g., H.R. REP. NO. 98-857, pt. 1, at 45 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678, 1984 WL 37416 (“The purpose of section[] 271(e)(1) . . . is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.” (emphasis added)).

to aid in their development of new drugs or generic drugs without regard to whether noninfringing methods are available.<sup>178</sup>

The most dangerous change brought about through the *Momenta* decision is that now, as never before, post-approval infringement is covered by the safe harbor.<sup>179</sup> This coverage—which applies to ANDA and new drugs alike—is far removed from the original purpose found in the congressional record, which was focused on protecting the consumers by bringing generics to the market swiftly, following the expiration of a drug patent.<sup>180</sup>

These two changes create a perfect storm for owners of patents on research tools: not only can such patents be infringed at the will of a manufacturer in bringing a drug to market, but the manufacturer can continue to infringe the research tool patent while selling the drug. At a minimum, the developers of new research tools and methods will need to consider these changes when deciding whether a patent is a worthwhile investment, or if a trade secret might be more effective.<sup>181</sup> While trade secrets provide less opportunity to extract license fees and fund future invention, at least the inventor will save the trouble of securing a patent that is worth less than the paper it is printed on.

This state of affairs will be detrimental initially only to the holders of these research tool patents. However, as new inventors are faced with the decision of disclosing their research tools through applying for patents—thereby giving up information in return for little protection—or instead retaining them as trade secrets, a different form of harm may occur. Many inventors may choose to keep their inventions secret, which would slow if not stifle innovation.<sup>182</sup> By setting the stage for this scenario, the unduly broad scope of the safe harbor in

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<sup>178</sup> *Momenta*, 686 F.3d at 1359 (“The safe harbor . . . does not mandate the use of a noninfringing alternative when one exists.”).

<sup>179</sup> *Compare Momenta*, 686 F.3d at 1359 (allowing the safe harbor to cover post-approval activities), with *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1071–72 (Fed. Cir. 2011) (excluding post-approval activities from the safe harbor), *cert. denied*, 133 S. Ct. 973 (2013).

<sup>180</sup> See *Senate Hearing*, *supra* note 20, at 1–2 (statement of Sen. Orrin Hatch, Chairman, S. Comm. on Labor & Human Resources) (“[O]ur people are paying too much for drugs whose patents have expired.”).

<sup>181</sup> Trade secrets are governed by state law and protect inventions from corporate espionage, but not against reverse engineering or independent development. See, e.g., *E. I. duPont deNemours & Co. v. Christopher*, 431 F.2d 1012, 1015 (5th Cir. 1970). Thus, they are not as effective for consumer-side inventions (e.g., commercial products) as they are for manufacturing-side inventions (e.g., methods).

<sup>182</sup> This is at odds with Congress’s power to promote and protect innovation. See U.S. CONST. art. I, § 8, cl. 8.

*Momenta* subverts both the *ex ante* and *ex post* incentives provided by patent law.<sup>183</sup>

### B. Pathways for Implementing the Proposed Scope of the Safe Harbor

The scope of the safe harbor proposed by this Comment would produce results both in line with the expectations of the pharmaceutical community (prior to the *Momenta* decision) and in conformance with binding Supreme Court and Federal Circuit precedent.<sup>184</sup> The pharmaceutical community—both patented drug makers and generic manufacturers—was deeply involved in the negotiations and passage of the Hatch-Waxman Act, and has had a strong monetary interest in the scope of the safe harbor over the nearly three decades since.<sup>185</sup> The scope of the safe harbor as proposed by this Comment would not disturb the expectations of this community, but instead would explicitly reinforce the balance enacted in the Hatch-Waxman Act. By limiting the types of patents eligible for safe harbor protection to those granted patent term extensions,<sup>186</sup> this scope would retain the “structural” equilibrium recognized in *Eli Lilly*.<sup>187</sup> This means that the only patents “harmed” by the safe harbor—in that they may be infringed—are also given a “benefit” in the form of additional years of patent protection to make up for time lost during the FDA approval process.

Restricting the scope of the safe harbor further to address only those acts of infringement prior to FDA approval, although more limited than the broad language employed by the statute, also achieves the results Congress intended.<sup>188</sup> The safe harbor portion of the Hatch-Waxman Act was intended in

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<sup>183</sup> *Ex ante* incentives are those that encourage inventors to develop new ideas; *ex post* are those that encourage inventors to disclose the ideas.

<sup>184</sup> Where the Supreme Court has issued dicta that do not explicitly agree with Federal Circuit precedent, this Comment applies the precedential decision. Compare *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 205 n.7 (2005) (eschewing any holding on whether research tools are eligible for the safe harbor exemption), with *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1264–66 (Fed. Cir. 2008) (holding that the safe harbor does not cover research tools).

<sup>185</sup> The value of market exclusivity for a pharmaceutical product can be enormous, and the presence of competition can bring this value much closer to marginal cost. See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1362 (Fed. Cir. 2012) (Rader, C.J., dissenting) (finding the value of market exclusivity was approximately \$520 million over a six-month period), *cert. denied*, 133 S. Ct. 2854 (2013); see also *House Hearing, supra* note 90, at 43 (statement of Kenneth N. Larsen, Chairman, Generic Pharmaceutical Industry Association) (bidding among manufacturers drove many drug prices down more than 50%).

<sup>186</sup> 35 U.S.C. § 156 (2006 & Supp. V 2011).

<sup>187</sup> See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990).

<sup>188</sup> See, e.g., H.R. REP. NO. 98-857, pt. 1, at 45 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678, 1984 WL 37416 (“The purpose of section[] 271(e)(1) . . . is to establish that experimentation with a patented drug

part to overturn *Roche Products, Inc. v. Bolar Pharmaceuticals, Inc.*,<sup>189</sup> which had the effect of defining the FDA application process as “commercial,” and thus beyond the scope of the judicially created “experimental use” defense.<sup>190</sup> If the safe harbor is limited to covering only pre-FDA approval activities, it serves as a replacement for the experimental use defense in this field of innovation—encouraging others to improve upon the patented invention without trespassing on the patentee’s rights.<sup>191</sup>

Despite these benefits, shaping the scope of the safe harbor to a more narrow, pre-*Momenta* form will not be an easy task, though options exist both for judicial and legislative intervention. One avenue for judicial review has been closed: despite the tension between *Classen* and *Momenta* and the uncertain scope of the safe harbor, the Supreme Court has denied certiorari in both cases. The other avenue would have the Federal Circuit take up *Momenta* en banc to amend the decision of the panel and adopt a single precedential interpretation. Until the Federal Circuit takes this issue en banc, whether in *Momenta* or in the next case to raise the issue, the outcome at the Federal Circuit will depend on the makeup of the three-judge panel.<sup>192</sup>

Another problem with relying on judicial review and reform for the safe harbor is that the current trend in statutory interpretation is *textualism*, which looks first to the text of the statute and applies the text as written unless there is some ambiguity with the text. The safe harbor has been interpreted through this method before—twice by Justice Scalia,<sup>193</sup> a leader in the textualist

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product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.”).

<sup>189</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (“[U]nlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention.”), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified at 35 U.S.C. § 271(e)(1) (2006)), *as recognized in* *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 977 F.2d 558 (Fed. Cir. 1992).

<sup>190</sup> The “experimental use” defense has been circumscribed severely, covering only infringement performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Id.* (citing *Pitcairn v. United States*, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976)).

<sup>191</sup> This is the opposite of the effect felt when the safe harbor has no limitation. *See supra* text accompanying note 183.

<sup>192</sup> *Wagner & Petherbridge*, *supra* note 87, at 1112.

<sup>193</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

movement<sup>194</sup>—and its broad language has been pronounced clear.<sup>195</sup> Without an ambiguous text, a textualist finds no motivation to seek out the intentions of Congress as expressed in the legislative history. In terms of the safe harbor provision, the legislative history provides a perspective on the intent of Congress that is not evident from the text—a perspective that may not be given effect if this provision is viewed only from a textualist standpoint. For this reason, congressional intervention will likely be required for the safe harbor to be returned to its former scope.

## CONCLUSION

The safe harbor performs a necessary role in pharmaceutical innovation: it encourages generic manufacturers and new drug makers to experiment with patented drugs, free from the fear of liability for patent infringement. Stretched beyond its proper scope, however, the safe harbor threatens the value of patents related to drug manufacturing, and in turn, threatens the innovation those patents represent. To prevent this harm from occurring, the safe harbor should be limited in subject matter to covering only those patents that are granted patent term extensions,<sup>196</sup> and to infringing acts taken prior to FDA approval.<sup>197</sup> Because of the broad language used in the safe harbor provision, these limitations are difficult to envision as judicial constructs—especially in a textualist climate—and will likely require congressional action to become a reality.

ROBERT A. JONES\*

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<sup>194</sup> Justice Scalia is well known for his outspoken stance *for* textualist interpretations and *against* detailed reviews of legislative histories. See ANTONIN SCALIA & BRIAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* (2012) (dedicating an entire book to the subject of textualist interpretation).

<sup>195</sup> *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1354 (Fed. Cir. 2012) (“Congress could not have been clearer in its choice of words . . .”), *cert. denied*, 133 S. Ct. 2854 (2013).

<sup>196</sup> This offsets the benefit of a term extension with the burden of possibly unchecked infringement.

<sup>197</sup> FDA approval is a very useful milestone: to qualify for the safe harbor, submissions to the FDA are involved, and after FDA approval, the uses of the patent begin to compete with the patent-owners’ monopoly.

\* Robert A. Jones © 2013, Emory University School of Law, *Juris Doctor* candidate 2014. Many thanks to the editors and staff of the *Emory Law Journal* for their assistance in preparing this Comment for publication, and to Professor Timothy Holbrook for his guidance.