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## APPLICATION OF THE HATCH-WAXMAN ACT'S SAFE HARBOR PROVISION FOLLOWING *MOMENTA*

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### ABSTRACT

The Federal Circuit's recent decision in *Momenta v. Amphastar* highlights the continuing uncertainty regarding the scope of the statutory exemption from patent infringement provided in 35 U.S.C. § 271(e)(1). The statute states that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” Since its adoption in 1984 with the passage of the Hatch-Waxman Act, however, the precise meaning of the statute has been the subject of considerable debate, triggering two U.S. Supreme Court decisions and multiple decisions of the Federal Circuit and various U.S. district courts. Judicial interpretations of key terms of § 271(e)(1), based on a textual analysis of the statute, the structure of the Hatch-Waxman Act and the legislative history of the Act, have resulted in conflicting views as to the scope and applicability of the statute. This Article provides a working interpretation of the meaning of the statute, based on currently controlling case law.

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## INTRODUCTION

The Federal Circuit's recent decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* highlights the continuing uncertainty regarding the scope of the statutory exemption from patent infringement provided in 35 U.S.C. § 271(e)(1), the so-called safe harbor statute.<sup>1</sup> The statute states that:

[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.<sup>2</sup>

Since its adoption in 1984 with the passage of the Hatch-Waxman Act, however, the precise meaning of the statute has been the subject of considerable debate, triggering two U.S. Supreme Court decisions and multiple decisions of the Federal Circuit and various U.S. district courts.<sup>3</sup> Judicial interpretations of key terms of § 271(e)(1), based on a textual analysis of the statute, the structure of the Hatch-Waxman Act and the legislative history of the Act, have resulted in conflicting views as to the scope and applicability of the statute.<sup>4</sup>

This Article provides a working interpretation of the meaning of the safe harbor statute, based on currently controlling case law. Part I begins with a brief review of the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, which prompted the proposal for the section of the Hatch-Waxman Act that added § 271(e)(1) to the federal patent laws.<sup>5</sup> It next discusses the structure and pertinent legislative history of the Act. Part II reviews judicial interpretations of the statutory terms "under a Federal law," "solely," "reasonably related," "patented invention," and "submission of information." In the course of the review, the tension among the Federal Circuit's recent decisions in *Proveris Scientific Corp. v. Innovasystems, Inc.*,<sup>6</sup>

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<sup>1</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1349 (Fed. Cir. 2012).

<sup>2</sup> 35 U.S.C. § 271(e)(1) (2012); *Momenta*, 686 F.3d at 1354.

<sup>3</sup> See generally Suneel Arora et al., *Medical Device Law: The Interplay Between FDA and Patent Law: Infusing Organizational Knowledge for Medical Device Companies*, 39 WM. MITCHELL L. REV. 1176, 1196-201 (2013).

<sup>4</sup> See *infra* Part II.

<sup>5</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863-64 (Fed. Cir. 1984).

<sup>6</sup> *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1268 (Fed. Cir. 2008).

*Classen Immunotherapies, Inc. v. Biogen IDEC*,<sup>7</sup> and *Momenta* is addressed. Specifically, these arguably conflicting holdings have created uncertainty regarding the applicability of the statutory exemption provided under § 271(e)(1) to certain types of patented inventions, such as research tools and manufacturing test methods, and to activities undertaken following the marketing approval of a product. Although some of the tension among these Federal Circuit decisions may have been resolved if the Supreme Court had granted the writ of certiorari in the *Momenta* case, its refusal to hear the case<sup>8</sup> has left this legal arena in a state of uncertainty. In the absence of a definitive statement from the Supreme Court, a party who intends to use a patented invention without authorization in reliance on the protection afforded by the safe harbor statute may have to accept some risk of infringement liability. Part III provides an analytical approach to the application of the statutory exemption to the unauthorized use of a patented invention, based on currently controlling case law.

## I. ENACTMENT OF 35 U.S.C. § 271(e)(1)

### A. *Roche Products, Inc. v. Bolar Pharmaceutical Co.*

The Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*<sup>9</sup> prompted the proposal for § 202 of the Hatch-Waxman Act, which added 35 U.S.C. § 271(e)(1), the safe harbor statute, to the federal patent laws.<sup>10</sup> The court addressed the question of whether a generic drug manufacturer could use a pharmaceutical company's patented drug during the patent's term to prepare required regulatory submissions for the United States Food and Drug Administration (FDA) for the purpose of marketing its own generic version of the drug upon patent expiration.<sup>11</sup> Roche, the pharmaceutical company, claimed that the unauthorized use of its patented drug prior to the expiration of the patent constituted patent infringement.<sup>12</sup> Bolar, the generics manufacturer, argued that its intended use was exempted from infringement liability on two grounds: "the first ground is based on a liberal interpretation of the traditional experimental use exception; the second ground is that public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing."<sup>13</sup> The Federal Circuit held that Bolar's intended use was indeed patent infringement, and rejected each of the manufacturer's grounds for an exception.<sup>14</sup>

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<sup>7</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1073 (Fed. Cir. 2011).

<sup>8</sup> *See Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, *cert. denied*, 133 S. Ct. 2854, 2854 (2013).

<sup>9</sup> *Roche*, 733 F.2d at 863–64.

<sup>10</sup> *See infra* Part I.B.1; Arora et al., *supra* note 3, at 1196.

<sup>11</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984).

<sup>12</sup> *Id.* at 860.

<sup>13</sup> *Id.* at 862.

<sup>14</sup> *Id.* at 863.

With respect to the “so-called experimental use defense to liability for infringement,”<sup>15</sup> the Federal Circuit concluded that Bolar’s concession that its intended use of Roche’s patented drug “does not fall within the ‘traditional limits’ of the experimental use exception”<sup>16</sup> was fatal. In the words of the court,

[d]espite Bolar’s argument that its tests are “true scientific inquiries” to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. . . . Bolar’s intended “experimental” use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar’s intended use of [the patented drug] to derive FDA required test data is thus an infringement of the . . . patent. Bolar may intend to perform “experiments,” but unlicensed 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. . . . We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of “scientific inquiry,” when that inquiry has definite, cognizable, and not insubstantial commercial purposes.<sup>17</sup>

The Federal Circuit then rejected Bolar’s argument that, as a public policy matter, the court should create a new exception to infringement liability to allow for FDA-required drug testing.<sup>18</sup> As the court explained,

Bolar argues that even if no *established* doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to the use prohibition. Parties and *amici* seem to think, in particular, that we must resolve a conflict between the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301–392 (1982), and the Patent Act of 1952, or at least the Acts’ respective policies and purposes. We decline the opportunity here, however, to engage in legislative activity proper only for the Congress. . . . No matter how persuasive the policy arguments are . . . this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation. . . . We will not rewrite the patent laws here.<sup>19</sup>

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<sup>15</sup> *Id.* at 862.

<sup>16</sup> *Id.* at 863.

<sup>17</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984); *see also* Alfred C. Server et al., *Reach-Through Rights and the Patentability, Enforcement and Licensing of Patents on Drug Discovery Tools*, 1 HASTINGS SCI. & TECH. L.J. 21, 58–59 (2009) (reviewing case law related to the common law “experimental use” exception).

<sup>18</sup> *Roche*, 733 F.2d at 863–65.

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

*B. The Statutory Safe Harbor Provision**1. The Hatch-Waxman Act and 35 U.S.C. § 271(e)(1)*

The Hatch-Waxman Act, officially named the Drug Price Competition and Patent Term Restoration Act of 1984,<sup>20</sup> was enacted by Congress five months after the Federal Circuit's decision in *Roche v. Bolar*. The Act contained two significant portions: Title I—Abbreviated New Drug Applications and Title II—Patent Extension.<sup>21</sup> Title I of the Act amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355)<sup>22</sup> in order to establish a generic drug approval procedure for pioneer drugs approved after 1962. Title II, which amended Title 35 of the U.S.C. (the patent law), contained two significant sections. Section 201 of Title II added § 156 (Extension of Patent Term) to the federal patent laws, with the goal of extending the normal term of a patent if a product that is covered by the patent is required by federal law to undergo regulatory review prior to its commercial marketing.<sup>23</sup> Section 202 amended 35 U.S.C. § 271 (Infringement of Patent) by adding § 271(e)(1)—the so-called statutory exemption or safe harbor provision—which reads as follows:

[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.<sup>24</sup>

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<sup>20</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 [hereinafter Hatch-Waxman Act].

<sup>21</sup> Hatch-Waxman Act, *supra* note 20, at 1585, 1598. A third portion, Title III—Amendments to the Textile Fiber Products Identification Act and the Wool Products Labeling Act of 1939, is not relevant to the issues discussed in this Article. *Id.* at 1603.

<sup>22</sup> *Id.* at 1585.

<sup>23</sup> *Id.* at 1598.

<sup>24</sup> *Id.* at 1603; 35 U.S.C. § 271(e)(1) (2012). Note that as originally enacted, § 271(e)(1) read as follows:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) 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.

Congress had already considered components of what was to become the Hatch-Waxman Act prior to the *Roche v. Bolar* decision. The Drug Price Competition Act of 1983, “to allow faster marketing of new generic drugs equivalent to approved new drugs,” and the Patent Term Restoration Act of 1983, “to add to the patent grant a period of time equivalent to that lost due to regulatory delay,” were both before Congress at the time of the Federal Circuit’s ruling in *Roche*.<sup>25</sup> However, the *Roche* decision prompted the proposal for section 202 of the Hatch-Waxman Act that added § 271(e)(1) to the patent laws.<sup>26</sup> The enactment of this safe harbor statute effectively reversed the Federal Circuit’s holding in the *Roche* case. Whether the *sole* purpose for the inclusion of section 202 in the Act was to reverse the *Roche* decision (and that fact sets a limit to the scope of the applicability of § 271(e)(1)) is the subject of active debate. Judge Rader of the Federal Circuit, in his dissent in *Momenta*, argued that “[a] review of [the legislative history] shows that section 202 of the Hatch-Waxman Act, enacted as § 271(e)(1), had the sole purpose of overruling this court’s holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* In particular, § 271(e)(1) applied only in limited situations, namely pre-approval experiments to obtain FDA approval.”<sup>27</sup> Justice Scalia, on the other hand, in his Supreme Court opinions in *Eli Lilly* and *Merck*, allowed for a considerably broader role for the statutory exemption when he stated that “[u]ndoubtedly the decision in *Roche* promoted the *proposal* of [section] 202; but whether that alone accounted for its *enactment* is quite a different question.”<sup>28</sup> As will be discussed in Part II of this Article, this debate as to the purpose of section 202 of the Hatch-Waxman Act, as well as the role of the legislative history of the Act in discerning that purpose, is at the core of the most significant disagreements as to the scope and applicability of § 271(e)(1).

## 2. Legislative History of the Act

Although it has been claimed that “[t]here is a paucity of legislative history on the Hatch-Waxman Act,”<sup>29</sup> “[t]he legislative history of § 271(e)(1) includes more than [two] House reports, [twenty-five] statements and letters, and many pages of

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Hatch-Waxman Act, *supra* note 20, at 1603. The subsequent amendments to § 271(e)(1) that brought the statute to its current form are not relevant to the issues addressed in this Article, with the exception of the expansion of the ambit of the safe harbor statute to include most new animal drugs and veterinary biological products. This change to § 271(e)(1) and the corresponding change to § 156 have been cited as evidence that the two sections are intended to work in tandem, an argument that has been used in construing the scope of the safe harbor statute. *See infra* note 191.

<sup>25</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 865 (Fed. Cir. 1984) (“Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues.”) (citations omitted). *See* Drug Price Competition and Patent Term Restoration Act of 1984, H.R. 3605, 98th Cong. (1984) (amending 21 U.S.C. § 355(b)).

<sup>26</sup> *See* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 n.3 (1990) (“Undoubtedly the decision in *Roche* promoted the proposal of § 202.”).

<sup>27</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1363 (Fed. Cir. 2012) (Rader, J., dissenting).

<sup>28</sup> *Eli Lilly*, 496 U.S. at 670 n.3 (emphasis added).

<sup>29</sup> Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

Congressional testimony.”<sup>30</sup> The two House reports—H.R. No. 98-857, Part I, from the Committee on Energy and Commerce,<sup>31</sup> and H.R. No. 98-857, Part II, from the Committee on the Judiciary<sup>32</sup>—are most frequently cited by those judges who are of the opinion that the legislative history of the Hatch-Waxman Act is relevant in construing § 271(e)(1).<sup>33</sup> While a detailed review of these House reports is beyond the scope of this Article, a few general statements regarding the reports are warranted.

First, according to the House reports, § 271(e)(1) was intended to overrule the Federal Circuit’s decision in *Roche v. Bolar*.<sup>34</sup> Part I of H.R. 98-857 stated the following in its analysis of section 202 of the proposed Act:

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. . . . In *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, the Court of Appeals for the Federal Circuit held that the experimental use of a drug product prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. It is the Committee’s view that experimental activity does not have any adverse economic impact on the patent owner’s exclusivity during the life of a patent, but prevention of such activity would extend the patent owner’s commercial exclusivity beyond the patent expiration date.<sup>35</sup>

Part II of H.R. 98-857 stated that “[t]he provisions of section 202 of the bill have the net effect of reversing the holding of the court in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*”<sup>36</sup>

Second, the House reports are replete with references to generic products and the objective of § 271(e)(1) to facilitate the prompt introduction of such products into the marketplace upon the expiration of the patent claiming the pioneer drug.<sup>37</sup> For example, Part I of H.R. 98-857 states that “[T]itle II provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent.”<sup>38</sup> Part II of H.R. 98-857 states,

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<sup>30</sup> *Momenta*, 686 F.3d at 1362 (Rader, J., dissenting).

<sup>31</sup> H.R. REP. NO. 98-857, pt. 1 (1984).

<sup>32</sup> H.R. REP. NO. 98-857, pt. 2 (1984).

<sup>33</sup> See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003); *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1350 (Fed. Cir. 2007) (Rader, J., dissenting); *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1362–66 (Fed. Cir. 2012) (Rader, J., dissenting); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1071 (Fed. Cir. 2011).

<sup>34</sup> H.R. REP. NO. 98-857, pt. 1, at 45–46; see also *Momenta*, 686 F.3d at 1362–63 (Rader, J., dissenting).

<sup>35</sup> H.R. REP. NO. 98-857, pt. 1, at 45–46 (citations omitted).

<sup>36</sup> H.R. REP. NO. 98-857, pt. 2, at 27 (citations omitted).

<sup>37</sup> H.R. REP. NO. 98-857, pt. 1, at 15; H.R. REP. NO. 98-857, pt. 2, 8–9.

<sup>38</sup> H.R. REP. NO. 98-857, pt. 1, at 15.

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. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial. . . . [Moreover,] the Committee accepted the public policy rationale of our sister Committee on Energy and Commerce. They reasoned that without Section 202 generic manufacturers would be required to engage in these bioequivalency tests after the expiration of the patent. This would result in delays of about two years after the expiration of the patent before a generic could go on the market. Thus, the Committee on Energy and Commerce reasoned that Section 202 of the bill was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent.<sup>39</sup>

The above quotation highlights the third general statement worth making with respect to the legislative history of the Hatch-Waxman Act, i.e., that the statutory exemption provided under § 271(e)(1) was intended to have only a limited impact on the rights of patent holders. Comments expressing this view were made in response to objections that the proposed safe harbor statute, which deprived a patent holder of its intellectual property rights under certain circumstances, constituted a “taking” without just compensation in violation of the Fifth Amendment of the Constitution.<sup>40</sup> In addition to the above statement that “the nature of the interference with the rights of the patent holder is not substantial,”<sup>41</sup> the Committee on the Judiciary argued that “the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is *de minimus* [sic].”<sup>42</sup>

Admittedly, many of the criticisms leveled at the reliance on legislative history in statutory interpretation<sup>43</sup> apply to a reliance on the House reports on the Hatch-Waxman Act. The House reports expressed the views of select committee members of a single house of Congress. They were not voted on and may not have been read by a majority by the House of Representatives. The only language that was approved by both houses of Congress and signed by the President in accordance with the requirements of the Constitution was the wording that appeared in § 271(e)(1), the enacted statute.<sup>44</sup> As will be discussed in Part II below, the statutory text of § 271(e)(1) can bear a considerably broader meaning than that reflected in the legislative history of the Hatch-Waxman Act. Nonetheless, it is noteworthy that a review of the legislative history yields little support for the broad reading of the safe

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<sup>39</sup> H.R. REP. NO. 98-857, pt. 2, at 8–9 (footnotes omitted).

<sup>40</sup> *Id.* at 8.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 30.

<sup>43</sup> See ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 369–90 (2012).

<sup>44</sup> See generally Hatch-Waxman Act, *supra* note 20, at 1585.

harbor statute endorsed by a number of federal courts, including, most significantly, the Supreme Court in *Eli Lilly* and *Merck*.

## II. JUDICIAL INTERPRETATIONS OF THE SAFE HARBOR STATUTE—35 U.S.C. § 271(e)(1)

### A. Overview

One of the canons of statutory interpretation (the whole-text canon)<sup>45</sup> holds that to properly interpret the meaning of a statute, one must consider its entire text, including each of its various phrases and the relationship between them. The text of 35 U.S.C. § 271(e)(1) has been the subject of considerable debate, requiring judicial interpretation of a number of key provisions. The acknowledged ambiguity of key statutory phrases in § 271(e)(1) supports the view that the statute as a whole is less than clear on its face. As Justice Scalia stated in *Eli Lilly & Co. v. Medtronic, Inc.*, “[n]o interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.”<sup>46</sup>

The fact that the judges deciding seminal safe harbor cases have adopted different approaches to statutory interpretation adds to the uncertainty regarding the meaning and scope of the safe harbor statute. For example, both of the Supreme Court cases considering the scope of § 271(e)(1), *Eli Lilly*<sup>47</sup> and *Merck*,<sup>48</sup> were written by Justice Scalia. An avowed textualist,<sup>49</sup> Justice Scalia eschewed any reliance on the legislative history of the Hatch-Waxman Act in construing the safe harbor as broad in scope.<sup>50</sup> In contrast, Judge Rader of the Federal Circuit, who heard a number of that court’s safe harbor cases, frequently turned to the legislative history of the Act in arguing that the safe harbor statute should be narrowly construed, in keeping with the intent of the drafters that § 271(e)(1) have only a *de minimis* impact on the rights of patent holders.<sup>51</sup>

This Part of the Article considers the key terms of § 271(e)(1) that have been the subject of judicial review. As will be discussed below, the meaning of certain of these

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<sup>45</sup> See SCALIA & GARNER, *supra* note 43, at 167–69; William N. Eskridge, Jr. & Philip P. Frickey, *The Supreme Court 1993 Term: Foreword: Law As Equilibrium*, 108 HARV. L. REV. 26, 98 (1994).

<sup>46</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990). The Court stated, “[a]s far as the text is concerned, therefore, we conclude that we have before us a provision [, i.e., “under a Federal law,”] that somewhat more naturally reads as the Court of Appeals determined, but that is not plainly comprehensible on anyone’s view.” *Id.* at 669; see also *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (“[T]he contours of this provision [, i.e., 35 U.S.C. § 271(e)(1),] are not exact in every respect.”).

<sup>47</sup> *Eli Lilly*, 496 U.S. at 662.

<sup>48</sup> *Merck*, 545 U.S. at 194.

<sup>49</sup> See SCALIA & GARNER, *supra* note 43, at 167–69.

<sup>50</sup> See *infra* Part II.B.

<sup>51</sup> *Id.*; see also *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003); *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1350 (Fed. Cir. 2007) (Rader, J., dissenting); *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1362–66 (Fed. Cir. 2012) (Rader, J., dissenting).

terms has emerged through either a clear statement from the Supreme Court or a consensus among lower federal court rulings. For other terms, however, ambiguity as to their meaning remains, leaving those who intend to use a patented invention without authorization in reliance on the protection afforded by the safe harbor statute with some risk of infringement liability.

## *B. Critical Terms*

### *1. Under a Federal Law*

The U.S. Supreme Court in *Eli Lilly* first addressed the applicability and scope of the safe harbor statute.<sup>52</sup> The Court considered whether the unauthorized use of a medical device, an implantable cardiac defibrillator, was shielded from infringement under § 271(e)(1).<sup>53</sup> The question arose from an apparent limit to the scope of § 271(e)(1) resulting from the words “submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs*.”<sup>54</sup> Where, according to this language, is the right to use a patented invention without authorization to generate information relating to a *medical device*? Unless the invention is used to develop and submit information relating to a drug (which was not the case in *Eli Lilly*), its unauthorized use does not appear to be exempted from infringement liability under the safe harbor statute.

Writing for the *Eli Lilly* majority, Justice Scalia sought the answer by first considering the meaning of the statutory term “under a Federal law.”<sup>55</sup> Focusing on the relevant text of the statute, Justice Scalia argued that the words “under a Federal law” in § 271(e)(1) refer to “an entire statutory scheme of regulation,”<sup>56</sup> i.e., an entire Act rather than a particular provision of law. In the words of the Justice,

[t]he phrase “a Federal law” can be used to refer to an isolated statutory section . . . . The phrase is also used, however, to refer to an entire Act. The Constitution, for example, provides that “Every Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a *Law*, be presented to the President of the United States.” And the United States Code provides that “whenever a bill . . . becomes a law or takes effect, it shall forthwith be received by the Archivist of the United States from the President.” This latter usage, which is probably the more common one, seems also the more natural in the present context. If § 271(e)(1) referred to “a Federal law which *pertains* to the manufacture, use, or sale of drugs” it might be more reasonable to think that an individual provision was referred to. But the phrase “a Federal law which

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<sup>52</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 663 (1990).

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

<sup>54</sup> 35 U.S.C. § 271(e)(1) (2012) (emphasis added); *see also Eli Lilly*, 496 U.S. at 666 (1990).

<sup>55</sup> *Eli Lilly*, 496 U.S. at 666.

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

*regulates* the manufacture, use, or sale of drugs” more naturally summons up the image of an entire statutory scheme of regulation. The portion of § 271(e)(1) that immediately precedes the words “a Federal law” likewise seems more compatible with reference to an entire Act. It refers to “the development and submission of information *under* a Federal law.” It would be more common, if a single section rather than an entire scheme were referred to, to speak of “the development and submission of information *pursuant to* a Federal law,” or perhaps “*in compliance with* a Federal law.” Taking the action “under a Federal law” suggests taking it in furtherance of or compliance with a comprehensive scheme of regulation. Finally, and perhaps most persuasively, the fact that [section] 202 of the 1984 Act (which established § 271(e)(1)) used the word “law” in its broader sense is strongly suggested by the fact that the immediately preceding—and . . . closely related—section of the 1984 Act, when it meant to refer to a particular provision of law rather than an entire Act, referred to “the first permitted commercial marketing or use of the product under *the provision of law*.”<sup>57</sup>

On the basis of this analysis, Justice Scalia concluded that the phrase “under a Federal law which regulates drugs” actually means “under a provision that happens to be included within an Act that, *in any of its provisions*, not necessarily the one at issue, regulates drugs.”<sup>58</sup> And because the Food, Drug, and Cosmetic Act (the “FDCA”) contains provisions that regulate drugs, as well as provisions that regulate medical devices, patented inventions that are used to generate information relating to medical devices are eligible for coverage under the safe harbor statute.<sup>59</sup>

Justice Scalia acknowledged that “[a]s far as the text [of § 271(e)(1)] is concerned . . . we conclude that we have before us a provision that somewhat more naturally reads as the Court of Appeals [and this Court have] determined, but that is not plainly comprehensible on anyone’s view.”<sup>60</sup> Accordingly, he turned to the

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<sup>57</sup> *Id.* at 666–67 (emphasis in original) (citations omitted); *see also* Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1683–84 (2012). The Supreme Court cited its prior *Eli Lilly* decision in interpreting broadly the term “under.” *Id.* In the words of the *Caraco* Court,

[f]or example, in *Eli Lilly* . . . we examined a similar statutory reference to the “submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” We noted there that submitting information “under a Federal law” suggests doing so “in furtherance of or compliance with a comprehensive scheme of regulation.”

*Id.*

<sup>58</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 668 (1990) (emphasis in original).

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

<sup>60</sup> *Id.* at 669. The opinion continues,

one must admit that while the provision more naturally means what respondent [Medtronic, the alleged infringer,] suggests, it is somewhat difficult to understand why anyone would *want* it to mean that. Why should the touchstone of noninfringement be whether the use is related to the development and submission of information under a provision that happens to be included within an Act that,

structure of the Hatch-Waxman Act, taken as a whole, for further support for his contention that the safe harbor statute was intended to cover medical devices. As he explained:

[T]he 1984 [Hatch-Waxman] Act was designed to respond to two unintended distortions of the . . . patent term produced by the requirement that certain products must receive premarket regulatory approval. First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the “clock” on his patent term will be running even though he is not yet able to derive any profit from the invention.

The second distortion occurred at the other end of the patent term. In 1984 . . . the Federal Circuit [in *Bolar*] decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement . . . even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. . . . Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee’s *de facto* monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.

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*in any of its provisions*, not necessarily the one at issue, regulates drugs? The first response is that this was a shorthand reference to the pertinent provisions Congress was aware of, all of which happened to be included in Acts that regulated drugs. But since it is conceded that all those pertinent provisions were contained within only two Acts (the FDCA and the Public Health Service Act . . .), that is not much of a time-saving shorthand. The only rejoinder can be that Congress anticipated future regulatory-submission requirements that it would want to be covered, which might not be included in the FDCA or the PHS Act but would surely (or probably) be included in another law that regulates drugs. That is not terribly convincing. On the other hand, this same awkwardness, in miniature, also inheres in petitioner’s [, the patent holder, Eli Lilly’s,] interpretation, unless one gives “under a Federal law” a meaning it simply will not bear. That is to say, if one interprets the phrase to refer to only a single *section* or even *subsection* of federal law, it is hard to understand why the fact that that section or subsection happens to regulate drugs should bring within § 271(e)(1) other products that it also regulates; and it does not seem within the range of permissible meaning to interpret “a Federal law” to mean only isolated portions of a single section or subsection. The answer to this, presumably, is that Congress would not expect two products to be dealt with in the same section or subsection—but that also is not terribly convincing.

*Id.* at 668–69 (emphasis added).

The 1984 Act sought to eliminate this distortion from both ends of the patent period. Section 201 of the Act established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval. The eligible products were described as follows:

“(1) The term ‘product’ means: (A) A human drug product [, which means the active ingredient of a new drug, antibiotic drug, or human biological product]. (B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.” 35 U.S.C. § 156(f).

The distortion at the other end of the patent period was addressed by [section] 202 of the Act. That added to the provision prohibiting patent infringement, 35 U.S.C. § 271, the paragraph at issue here, establishing that “[i]t shall not be an act of infringement to make, use, 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.” § 271(e)(1). This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.<sup>61</sup>

The thrust of Justice Scalia’s argument was that a review of the structure of the Hatch-Waxman Act indicates that the Act intended that § 156 and § 271(e)(1) work in parallel to redress the “two unintended distortions of the . . . patent term produced by the requirement that certain products must receive premarket approval.”<sup>62</sup> By linking sections 156 and 271(e)(1), Justice Scalia was able to rely on the reference in § 156(f) to “any medical device” to bring the medical device under consideration in *Eli Lilly* within the scope of the § 271(e)(1) safe harbor.<sup>63</sup>

A review of the text of the Hatch-Waxman Act provided additional support for the view that sections 156 and 271(e)(1) were intended to work in tandem. In the words of Justice Scalia,

there are textual indications that sections 201 and 202 are meant generally to be complementary. That explains, for example, [section] 202’s exception for “a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913).” 35 U.S.C. § 271(e)(1). Although new animal drugs and veterinary biological products are subject to premarket regulatory licensing and approval under the FDCA, see 21 U.S.C. §360b (new animal drugs), and the Act of March 4, 1913, see 21 U.S.C. §§ 151, 154 (veterinary biological products)—each “a Federal law which regulates the manufacture, use, or sale of drugs”—neither product was included in the patent-term extension

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<sup>61</sup> *Id.* at 669–71.

<sup>62</sup> *Id.* at 669.

<sup>63</sup> *Id.* at 670–71.

provision of § 201. They therefore were excepted from § 202 as well. Interpreting § 271(e)(1) as the Court of Appeals did here appears to create a perfect “product” fit between the two sections. All of the products eligible for a patent term extension under [section] 201 are subject to [section] 202, since all of them—medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products—are subject to premarket approval under various provisions of the FDCA . . . And the products subject to premarket approval under the FDCA and the Act of March 4, 1913 that are *not* made eligible for a patent term extension under [section] 201—new animal drugs and veterinary biological products—are excluded from [section] 202 as well.<sup>64</sup>

Justice Scalia acknowledged that there may be exceptions to the “perfect ‘product’ fit” reflected in sections 156 and 271(e)(1).<sup>65</sup> However, according to Justice Scalia, these exceptions are rare and do not undermine the force of the argument that as a general rule, under the Hatch-Waxman Act, the “patented inventions” that are subject to the disadvantage of the § 271(e)(1) noninfringement provision are the ones that are eligible for the benefit of the § 156 patent term extension.<sup>66</sup> As Justice Scalia explained:

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<sup>64</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 673 (1990) (emphasis added) (internal citations omitted).

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

<sup>66</sup> *See id.* at 672, 674–75 nn. 4, 6. Justice Scalia opined,

[i]t must be acknowledged that the seemingly complete product-correlation between [section] 201 and [section] 202 was destroyed in 1986, when, without adding “new infant formula” to the defined products eligible for the patent-term extension under § 156, Congress established a premarket approval requirement for that product, and thus automatically rendered it eligible for the § 271(e)(1) exemption from patent infringement. That subsequent enactment does not change our view of what the statute means. That isolated indication of lack of correlation between § 156 and § 271(e)(1) is in any event contradicted by the 1988 amendment that added most new animal drugs and veterinary biological products to § 156 and simultaneously deleted from § 271(e)(1) the infringement exception for those products.

*Id.* at 674–75, n.6 (citations omitted). Justice Scalia also stated that:

We cannot readily imagine such situations [in which the advantage of the § 156 extension is not paired with the disadvantage of the § 271(e)(1) noninfringement provision] (and petitioner has not described any), except where there is good enough reason for the difference. Petitioner states that disequilibrium of this sort will often occur because the § 271(e)(1) noninfringement provision applies “whether the patent term is extended or not,” and even with respect to “patents which cannot qualify for a term extension.” But if the patent term is not extended only because the patentee does not apply, he surely has no cause for complaint. And the major reason relevant patents will not qualify for the term extension is that they pertain to “follow-on” drug products rather than “pioneer” drug products . . . For these, however, the abbreviated regulatory approval procedures established by Title I of the 1984 Act . . . eliminate substantial regulatory delay at

Under respondent's interpretation, there may be some relatively rare situations in which a patentee will obtain the advantage of the § 201 extension but not suffer the disadvantage of the § 202 noninfringement provision, and others in which he will suffer the disadvantage without the benefit. Under petitioner's interpretation, however, that sort of disequilibrium becomes the general rule for patents relating to all products (other than drugs) named in § 201 and subject to premarket approval under the FDCA. Not only medical devices, but also food additives and color additives, since they are specifically named in § 201, see 35 U.S.C. § 156(f), receive the patent-term extension; but since the specific provisions requiring regulatory approval for them, though included in the FDCA, are not provisions requiring regulatory approval for drugs, they are (on petitioner's view) not subject to the noninfringement provision of § 271(e)(1). It seems most implausible to us that Congress, being demonstrably aware of the *dual* distorting effects of regulatory approval requirements in this entire area—dual distorting effects that were roughly offsetting, the disadvantage at the beginning of the term producing a more or less corresponding advantage at the end of the term—should choose to address both those distortions only for drug products; and for other products named in § 201 should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating distortion of the [period of] patent protection. It would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence here.<sup>67</sup>

In sum, Justice Scalia relied on the text of § 271(e)(1) and the structure and text of the Hatch-Waxman Act to adopt an expansive reading of the term “under a Federal law” that brought the medical device in *Eli Lilly* within the ambit of the safe harbor statute.<sup>68</sup> His analysis, however, left questions as to the breadth of the statutory term “patented invention,” as will be discussed in Part II.B.4. In keeping with his bias against the use of legislative history in statutory interpretation, Justice Scalia noted that the legislative history of section 202 of the Hatch-Waxman Act “shed[] no clear light”<sup>69</sup> on the issue before the Court in *Eli Lilly*.

## 2. *Solely*

Shortly after the passage of the Hatch-Waxman Act, the district court of the Northern District of California in *Scripps Clinic and Research Foundation v.*

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the outset of the patent term and thus eliminate the justification for the § 156 extension.

*Id.* at 672, n.4 (citations omitted).

<sup>67</sup> *Id.* at 671–73 (emphasis in original).

<sup>68</sup> *Id.* at 679.

<sup>69</sup> *Id.* at 669.

*Genentech, Inc.* endorsed a narrow reading of § 271(e)(1), based on its interpretation of the effect of the word “solely” in the statute.<sup>70</sup> According to the *Scripps* court, for the exemption to apply, each allegedly infringing use must be “*solely for purposes* reasonably related to meeting the reporting requirements of federal drug laws.”<sup>71</sup> Where an alleged infringer’s uses of the patented invention are reasonably related to meeting the FDA requirements but are not solely related to that purpose, the benefit of the safe harbor must be denied.<sup>72</sup> Because the uses of the patented invention in the *Scripps* case also related, among other things, to the preparation of a European patent application and to the performance of the alleged infringer’s obligations under an agreement, the alleged infringer’s activities were not shielded from infringement liability under § 271(e)(1).<sup>73</sup> As the *Scripps* court explained,

[T]he construction of § 271(e)(1) that Genentech [the alleged infringer] urges the Court to adopt would, in effect, eliminate the express statutory limitation “solely for” and thereby immunize any use of a patented invention so long as some aspect of that use is reasonably related to FDA testing. This broad construction defies the plain mandate of the statute and the intent of Congress. The statut[ory] . . . interpretation [endorsed by this Court, on the other hand,] accords with the intent of Congress in enacting § 271(e)(1). The comments of the authors of the House Report emphasize the narrowness of the exemption.<sup>74</sup>

A number of federal courts<sup>75</sup> have subsequently rejected the *Scripps* court’s narrow construction of § 271(e)(1) in favor of some version of the following interpretation of the meaning of the word “solely” in the statute: Each allegedly infringing activity (i.e., each act of manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of a patented invention that would constitute infringement but for the protection of the exemption) can have multiple purposes, in the sense of a party’s motives or goals in undertaking such activity, (e.g., to obtain regulatory approval in the U.S. and abroad, to obtain data to support the filing of a patent application, to attract investors), have multiple

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<sup>70</sup> *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1396 (N.D. Cal. 1987).

<sup>71</sup> *Id.* (emphasis added).

<sup>72</sup> *Id.*

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

<sup>74</sup> *Id.* (internal citation omitted). The *Scripps* case is the first of a number of examples in this Article where a judicial opinion that has construed § 271(e)(1) as narrow in scope has relied on the legislative history of the Hatch-Waxman Act.

<sup>75</sup> See *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1288 (N.D. Cal. 1991), *aff’d* 991 F.2d 808 (Fed. Cir. 1993) (non-precedential); *Elan Transdermal Ltd. v. Cygnus Therapeutic Sys.*, No. C-91-1413 WHO, 1992 U.S. Dist. LEXIS 20004, at \*18–19 (N.D. Cal. June 23, 1992); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992); *Chartex Int’l PLC v. M.D. Personal Prods. Corp.*, No. 92-1556, 1993 U.S. App. LEXIS 20560, at \*13 (Fed. Cir. Aug. 12, 1993); *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 208, 210 (D.N.J. 1994); *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029–30 (Fed. Cir. 1997); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 107–08 (D. Mass. 1998); *Nexell Therapeutics, Inc. v. Amcell Corp.*, 199 F. Supp. 2d 197, 204 (D. Del. 2002).

consequences (e.g., regulatory approval, issuance of a patent, a successful financing), and be associated with non-infringing activities (e.g., use of clinical data to attract investors or to publish scientific articles). As long as, with respect to each allegedly infringing activity, such activity is solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products, the exemption is available to the alleged infringer, and neither the underlying purpose(s) or attendant consequence(s) of such activity,<sup>76</sup> nor any associated non-infringing activities,<sup>77</sup> will deprive the alleged infringer of the benefit of the exemption.

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<sup>76</sup> See *Intermedics*, 775 F. Supp. at 1280. The court said,

if a party were to lose the exemption every time a business purpose was detectable in its otherwise infringing activities, the exemption would virtually never be available and thus would fail to achieve Congress' objective. . . . Congress sensibly chose words in the exemption that would lead courts to focus not on "purposes" or motives, but on "uses," and not on collateral activities, but only on the kinds of conduct which, absent the exemption, would constitute infringement. In the context of this understanding, we have struggled with the question of what analytical significance, if any, to ascribe to the "effects" of the otherwise infringing "uses" by defendant of the patented material. Because we believe that Congress contemplated a strictly objective test (to determine whether the exemption attaches), and because we believe that Congress did not intend the availability of the exemption to turn on findings about a party's "purposes" or "motives," we believe that we should consider "effects" only to the extent that doing so is helpful in identifying what the actual uses have been, and not, obviously, to shed light on the designs or ambitions or goals ("purposes") that might have underlay those uses. Moreover, since what we are examining is actual, otherwise infringing uses, not purposes and not collateral activity, we conclude that the only kinds of "effects" to which it might be appropriate to ascribe appreciable significance in this analysis are those that are immediate and direct. We will concern ourselves little, if at all, with effects that are indirect, or in which the causal chain has several links. We will ignore altogether effects that are speculative or remote. Thus, our inquiry is relatively straightforward. We focus only on those acts by Ventritex [, the alleged infringer,] which would be deemed "infringing" but for § 271(e)(1) and in which Ventritex actually has engaged (as opposed to the acts in which the company might engage in the future). With respect to those actual acts, we do not ask what underlying motives might have inspired them or what indirect, ripple effects (e.g., long range consequential benefits) they might bring. Instead, we simply ask: are these actual uses "solely . . . reasonably related to the development and submission of information" to the FDA. If so, the exemption protects Ventritex. But if there are any actual, non-*de minimis* uses that are not reasonably related to generating data for the FDA, the exemption will not protect Ventritex.

*Id.*; see also *AbTox*, 122 F.3d at 1030 ("The statute . . . does not look to the underlying purposes or attendant consequences of the activity (e.g., tests led to the sale of the patent), as long as the activity is reasonably related to obtaining FDA approval."); *Amgen*, 3 F. Supp. 2d at 107–08.

The phrase "solely for uses reasonably related" is not equivalent to the phrase "use is solely for purposes reasonably related." The later reflects a more restrictive view of permissible activities under the statute. Uses, such as animal testing, human clinical trials, or chemical composition analysis, may be related to FDA approval, and yet be conducted for purposes other than, or in addition to,

According to this interpretation, the word “solely” in the safe harbor statute modifies the word “uses” and not the expressed words “reasonably related” or the unstated words “for purposes.”<sup>78</sup> Moreover, the focus of the inquiry under a

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obtaining FDA approval. The Federal Circuit precedents indicate that such ulterior motives or alternate purposes do not preclude application of the section 271(e)(1) exemption.

*Id.*

[T]he use [of a patented invention] must be reasonably related to (albeit not for the exclusive purpose of) FDA approval. . . . In order to come within the protection of section 271(e)(1), the Defendants thus must make, use, or sell the patented invention in ways that objectively bear reasonable prospects of yielding information that might be relevant in the FDA approval process. If the Defendants have confined themselves to such uses, then their subsequent use of the information gathered, their ulterior motives for engaging in the research, and the existence of other more promising or less extensive uses that also might have lead [sic] to FDA acceptance are all statutorily irrelevant factors.

*Id.* at 108.

<sup>77</sup> See *Intermedics*, 775 F. Supp. at 1278 (“[T]he exemption Congress provided is not lost simply as a result of a showing that the defendant has engaged in *non-infringing* acts whose ‘uses’ fall outside those permitted by the statute.”); *Elan Transdermal*, 1992 U.S. Dist. LEXIS 20004, at \*20 (“A party that engages in otherwise noninfringing acts for purposes other than FDA approval does not lose the benefits of this exemption.”).

To adopt [the patent holder’s] interpretation we would have to read into this statute an unspoken requirement that the disclosure of information obtained during clinical trials to persons other than FDA officials, although not itself an act of infringement, somehow “repeals” the exemption. We do not find that requirement in the words of the statute.

*Telectronics Pacing Sys.*, 982 F.2d at 1524.

If Congress intended to make . . . [immediate competition following patent expiration] more difficult, if not impossible, by preventing competitors from using, in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes, it would have made that intent clear. The statute contains no such provision.

*Id.* at 1525.

<sup>78</sup> See *Intermedics*, 775 F. Supp. at 1278. The court said,

we feel that it is significant that when Congress chose the words in which to articulate the conditions under which the exemption would attach it did *not* use the word “*purposes*” at all, *but, instead*, settled on the word “*uses*.” It is plaintiff [, the patent holder], not Congress, that has insisted that the word “*purposes*” is fungible in this context with the word “*uses*.” We are not at all sure, however, that Congress intended any such fungibility. The relevant phraseology is “solely for uses reasonably related,” not “solely for purposes reasonably related.” Obviously Congress is familiar with the word “*purposes*.” If Congress had wanted courts to focus on “*purposes*” it probably would have selected that word instead of the substantially more awkward word “*uses*” (the awkwardness is compounded in this context, where “*uses*” appears earlier in the same sentence, as a verb instead

§ 271(e)(1) analysis is only on conduct with respect to a patented invention that would constitute an act of infringement but for the exemption.<sup>79</sup> The word “solely” is not superfluous in that it was added by Congress to indicate that for the exemption to immunize an alleged infringer who uses a patented invention without authorization,

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of a noun, in the listing of categories of conduct that can constitute infringement). Given the obviousness of the alternative, we think that the selection by Congress of the word “uses” at this critical juncture in the exemption supports two related inferences: (1) that Congress intended the “test” for determining whether the exemption has been lost to be “objective” rather than “subjective” (focusing on conduct rather than motive or ultimate aim) and (2) that Congress wanted the courts, in applying this statute, to focus on *conduct (“uses”) that actually has occurred* (as opposed to uses to which a party might put its product in the future) *and that would constitute infringement* but for the exemption.

*Id.* (emphasis in original); see also *Elan Transdermal*, 1992 U.S. Dist. LEXIS 20004, at \*19 (“[The *Intermedics*] court recognized that ‘solely’ in § 271(e)(1) is correctly read as modifying ‘uses,’ not ‘reasonably related.’”).

This Court determines that the *Scripps* case misconstrues the exemption. Although § 271(e)(1) exempts otherwise infringing activity that is “solely for uses reasonably related” to FDA approval, the *Scripps* case repeatedly refers to “purposes reasonably related” to FDA approval. Because the *Scripps* court found broader purposes than simple FDA approval behind the defendant’s action, that court held that the exemption did not apply. The leap from “uses” to “purposes” represents an unwarranted rewriting of the statute to limit the reach of the exemption. As conscientiously discussed in *Intermedics*, Congress would have used the term “purposes” instead of the substantially more awkward term “uses” if that had been Congress’ intent. An alternative potential purpose is irrelevant so long as the “use” itself is reasonably related to FDA approval.

*Id.* at \*22–23 (emphasis in original).

<sup>79</sup> See *Intermedics*, 775 F. Supp. at 1277. The court said:

Through § 271(e)(1), Congress changed the status in law only of acts which, but for this exemption, would constitute acts of infringement. Thus the only kinds of acts to which this legislation applies are acts which would constitute acts of infringement. When trying to determine whether a party is protected by this exemption, the *target of a court’s inquiry* is on *those acts of manufacture, use, or sale of a patented invention that would constitute acts of infringement* but for this exemption. It is these kinds of acts, only, that must be “solely for uses reasonably related” to generating data for submission to the FDA. It is these kinds of acts whose “uses” are in issue, and the exemption is lost only if the court concludes that acts of these kinds have been undertaken for “uses” that are outside those permitted under the statute.

*Id.* (emphasis in original); see also *NeoRx*, 877 F. Supp. at 206 (“Application of Section 271(e)(1) requires a two-step inquiry: (1) whether the activity at issue is a potentially infringing one; and (2) whether the exemption applies to that activity.”); *Amgen*, 3 F. Supp. 2d at 107.

[S]ection 271 applies generally only to activities that might constitute infringement. Thus, a defendant need not show that all of its conduct falls under the section 271(e)(1) exemption, only the making, using, or selling of the claimed invention. All other conduct falls outside the section 271(a) definition of infringement in the first instance.

each of the allegedly infringing acts must constitute, or result in, a use of the patented invention that is reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products (an “immunizing use”) and *no other type of use*.<sup>80</sup> In the words of the district court in *Intermedics, Inc. v. Ventritex, Inc.*,<sup>81</sup> whose thoughtful interpretation of the safe harbor statute has been endorsed by both the Federal Circuit<sup>82</sup> and the Supreme Court,<sup>83</sup> “by enacting this exemption, congress [sic] has said to the public: ‘You may commit acts of *infringement* only so long as *those* acts are solely for uses reasonably related to gaining FDA approval to market your product. If you engage in infringing activities for other uses, the exemption will not protect you.’”<sup>84</sup> As noted above, the purpose(s) for such allegedly infringing acts, the consequence(s) of such acts, and any associated non-infringing activities are irrelevant to the analysis. In essence, this view of the meaning of § 271(e)(1) holds that an immunizing use, in the absence of any other type of use, is necessary and sufficient for the statutory exemption to shield an alleged infringer from infringement liability.

The consensus among the federal court decisions that followed the *Scripps* holding provides a working interpretation of the statutory term “solely” in § 271(e)(1). Nonetheless, the term remains a source of some confusion and is still applied with a lack of precision.<sup>85</sup>

### 3. Reasonably Related

The Supreme Court’s decision in *Merck KGaA v. Integra, Lifesciences I, Ltd.*<sup>86</sup> is the leading opinion on the interpretation of the statutory term “reasonably related”

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<sup>80</sup> See *Intermedics*, 775 F. Supp. at 1277–78.

<sup>81</sup> *Id.*

<sup>82</sup> See *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525, n.5 (Fed. Cir. 1992) (“For a carefully reasoned and exhaustive analysis of this point [regarding the meaning of the statutory term “solely” and the effect of engaging in associated non-infringing conduct], arriving at the same conclusion, see the opinion of Magistrate Wayne D. Brazil in *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D.Cal.1991).”).

<sup>83</sup> See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005) (endorsing the *Intermedics* court’s construction of the statutory term, “reasonably related”).

<sup>84</sup> *Intermedics*, 775 F. Supp. at 1277–78 (emphasis in original); see also *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d. 104, 108 n.3 (D. Mass. 1998).

The word “solely” is not rendered superfluous by the Federal Circuit’s reading [of the meaning of the term in its precedents] . . . Rather, it mandates that the making, using, or selling of the patented invention cannot be for uses that are not reasonably related to FDA approval; that is, uses which could not reasonably be expected to lead to the production of information that could be used to satisfy FDA reporting requirements.

*Id.*

<sup>85</sup> See *infra* Part II.B.5 (discussing the statutory term “solely” in the majority and the dissenting opinions in the *Momenta* case).

<sup>86</sup> *Merck*, 545 U.S. at 202.

in § 271(e)(1). In *Merck*, Integra owned a number of patents that claimed peptides containing the amino acid sequence Arg-Gly-Asp.<sup>87</sup> These peptides had been shown to promote cell adhesion by interacting with certain protein receptors on the cell surface and were, therefore, potentially useful in promoting wound healing and the biocompatibility of prosthetic devices.<sup>88</sup> A scientist at Scripps Research Institute subsequently discovered that using the patented peptides to block the same cell surface receptors inhibited angiogenesis, the process of generating new blood vessels that could be useful in treating a variety of diseases, including cancer.<sup>89</sup> Merck entered into an agreement with Scripps to fund experiments using the patented peptides to identify potential drug candidates that might inhibit angiogenesis.<sup>90</sup> Upon learning of this agreement, Integra sued Merck for patent infringement.<sup>91</sup> Merck responded that its activities were shielded from infringement liability under § 271(e)(1).<sup>92</sup> The Federal Circuit disagreed on the basis of its narrow reading of the scope of the safe harbor statute.<sup>93</sup> According to the court, “the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds.”<sup>94</sup> As such, the work fell outside of the ambit of § 271(e)(1), which was intended to allow for only a “de minimis [sic] encroachment on the rights of the patentee.”<sup>95</sup> The Federal Circuit concluded its analysis by stating that the safe harbor under § 271(e)(1) “does not reach any exploratory research that may rationally form only a predicate for future FDA clinical tests.”<sup>96</sup> Merck appealed to the Supreme Court and, in its landmark decision, the Court overruled the Federal Circuit.<sup>97</sup> Finding for the alleged infringer, the Court focused on the statutory term “reasonably related” in adopting a construction of § 271(e)(1) that was considerably broader than the one endorsed by the Federal Circuit.<sup>98</sup>

The *Merck* Court addressed the substantive standard to be applied in determining whether the “reasonably related” requirement in the safe harbor statute has been met when it reviewed the jury instruction of the district court in the case.<sup>99</sup> According to the district court,

[t]o prevail on this defense, [the alleged infringer] must prove by a preponderance of the evidence that it would be objectively reasonable for a party in [the alleged infringer’s] situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in

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<sup>87</sup> *Id.* at 197.

<sup>88</sup> *Id.*

<sup>89</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 197 (2005).

<sup>90</sup> *Id.* at 198–99.

<sup>91</sup> *Id.* at 200.

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

<sup>93</sup> *Id.* at 201–02.

<sup>94</sup> *Id.* (citing *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 866 (Fed. Cir. 2003)).

<sup>95</sup> *Integra Lifesciences I*, 331 F.3d at 867.

<sup>96</sup> *Id.*

<sup>97</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 208 (2005).

<sup>98</sup> *Id.* at 207–08.

<sup>99</sup> *Id.* at 200.

the processes by which the FDA would decide whether to approve the product in question.<sup>100</sup>

The instruction closely tracked, and was obviously based on, a prior statement in the *Intermedics* opinion:

[W]ith respect to this aspect of the test [for determining whether a “use” qualifies as “reasonably related” under § 271(e)(1),] we should ask: would it have been reasonable, objectively, for a party in defendant’s situation to believe that there was a decent prospect that the “use” in question would contribute (relatively directly) to the generation of [the] kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product?<sup>101</sup>

In vacating the judgment of the Court of Appeals and remanding the case, the Supreme Court in *Merck* endorsed the district court’s jury instruction (and the interpretation of the meaning of the term “reasonably related” provided by the *Intermedics* court) in stating that “the evidence presented at trial has yet to be reviewed under the standards set forth in the jury instruction, which we believe to be

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

<sup>101</sup> *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp 1269, 1280 (N.D. Cal. 1991), *aff’d* 991 F.2d 808 (Fed. Cir. 1993) (non-precedential). The full quotation is below:

We infer that the phrase “reasonably related” (to development of information for the FDA) as used in § 271(e)(1) reflects Congress’ acknowledgement that it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency’s approval. Thus, Congress used this phrase to communicate its intention that the courts give parties some latitude in making judgments about the nature and extent of the otherwise infringing activities they would engage in as they sought to develop information to satisfy the FDA. Contrary to the suggestion seemingly made by plaintiff [, the patent holder], we do not believe that Congress intended a party to lose the exemption simply because it turns out, after the fact, that some of that party’s otherwise infringing “uses” either failed to generate information in which the FDA was interested or generated more information than turned out to be necessary to secure FDA approval. Instead, with respect to this aspect of the test we should ask: would it have been reasonable, objectively, for a party in defendant’s situation to believe that there was a decent prospect that the “use” in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product? If the answer is yes, it should not matter that other reasonable persons might have concluded that FDA approval could be secured even without the information in question.

*Id.* at 1280–81. “Strong textual support for the view that Congress intended the test to be objective derives from the legislators’ selection of the phrase ‘reasonably related’ to modify the word ‘uses.’ ‘Reasonably related’ is language that clearly has become associated with objective standards. *Id.* at 1279.

consistent with, if less detailed than, the construction of § 271(e)(1) that we adopt today.”<sup>102</sup>

The additional detail that the *Merck* Court provided with respect to the meaning of the statutory term “reasonably related” focused on the upstream activities on the critical path of drug development that the Federal Circuit had concluded were outside of the ambit of § 271(e)(1). In the words of Justice Scalia, writing for a unanimous Court, “[w]e decline to read the ‘reasonable relation’ requirement so narrowly as to render § 271(e)(1)’s stated protection of activities leading to FDA approval for all drugs illusory. Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval.”<sup>103</sup> The *Merck* Court acknowledged the Federal Circuit’s view that the safe harbor “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.”<sup>104</sup> Nonetheless, the Court argued that if the substantive standard for the “reasonably related” requirement is met, the generation of information in a preclinical study is eligible for protection under § 271(e)(1),<sup>105</sup> irrespective of whether the study (i) addresses the safety, efficacy, mechanism of action, pharmacokinetics, or pharmacology of a drug candidate,<sup>106</sup> (ii) is conducted in accordance with good laboratory practice regulations,<sup>107</sup> or (iii) is ever actually included in a submission to the FDA.<sup>108</sup>

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<sup>102</sup> *Merck*, 545 U.S. at 208.

<sup>103</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005). In reaching this conclusion, the *Merck* Court again relied on the reasoning set forth in the *Intermedics* decision. *Id.* (“As a District Court has observed, “[I]t will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency’s approval.””).

<sup>104</sup> *Id.* at 205 (citing *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003)).

<sup>105</sup> *Id.* at 202. The Court stated,

we think it 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. . . . This necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process.

*Id.* (emphasis in original).

<sup>106</sup> *Id.* at 203. The Court explained,

[the patent holder argues] that the only preclinical data of interest to the FDA is that which pertains to the safety of the drug in humans. In [the patent holder’s] view, preclinical studies related to a drug’s efficacy, mechanism of action, pharmacokinetics, and pharmacology are not reasonably included in an IND or an NDA, and are therefore outside the scope of the exemption. We do not understand the FDA’s interest in information gathered in preclinical studies to be so constrained.

*Id.*

<sup>107</sup> *Id.* at 204–05. The Court stated:

[The patent holder contends] that, even accepting that the FDA is interested in preclinical research concerning drug characteristics other than safety, the

The *Merck* Court effectively broadened the Federal Circuit's narrow interpretation of § 271(e)(1) by extending the upstream reach of the statute. But its holding did not clearly articulate a test to be used in distinguishing between the research activities on the critical path of drug development that are exempted under the statute and the discovery activities on that path that are outside of the ambit of the exemption. A careful reading of the Supreme Court's ruling, however, provides some guidance as to the upstream boundary of § 271(e)(1).

According to the *Merck* Court,

[b]asic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not "reasonably related to the development and submission of information" to the FDA.<sup>109</sup>

However,

[w]here 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

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experiments in question here are necessarily disqualified because they were not conducted in conformity with the FDA's good laboratory practices regulations. This argument fails for at least two reasons. First, the FDA's requirement that preclinical studies be conducted under "good laboratory practices" applies only to experiments on drugs "to determine their safety," 21 CFR § 58.3(d). . . . The good laboratory practice regulations do not apply to preclinical studies of a drug's efficacy, mechanism of action, pharmacology, or pharmacokinetics. Second, FDA regulations do not provide that even safety-related experiments not conducted in compliance with good laboratory practices regulations are not suitable for submission in an IND. Rather, such studies must include "a brief statement of the reason for the noncompliance."

*Id.*

<sup>108</sup> *Id.* at 207. The Court noted,

[T]he use of a patented compound in experiments that are not themselves included in a "submission of information" to the FDA does not, standing alone, render the use infringing. The relationship of the use of a patented compound in a particular experiment to the "development and submission of information" to the FDA does not become more attenuated (or less reasonable) simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA.

*Id.* The Supreme Court in *Merck* also held that § 271(e)(1) is not limited to information relevant to the filing of an Abbreviated New Drug Application ("ANDA") for the approval of a generic drug, but is sufficiently broad in scope to include information relevant to the filing of an Investigational New Drug Application ("IND") or a New Drug Application ("NDA"). This aspect of the *Merck* Court's holding is discussed below in Part II.B.5 ("Submission of Information").

<sup>109</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 205–06 (2005).

use is “reasonably related” to the “development and submission of information under . . . Federal law.”<sup>110</sup>

Taken together, these two statements suggest that there is a critical threshold on the path of drug development that must be crossed before the statutory exemption from infringement provided under § 271(e)(1) applies. Specifically,

that threshold is where “a researcher endures the unpredictable and open-ended process of screening untested structures and emerges with unmistakable evidence that a particular structure shows promise . . . in treating a particular disease through a known mechanism.” It is only after the researcher has crossed this critical threshold that the exemption provided under § 271(e)(1) can apply to future experiments undertaken to study the identified drug candidate.<sup>111</sup>

In other words, there must, at least, be a product candidate under study for the statutory exemption to apply.<sup>112</sup>

The facts in *Merck* did not raise the question of whether § 271(e)(1) applies to activities undertaken with respect to a product that has already received marketing approval, and there remains uncertainty as to a downstream cutoff (in terms of the stage of a product’s development) of the statutory phrase “reasonably related.” In *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, the Federal Circuit held that there is no such downstream cutoff, based, *inter alia*, on the *Merck* Court’s statement that,

we think it 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. . . . There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed.<sup>113</sup>

While the *Merck* Court focused on pre-approval activities, the Court’s statement that the exemption can extend to activities for uses that are “reasonably related to the development and submission of *any* information” suggests that such activities can take place both pre- and post-approval of a product. This view is, arguably, inconsistent with the Federal Circuit’s prior holding in *Classen Immunotherapies, Inc. v. Biogen IDEC*, in which the court looked to the legislative history of the Hatch-Waxman Act to conclude that the safe harbor provision was not intended to apply to

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<sup>110</sup> *Id.* at 207.

<sup>111</sup> See Server, *supra* note 17, at 51–54 (citing Brief for Petitioner at 39, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (No. 03-1237)).

<sup>112</sup> See *id.* at 45–55 (discussing the *Merck* case in the context of an analysis of whether § 271(e)(1) applies to the unauthorized use of drug discovery tools).

<sup>113</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (emphasis in original).

post-marketing approval activities.<sup>114</sup> The tension between the Federal Circuit’s decision in *Momenta* and *Classen* is discussed in detail below.<sup>115</sup>

#### 4. Patented Invention

In the *Eli Lilly* case,<sup>116</sup> as in the *Roche* case<sup>117</sup> before it and, as will be discussed below, the *AbTox*<sup>118</sup> and *Merck*<sup>119</sup> cases after it, the alleged infringement resulted from the investigational testing of an allegedly infringing medical product. In this circumstance, the patented invention used without authorization and the product candidate with respect to which the information was being generated were identical or, at least, covered by the same patent, i.e., a patented drug or medical device was used to study the alleged infringer’s candidate drug or medical device. The *Eli Lilly* Court relied on its expansive interpretation of the meaning of the term “under a Federal law” to argue that the statutory exemption covered the generation of information for submission to the FDA that related to a candidate medical device.<sup>120</sup> However, the Court was also required to effectively argue that the statutory term “patented invention” was sufficiently broad in scope to include the patented medical device that was used to generate such information.<sup>121</sup> As discussed in this Part, the *Eli Lilly* Court did so, but in a manner that left questions as to the breadth of the term “patented invention” that were relevant to the outcome of subsequent safe harbor cases, where the nature of the invention used without authorization had changed (*see* Table 1—“Patented Invention” Cases).

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<sup>114</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1071 (Fed. Cir. 2011).

<sup>115</sup> *See infra* Part II.B.5 (“Submission of Information”).

<sup>116</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 663–64 (1990).

<sup>117</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984).

<sup>118</sup> *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027–28 (Fed. Cir. 1997).

<sup>119</sup> *Merck*, 545 U.S. at 195.

<sup>120</sup> *See supra* Part II.B.1; *Eli Lilly*, 496 U.S. at 668–69.

<sup>121</sup> *Eli Lilly*, 496 U.S. at 672–73.

**TABLE 1**  
**“PATENTED INVENTION” CASES**

| Case  | Product Candidate <sup>122</sup>  | Patented Invention Used Without Authorization                               | Is the patented invention that was used without authorization of a type that is eligible for a patent term extension? | Was the product candidate under study covered by a patent that covered the patented invention that was used without authorization? <sup>123</sup> | Does the § 271(e)(1) safe harbor statute exempt the unauthorized use from infringement liability? |
|---|---|---|---|---|---|
| <i>Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.</i> , 733 F.2d 858 (Fed. Cir. 1984) | Flurazepam hydrochloride—generic version of the patented sleeping pill “Dalmane” <sup>124</sup> | Flurazepam hydrochloride <sup>125</sup>                                     | Yes (had the Hatch-Waxman Act been in effect at the time) <sup>126</sup>  | Yes <sup>127</sup>  | Yes (had the Hatch-Waxman Act been in effect at the time) <sup>128</sup>                          |
| <i>Eli Lilly &amp; Co. v. Medtronic, Inc.</i> , 496 U.S. 661 (1990)                           | Implantable cardiac defibrillator—a class III medical device <sup>129</sup>                     | Implantable cardiac defibrillator—a class III medical device <sup>130</sup> | Yes <sup>131</sup>  | Yes <sup>132</sup>  | Yes <sup>133</sup>  |

<sup>122</sup> Note that in *Classen* and in *Momenta* the “product candidate” under study had already received regulatory approval, however, this fact is not relevant to the analysis presented in Table 1.

<sup>123</sup> If the answer to the question is *yes*, the holder of the patent on the invention used without authorization lacks the right, based on application of the safe harbor statute, to block the unauthorized manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its patented invention for uses reasonably related to the “development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” 35 U.S.C. § 271(e)(1) (2012). But the patent holder has the right to block the commercialization of the product candidate for the life of the patent. 35 U.S.C. § 271(a) (2012). In this circumstance, the patent holder retains an opportunity to exclusively exploit the value of its patent for commercial purposes and the impact of the safe harbor statute on the patent holder’s right would qualify as “*de minimis*,” as discussed in the legislative history of the Hatch-Waxman Act. If the answer to the question is *no*, however, the holder of the patent on the invention used without authorization not only lacks the right, based on application of the safe harbor statute, to block the unauthorized manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its patented invention for uses reasonably related to the “development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” 35 U.S.C. § 271(e)(1) (2012). But the patent holder may also lack the right, under a broad construction of the statutory term “patented invention,” to derive any commercial value from its invention if, for example, the invention is a research tool or a manufacturing test method whose only commercially-viable use is for an activity that is shielded from infringement liability by § 271(e)(1). In this circumstance, the safe harbor statute could render the patent holder’s right to exclude worthless for the life of its patent.

<sup>124</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 860 (Fed. Cir. 1984).

<sup>125</sup> *Id.*

<sup>126</sup> As discussed *supra* in Part I, the Hatch-Waxman Act was enacted after and in response to the Federal Circuit’s *Roche* decision.

<sup>127</sup> *Id.* at 860.

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

<sup>129</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 663 (1990).

<sup>130</sup> *Id.* at 664.

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

|  |  |  |                                    |                                   |   |
|--|--|--|------------------------------------|-----------------------------------|---|
| <i>AbTox, Inc. v. Exitron Corp.</i> , 122 F.3d 1019 (Fed. Cir. 1997)                     | Class II medical device used to sterilize medical instruments <sup>134</sup> | Class II medical device used to sterilize medical instruments <sup>135</sup>                     | No <sup>136</sup>                  | Yes <sup>137</sup>                | Yes <sup>138</sup>  |
| <i>Merck KGaA v. Integra Lifesciences I, Ltd.</i> , 545 U.S. 193 (2005)                  | Cyclic Arg-Gly-Asp peptides<br>-----<br>Peptidomimetics <sup>139</sup>       | Cyclic Arg-Gly-Asp peptides<br>-----<br>Cyclic Arg-Gly-Asp peptides <sup>140</sup>               | Yes<br>-----<br>Yes <sup>141</sup> | Yes<br>-----<br>No <sup>142</sup> | Yes<br>-----<br>Yes<br>(based on the Supreme Court's conclusion that the cyclic Arg-Gly-Asp peptides were not used as research tools) <sup>143</sup>  |
| <i>Proveris Scientific Corp. v. Innovasystems, Inc.</i> , 536 F.3d 1256 (Fed. Cir. 2008) | Aerosol drug delivery device of a third party <sup>144</sup>                 | Apparatus for characterizing the aerosol spray of an aerosol drug delivery device <sup>145</sup> | No <sup>146</sup>                  | No <sup>147</sup>                 | No<br>(based on the Federal Circuit's conclusion that the apparatus under consideration in the case that was used without authorization was <i>not</i> a "patented invention" for purposes of § 271(e)(1)) <sup>148</sup> |

<sup>132</sup> *Id.*<sup>133</sup> *Id.* at 678.<sup>134</sup> *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1020–21 (Fed. Cir. 1997).<sup>135</sup> *Id.* at 1022–23.<sup>136</sup> *Id.* at 1029.<sup>137</sup> *Id.* at 1030.<sup>138</sup> *Id.*<sup>139</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 197 (2005).<sup>140</sup> *Id.* at 200.<sup>141</sup> *Id.* at 199–200.<sup>142</sup> *Id.* at 201–02.<sup>143</sup> *Id.* at 207–08.<sup>144</sup> *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1258 (Fed. Cir. 2008).<sup>145</sup> *Id.* at 1260.<sup>146</sup> *Id.* at 1266.<sup>147</sup> *Id.*<sup>148</sup> *Id.* at 1265–66.

|  |  |  |                   |                   |  |
|--|--|--|-------------------|-------------------|--|
| <i>Classen Immunotherapies, Inc. v. Biogen IDEC</i> , 659 F.3d 1057 (Fed. Cir. 2011)                     | Childhood vaccines <sup>149</sup>  | Method for determining schedules for vaccine administration that have lower risks of triggering chronic immune-mediated disorders <sup>150</sup> | No <sup>151</sup> | No <sup>152</sup> | No (based on the Federal Circuit's conclusion that § 271(e)(1) <i>does not</i> cover post-approval activities, where the meaning of the term "patented invention" was not addressed in the opinion) <sup>153</sup>                           |
| <i>Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.</i> , 686 F.3d 1348 (Fed. Cir. 2012) | Enoxaparin—generic version of mixture of polysaccharide molecules that prevents blood clots <sup>154</sup> | Manufacturing test method used to characterize mixture of polysaccharide molecules <sup>155</sup>  | No <sup>156</sup> | No <sup>157</sup> | Yes (based on the Federal Circuit's conclusion that § 271(e)(1) <i>does</i> cover post-approval activities, where the meaning of the term "patented invention" was addressed in the opinion, but only briefly and indirectly) <sup>158</sup> |

The *Eli Lilly* Court adopted a broad reading of the term “patented invention.” In the words of the Court, “[t]he phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone. See 35 U.S.C. § 100(a) (‘When used in this title unless the context otherwise indicates . . . [t]he term ‘invention’ means invention or discovery’).”<sup>159</sup> However, Justice Scalia’s reliance on the “perfect ‘product’ fit” between sections 156 and 271(e)(1) reflected in the structure and text of the Hatch-Waxman Act to bring medical devices within the ambit of the safe harbor statute arguably placed a significant limitation on the type of “patented invention” covered by the statute, namely, that the patented invention be eligible for a patent term extension under § 156.<sup>160</sup> This apparent limit presented no issue in *Eli Lilly*, where the implantable cardiac defibrillator used without authorization to develop and submit information to the FDA was a Class III medical device that required premarket approval.<sup>161</sup> For other types of patented inventions, however, the

<sup>149</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1060 (Fed. Cir. 2011).

<sup>150</sup> *Id.* at 1061.

<sup>151</sup> *Id.* at 1072.

<sup>152</sup> *Id.* at 1069–70.

<sup>153</sup> *Id.* at 1072.

<sup>154</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1349 (Fed. Cir. 2012).

<sup>155</sup> *Id.* at 1352.

<sup>156</sup> *Id.* at 1357.

<sup>157</sup> *Id.* at 1360.

<sup>158</sup> *Id.* at 1361.

<sup>159</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665 (1990).

<sup>160</sup> *Id.* at 673–74; *see also supra* Part II.B.1.

<sup>161</sup> *Eli Lilly*, 496 U.S. at 673–74.

Supreme Court's *Eli Lilly* decision left uncertainty as to whether such inventions were covered by the safe harbor statute. Specifically, was the term "patented invention" intended to include *any* patented invention (other than those expressly excluded in § 271(e)(1))<sup>162</sup> that could be employed to develop and submit information that relates to one of the product types listed in § 156(f) under any Federal law that includes as one of its provisions a law that regulates drugs? Alternatively, was the term "patented invention" limited to only those patented inventions that are eligible for a patent term extension under § 156 or, at least, to the product types listed in § 156(f)?

The uncertainty regarding the Supreme Court's interpretation of the term "patented invention" was subsequently addressed by the Federal Circuit in its decision in *AbTox, Inc. v. Exitron Corp.*<sup>163</sup> In that case, the Federal Circuit relied on the *Eli Lilly* holding to further broaden the scope of § 271(e)(1) to include Class II medical devices which do not require premarket approval and whose covering patents are not eligible for a term extension under § 156.<sup>164</sup> In so doing, the Federal Circuit was required to deviate from the rule of "perfect 'product' fit" reflected in the symmetry between sections 156 and 271(e)(1). As Judge Rader, writing for the *AbTox* court, explained:

The Supreme Court . . . interpreted the phrase "a Federal law" to refer to "an entire statutory scheme of regulation" not merely to single sections or subsections related to drugs or veterinary biological products. Therefore, the Court broadly held that section 271(e)(1) applies to any use reasonably related to regulation under the FDCA, which certainly includes Class II devices.

The Court, however, also based its analysis on the entire statutory scheme of the Drug Price Competition and Patent Term Restoration Act of 1984 [the Hatch-Waxman Act] . . . and found support for its interpretation in the interplay between section 156 and section 271(e) *Eli Lilly*, 496 U.S. at 673 . . . ("[T]here are textual indications that sections 201 and 202 [of the 1984 Act] are meant generally to be complementary."). In other words, in determining which products fit within the bounds of § 271(e)(1), the Court looked to the far more explicit § 156. The Court stated:

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<sup>162</sup> 35 U.S.C. § 271(e)(1) (2012). Section 271(e)(1) specifically excludes from the term "patented invention" any "new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques." *Id.* According to one of the canons of statutory interpretation, the explicitly excluded exceptions to the term "patented inventions" are the only ones Congress intended, and others must not be added through judicial interpretation. *See Eskridge & Frickey, supra* note 45, at 99 ("Do not create exceptions in addition to those specified by Congress.").

<sup>163</sup> *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997).

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

. . . [Section] 271(e)(1) . . . appears to create a perfect “product” fit between the two sections. All of the products eligible for a patent term extension under [§ 156] are subject to [§ 271(e)(1)], since all of them . . . are subject to premarket approval under various provisions of the FDCA . . . .

This Supreme Court reasoning creates the rub for this case. As the Supreme Court reasoned, Class III devices are eligible for a patent term extension under § 156, and therefore application of the § 271 infringement shield to these devices creates a convenient statutory symmetry. Title 35 both giveth and taketh away. Class II devices, however, are not eligible for patent term extensions. . . .

Therefore, under the broad holding of *Eli Lilly*, all classes of medical devices fall within the plain meaning of section 271(e)(1). Nevertheless, under the Court’s narrower justification of statutory symmetry, only Class III devices fall within the section. Ultimately, this court must follow the Supreme Court’s broader holding, which remains in force despite a potential conflict with its own narrower reasoning. Section 271(e)(1) makes no distinctions based upon the different FDA classes of medical devices or drugs. Moreover, the Court explicitly accepted a statutory interpretation “in which a patentee will obtain the advantage of the [§ 156] extension but not suffer the disadvantage of the [§ 271(e)(1)] noninfringement provision, and others in which he will suffer the disadvantage without the benefit.” In other words, the Supreme Court commands that statutory symmetry is preferable but not required. Therefore, the Supreme Court disposed of the argument, made here by AbTox, that § 271(e)(1) is limited to Class III devices. Section 271(e)(1) contains no such limitation.<sup>165</sup>

The Federal Circuit honored this preference for statutory symmetry in its decision in *Proveris Scientific Corp. v. Innovasystems, Inc.*,<sup>166</sup> although it did so in *limiting* the scope of § 271(e)(1), *rather than expanding* the scope as the Supreme Court had done in *Eli Lilly*.<sup>167</sup> Moreover, the *Proveris* court adopted the most restrictive interpretation of Justice Scalia’s opinion in *Eli Lilly* in order to achieve this result.<sup>168</sup> Specifically, the Federal Circuit in *Proveris* cited *Eli Lilly* for the proposition that the term “patented invention” in § 271(e)(1) is limited to only those products listed in § 156(f) that are eligible for a patent term extension in order to conclude that the research tool used without authorization in *Proveris* is not the type of invention that the safe harbor statute was intended to cover.<sup>169</sup>

The facts in *Proveris* are as follows. Proveris held a patent that covered a system and apparatus for the calibration of the aerosol spray characteristics of

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<sup>165</sup> *Id.* at 1028–29 (internal citations omitted).

<sup>166</sup> *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1263 (Fed. Cir. 2008).

<sup>167</sup> *Id.* at 1258–59.

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

<sup>169</sup> *Id.* at 1265–66.

medical devices that deliver aerosol-based drugs.<sup>170</sup> Innova, the alleged infringer, manufactured an optical spray analyzer (“OSA”) that the district court concluded was covered by claims in the Proveris patent.<sup>171</sup> Innova offered for sale and sold the OSA to third party manufacturers of aerosol drug delivery devices for use by the manufacturers in developing and submitting information to the FDA for pre-market approval of their product candidates.<sup>172</sup> In contrast to the drug delivery devices characterized by the OSA, the invention claimed in the Proveris patent and embodied in Innova’s OSA did not require pre-market approval.<sup>173</sup>

In defense of Proveris’ claim that Innova’s manufacture, offer for sale, and sale of the OSA infringed Proveris’ patent, Innova argued, *inter alia*, that its activities were shielded by the safe harbor statute.<sup>174</sup> The *Proveris* court provided the following summary of the positions taken by the parties in the case:

Innova argues that it is entitled to the benefit of the § 271(e)(1) safe harbor because it is undisputed that it has only offered to sell the OSA to pharmaceutical companies and the FDA. Innova also states that it is undisputed that the OSA is and was used exclusively in applications for regulatory approval in accordance with the requirements of the FDCA. . . . According to Innova, Congress intended to include within the safe harbor all “patented inventions” unless specifically excluded . . . and that the safe harbor provision should not be limited so as to exclude research tools—assuming its OSA device is viewed as such.

Proveris responds that “[t]he patented inventions that fall within the scope of § 271(e)(1) do not include patents on equipment that may be used in a pharmaceutical laboratory, such as microscopes, analytical balances, computers, and Proveris’s . . . equipment.” Proveris states that Congress created the patent term extension for “products” in 35 U.S.C. § 156(a) when it created the safe harbor in section 271(e)(1), doing so within the context of providing generic drug developers with the means to compete commercially immediately upon the expiration of a drug’s patent. Under these circumstances, Proveris reasons, section 271(e)(1) extends only to the infringement of patents that claim “products” as that term is defined in section 156(f) and to other patented inventions that are inherent to the development of “products.” Thus, in Proveris’s view, the patents which may be infringed with immunity, if the infringement is solely for uses reasonably related to the development and submission of information to the FDA, include patents on drug products, medical devices, food additives, and color

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<sup>170</sup> *Id.* at 1258.

<sup>171</sup> *Id.* at 1260.

<sup>172</sup> *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1259 (Fed. Cir. 2008).

<sup>173</sup> *Id.* at 1258–59.

<sup>174</sup> *Id.* at 1266.

additives. According to *Proveris*, section 271(e)(1) does not immunize infringement of patents on laboratory or manufacturing equipment.<sup>175</sup>

In ruling that *Innova* had indeed infringed the *Proveris* patent, the Federal Circuit relied on the Supreme Court's *Eli Lilly* opinion and its interpretation of the structure and text of the Hatch-Waxman Act.<sup>176</sup> As the *Proveris* court explained:

[I]n *Eli Lilly* the Court spoke of its interpreting the phrase “patented invention” in section 271(e)(1) to include all products listed in section 156(f) as producing a “perfect ‘product’ fit” between the two provisions. The result we reach today achieves the same kind of fit, or symmetry. Because *Proveris*'s patented product [, which embodies the same patented invention as *Innova*'s OSA,] is not subject to a required FDCA approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because *Innova*'s OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1). . . .

*Innova* argues that it is entitled to the protection of section 271(e)(1)'s safe harbor because it is offering for sale and selling a “patented invention” (the invention claimed in the [*Proveris*] patent) “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” *Innova*'s position is that its offering for sale and its sale of the OSA device fit squarely within the statutory language because, like the product claimed in the . . . [*Proveris*] patent, the OSA is used in a way which is “reasonably related” to the “development and submission of information” pertinent to the FDA premarket approval required for inhaler-based drug delivery devices. *The problem with that argument is that it is premised on the proposition that the device claimed in the [*Proveris*] patent is, for purposes of section 271(e)(1), a “patented invention.” As we have just seen, it is not. We therefore reject the argument . . . [and] . . . see no error in the ruling of the district court that *Innova*'s marketing and sale of its OSA device are not exempted from infringement by the safe harbor provision of 35 U.S.C. § 271(e)(1).<sup>177</sup>*

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<sup>175</sup> *Id.* at 1264.

<sup>176</sup> *Id.* at 1265–66.

<sup>177</sup> *Id.* (emphasis added) (citations omitted). The Federal Circuit in *Proveris* acknowledged that the products listed in § 156(f) have changed over time. However, matching changes have been made in § 271(e)(1) to maintain the symmetry between sections 156(f) and 271(e)(1), providing confirmation that the sections are intended to work in tandem to preserve the perfect product fit. *See id.* at 1262 n.3 (“At the time *Eli Lilly* was decided, the products named in section 156(f) were ‘[a] human drug product’ and ‘[a]ny medical device, food additive, or color additive subject to regulation under the [FDCA].’”).

The significance of the Federal Circuit's holding in *Proveris* is three-fold. First, the *Proveris* court adopted the narrowest reading of the Supreme Court's *Eli Lilly* decision in concluding that the term "patented invention" in § 271(e)(1) is limited to only those products listed in § 156(f) that are eligible for a patent term extension.<sup>178</sup> Second, unlike the "patented invention" in *Roche, Eli Lilly* or *AbTox*, the "patented invention" used without authorization in *Proveris* was not covered by the patent that covered the product candidate under study<sup>179</sup> Rather, the "patented invention" in *Proveris* was a research tool used to study the product candidate.<sup>180</sup> Moreover, the "patented invention" in *Proveris* was neither a type of product listed in § 156(f) (unlike the "patented invention" in *Roche, Eli Lilly* or *AbTox*), nor eligible for a patent term extension under § 156 (unlike the "patented invention" in *Roche* or *Eli Lilly*).<sup>181</sup> Each of these distinctions between the *Innova OSA* and the patented inventions in the prior cases was recognized by the Federal Circuit in *Proveris*,

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It is to be noted that the versions of sections 271(e)(1) and 156(f) which were before the Supreme Court in *Eli Lilly* in 1990 differed slightly from the current versions of both provisions. As the Court noted in *Eli Lilly*, at that time, new animal drugs and veterinary biological products were simultaneously excluded from both provisions. 496 U.S. at 674. In contrast, sections 271(e)(1) and 156(f) now include new animal drugs and veterinary biological products, unless they have been "primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques." These slight statutory differences do not undermine the relevance of the Court's *Eli Lilly* analysis. Instead, we think the persisting symmetry between both provisions over time further confirms the Court's view that sections 271(e)(1) and 156 operate in tandem.

*Id.* at 1263 n.4. Section 156(f) currently reads as follows:

(f) For purposes of this section: (1) The term "product" means: (A) A drug product. (B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act. (2) The term "drug product" means the active ingredient of—(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or (B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

35 U.S.C. § 156 (2012).

<sup>178</sup> *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265–66 (Fed. Cir. 2008).

<sup>179</sup> See *supra* Table 1 ("Patented Invention" Cases).

<sup>180</sup> *Proveris*, 536 F.3d at 1258. This distinction had previously been recognized by the Federal Circuit. See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., dissenting) ("Use of an existing tool in one's research is quite different from study of the tool itself."). Although Judge Newman's comment was made in the course of her discussion of the common law research exemption, it is also relevant to a discussion of the safe harbor statute. In the same discussion, Judge Newman objected to the "failure to distinguish between investigation into patented things . . . and investigation using patented things." *Id.* at 878 n.6.

<sup>181</sup> *Proveris*, 536 F.3d at 1263.

although, as noted above, the *Proveris* court based its holding on the fact that the OSA was not a type of product listed in § 156(f) and was not eligible for a patent term extension.<sup>182</sup> Finally, the holding in *Proveris* remains good law and is consistent with the position that § 271(e)(1) does not cover certain categories of “patented invention,” e.g., research tools and manufacturing test methods, *in addition to* those expressly excluded in the safe harbor statute.<sup>183</sup> However, as discussed below, there remains a question as to whether this position is consistent with a proper reading of the Supreme Court’s *Eli Lilly* holding and it is clearly inconsistent with the Federal Circuit’s recent holding in *Momenta*.

Between the Federal Circuit’s decision in *AbTox* and its decision in *Proveris*, the Supreme Court decided the *Merck* case.<sup>184</sup> The relevance of the *Merck* case for the purpose of this discussion is that it addressed, but ultimately did not resolve, the question of whether research tools as a category are excluded from the statutory term “patented invention” in § 271(e)(1).<sup>185</sup> In a footnote to his *Merck* opinion, Justice Scalia stated the following:

The Court of Appeals . . . suggested that a limited construction of § 271(e)(1) is necessary to avoid depriving so-called “research tools” of the complete value of their patents. Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record that they were not. . . . 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>186</sup>

While the Supreme Court interpreted the facts in *Merck* in a way that allowed it to side-step the research tool question, Judge Rader of the Federal Circuit, in that court’s initial ruling in the *Merck* case<sup>187</sup> and, again, on remand of the case from the Supreme Court,<sup>188</sup> provided a compelling argument for a research tool exception to the application of the safe harbor provision. In *Integra Lifesciences I, Ltd. v. Merck KGaA*, the Federal Circuit construed § 271(e)(1) narrowly and ruled that the activities of the alleged infringers in the case did not fall within the ambit of the statutory safe harbor.<sup>189</sup> One of the arguments proffered by the appellate court was that *Integra*’s patented compounds were used, among other things, as research tools to characterize the product potential of synthetic peptide analogs.<sup>190</sup> Such uses,

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<sup>182</sup> *Id.* at 1266.

<sup>183</sup> *Id.*

<sup>184</sup> *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *see also supra* Part II.B.3.

<sup>185</sup> *Merck*, 545 U.S. at 205 n.7.

<sup>186</sup> *Id.* at 205 n.7.

<sup>187</sup> *Integra Lifesciences I Ltd. v. Merck KGaA*, 331 F.3d 860, 878 (Fed. Cir. 2003).

<sup>188</sup> *Integra Lifesciences I Ltd. v. Merck KGaA*, 496 F.3d 1334, 1334 (Fed. Cir. 2007).

<sup>189</sup> *See supra* Part II.B.3.

<sup>190</sup> *See Integra Lifesciences I*, 331 F.3d at 872 n.4 (“The dissent asserts that *Integra*’s patented RGD peptides are not research tools, ‘but simply new compositions having certain uses.’ . . . The dissent does not explain why one of those ‘certain uses’ cannot embrace use of an RGD peptide as a laboratory tool to facilitate identification of a new therapeutic.”) (internal citation omitted).

according to the Federal Circuit, raised an additional concern regarding an expansive interpretation of the statutory safe harbor. Writing for the majority, Judge Rader noted the dire consequence of a broad reading of § 271(e)(1) for the research tool industry:

[E]xpansion of § 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents. After all, patented tools often facilitate general research to identify candidate drugs, as well as downstream safety-related experiments on those new drugs. Because the downstream clinical testing for FDA approval falls within the safe harbor, these patented tools would only supply some commercial benefit to the inventor when applied to general research. Thus, exaggerating § 271(e)(1) out of context would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions. Needless to say, the 1984 [Hatch-Waxman] Act was meant to reverse the effects of Roche under limited circumstances, not to deprive entire categories of inventions of patent protection.<sup>191</sup>

On remand of the *Merck* case, the Federal Circuit applied the Supreme Court's interpretation of the scope of § 271(e)(1) in finding that all of the challenged actions of the alleged infringers fell within the statutory exemption.<sup>192</sup> The court avoided the research tool question by noting that counsel for Integra, in a letter to the panel, had adopted the position that Merck's unauthorized use of Integra's patented peptides did not include uses as a research tool.<sup>193</sup> In a separate opinion, however, Judge Rader objected to the court's reliance on the Integra counsel's letter in refusing to address the "research tool exception."<sup>194</sup> Moreover, he noted that,

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<sup>191</sup> *Id.* at 867.

<sup>192</sup> *Integra Lifesciences I Ltd. v. Merck KGaA*, 496 F.3d 1334, 1348 (Fed. Cir. 2007).

<sup>193</sup> *See id.* The court noted:

Contrary to the position of our colleague in dissent, the Court's ruling and our application thereof casts no "large shadow" on the subject of "research tools." On remand to this court, the parties emphatically confirmed that research tools were not at issue. *See, e.g.*, Letter from Mauricio A. Flores, Counsel for Integra, to the panel (June 13, 2006) ("Integra agrees with Merck that this is not an appropriate case in which to make new law on the issue of whether patent claims to research tools (however that term may be defined) are excluded from the ambit of Section 271(e)(1). The Supreme Court has ruled that this case does not raise that issue. Hence, its resolution is outside the Supreme Court's mandate. Integra has never argued, and does not now contend, that any of its claims at issue belong to a class of patent claims outside the reach of that statutory exemption."). There is no "devastating impact on research tool inventions" . . . ; indeed, the issue is not present, and the criticism inapt.

*Id.* (internal citation omitted).

<sup>194</sup> *See id.* at 1349 (Rader, J., dissenting). Judge Rader stated:

[T]his court relies on a letter from one of the parties explaining that it does not wish to rely on the research tool exception. This supposedly authoritative letter

the Supreme Court [in *Merck v. Integra*] extended the exemption back up the experimentation chain to include selection of particular species for FDA approval out of a patented genus. The Supreme Court did not, however, extend the exemption to encompass any method or process or other research tool that might be used in a pharmaceutical laboratory.<sup>195</sup>

Judge Rader warned that “[b]y treating . . . research tools the same as drugs potentially needing FDA clearance, this court’s opinion poses a danger to the entire research tool industry.”<sup>196</sup> As indicated above, Judge Rader’s concern regarding the research tool industry clearly registered with the Federal Circuit panel that decided *Proveris*.<sup>197</sup>

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appeared after the oral argument before this court in an attempt to rectify counsel’s unresponsive performance. With the patents already expired, *Integra* may pursue a strategy to protect its entire multi-million-dollar verdict. If *Integra* had really not wished to rely on research tool patents, then it would not have asserted them in the first place.

*Id.*

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

A hypothetical example will help illustrate the importance of protecting research tool patent rights. Suppose a university professor or small independent research company invents and obtains a patent for a novel and extremely useful research tool. This invention represents the work of a lifetime for its inventors and perhaps most of the research budget for the university department or the small company—perhaps millions of dollars in investment. The only use of the invention tests other pharmaceutical compounds for effectiveness in fighting cancer. The invention does not itself fight cancer, but instead simply identifies the cancer fighting characteristics in other compounds. This patented invention would, of course, be of great use to the pharmaceutical industry. It would also benefit the public by identifying cancer treatments. The patent system of course would wish to protect this invention and give incentives for more investment in developing this kind of valuable research tool. Sadly today’s opinion misreads the Supreme Court’s decision. This court reads the Supreme Court’s decision too broadly because it includes within the exemption the [patent holder’s] . . . patents, which are obviously research tools. This overbroad interpretation could obliterate all value for the hypothetical invention discussed above and with it the incentives for development of these inventions . . . . The university professor or small company might expect a reward for the lifetime of labor and investment that produced the research tool. The inventor might also hope to use that reward to further his pioneer research. These benefits to the public and that inventor would flow from the patent’s right to exclude that would produce reasonable royalties. However, under today’s opinion, the exemption would swallow that lifetime of labor and investment because the nature of the use itself, without any concern for the object of the patented invention, would be the gauge upon which the exemption would be measured. . . . In effect, any use of the hypothetical invention would automatically translate to non-infringement based on this court’s expansive application of 35 U.S.C. §271(e)(1).

*Id.* at 1352–53.

<sup>197</sup> *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1266 (Fed. Cir. 2008).

Following *Proveris*, the Federal Circuit's next significant decision regarding the statutory safe harbor was in *Classen Immunotherapies, Inc. v. Biogen IDEC*.<sup>198</sup> It is relevant to a discussion of the term "patented invention" only in the sense that the patented invention used without authorization in *Classen* was not of a type that is listed in § 156(f) and was not eligible for a patent term extension.<sup>199</sup> *Classen*'s patented method for determining schedules for vaccine administration that have lower risks of triggering chronic immune-mediated disorders was not a product or product candidate like the patented invention used in *Roche, Eli Lilly, AbTox, or Merck*,<sup>200</sup> but was a research tool like the OSA in *Proveris*.<sup>201</sup> The Federal Circuit in *Classen* determined that the § 271(e)(1) statutory exemption was not available to shield the alleged infringers in the case because the exemption did not cover the post-marketing approval activities under consideration.<sup>202</sup> Accordingly, the *Classen* court was not required to, and did not, address the question of whether the statutory exemption was also unavailable based on the fact that the research tool used without authorization in the case was not a "patented invention" for the purpose of § 271(e)(1).<sup>203</sup>

The Federal Circuit's most recent safe harbor decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*,<sup>204</sup> however, did address the "patented invention" issue, albeit indirectly. In *Momenta*, the patented invention used without authorization was a manufacturing test method used to characterize a marketed product in accordance with FDA requirements.<sup>205</sup> While not a research tool, the test method was not a type of patented invention listed in § 156(f) and was not eligible for a patent term extension.<sup>206</sup> In that way the manufacturing test method in *Momenta* was more like the research tool in *Proveris* and distinct from the product or product candidate used in *Roche, Eli Lilly, AbTox, or Merck*. In contrast to the Federal Circuit's holding in *Classen*, the majority in *Momenta* held that § 271(e)(1) is available to shield the alleged infringer's activities from infringement liability, despite the nature of the patented invention used without authorization and the fact that the allegedly infringing activities were undertaken following marketing approval.<sup>207</sup>

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<sup>198</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1073 (Fed. Cir. 2011); see also *infra* Part II.B.5.

<sup>199</sup> See *supra* Table 1 ("Patented Invention" Cases).

<sup>200</sup> Note that, as indicated in Table 1—"Patented Invention" Cases, the *Merck* case is remarkable for the fact that the patented compounds used without authorization were used both to evaluate the compounds themselves as potential products and as research tools to characterize peptido-mimetics. See *supra* Table 1. The references to *Merck* in the footnoted-sentence and in the following paragraph in the text are with respect to the first and not the second use of the patented compounds.

<sup>201</sup> *Classen*, 659 F.3d at 1060.

<sup>202</sup> *Classen*, 659 F.3d at 1073.

<sup>203</sup> *Id.*

<sup>204</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1361 (Fed. Cir. 2012); see also *infra* Part II.B.5.

<sup>205</sup> *Id.* at 1351–52.

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

<sup>207</sup> *Id.* at 1361.

While the majority in *Momenta* spent considerable effort in distinguishing the Federal Circuit's prior *Classen* holding regarding the applicability of the safe harbor statute in shielding post-marketing approval activities, the *Momenta* court largely avoided the "patented invention" issue and the relevance of the court's prior holding in *Proveris*.<sup>208</sup> However, the dissent in *Momenta* (not surprisingly, authored by Judge Rader, who had advocated for a research tool exception to § 271(e)(1) in the Federal Circuit's *Merck* decisions) did raise arguments that were relied on by the *Proveris* majority to limit the scope of the statutory term "patented invention" in the safe harbor provision to a type of product listed in § 156(f) that is eligible for a patent term extension.<sup>209</sup>

While not specifically referencing the term "patented invention," Judge Rader cited the Supreme Court's *Eli Lilly* decision<sup>210</sup> for its reliance on the structure and text of the Hatch-Waxman Act and its emphasis on the relationship between sections 201 and 202 of the Act, which establishes a "perfect 'product' fit" between § 156 (the patent term extension statute) and § 271(e)(1) (the safe harbor statute).<sup>211</sup> Judge Rader further noted that the *Eli Lilly* Court "rejected . . . [an] attempt to create a 'disequilibrium' between the two sections."<sup>212</sup> However, according to Judge Rader, the majority's holding in *Momenta* ignored the need to maintain a balance between sections 201 and 202, as intended in the Hatch-Waxman Act.<sup>213</sup> In the words of Judge Rader,

[t]his court's new interpretation in this case would apply the disadvantage of [section] 202 to a patentee who would not be able to obtain the benefits of [section] 201. The patentee of a manufacturing patent does not obtain the patent extension created in [section] 201, yet this court's new expansion of [section] 202 would allow its competitors to infringe during the life of its patent. The Supreme Court rejected this sort of disequilibrium. See *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008) (. . . hold[ing] that § 271(e)(1) does not apply to infringement of patented product not eligible to obtain patent extension).<sup>214</sup>

In essence, Judge Rader was objecting to the fact that the *Momenta* majority's holding allowed an alleged infringer to use without authorization a patented invention that was not eligible for a patent term extension and to continue such use throughout the life of the patent in order to manufacture for commercial sale the alleged infringer's product long after that product had received marketing approval. According to Judge Rader, such an allowance is not consistent with the purpose of

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<sup>208</sup> *Id.* at 1357–60.

<sup>209</sup> *Id.* at 1371–72 (Rader, J., dissenting).

<sup>210</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1370–72 (Fed. Cir. 2012) (Rader, J., dissenting) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671–73 (1990)).

<sup>211</sup> *Id.*

<sup>212</sup> *Id.* at 1371 (Rader, J., dissenting).

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

the Hatch-Waxman Act, as interpreted by the Supreme Court in *Eli Lilly*, and is incompatible with the Federal Circuits' prior decision in *Proveris*.<sup>215</sup>

Judge Moore, writing for the majority in *Momenta*, summarily rejected Judge Rader's argument.<sup>216</sup> As she explained,

the dissent suggests that we must reject any disequilibrium between sections 201 and 202 of the Hatch-Waxman Act, that is, the safe harbor should not be available unless a patent term extension is also available. This is not correct. The Supreme Court in *Eli Lilly* noted that equilibrium was not always achieved. We too have rejected this strict interpretation of the safe harbor, explaining that "statutory symmetry is preferable but not required." *Abtox*, 122 F.3d at 1029 (holding that Class II medical devices, which are not subject to a "rigorous premarket approval process" and thus cannot receive patent term extensions, are nonetheless covered by the safe harbor).<sup>217</sup>

In the end, uncertainty remains with respect to the types of "patented invention" that are covered by the safe harbor statute. The Federal Circuit's decision in *Momenta* supports a conclusion that the text of the statutory exemption does not provide any basis for the exclusion of categories of patented inventions (other than those expressly excluded in § 271(e)(1)) such as patented research tools or manufacturing test methods.<sup>218</sup> The difficulty with this view is that it fails to take into consideration Justice Scalia's reliance in *Eli Lilly* on the "perfect 'product' fit" between § 156 and § 271(e)(1) reflected in the structure and text of the Hatch-Waxman Act.<sup>219</sup> In particular, it ignores Justice Scalia's admonition to avoid interpretations of the safe harbor statute that make a disequilibrium between receipt of the advantage of the § 156 patent term extension and the disadvantage of the § 271(e)(1) non-infringement provision the general rule, rather than a rare exception.<sup>220</sup> Moreover, the Federal Circuit's *Momenta* decision is, arguably,

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<sup>215</sup> *Id.* at 1371–72 (Rader, J., dissenting).

<sup>216</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1361 (Fed. Cir. 2012).

<sup>217</sup> *Id.* (internal citations omitted).

<sup>218</sup> *Id.* at 1354–55.

<sup>219</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671–73 (1990).

<sup>220</sup> *Id.* The court stated,

[u]nder respondent's interpretation, there may be some relatively rare situations in which a patentee will obtain the advantage of the [section] 201 extension but not suffer the disadvantage of the [section] 202 noninfringement provision, and others in which he will suffer the disadvantage without the benefit. Under petitioner's interpretation, however, that sort of disequilibrium becomes the general rule for patents relating to all products (other than drugs) named in [section] 201 and subject to premarket approval under the FDCA. Not only medical devices, but also food additives and color additives, since they are specifically named in [section] 201, see 35 U.S.C. § 156(f) (2012), receive the patent-term extension; but since the specific provisions requiring regulatory approval for them, though included in the FDCA, are not provisions requiring regulatory approval for drugs, they are (on petitioner's view) not subject to the noninfringement provision of § 271(e)(1). It seems most implausible to us that

inconsistent with its holding in *Proveris*. Absent clarification from the courts or Congress, the user without authorization of a patented research tool or a manufacturing test method who otherwise qualifies for an exemption from infringement under § 271(e)(1) may take comfort in the Federal Circuit's recent *Momenta* decision and the Supreme Court's record of construing the scope of the safe harbor statute broadly.<sup>221</sup> Such a use, however, is not without some risk.

As Judge Rader noted in each of his *Merck* opinions and in his dissenting opinion in *Momenta*, an expansive reading of the statutory term "patented invention" in § 271(e)(1) "would effectively vitiate the exclusive rights of patentees" owning certain categories of inventions.<sup>222</sup> Yet the legislative history of the Hatch-Waxman Act provides no indication that the legislature intended the safe harbor statute to have such a significant effect on the rights of the patent holder.<sup>223</sup> To the contrary, in response to a claim that passage of section 202 of the Act would result in a "taking" without just compensation in violation of the Fifth Amendment, it was emphasized that the nature of the proposed safe harbor statute's interference with patent rights would be *de minimis*.<sup>224</sup> Whether legislative history has a proper role in statutory

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Congress, being demonstrably aware of the *dual* distorting effects of regulatory approval requirements in this entire area—dual distorting effects that were roughly offsetting, the disadvantage at the beginning of the term producing a more or less corresponding advantage at the end of the term—should choose to address both those distortions only for drug products; and for other products named in [section] 201 should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating distortion of the 17-year patent protection. It would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence here.

*Id.* (emphasis in original).

<sup>221</sup> *Momenta*, 686 F.3d at 1354–55.

<sup>222</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003); *see also* *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1349 (Fed. Cir. 2007) (Rader, J., dissenting-in-part and concurring-in-part) ("By treating these research tools the same as drugs potentially needing FDA clearance, this court's opinion poses a danger to the entire research tool industry."); *Momenta*, 686 F.3d at 1369 (Fed. Cir. 2012) (Rader, J., dissenting) ("This court's interpretation of § 271(e)(1) would essentially render manufacturing method patents worthless.")

<sup>223</sup> *See supra* Part I.B.2.

<sup>224</sup> H.R. REP. NO. 98–857, pt. 2, at 30 (1984) ("[T]he generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is *de minimis* [sic]."). Note that the Fifth Amendment "taking" issue was also addressed in the following footnote to Justice Scalia's opinion for the Court in *Eli Lilly*:

Although petitioner has not challenged § 271(e)(1) on constitutional grounds, it argues that we should adopt its construction because of the "serious constitutional question under the takings clause of the Fifth Amendment . . . [that would arise] if the statute is interpreted to authorize the infringing use of medical devices." We do not see how this consideration makes any difference. Even if the competitive injury caused by the noninfringement provision is *de minimis* with respect to most drugs, surely it is substantial with respect to some of them—so

interpretation can be debated. What is clear, however, is that a reasonable argument can be made, should a judge elect to make it, that the term “patented invention” in the safe harbor statute excludes categories of inventions, such as research tools and manufacturing test methods, in addition to those expressly excluded by the statute.

### 5. *Submission Of Information*

#### a. *Background*

The Supreme Court in *Merck* stated that:

[W]e think it 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. . . . There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.<sup>225</sup>

The *Merck* Court’s reference to “*any* information” suggests that the statutory exemption can extend to activities undertaken to generate information for submission to the FDA, irrespective of whether such activities take place prior to or after the marketing approval of the product candidate or product under study.<sup>226</sup> This Part of the Article considers this issue in the context of a discussion of the meaning and scope of the statutory term “submission of information.” In particular, it focuses on the current debate among judges of the Federal Circuit with respect to the applicability of § 271(e)(1) to information generated in the course of post-approval activities as reflected in the arguably conflicting holdings in *Classen Immunotherapies, Inc. v. Biogen IDEC*, and *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*<sup>227</sup> The dialogue among the Federal Circuit judges who decided these two cases is noteworthy not only for the analysis of the term “submission of information,” but also because it highlights the judges’ differing views regarding the role of legislative history in statutory interpretation.

The *Merck* Court focused its analysis on information generated through activities that take place prior to the marketing approval of a product.<sup>228</sup> The Court

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the “serious constitutional question” (if it is that) is not avoided by petitioner’s construction either.

*Eli Lilly*, 496 U.S. at 678 (internal citation omitted).

<sup>225</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

<sup>226</sup> *See id.*

<sup>227</sup> *See Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1083 (Fed. Cir. 2011); *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1374 (Fed. Cir. 2012) (Rader, J., dissenting).

<sup>228</sup> *Merck*, 545 U.S. at 208.

concluded that the scope of § 271(e)(1) is sufficiently broad to include pre-clinical activities that are “reasonably related” to the development and submission of information to the FDA, including information relating to the safety, efficacy, mechanism of action, pharmacology, or pharmacokinetics of a drug candidate.<sup>229</sup> The *Merck* Court also concluded that the statutory exemption is not limited to pre-approval activities that generate information on drugs that ultimately form the basis of an FDA submission.<sup>230</sup> Such a limitation would restrict the application of § 271(e)(1) to activities required for the approval of a generic drug since “[o]ne can know at the outset that a particular compound will be the subject of an eventual application to the FDA only if the active ingredient in the drug being tested is identical to that in a drug that has already been approved [as in the case of a generic drug].”<sup>231</sup> The *Merck* Court, however, did not read the statute so narrowly as to apply only to the study of generics, and specifically rejected the view that the “exemption [is] applicable only to the research relevant to filing an ANDA for approval of a generic drug.”<sup>232</sup> Pre-approval activities that produce the types of information relevant to the filing of an IND or NDA are also eligible for protection under § 271(e)(1).<sup>233</sup>

*b. Classen Immunotherapies, Inc. v. Biogen IDEC*

In *Classen*, the Federal Circuit first considered the question of whether the statutory exemption applies to information generated in the course of activities that take place after the marketing approval of a product.<sup>234</sup> In that case, *Classen* held patents that claimed a method for determining schedules for vaccine administration that have lower risks of triggering chronic immune-mediated disorders in children.<sup>235</sup> The alleged infringers used the patented methods without authorization, to evaluate their already-approved vaccines in studies whose results were potentially reportable

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<sup>229</sup> See *supra* notes 106–111 and accompanying text.

<sup>230</sup> *Merck*, 545 U.S. at 206. The court noted,

It does not follow . . . that § 271(e)(1)'s exemption from infringement categorically excludes . . . experimentation on drugs that are not ultimately the subject of an FDA submission. . . . Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in . . . [this] situation[].

*Id.*

<sup>231</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005).

<sup>232</sup> *Id.*

<sup>233</sup> *Id.* at 208. The court stated,

We . . . agree with the Government that the use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce “the types of information that are relevant to an IND or NDA.”

*Id.* (internal citation omitted).

<sup>234</sup> See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011).

<sup>235</sup> See *id.* at 1060.

to the FDA.<sup>236</sup> The alleged infringers defended by arguing that their activities were protected under § 271(e)(1).<sup>237</sup> The majority in *Classen* (consisting of Judges Newman and Rader, with the opinion for the court filed by Judge Newman) held that § 271(e)(1) “provides an exception to the law of infringement in order to expedite development of information for regulatory *approval* of generic counterparts of patented products. The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.”<sup>238</sup>

The opinion for the majority relied on the legislative history of the Hatch-Waxman Act for the proposition that “the legislation concerns premarketing approval of generic drugs.”<sup>239</sup> Quoting from the House Report that explained the Act, the majority noted “that ‘the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval.’”<sup>240</sup> The *Classen* court concluded that “the activity of which . . . [the alleged infringers in the case] are accused by *Classen* cannot be stretched into this role.”<sup>241</sup>

The Federal Circuit in *Classen* also relied on Supreme Court case law to restrict the scope of the safe harbor statute to pre-approval activities, noting that the Court’s decisions in both *Eli Lilly* and *Merck* were “directed to premarketing approval of generic counterparts before patent expiration.”<sup>242</sup> According to the *Classen* majority, the Court in *Eli Lilly* limited its analysis to allegedly infringing activities necessary to *obtain* regulatory approval.<sup>243</sup> Moreover, the *Eli Lilly* Court’s reliance on the structure of the Hatch-Waxman Act in making its argument was further evidence that the safe harbor statute addresses only premarket approval.<sup>244</sup> The Court in *Eli Lilly* justified the inclusion of Class III medical devices within the ambit of § 271(e)(1) by reasoning that the inclusion of a medical device that requires premarket approval was consistent with the Act’s purpose of remedying the dual distorting effects that result from *premarket regulatory approval* of products.<sup>245</sup> This rationale is not applicable to the consideration of allegedly infringing activities that take place “long after marketing approval has been obtained,”<sup>246</sup> as in *Classen*.<sup>247</sup> The Supreme Court in *Merck*, as in *Eli Lilly*, only considered allegedly infringing pre-approval activities.<sup>248</sup> In that case, “the Court again analyzed the statutory purpose, and explained that ‘§ 271(e)(1) leaves adequate space for experimentation and failure *on the road to regulatory approval*.’”<sup>249</sup> Since the activities of the alleged infringers in

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<sup>236</sup> *See id.* at 1069–70.

<sup>237</sup> *Id.* at 1070.

<sup>238</sup> *Id.* (emphasis added).

<sup>239</sup> *Id.* at 1071.

<sup>240</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1071 (Fed. Cir. 2011) (quoting H.R. REP. NO. 98–857, pt. 2, at 30 (1984)).

<sup>241</sup> *Id.*

<sup>242</sup> *Id.*

<sup>243</sup> *See id.*

<sup>244</sup> *See id.*

<sup>245</sup> *Id.*; *see also supra* Part II.B.1.

<sup>246</sup> *Id.* at 1070.

<sup>247</sup> *Id.*

<sup>248</sup> *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005).

<sup>249</sup> *Classen*, 659 F.3d at 1071 (quoting *Merck*, 545 U.S. at 207) (emphasis added)).

*Classen* were not related to producing information that could lead to marketing approval, the *Classen* court concluded that “*Merck v. Integra* does not provide a § 271(e)(1) safe harbor for these activities.”<sup>250</sup>

The *Classen* majority concluded its opinion regarding the scope of the safe harbor provision by noting that “[e]xtensive precedent recites the purpose of § 271(e)(1) to facilitate market entry upon patent expiration. . . . There is no dispute as to the statutory purpose, and no contrary precedent.”<sup>251</sup> Judge Newman, writing for the *Classen* majority, dismissed Judge Moore’s dissent in the case with the following comment:

Our colleague in dissent strays from statute and precedent, in arguing that any activity by any entity concerning any adversely patented product or method is exempted from infringement by § 271(e)(1), provided only that the information obtained is “reasonably related to submitting *any* information under the FDCA, including information regarding post-approval uses.” Such a massive enlargement of the statutory exemption is incorrect.<sup>252</sup>

Judge Moore filed the dissenting opinion in *Classen* in which she rejected the majority’s position that the application of § 271(e)(1) is limited to pre-approval activities.<sup>253</sup> In the words of Judge Moore, “[t]he majority’s construction is contrary to the plain language of the statute and Supreme Court precedent.”<sup>254</sup> Looking to the statutory text, Judge Moore noted that “[n]owhere does the statute limit the safe harbor to pre-approval uses.”<sup>255</sup> Moreover, she relied on the language of the Supreme Court in its *Merck* decision to conclude that “the safe harbor extends to *all* uses that are reasonably related to submitting *any* information under the FDCA, including information regarding post-approval uses.”<sup>256</sup> Specifically, Judge Moore quoted the *Merck* Court’s statement that “we think it is apparent from the statutory text that § 271(e)(1)’s exemption from infringement extends to all uses of patented intentions that are reasonably related to the development and submission of *any* information under the FDCA.”<sup>257</sup> She also repeated the *Merck* Court’s subsequent conclusion that “[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.”<sup>258</sup> Judge Moore acknowledged that all of the allegedly infringing activities under consideration in *Merck* took place in the pre-approval phase of research, but rejected the majority’s conclusion that this fact limited the *Merck* Court’s construction of the safe harbor provision to exclude

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<sup>250</sup> *Id.* at 1072.

<sup>251</sup> *Id.*

<sup>252</sup> *Id.* at 1072 n.4 (internal citations omitted).

<sup>253</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1083 (Fed. Cir. 2011) (Moore, J., dissenting).

<sup>254</sup> *Id.*

<sup>255</sup> *Id.*

<sup>256</sup> *Id.* (emphasis in original).

<sup>257</sup> *Id.* (quoting *Merck KGaA v. Integra Lifesciences, Ltd.*, 545 U.S. 193, 202 (2005)).

<sup>258</sup> *Id.*

post-approval activities.<sup>259</sup> In her view, “the Court [in *Merck*] repeatedly underscored the breadth of the statute’s text.”<sup>260</sup>

With respect to the majority’s reliance on the legislative history of the Hatch-Waxman Act in justifying its narrow interpretation of the safe harbor statute, Judge Moore stated the following:

The majority cites extensively from the legislative history in an attempt to justify its construction. But these citations miss the point entirely. There is no dispute that § 271(e)(1) covers pre-approval studies, as the legislative history indicates. None of the legislative history cited by the majority, nor the cases it references, speak to the question at issue here—whether the statute as enacted also covers post-approval activities. The question is not whether Congress intended to protect pre-approval activity—but whether the enacted legislation covers *more* than just preapproval activity. The language Congress chose to enact and that was signed into law by the President is plain on its face. There is no “pre-approval” limitation. The statute includes within the safe harbor activity “solely for uses reasonably related to the development and submission of information under a Federal law.” This statute could have been written to indicate solely for uses seeking federal approval or solely for pre-approval uses. It was not. The plain language of this statutory text is broader. Any activity solely for uses reasonably related to the development and submission of information under a Federal law is included in § 271(e)(1).<sup>261</sup>

Judge Moore ended her dissent by arguing that only certain of the unauthorized activities of the alleged infringers in *Classen* were shielded from infringement liability under § 271(e)(1).<sup>262</sup> “[T]he . . . participation by [the alleged infringers] in studies evaluating risks associated with different vaccination schedules is reasonably related to their requirement to review and report adverse information to the FDA” and was, therefore, protected under the safe harbor statute.<sup>263</sup> However, the alleged infringers also “immuniz[ed] subjects in accordance with a lower risk schedule”<sup>264</sup> and such activities did not fall within the statutory harbor exception. As stated by Judge Moore,

[a]lthough [the alleged infringers] might be required to report adverse events that occur as a result of their vaccines, they are not required by law or regulation to perform such post-approval vaccinations in order to generate data. . . . The general administration of drugs or vaccines is not reasonably related to post-approval reporting requirements. For example, while the FDA requires the reporting of post-approval adverse reactions,

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<sup>259</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1083 (Fed. Cir. 2011) (Moore, J., dissenting).

<sup>260</sup> *Id.*

<sup>261</sup> *Id.* at 1083–84.

<sup>262</sup> *Id.* at 1084.

<sup>263</sup> *Id.*

<sup>264</sup> *Id.*

this does not mean that all commercial uses of the vaccine are “solely for uses reasonably related to the development and submission of information under a Federal law.” The fact that [the alleged infringers] would have to report to the FDA any adverse reaction after administering a vaccine does not mean the administration itself is noninfringing.<sup>265</sup>

*c. Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*

The Federal Circuit revisited the question of whether the statutory exemption applies to information generated in the course of post-marketing approval activities in its *Momenta* decision.<sup>266</sup> The issue in that case involved the unauthorized use by the alleged infringer Amphastar of Momenta's patented manufacturing test method which enabled Amphastar to manufacture for commercial sale a generic product that competed with that of Momenta.<sup>267</sup> In contrast to its ruling in *Classen*, the Federal Circuit in *Momenta* held that the scope of the safe harbor provided under § 271(e)(1) was sufficiently broad to cover post-approval activities.<sup>268</sup>

The panel majority in *Momenta* consisted of Judges Dyk and Moore.<sup>269</sup> Judge Rader filed a dissenting opinion.<sup>270</sup> Judge Moore, who dissented in *Classen*, filed the opinion for the court in *Momenta*.<sup>271</sup> In addition to addressing issues that were specific to the facts in *Momenta*, Judge Moore relied on the arguments that she had made in her *Classen* dissent.<sup>272</sup> In essence, she concluded that: (i) the relevant language of § 271(e)(1) is clear and provides no basis for categorically excluding information generated in the course of post-approval activities from the ambit of the safe harbor statute; (ii) because there is no ambiguity in the relevant language of the statute, there is no need to consider the legislative history of the Hatch-Waxman Act; (iii) the Supreme Court's prior decisions in *Eli Lilly* and *Merck* regarding the scope of § 271(e)(1) support the broad reading of the safe harbor statute that is being adopted by the Federal Circuit in *Momenta*; and (iv) while the Federal Circuit's prior decision in *Classen* is binding on the judges that comprise the *Momenta* panel, the holding in *Classen* can be distinguished and, in fact, is consistent with the majority's ruling in *Momenta*.<sup>273</sup>

With respect to the language of the safe harbor statute, Judge Moore described the task of the court as follows:

“[A]ll statutory construction cases . . . begin with the language of the statute.” The “first step in interpreting a statute is to determine whether

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<sup>265</sup> *Id.*

<sup>266</sup> *See Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1368 (Fed. Cir. 2012).

<sup>267</sup> *Id.* at 1362.

<sup>268</sup> *Id.* at 1355.

<sup>269</sup> *Id.* at 1349.

<sup>270</sup> *Id.*

<sup>271</sup> *Id.*

<sup>272</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1358 (Fed. Cir. 2012).

<sup>273</sup> *See id.* at 1354, 1356–57, 1358.

the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case.” If the language of the statute is unambiguous, there is no second step: “Our inquiry must cease if the statutory language is unambiguous and ‘the statutory scheme is coherent and consistent.’” Whether the text of a statute is plain or ambiguous “is determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole.”<sup>274</sup>

Judge Moore focused her analysis on the statutory language “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>275</sup> She relied on the text of § 271(e)(1) and the closely related infringement provision 35 U.S.C. § 271(e)(2) to conclude that § 271(e)(1) does not restrict the type of information covered by the safe harbor provision to that necessary for an ANDA submission or required by the Federal Food, Drug, and Cosmetic Act generally.<sup>276</sup> As she explained, “Congress used more flexible and expansive language to define the scope of § 271(e)(1) . . . [which] unambiguously applies to submissions under any federal law, providing that the law ‘regulates the manufacture, use, or sale of drugs.’”<sup>277</sup> According to Judge Moore, “[a]s long as the allegedly infringing use is ‘for uses reasonably related’ to the development and submission of that information it is not an act of infringement, regardless of where that requirement resides in the [federal] law [that regulates drugs].”<sup>278</sup> A narrower interpretation of the safe harbor statute, e.g., one that categorically excludes information developed in the course of post-approval activities, “would read words into the statute in violation of the express language chosen by Congress.”<sup>279</sup> Judge Moore concluded by noting that “[s]ince there is no ambiguity in the language used by Congress in 35 U.S.C. § 271(e)(1), our inquiry into the scope of the safe harbor is complete. When the intent of Congress is expressed so clearly and consistently throughout the statute, there is neither the need nor the occasion to refer to the legislative history.”<sup>280</sup>

Judge Moore next argued, as she did in her *Classen* dissent, that her expansive construction of the safe harbor statute is consistent with Supreme Court precedent.<sup>281</sup> In the words of Judge Moore,

[t]his analysis is not groundbreaking: the Supreme Court came to essentially the same conclusion [regarding the breadth of the statutory language under consideration] in 1990. In *Eli Lilly & Co. v. Medtronic, Inc.*, the Court explained that “the phrase ‘a Federal law which regulates the manufacture, use, or sale of drugs’ more naturally summons up the image of

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<sup>274</sup> *Id.* at 1353–54 (internal citations omitted).

<sup>275</sup> *Id.* at 1354 (quoting from 35 U.S.C. § 271(e)(1) (2012)) (emphasis omitted).

<sup>276</sup> *Id.*

<sup>277</sup> *Id.*

<sup>278</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1355 (Fed. Cir. 2012).

<sup>279</sup> *Id.* at 1354.

<sup>280</sup> *Id.* at 1355 (internal citations omitted).

<sup>281</sup> *Id.* at 1355–56.

*an entire statutory scheme of regulation,*” and not just a particular provision of the law. . . .

The Court later reaffirmed this expansive view, explaining: “we think it 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 [(Food, Drug, and Cosmetic Act)].” *Merck KGaA v. Integra Lifesciences, Ltd.*, 545 U.S. 193, (2005) (citing *Eli Lilly*, 496 U.S. at 665–69). *Merck KGaA* expressly rejected the notion that the safe harbor only applies to information developed during a clinical trial. Instead, “the statutory text makes clear that it provides a wide berth for the use of patented drugs in *activities related to the federal regulatory process.*” In light of the unqualified exemption for uses reasonably related to the development and submission of information, “[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or *the particular submission in which it could be included.*”<sup>282</sup>

Judge Moore also relied on the Supreme Court’s interpretation of the word “under” in the phrase “under a Federal law” to support her broad reading of the safe harbor statute.<sup>283</sup> Quoting from the Supreme Court’s decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*,<sup>284</sup> she stated that “[u]nder a federal law’ extends beyond just the ‘most barebones information’ required by the FDA, and instead encompasses all ‘materials the FDA demands in the regulatory process.’”<sup>285</sup>

Judge Moore acknowledged that there is a critical limitation in the application of the statute.<sup>286</sup> She stated that “[w]hile it is clear that the safe harbor applies to a broad set of ‘activities related to the federal regulatory process,’ *Merck KGaA*, 545 U.S. at 202, there is an important limitation: the use must be ‘for uses reasonably related to the development and submission of information,’ 35 U.S.C. § 271(e)(1).”<sup>287</sup> However, she went on to emphasize the breadth provided by this limiting language:

“Reasonably related” . . . does not mean that the use of the patented invention must necessarily result in submission of information to the FDA: “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.” Instead, the Court explained that the safe harbor “exempted from infringement *all* uses of patented compounds

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<sup>282</sup> *Id.* (emphasis in original) (internal citations omitted).

<sup>283</sup> *See id.* at 1356 (internal citation omitted).

<sup>284</sup> 132 S. Ct. 1670, 1684 (2012).

<sup>285</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1356 (Fed. Cir. 2012).

<sup>286</sup> *Id.*

<sup>287</sup> *Id.* (internal citation omitted).

‘reasonably related’ to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs.” Thus, the Court explicitly rejected the notion that § 271(e)(1) was limited “to the activities necessary to seek approval of a generic drug.” As long as the accused infringer “has a reasonable basis for believing” that use of the patented invention might yield information that “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>288</sup>

Judge Moore also relied on the Supreme Court’s *Merck* decision to address an issue, specific to the facts in *Momenta*, regarding the statutory term “submission.”<sup>289</sup> The information generated by Amphastar through the unauthorized use of Momenta’s patented manufacturing test method was not developed for actual submission to the FDA.<sup>290</sup> Instead, it was retained by Amphastar for possible inspection by the FDA at a later date, in accordance with applicable regulations regarding the manufacture of a generic drug product for commercial sale.<sup>291</sup> It was argued that the mere retention of this information by Amphastar did not qualify as a “submission” under § 271(e)(1).<sup>292</sup> That argument was rejected by the *Momenta* majority, however, which cited the Supreme Court’s decision in *Merck*.<sup>293</sup> As stated by Judge Moore,

[w]e think that the requirement to maintain records for FDA inspection satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA. It is not disputed by the parties that these records are produced in order to develop and submit to the FDA proof that the Amphastar products comply with a Federal law. The fact that the FDA does not in most cases actually inspect the records does not change the fact that they are for the “development and submission of information under a Federal law.” 35 U.S.C. § 271(e)(1); *cf. Merck KGaA*, 545 U.S. at 207 (holding that uses which are not ultimately included in a submission to the FDA are nonetheless exempted by the safe harbor). Thus, we consider this information “submitted” for purposes of the statute. We turn then to the question of whether these submissions are within the safe harbor.

In *Merck KGaA v. Integra Lifesciences I, Ltd.*, the Supreme Court held that uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the FDA, are nevertheless exempted from infringement by the safe harbor provision . . . [provided

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<sup>288</sup> *Id.* at 1356–57 (emphasis in original) (internal citations omitted).

<sup>289</sup> *Id.* at 1367.

<sup>290</sup> *Id.* at 1357.

<sup>291</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1357 (Fed. Cir. 2012).

<sup>292</sup> *Id.*

<sup>293</sup> *Id.*

that] “there [was] a reasonable basis for believing that the experiments [would] produce the types of information that are relevant to [a submission under any federal law regulating the manufacture, use, or distribution of drugs].”<sup>294</sup>

Judge Moore next distinguished the Federal Circuit’s prior holding in *Classen*, in which the court had ruled that the safe harbor statute did not exempt from infringement liability the post-approval activities under consideration in that case.<sup>295</sup> Judge Moore acknowledged that the court’s prior *Classen* decision was controlling precedent for the *Momenta* panel.<sup>296</sup> She stated that “[w]e, of course, are bound by the *Classen* decision unless it is overruled en banc or by the Supreme Court.”<sup>297</sup> However, Judge Moore interpreted the *Classen* holding narrowly so as to allow the *Momenta* court to rule that the unauthorized post-approval activities under consideration in *Momenta* were, in fact, covered by an exemption provided under § 271(e)(1).<sup>298</sup> According to Judge Moore, “in *Classen Immunotherapies, Inc. v. Biogen IDEC*, we held that § 271(e)(1) ‘does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.’”<sup>299</sup> She focused on the word “routinely” and, arguably, conflated the concepts of “obtaining marketing approval” and “maintaining marketing approval” in order to distinguish the Federal Circuit’s ruling in *Classen* from that of the court in the instant case.<sup>300</sup> The post-approval studies undertaken in *Classen* explored the association between the timing of the administration of childhood vaccines and the risk of developing immune-mediated disease.<sup>301</sup> While these studies could generate adverse experience data that would have to be submitted to the FDA, the studies themselves were not undertaken to satisfy an FDA requirement. According to Judge Moore’s interpretation of the Federal Circuit’s *Classen* holding, any information generated in the course of these voluntary studies would be reported as part of a “routine” submission to the FDA that was not covered by the safe harbor provision.<sup>302</sup> In contrast, the testing undertaken by Amphastar in the *Momenta* case was mandated by the FDA and the submission of information generated by the tests was “necessary both to the continued approval of the ANDA and to the ability to market the generic drug. Here, the submissions are *not* ‘routine submissions’ to the FDA, but instead are submissions that are *required to maintain FDA approval*.”<sup>303</sup> As Judge Moore explained,

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<sup>294</sup> *Id.* (citing *Merck KGaA v. Integra Lifesciences, Ltd.*, 545 U.S. 193, 208 (2005)).

<sup>295</sup> *See id.* at 1358.

<sup>296</sup> *Id.*

<sup>297</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1358 (Fed. Cir. 2012).

<sup>298</sup> *Id.* at 1358.

<sup>299</sup> *Id.* at 1357.

<sup>300</sup> *See id.*

<sup>301</sup> *See id.* at 1358.

<sup>302</sup> *See id.*

<sup>303</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1358 (Fed. Cir. 2012) (emphasis added).

[t]he submissions to the FDA in this case are anything but “routine”—they implicate Amphastar’s very ability to continue its FDA approval for its ANDA and to continue manufacturing and marketing [its generic version of the drug] enoxaparin under its ANDA. We also note that, unlike in *Classen* where the patented studies performed were not mandated by the FDA, the information here is not generated voluntarily by the manufacturer but is generated by FDA requirements the manufacturer is obligated under penalty of law to follow. Under such circumstances, the information can be said to have been gathered solely for submission to the FDA and not, as in *Classen*, primarily for non-FDA purposes.<sup>304</sup>

Judge Moore specifically rejected the argument made by Momenta (and endorsed by Judge Rader in his dissenting opinion in *Momenta*) that the *Classen* holding cannot be so narrowly construed in that the Federal Circuit in that case drew a sharp line between pre-approval activities, which can be shielded under the safe harbor provision, and post-approval activities, which cannot be so shielded.<sup>305</sup> In the words of Judge Moore, “[w]hile Momenta urges us to adopt the pre-/post-approval distinction used by the district court, we cannot: *Classen* did not turn on this artificial distinction, and the plain language of the statute is not restricted to pre-approval activities.”<sup>306</sup> She concluded this portion of her opinion as follows:

Under a proper construction of 35 U.S.C. § 271(e)(1), the fact that Amphastar’s testing is carried out to “satisfy the FDA’s requirements” means it falls within the scope of the safe harbor, even though the activity is carried out after approval. Unlike *Classen*, where the allegedly infringing activity “may” have eventually led to an FDA submission, there is no

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<sup>304</sup> *Id.* Note that Judge Moore’s use of the words “primarily” and “purposes” in the last sentence of this excerpt is an example of the imprecision that often characterizes a discussion of the statutory term “solely.” *Id.* As noted *supra* in Part II.B.2 (“Solely”), an alleged infringer whose activity is otherwise shielded from infringement liability under § 271(e)(1) loses that protection if such activity is also for a use that is not an “immunizing use.” See *supra* Part II.B.2. However, the underlying purpose or intent of the alleged infringer is irrelevant to a safe harbor analysis, and the statutory exemption is not lost if information generated through the unauthorized use of a patented invention is used in the conduct of non-infringing activities. Later in her *Momenta* opinion, Judge Moore endorsed aspects of this interpretation of the term “solely” in § 271(e)(1) when she stated that,

We have interpreted [the] language of the safe harbor to allow alleged infringers to use “data from tests for more than FDA approval,” such as for fund raising and other business purposes. *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) (holding that the alleged infringer’s “intent or alternate uses [of test data] are irrelevant to its qualification to invoke the section 271(e)(1) shield”).

*Id.* at 1360.

<sup>305</sup> *Id.* at 1358–59.

<sup>306</sup> *Id.*

dispute in this case that Amphastar's allegedly infringing activities are carried out to "satisfy the FDA's requirements."<sup>307</sup>

Judge Moore then addressed *Momenta*'s argument "that even if 35 U.S.C. § 271(e)(1) extends to post-approval activities, Amphastar's testing is not protected because there are FDA endorsed non-infringing alternatives available."<sup>308</sup> As she explained, "*Momenta*'s interpretation is predicated upon the incorrect assumption that 'solely' in the context of 35 U.S.C. § 271(e)(1) means that the patented invention must be the 'sole' means of providing the information for the safe harbor to apply."<sup>309</sup> The *Momenta* majority rejected this argument, however, in stating that,

[t]he safe harbor... does not mandate the use of a noninfringing alternative when one exists. The only limitation in the safe harbor is that the use must be "reasonably related to the development and submission of information" pursuant to a federal law regulating the "manufacture, use, or sale of drugs or veterinary biological products." 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. Instead, the safe harbor expressly allows the submitter the freedom to use an otherwise patented means to develop the necessary information demanded by the "Federal law."<sup>310</sup>

With respect to *Momenta*'s interpretation of the word "solely," Judge Moore stated that,

[t]his is not the language of the statute: under 35 U.S.C. § 271(e)(1), as long as the use is "reasonably related to the development and submission of information" under a relevant statute, it is not an act of infringement. "Solely" modifies "uses reasonably related to the development and submission of information," but does not place any other restriction on when the patented invention may be used without infringing. As long as the use of the patented invention is done to generate information that will be submitted pursuant to a relevant federal law, that use falls within the safe harbor. *Merck KGaA*, 545 U.S. at 205–06. *Momenta* is therefore incorrect that the possibility that the FDA would accept the use of other, non-patented, testing methods for the development and submission of information precludes Amphastar from relying on the safe harbor in this case.<sup>311</sup>

Moreover, Judge Moore noted that "[e]ven if *Momenta*'s strained reading of the statute was supportable, Amphastar's allegedly infringing activities are clearly

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<sup>307</sup> *Id.* at 1359.

<sup>308</sup> *Id.* at 1360.

<sup>309</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1359 (Fed. Cir. 2012).

<sup>310</sup> *Id.*

<sup>311</sup> *Id.* at 1359–60 (internal citations omitted).

carried out according to the dictates of the Federal Food, Drug, and Cosmetic Act.”<sup>312</sup> Based on her interpretation of the FDA’s testing requirements with respect to the generic product at issue in *Momenta*, Amphastar was obligated to undertake testing in accordance with the methods articulated in the official compendium (in this case the USP) in order to demonstrate that its product was not adulterated.<sup>313</sup> She agreed with the interpretation of the district court in the case that any such testing fell within the scope of the *Momenta* patent, undermining any argument that alternative non-infringing test methods were available to Amphastar.<sup>314</sup>

Judge Moore concluded her opinion for the majority in *Momenta* by rejecting an argument made by Judge Rader in his dissent based on the structure of the Hatch-Waxman Act.<sup>315</sup> As discussed above,<sup>316</sup> Judge Rader objected to the fact that the majority’s holding in *Momenta* impermissibly disrupts the intended equilibrium between § 156 and § 271(e)(1) by applying the disadvantage of the infringement exemption to a patentee who is unable to obtain the advantage of a patent term extension.<sup>317</sup> Citing language in the Supreme Court’s *Eli Lilly* opinion and the Federal Circuit’s prior decision in *AbTox*, Judge Moore responded that such equilibrium is not always achieved in the application of the safe harbor statute.<sup>318</sup>

Judge Rader, who was a part of the *Classen* majority, filed a vigorous dissenting opinion in *Momenta*.<sup>319</sup> He began with the following indictment of Amphastar’s trespass on *Momenta*’s patent rights and the *Momenta* majority’s endorsement of such action:

Amphastar is only able to compete with *Momenta* by taking its patented invention. Amphastar has not developed its own method, but instead delights in trespassing and refuses to pay a reasonable royalty to make the trespass lawful. This court would allow this arrogance to continue by expanding the limited reach of 35 U.S.C. § 271(e)(1). This expansion of the law circumvents the purpose of the law and ignores the binding precedent of *Classen Immunotherapies, Inc. v. Biogen IDEC*. Sadly this result will render worthless manufacturing test method patents. Accordingly, I must respectfully dissent.<sup>320</sup>

Judge Rader then crafted a dissenting opinion which, in summary, relied on the following arguments: (i) the text of § 271(e)(1) is not plainly comprehensible and, accordingly, one must look to the legislative history of the Hatch-Waxman Act (which focuses on pre-approval activities) for the purpose of the text; (ii) a proper reading of the word “solely” in the text of § 271(e)(1) indicates that Amphastar’s infringing activities do not fall within the protection of the safe harbor statute; (iii) the plain

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<sup>312</sup> *Id.* at 1360.

<sup>313</sup> *Id.* at 1361.

<sup>314</sup> *Id.*

<sup>315</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1361 (Fed. Cir. 2012).

<sup>316</sup> See *supra* Part II.B.4. (“Patented Invention”).

<sup>317</sup> *Momenta*, 686 F.3d at 1361.

<sup>318</sup> *Id.*

<sup>319</sup> *Id.* at 1362 (Rader, J., dissenting).

<sup>320</sup> *Id.* (internal citations omitted) (paragraphing omitted).

meaning of the word “submission” in § 271(e)(1) does not include the mere retention of information by Amphastar; (iv) the majority’s attempt to distinguish the Federal Circuit’s prior *Classen* decision is unconvincing and reliance on the binding precedent established in that case requires a holding that Amphastar’s post-approval unauthorized use of *Momenta*’s patent is not shielded from infringement liability under the safe harbor statute; (v) the broad reading of § 271(e)(1) by the majority renders manufacturing method patents worthless and negates incentives and protections under the patent act; and (vi) the narrow reading of the safe harbor provision adopted in *Classen* and endorsed in this dissent is consistent with the Supreme Court’s rulings in *Eli Lilly* and *Merck*.<sup>321</sup>

Judge Rader rejected the contention of the *Momenta* majority that the text of § 271(e)(1) is plain and unambiguous, eliminating a need to consider the legislative history of the Hatch-Waxman Act.<sup>322</sup> He cited the Supreme Court’s decision in *Eli Lilly* to make the point that “the text alone of § 271(e)(1) can be ‘not plainly comprehensible,’”<sup>323</sup> but noted that “[t]he purpose of this text, which ought to inform its application . . . is evident from the legislative history.”<sup>324</sup> Having justified an examination of the legislative history of the Hatch-Waxman Act, Judge Rader proceeded to review relevant sections of the House reports, Congressional testimony and contemporaneous commentaries discussing the purpose of the Act.<sup>325</sup> On the basis of his review, he concluded that “section 202 of the Hatch-Waxman Act, enacted as § 271(e)(1), had the sole purpose of over-ruling this court’s holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* In particular, § 271(e)(1) applied only in limited situations, namely pre-approval experiments to obtain FDA approval.”<sup>326, 327</sup>

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<sup>321</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1361–76 (Fed. Cir. 2012) (Rader, J., dissenting).

<sup>322</sup> *Id.* at 1367.

<sup>323</sup> *Id.* at 1362 (Rader, J., dissenting) (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990), in which Justice Scalia stated that “[a]s far as the text is concerned . . . we conclude that we have before us a provision that . . . is not plainly comprehensible on anyone’s view.”). As noted *supra* in Part II.B.1. (“Under a Federal Law”), Justice Scalia was interpreting a specific phrase in the safe harbor statute (“a Federal law”) and concluded that the legislative history of the Hatch-Waxman Act “sheds no clear light” on the meaning of that phrase. *Eli Lilly*, 496 U.S. at 669.

<sup>324</sup> *Momenta*, 686 F.3d at 1362 (Rader, J., dissenting).

<sup>325</sup> *See id.*

<sup>326</sup> *Id.* (internal citation omitted). Judge Rader focused his analysis on the following sections of H.R. REP. NO. 98-857 (1984):

The purpose of 271(e)(1) and (2) 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. Since the Committee’s Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of *experimentation* is infringement. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the Court of Appeals for the Federal Circuit held that the *experimental use* of a drug product prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though *the only purpose of the experiments is to seek FDA approval* for the commercial sale of the drug after the patent expires. It is the Committee’s view that *experimental activity* does not have any adverse economic impact on the patent owner’s exclusivity during the life of a patent, but prevention of such activity would

Judge Rader noted the concern, expressed by the pharmaceutical industry at the time that the Hatch-Waxman Act was under consideration, that section 202 of the Act permitted trespass on the rights of a patent holder.<sup>328</sup> But, as Judge Rader explained,

this concern dissipated with promises that § 271(e)(1) only allowed “limited testing of drugs” See H.R. REP. NO. 98-857, pt. 2, at 29 (1984):

In this case the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug *for purposes of submitting data to the FDA for approval*. Thus, the nature of the interference is *de minimis*.<sup>329</sup>

Judge Rader relied on the legislative history of the Hatch-Waxman Act in reaching the following conclusions:

Specifically, § 271(e)(1) won approval because it was limited in time, quantity, and type. First, as to time, § 271(e)(1) only applies to *pre*-marketing approval. . . . Second, as to quantity and type, § 271(e)(1) only applies to experimentation—and therefore would have limited impact on the patentee’s exclusivity during the life of the patent. . . . In particular, . . . [it was] clear that section 271(e)(1) would not apply to commercial sales, i.e., the “infringing” product would not enter the market until *after* the patent’s life.<sup>330</sup>

Judge Rader concluded his review of the legislative history of § 271(e)(1) with the following compelling summation:

The authors of this section (and I hesitate to add that I was present through this legislative process) did not imagine that § 271(e)(1) would allow *continuous, commercial* infringing sales during any portion of the life of the patent. . . . Amphastar has already obtained FDA regulatory approval, and

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extend the patent owner’s commercial exclusivity beyond the patent expiration date.

H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984) (internal citation omitted) (emphasis added). The testimony continued, “The provisions of section 202 of the bill have the net effect of reversing the holding of the court in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*” H.R. REP. NO. 98-857, pt. 2, at 27 (1984).

<sup>327</sup> Judge Rader’s conclusion that the *sole* purpose of § 271(e)(1) was to overrule the Federal Circuit’s holding in *Roche* is not consistent with the view expressed by Justice Scalia in his *Eli Lilly* decision. In the words of Justice Scalia, “[u]ndoubtedly the decision in *Roche* prompted the *proposal* of § 202; but whether that alone accounted for its *enactment* is quite a different question.” *Eli Lilly*, 496 U.S. at 670 n.3 (emphasis in original).

<sup>328</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1363–64 (Fed. Cir. 2012) (Rader, J., dissenting).

<sup>329</sup> *Id.* at 1365 (emphasis in original).

<sup>330</sup> *Id.* at 1365–66 (emphasis added) (internal citations omitted).

today this court rewrites the law to allow Amphastar to infringe *Momenta's* patent throughout *the entire life of Momenta's patent* and for the purpose of obtaining profits on *commercial sales* of a product that *competes with the patentee*.

Nowhere in the legislative history can this court find any suggestion that § 271(e)(1) would apply other than in the limited scenario of conducting *de minimis* experiments pre-approval (i.e., to obtain FDA approval). Nowhere in the legislative history can this court find a hint that an “infringer” could continue to use its competitor’s patented method in manufacture of each commercial batch for contemporaneous sale. Nowhere in the legislative history can this court find any mention of the post-approval, continuous, commercial sales allowed by this decision. Nowhere in the legislative history can this court find any suggestion that the mere maintenance or retention of information as part of a company’s records is considered a submission that would trigger § 271(e)(1). In fact, this court makes no attempt to examine the legislative history of this section at all—a very telling silence.<sup>331</sup>

Judge Rader then returned to the text of § 271(e)(1) to consider the words “solely” and “submission” in the context of the facts in the *Momenta* case to support his position that the safe harbor statute does not shield Amphastar’s post-approval activities from infringement liability.<sup>332</sup> He argued that,

[t]o facilitate a post-approval, continuous, commercial use, the court discounts the word “solely.” Indeed, throughout its opinion, the court cites the language of the statute yet omits the word “solely.” If one properly reads “solely” as the statute says, the result must be that Amphastar’s activity is not within the statute. Its infringing activity is *not solely* for developing and submitting information to the FDA. Instead, Amphastar uses this method for the purpose of manufacturing a product to sell on the market in commerce.<sup>333</sup>

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<sup>331</sup> *Id.* at 1366. Note that this passage from Judge Rader’s dissenting opinion in *Momenta* makes reference to what the Judge considered to be a particularly egregious assault on *Momenta's* rights. Not only did Amphastar make use of *Momenta's* patented manufacturing method without providing any consideration to *Momenta*, but such use permitted Amphastar to commercialize a generic product that directly competes with *Momenta's* product, eroding the latter’s share in a generic market estimated to be over one billion dollars per year. While the focus of the case before the *Momenta* court was on the unauthorized use of *Momenta's* patented method, rendering the method essentially worthless, the significant impact of that use on *Momenta's* share of the generic’s market is noted throughout Judge Rader’s dissenting opinion.

<sup>332</sup> *Id.* at 1367.

<sup>333</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1367 (Fed. Cir. 2012) (Rader, J., dissenting) (emphasis in original) (internal citation omitted). Judge Rader’s use of the word “purpose” in the last sentence of this excerpt was ill-advised in that it introduced imprecision into his argument. As discussed *supra* in Part II.B.2. (“Solely”), judicial interpretations of the term “solely” in § 271(e)(1) distinguish between the word “purpose,” which is understood to mean motive

With respect to the word “submission,” Judge Rader stated that “the court claims that the mere retention of records can satisfy the ‘submission’ requirement in § 271(e)(1). By essentially stating that ‘submission’ can mean not really submitting, this new interpretation reads this requirement out of the statute as well.”<sup>334</sup> As the Judge explained,

despite the plain meaning of “submission of information” to mean the company actually submitting information to the FDA, the court interprets “submission of information” to mean the mere retention of information as part of a company’s records. . . . Maintaining or keeping a document has the exact opposite meaning of submitting a document. In other words, “submission” means not really submitting anything—a strange construction of an “unambiguous” term.<sup>335</sup>

According to Judge Rader, this “strange construction” of the word “submitted” broadens the potential reach of the safe harbor statute well beyond its intended purpose:

This new interpretation would allow almost all activity by pharmaceutical companies to constitute “submission” and therefore justify a free license to trespass. The FDA can inspect records of any drug manufacturer and seller. Thus, the drug manufacturer need only make a record, which could potentially be inspected by the FDA, and then any activity could satisfy this new meaning of “submission.”<sup>336</sup>

Judge Rader concluded this portion of his analysis by remarking that “a reading of *all* the words in the statute and a reading of those words in light of their legislative history shows that § 271(e)(1) only permits a limited amount of pre-approval experiments to obtain FDA approval.”<sup>337</sup>

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or goal, and the word “use.” *See supra* Part II.B.2. Judge Rader’s argument appears to be that Amphastar’s unauthorized use of Momenta’s patented method in the manufacture of Amphastar’s generic product is not simply to generate information that may be reviewed by the FDA, but also to make product that can be marketed and sold. This additional use, according to Judge Rader, deprives Amphastar of the benefit of the statutory exemption. The difficulty with this argument is that Amphastar’s commercialization of its generic product does not constitute an infringement of Momenta’s patent (since it is not a use of the patented invention). As noted *supra* in Part II.B.2, an alleged infringer’s participation in associated, non-infringing activities does not deprive it of the benefit of the statutory exemption where it is otherwise available. *See supra* Part II.B.2 (“Solely”). However, Judge Rader’s argument, based on the effect of the word “solely” in § 271(e)(1) is only one prong of his attack on Amphastar’s unauthorized use of Momenta’s patented invention, and a minor one at that. As is clear from a review of his entire dissenting opinion, the main argument proffered by Judge Rader in *Momenta* is that the unauthorized use of a patented invention to generate information relating to a product that has already received marketing approval is outside of the ambit of § 271(e)(1) and, accordingly, such activity lacks the “immunizing use” necessary for application of the safe harbor statute.

<sup>334</sup> *Momenta*, 686 F.3d at 1367 (Rader, J., dissenting).

<sup>335</sup> *Id.*

<sup>336</sup> *Id.* (internal citation omitted).

<sup>337</sup> *Id.* (emphasis in original).

Judge Rader next offered his most convincing criticism of the majority's opinion, namely, that the issue under consideration in *Momenta* had already been addressed by the Federal Circuit in its *Classen* decision, in which the court had ruled that the safe harbor provision does not apply to the generation of information in the course of post-approval activities.<sup>338</sup> In the words of the Judge,

[t]his court has already decided the meaning of this statute in *Classen*. The *Classen* majority held “§ 271(e)(1) provides an exception to the law of infringement in order to expedite development of information for regulatory approval of generic counterparts of patented products. The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.”<sup>339</sup>

Judge Rader rejected the claim by the *Momenta* majority that “*Classen* did not turn on the pre-/post-approval distinction.”<sup>340</sup> To the contrary, he stressed that this distinction was central to the Federal Circuit's holding in *Classen* and that the dissent in that case, written by Judge Moore, recognized this. As Judge Rader noted,

[t]he *Classen* dissent stated: “The majority concludes that the district court incorrectly interpreted the safe harbor of § 271(e)(1) because, according to the majority, § 271(e)(1) is limited to pre-approval activities. . . . Accordingly, I conclude that the safe harbor extends to all uses that are reasonably related to submitting any information under the FDCA, including information regarding post-approval uses.”<sup>341</sup>

Moreover, Judge Rader took issue with the *Momenta* majority's contention that,

*Classen* merely held that § 271(e)(1) does not apply to “routine” submissions . . . [but] “[t]his case . . . fits well within *Classen* because the information submitted is necessary both to the continued approval of the ANDA and to the ability to market the generic drug. Here, the submissions are not ‘routine submissions’ to the FDA, but instead are submissions that are required to maintain FDA approval.”<sup>342</sup>

According to Judge Rader,

this court in *Classen* did not at any point state that § 271(e)(1) applies to information “necessary both to the continued approval of the ANDA and to the ability to market the generic drug.” Indeed, this post-approval, continuous, commercial use is the exact opposite of the *Classen* rule.

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<sup>338</sup> *Id.* at 1367–68.

<sup>339</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1367 (Fed. Cir. 2012) (Rader, J., dissenting) (emphasis in original).

<sup>340</sup> *Id.* at 1368.

<sup>341</sup> *Id.* at 1369 (emphasis in original).

<sup>342</sup> *Id.* at 1368.

*Classen* rested its holding on “premarketing approval,” “limited amount of testing,” and “experimentation.” This decision (“post-approval studies”; “after approval”; “not restricted to pre-approval activities”) cannot be genuinely reconciled with *Classen* (“pre-marketing approval”). Instead, the court in this decision uses the same language as the dissent in *Classen*.<sup>343</sup>

The clear conflict between the Federal Circuit’s prior controlling decision in *Classen* and the majority’s opinion in *Momenta* prompted Judge Rader to argue that, because the *Momenta* majority declined to follow the court’s holding in *Classen*, it should at least have “request[ed] the entire court to resolve the issue *en banc*.”<sup>344</sup>

Judge Rader then argued that the *Momenta* majority’s broad reading of § 271(e)(1) “would essentially render manufacturing method patents worthless.”<sup>345</sup> Not only is *Momenta* deprived of any compensation for the unauthorized use of its government-conferred intellectual property right to exclude, but such an outcome “repeals the incentives and protections of the patent act in this area.”<sup>346</sup> While Judge Rader did not dwell on the constitutional ramifications of the *Momenta* majority’s construction of the safe harbor statute,<sup>347</sup> he noted that the majority’s interpretation “does violence”<sup>348</sup> to federal patent law (enacted by Congress pursuant to a grant of power under the Constitution<sup>349</sup>) and the wording of his dissent raised questions of a “taking” of property without just compensation in violation of the Fifth Amendment.<sup>350</sup>

Judge Rader next argued that the Supreme Court’s holdings in *Eli Lilly* and *Merck* support the Federal Circuit’s prior decision in *Classen* and do not support the majority’s decision in *Momenta*.<sup>351</sup> In the words of the Judge, “[b]oth holdings in *Eli Lilly* and *Merck* dealt with *pre-approval* activity and submissions, meaning *before* obtaining FDA approval. Further, neither even suggested that the mere maintenance or retention of information as part of a company’s records could be a ‘submission’ to the FDA.”<sup>352</sup> As discussed above<sup>353</sup> and in this Part’s review of the majority’s decision in *Momenta*, Judge Rader cited the Supreme Court’s *Eli Lilly* decision for its reliance on the balance between § 156 and § 271(e)(1), as reflected in the structure of the Hatch-Waxman Act, which is destroyed by the *Momenta*

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<sup>343</sup> *Id.* at 1369 (internal citations omitted).

<sup>344</sup> *See id.* As indicated *infra* in note 368 and accompanying text, the Federal Circuit denied *Momenta*’s petition for a rehearing *en banc* in November of 2012.

<sup>345</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1369 (Fed. Cir. 2012) (Rader, J., dissenting).

<sup>346</sup> *Id.* at 1370.

<sup>347</sup> *See* SCALIA & GARNER, *supra* note 43 at 247–51. Note that one of the canons of statutory interpretation, the constitutional-doubt canon, holds that a statute should be interpreted in a way that avoids placing its constitutionality in doubt. *Id.*

<sup>348</sup> *Momenta*, 686 F.3d at 1370 (Rader, J., dissenting).

<sup>349</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>350</sup> *See Momenta*, 686 F.3d at 1370 (Rader, J., dissenting).

<sup>351</sup> *See Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1370 (Fed. Cir. 2012) (Rader, J., dissenting).

<sup>352</sup> *Id.*

<sup>353</sup> *See supra* Part II.B.4 (“Patented Inventions”).

majority's holding.<sup>354</sup> He cited the Supreme Court's *Merck* decision for the proposition "that § 271(e)(1) is intended for pre-approval, experimental, limited use."<sup>355</sup> Quoting from various sections of the *Merck* opinion, the Judge emphasized that all of the allegedly infringing activities under consideration in that case involved pre-approval research that was intended to generate information for submission to the FDA.<sup>356</sup> According to Judge Rader, "[n]owhere does *Merck* suggest that post-approval, commercial, continuous infringing use would be permitted."<sup>357</sup>

Judge Rader then questioned the majority's actual reliance on the Supreme Court's *Merck* decision to support its holding in *Momenta*. As he explained,

[t]his court relies on some text from *Merck* that appears superficially to suggest an expansive interpretation of § 271(e)(1). But, read in context, that language has another meaning entirely. This language appears to suggest that § 271(e)(1) covers any sort of information or submission. But, this language actually appears in the context of the issue in *Merck* of whether information *intended* for submission to the FDA for approval should be covered when the information was ultimately not submitted because the drug candidate in that case lacked potential. . . . [However,] [h]olding that preclinical research reasonably expected to generate information for regulatory approval does not fall outside § 271(e)(1) simply because the research fails and does not result in a regulatory application . . . is a far cry from permitting infringement during manufacture of a commercial product merely because the infringing act also generates information that might someday be submitted to the FDA, long after marketing approval is granted.<sup>358</sup>

In addition, Judge Rader continued,

[T]his court claims that "the Court explicitly rejected the notion that § 271(e)(1) was limited 'to the activities necessary to seek approval of a generic drug.'" But, it is important to understand what *Merck* was trying to distinguish. Read in context, that phrase is referring to allowing § 271(e)(1) to include *pre-approval* activities for a *branded drug*. It was *not* stating that § 271(e)(1) included *post-approval* activities for a *generic drug*. In other words, the Supreme Court was emphasizing the words "generic drug," not the words "necessary to seek approval." . . . [Moreover,] [j]ust because *Merck* held that § 271(e)(1) could cover pre-approval activities for not only the ANDA but also the NDA and IND, does not mean that the mere

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<sup>354</sup> See *Momenta*, 686 F.3d at 1370.

<sup>355</sup> *Id.* at 1373.

<sup>356</sup> *Id.*

<sup>357</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1373 (Fed. Cir. 2012).

<sup>358</sup> *Id.* at 1373–74 (paragraphing omitted).

retention of documents as part of a company's records could be considered a "submission" to the FDA.<sup>359</sup>

Judge Rader concluded his interpretation of the Supreme Court's *Merck* decision and his critique of the *Momenta* majority's reliance on that decision as follows:

Thus, while *Merck* said that as long as an activity was *intended* for submission to obtain approval, then § 271(e)(1) applies even if the information is not actually submitted (because it is difficult to predict which drug candidates ultimately will be successful), it did not say that § 271(e)(1) applies even if the activity was *never intended to obtain approval at all*. Or if the information was *not even intended for submission to the FDA*. This court's interpretation (that the mere retention of information as part of a company's records can be a "submission" to the FDA) is indeed "groundbreaking" and the Supreme Court did not "come to essentially the same conclusion."<sup>360</sup>

In the final section of his dissenting opinion, Judge Rader addressed what he believed to be a common misconception with respect to U.S. patent law that, presumably, encourages efforts such as that of the majority in *Momenta* to shield infringers from liability, namely, the view that patent law does more to hinder than to promote innovation.<sup>361</sup> Contrary to the position taken by certain legal scholars, Judge Rader argued that, in practice "patents have not been proven to impede more than stimulate technological advance."<sup>362</sup> In the words of the Judge,

[P]atents properly remain a tool for research and experimentation because the system encourages publication and sharing of research results. Disclosure of how to make and use the invention is the "quid pro quo" of the patent grant. In exchange for disclosure, the inventor receives a limited term of exclusivity to benefit from commercialization of his invention. Without this promise of exclusivity, researchers at corporations would be forced to turn to secrecy as the best protection for their inventions.<sup>363</sup>

Judge Rader concluded his dissent in *Momenta* as follows:

Every day, Amphastar, a competitor of Momenta, is infringing Momenta's patent. This decision allows that trespass. Moreover, to reach that result, this court must ignore its own prior decision in *Classen* and the purpose of the statute explained in the legislative history. Sadly this decision abrogates Momenta's hard-achieved property right and reallocates that

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<sup>359</sup> *Id.* at 1374 (paragraphing omitted).

<sup>360</sup> *Id.*

<sup>361</sup> *Id.* 1375–76.

<sup>362</sup> *Id.* at 1375.

<sup>363</sup> *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d. 1348, 1373 (Fed. Cir. 2012) (Rader, J., dissenting) (internal citations omitted).

entitlement to its competitors—a sad day for property owners and an undeserved victory for those who decline to invest in the expense and difficulty of discovery and invention.<sup>364</sup>

*d. Summation*

The above review of the relevant case law indicates that there is considerable uncertainty regarding the meaning and scope of the statutory term “submission of information” in § 271(e)(1). In particular, questions remain as to what constitutes a “submission” under the statute and whether the information generated in the course of post-marketing approval activities falls within the ambit of § 271(e)(1). Despite Judge Moore’s effort in her *Momenta* opinion to distinguish the Federal Circuit’s prior holding in *Classen*, a strong argument can be made that the interpretations provided in *Classen* and in *Momenta* of the term “submission of information” are inconsistent. While Judge Moore’s holding in *Momenta* may conform to the Supreme Court’s broad reading of § 271(e)(1) in *Eli Lilly* and in *Merck*, there is support for the view that the Federal Circuit in *Momenta* should have relied on *stare decisis*<sup>365</sup> to rule against the application of the statutory exemption to post-approval activities (based on that court’s prior holding in *Classen*) or, at least, requested that this issue in the *Momenta* case be resolved by the Federal Circuit *en banc*.<sup>366</sup> Efforts by the parties in the two cases to clarify the situation have proven unsuccessful. In January of this year, the Supreme Court declined to review the Federal Circuit’s *Classen*

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<sup>364</sup> *Id.* at 1376 (Rader, J., dissenting).

<sup>365</sup> With respect to the doctrine of *stare decisis*, the Supreme Court has noted that “[s]*tare decisis* . . . reflects a policy judgment that ‘in most matters it is more important that the applicable rule of law be settled than that it be settled right.’” *Agostini v. Felton*, 521 U.S. 203, 235 (1997) (quoting *Burnet v. Coronado Oil & Gas Co.*, 285 U.S. 393, 406 (1932) (Brandeis, J., dissenting)). It “is the preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process.” *Payne v. Tenn.*, 501 U.S. 808, 827 (1991). The Court has expressed its reluctance to overrule decisions involving statutory interpretation. *See, e.g.*, *Ill. Brick Co. v. Ill.*, 431 U.S. 720, 736 (1977). The Court has acknowledged that *stare decisis* concerns are “at their acme in cases involving property and contract rights.” *Payne*, 501 U.S. at 828. The failure of the majority in *Momenta* to rely on the Federal Circuit’s prior holding in *Classen* to rule that the statutory exemption does not protect post-approval activity (or to even acknowledge the inconsistency between its decision in *Momenta* and the decision in *Classen*) undermines the goal of “promot[ing] the evenhanded, predictable, and consistent development of legal principles, foster[ing] reliance on judicial decisions, and contribut[ing] to the actual and perceived integrity of the judicial process.” *Id.* at 827.

<sup>366</sup> *See* Stephen L. Wasby, *Why Sit En Banc?* 63 HASTINGS L.J. 747, 749 (2012) (“The formal bases [for an *en banc* rehearing by a U.S. court of appeals] include the three desiderata of Federal Rule of Appellate Procedure (“FRAP”) 35—conflict with circuit precedent (*intracircuit* conflict), conflict with Supreme Court rulings, and presence of an issue of ‘exceptional importance’—and the court’s rules and general orders.”) (emphasis added). It could be argued that an *en banc* rehearing of the *Momenta* case was justified on the basis of any or all of the three elements of FED. R. APP. P. 35. The Federal Circuit did not agree, however, and denied *Momenta*’s petition for a rehearing *en banc* in November of 2012. *See infra* note 368.

decision.<sup>367</sup> In November of 2012, the Federal Circuit denied a petition for a rehearing of the *Momenta* case *en banc*,<sup>368</sup> and in June of this year the Supreme Court declined to review the Federal Circuit's decision in the case.<sup>369</sup> Unless and until the uncertainty generated by the Federal Circuit's holdings in *Classen* and in *Momenta* is addressed by a definitive ruling by the Supreme Court, a party that intends to use a patented invention without authorization to generate information in the course of post-approval activities in reliance on the protection afforded by the safe harbor statute will have to accept some risk of infringement liability.

### III. APPLICATION OF THE SAFE HARBOR STATUTE

Despite the many judicial reviews of § 271(e)(1), determining whether the statutory exemption applies to a specific unauthorized use of a patented invention can present a challenge. This Part of the Article provides an analytical approach to the application of the safe harbor statute, based on currently controlling case law. It involves answering a series of questions that highlight the critical issues raised by the interplay of key terms in the statute, as those terms have been construed by the courts. The approach is intended to streamline a safe harbor analysis by ordering the questions in a way that terminates the analysis with the first *no* answer. The utility of the approach is limited, however, as a result of the uncertainty that persists as to the meaning and scope of certain key terms of the statute, i.e., “patented invention” and “submission of information.”

The following questions should be addressed in determining whether an activity falls within the protection of the safe harbor statute:

*Question One: Does the activity under consideration involve the use of a third party's patented invention?*

A review of the relevant case law raises a question as to the meaning and scope of the term “patented invention” in § 271(e)(1).<sup>370</sup> Does the term include *any* patented invention, other than those specifically excluded in the statute, that could be employed to develop and submit information that relates to one of the product types listed in § 156(f), as suggested by the broad holding in the Supreme Court's *Eli Lilly* decision? Alternatively, is the term restricted to the product types listed in § 156(f) or even further limited to only those patented inventions that are eligible for a patent term extension under § 156? These restricted interpretations of the statutory term “patented invention” find

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<sup>367</sup> See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1071 (Fed. Cir. 2011), *cert. denied sub nom.*, *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 133 S. Ct. 973, 973 (Jan. 14, 2013).

<sup>368</sup> See *Petition for Writ of Certiorari, Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, No. 12-1033 (U.S. Feb. 15, 2013) (reciting that “[a] petition for rehearing *en banc* was denied on November 20, 2012”).

<sup>369</sup> See *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, *cert. denied*, 133 S. Ct. 2854, 2854 (2013).

<sup>370</sup> See *supra* Part 0 (“Patented Invention”).

support in the *Eli Lilly* Court's narrow justification for its holding, as relied on by the Federal Circuit in its decisions in *AbTox* and *Proveris*.<sup>371</sup> This uncertainty regarding the term "patented invention" is relevant to a safe harbor analysis in that it increases the risk of relying on the statutory exemption when using, without authorization, a patented invention such as a research tool (as in *Proveris*) or a manufacturing test method (as in *Momenta*). Final resolution of this issue will, almost certainly, require a definitive ruling by the Supreme Court.

*Question Two: If the answer to the first question is "yes," does the activity under consideration involve the making, using, offering for sale, or selling within the U.S., or the importation into the U.S. of the third party's patented invention without authorization?*

As clearly articulated in *Intermedics* and subsequently endorsed by a number of federal courts,<sup>372</sup> "the only kinds of acts to which . . . [§ 271(e)(1)] applies are acts which would constitute acts of infringement."<sup>373</sup>

*Question Three: If the answer to the second question is "yes," could the allegedly infringing activity constitute, or result in, a use of the patented invention that generates information regarding a potential (or approved) product?*

Reflected in this question is the conclusion that the Supreme Court's *Merck* decision requires that there at least be a product candidate under study for the statutory exemption to apply to an otherwise infringing activity involving the unauthorized use of a patented invention.<sup>374</sup> According to this view, it is only after this critical threshold on the path of product development has been crossed that the alleged infringer's information-generating activities will no longer be considered basic science research outside of the ambit of § 271(e)(1). This question also acknowledges, with the words "or approved" in parenthesis, the uncertainty regarding the downstream reach of the safe harbor statute resulting from the tension between the Federal Circuit's holdings in *Classen* and *Momenta*. As discussed above,<sup>375</sup> it is not clear at the moment which, if any, allegedly infringing activities relating to an approved product are eligible for protection under § 271(e)(1).

*Question Four: If the answer to the third question is "yes," "would it . . . [be] reasonable, objectively, for a party in . . . [the alleged infringer's] situation to believe that there was a decent prospect that the 'use' in question would contribute (relatively directly) to the generation of [the] kind[] . . . of information that . . ."*<sup>376</sup> *could be*

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<sup>371</sup> *Id.*

<sup>372</sup> See *supra* note 79 and accompanying text.

<sup>373</sup> *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1277 (N.D. Cal. 1991), *aff'd* 991 F.2d 808 (Fed. Cir. 1993) (non-precedential).

<sup>374</sup> See *supra* Parts II.B.3 & II.B.5.

<sup>375</sup> See *supra* Part II.B.5.

<sup>376</sup> *Intermedics*, 775 F. Supp. at 1280.

*submitted under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products (an “immunizing use”)?*

This question incorporates the substantive standard for the “reasonably related” requirement in the safe harbor statute as first articulated in *Intermedics* and subsequently endorsed by the Supreme Court in *Merck*.<sup>377</sup> It also incorporates the view that an “immunizing use” must be identified for the statutory exemption to apply.<sup>378</sup> The term “under a Federal law” must be given the expansive meaning ascribed to it by the Supreme Court in *Eli Lilly*, i.e., “under a provision that happens to be included within an Act that, *in any of its provisions*, not necessarily the one at issue, regulates drugs [or veterinary biological products].”<sup>379</sup> As discussed above,<sup>380</sup> there is a question as to the meaning of the statutory term “submission,” based on the conflicting views expressed by Judges Moore and Rader in their opinions in *Momenta*. Recall that Judge Moore, who authored the majority opinion in *Momenta*, adopted a broad reading of the term “submission” to include information that is merely retained for possible review by a regulatory authority at a later date.<sup>381</sup> It remains to be determined whether this interpretation of the term will withstand future judicial review, if any.

*Question Five: If the answer to the fourth question is “yes,” is it the case that the allegedly infringing activity under consideration does not constitute, nor result in, any use of the patented invention that is not an immunizing use?*

This last question reflects the effect of including the word “solely” in § 271(e)(1).<sup>382</sup> As noted above, (i) neither the underlying purposes for, nor the consequences of, the allegedly infringing activity under consideration are relevant to a determination of whether the statutory exemption is available to the alleged infringer, and (ii) the participation in additional activities that do not constitute infringement does not deprive the alleged infringer of the benefit of the exemption.<sup>383</sup>

If the answer to each of the above five questions is “yes” with respect to the activity under consideration, then it is very likely that the safe harbor statute shields the activity from infringement liability. This statement is qualified to reflect the uncertainty that persists with respect to the meaning and scope of key terms in § 271(e)(1).

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<sup>377</sup> See *supra* Part II.B.3.

<sup>378</sup> See *supra* Part II.B.2 (“Solely”).

<sup>379</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 668 (1990) (emphasis in original); see also *supra* Part II.B.1.

<sup>380</sup> See Part II.B.5. (“Submission of Information”).

<sup>381</sup> See *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348, 1357 (Fed. Cir. 2012) (Rader, J., dissenting).

<sup>382</sup> See Part II.B.2 (“Solely”).

<sup>383</sup> *Id.*

## CONCLUSION

Despite the many judicial interpretations of § 271(e)(1), questions persist as to the applicability of the statutory exemption from patent infringement. The meaning of certain of the key terms of the statute has emerged through either a clear statement from the Supreme Court or a consensus among lower federal court rulings. However, ambiguity remains as to other terms, specifically “patented invention” and “submission of information.” The tension among the Federal Circuit’s recent holdings in *Proveris*, *Classen*, and *Momenta*, resulting from the recurring effort by select Federal Circuit judges to narrow the scope of § 271(e)(1), is evidence of the uncertainty regarding the meaning of the safe harbor statute. Unless and until this uncertainty is addressed by a definitive ruling by the Supreme Court, those who intend to use a patented invention without authorization in reliance on the protection afforded by the statutory exemption must accept some risk of infringement liability.