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Original Article

Research Tools and the Hatch-Waxman Safe Harbor

By BRIAN D. COGGIO*

THE HATCH-WAXMAN ACT[1] was enacted to accommodate the competing interests of innovators and generic pharmaceutical companies.[2] In particular, the legislative history indicates that the key purpose of the Act was to expedite the commercial introduction of generic drugs. Before the Act, a potential infringer could not, without risking a claim of infringement, conduct the research necessary to prepare an application seeking FDA approval of its pharmaceutical product—generic or branded—before the relevant patent(s) expired.[3] Accordingly, even when the patent(s) expired, a patentee enjoyed extended market exclusivity while its competitors sought FDA approval. To eliminate this situation, the Act exempted pharmaceutical companies from infringement by creating a "safe harbor" that allows them to use a patented invention "solely for uses reasonably related to the development and submission of information to the [FDA]."[4] To compensate patentees for exempting this otherwise-infringing conduct and for their loss in patent life while they awaited FDA approval of their own products, the Act permits patentees to extend the life of certain types of patents for as long as 5 years.[5]

Both §156(a)(patent term extension) and §271(e)(1)(safe harbor exemption) were enacted as part of the compromise reflected in the Act. Significantly, §271(e)(1) covers "patented inventions" without limitation, whereas §156(a) covers patents that claim a product, a method of using a product, or a method of manufacturing a product, where the product is subject to regulatory review before marketing. Thus, the scope of the two sections is different. Some courts have interpreted the Act to require that §§156(a) and 271(e)(1) work in tandem, *i.e.*, only those patents that can be extended under §156(a) are subject to the §271(e)(1) safe harbor. This relation between these sections does not exist, however.

Most of the early decisions addressing §271(e)(1) focused on whether conduct to obtain regulatory approval of a competing version of a patented compound was exempt. Decisions of various district courts, the Federal Circuit, and the Supreme Court consistently expanded the protective scope of the Act. More recently, however, decisions have specifically addressed whether patents covering "research tools," which are not extendable under §156(a), are subject to the §271(e)(1) exemption.[6] This paper analyzes those decisions and the portions of the Act's legislative history that bear on this subject.

Any discussion of the present issue must begin with *Eli Lilly and Co. v. Medtronic, Inc.*[7] There, the plaintiff alleged infringement of a patent covering ventricular defibrillation devices. The central issue was whether medical devices were covered by §271(e)(1). In holding that such devices were covered, the Supreme Court stated: "The phrase 'patented invention' in §271(e)(1) is defined to include all inventions, not drug-related inventions alone."[8] As pertinent here, the Court analyzed the two "distortions" remedied by the Act—the patent term extension of §156(a) and the safe harbor of §271(e)(1). The Court held that the accused products—Class III medical devices—were covered by §271(e), even though the statute used the term "drugs." Moreover, the Court implied that §156(a) and §271(e)(1) should be applied in tandem when possible. Thus, if a patent were not extendable under §156(a)—*i.e.*, if the patented

*Brian D. Coggio is a Senior Principal at Fish & Richardson in New York City and an Adjunct Professor at Fordham Law School. He can be reached at coggio@fr.com

[1]Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, codified in part at 35 U.S.C. §§156, 271, 282 (1984).
[2]*See Allergan, Inc. v. Alcon Labs., Inc.,* 324 F.3d 1322, 1325 (Fed. Cir. 2003).
[3]*Roche Prods., Inc. v. Bolar Pharm. Co*., 733 F.2d 858 (Fed. Cir. 1984).
[4]35 U.S.C. §271(e)(1).
[5]35 U.S.C. §156(a)(4).
[6]The National Institutes of Health defines "research tools" as "tools that scientists use in the laboratory including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999).
[7]496 U.S. 661 (1990).
[8]*Id*. at 665.

product were not subject to FDA approval—§271(e)(1) did not apply. Significantly, however, the Court explicitly recognized that this symmetry would not always exist.

> [T]here may be some relatively rare situations in which a patentee will obtain the advantage of a [§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.[9]

Although the Court could not "readily imagine such situations," they clearly exist. The Court's emphasis on the supposed symmetry between the two sections underlies, in large measure, the dispute as to whether patents covering research tools are subject to §271(e)(1). However, because *Eli Lilly* dealt with patents covering Class III medical devices (which can be extended), rather than Class I and Class II devices (patents on which cannot be extended), the Court never faced the present issue directly.

Initially, the symmetry approach took hold. For example, in *Baxter Diagnostics, Inc. v. AVL Scientific Corp.*,[10] the district court found that Class I and Class II devices—as opposed to Class III devices—were not subject to §271(e)(1) because the safe harbor and the patent term extension provision of §156(a) were linked.[11] Because only patents covering Class III medical devices could be extended, the district court, relying on *Eli Lilly*, held that only such patents were subject to §271(e)(1).[12] On reconsideration, however, the court reversed its decision.[13]

Other courts rejected the symmetry approach.[14] For example, in *Abtox*,[15] the Federal Circuit noted that the Supreme Court in *Eli Lilly* had "explicitly accepted a statutory interpretation" in which the patentee (*e.g.*, the owner of a research tool patent) "will suffer the disadvantage [of §271(e)(1)] without the benefit [of the §156 extension]."[16] In *Chartex*,[17] the Federal Circuit stated that it would not read the limitations of §156(a) on the types of eligible patents into §271(e)(1). There, the patentee alleged infringement of a patented female condom, which is neither a Class I nor II medical device, arguing that §271(e)(1) did not apply because the patent covering the infringing product was not eligible for a §156(a) extension. The Federal Circuit rejected this argument and stated:

> Chartex would read limitations [on the term "patented invention"] that may apply to 35 U.S.C. §§155 and 156 into section 271(e)(1). Sections 155 and 156, however, deal with term extensions for patents relating to products subject to lengthy delays. Although section 156 and section 271(e)(1) of Title 35 passed Congress as sections 201 and 202 of the Drug Price Competition and Patent Term Restoration Act of 1984, this court declines to read possible limitations from one section into another.[18]

Abtox and *Chartex* held—as stated by *Eli Lilly*—that the term "patented invention" in §271(e)(1) means "*all* patented inventions" and not merely those covered by §156(a).[19]

Other courts read *Eli Lilly* differently. In *Infigen, Inc. v. Advanced Cell Technology, Inc.*,[20] Infigen alleged infringement of a patent covering a process for activating bovine oocytes for use in cloning cattle. The district court rejected the §271(e)(1) exemption, adopted the rationale of the initial *Baxter Diagnostics* decision, and limited the types of patents embraced by §271(e)(1). According to the court's reading of *Eli Lilly*, only patents whose terms could be extended under §156(a) were subject to the safe harbor. The court stated:

> A patent holder whose patent is *ineligible* for the five-year [patent term] extension [under §156] is *not* precluded from suing for infringement damages (except in unusual circumstances not present here, such as those involving patents pertaining to "follow-on" drug products rather than pioneers).[21]

Under this reasoning, research tool patents would not be subject to §271(e)(1).

The *Infigen* court, however, misperceived the holding in *Eli Lilly*, which did *not* limit the patents covered by §271(e)(1) to those eligible for §156(a) extensions. To the contrary, as previously noted, the Court recognized that in "some relatively rare situations," patents will not be eligible for a §156(a) extension, but still be subject to the §271(e)(1) exemption.[22] Although

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[9] *Id.* at 671–72.
[10] 798 F. Supp. 612 (C.D. Cal. 1992)(Class I and II devices were not subject to §271(e)(1)).
[11] *Id.* at 620.
[12] *Id.* at 618–20.
[13] *Baxter Diagnostics, Inc. v. AVL Scientific Corp.*, 954 F. Supp. 199 (C.D. Cal. 1996).
[14] *See, e.g., Abtox, Inc. v. Exitron Corp.*, 888 F. Supp. 6, 8–9 (D. Mass. 1995), *aff'd*, 122 F. 3d 1019 (Fed. Cir. 1997), *amended by* 131 F. 3d 1009 (Fed. Cir. 1997); *Chartex Int'l PLC v. M.D. Personal Prods. Corp.*, 1993 WL 306169, at *2 n. 2 (Fed. Cir. 1993).
[15] *Abtox*, 122 F.3d at 1028.
[16] *Id.* at 1029 (quoting *Eli Lilly*, 456 U.S. at 671–72).
[17] *Chartex Int'l PLC v. M.D. Personal Prods. Corp.*, 1993 WL 306169, at *2 n.2 (Fed. Cir. 1993).
[18] *Id.*
[19] *See also Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2001 WL 1512597 (S.D.N.Y. 2001)(holding that a patented intermediate was subject to §271(e)(1)).
[20] 65 F. Supp. 2d 967 (W.D. Wis. 1999).
[21] *Id.* at 980 (emphasis added).
[22] *Eli Lilly*, 496 U.S. at 671–72.

the Court could not "readily imagine such situations,"[23] countless possibilities do exist. Despite *Infigen*, by 2000, it was seemingly settled that patents not eligible for a §156(a) extension were still subject to the §271(e)(1) exemption.

In 2003, *Integra Lifesciences I, Ltd. v. Merck KGaA*[24] brought renewed attention to the interplay between research tools and §271(e)(1). There, Merck, through Scripps, had been testing patented peptides as potential drugs. Two of the four patents-in-suit covered the use of such peptides as research tools. Indeed, Scripps used certain peptides as positive controls, *i.e.*, as research tools. Although the central issue was the scope of the safe harbor, research tools, which were not implicated by the facts as presented by the parties, were discussed. The Federal Circuit, per Judge (now Chief Judge) Rader, noted that extending §271(e)(1) to cover Scripps' research "would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents" and would certainly not be the "*de minimis* encroachment on the rights of the patentee" that the Act's legislative history indicates Congress envisioned.[25] According to Judge Rader, "the 1984 Act was meant…not to deprive entire categories of inventions of patent protection."[26] Judge Rader was correct in that the legislative history indicates that the overriding purpose of the Act was to allow generic companies to conduct a limited amount of testing before filing an ANDA without fear of a claim for patent infringement. The patentee would receive financial rewards after the generic product was marketed, assuming, of course, it infringed. But this does not aid holders of research tool patents, because such tools are not usually marketed.

Judge Newman, in dissent, differentiated between the use of a tool to conduct research and research on the tool itself. Research "on" the tool should be exempt, but the use of a tool "for the purpose for which it was made" infringes.[27] Under Judge Newman's view, if a research tool, *e.g.*, an assay, is used to identify new drug candidates —the "purpose for which it was made"—such conduct would infringe.[28]

The Supreme Court granted *certiorari*, but its opinion did not address the relation between research tool patents and the safe harbor exemption.[29] In its Brief as *amicus curiae*, however, the government argued that the purported symmetry between §156(a) and §271(e)(1) indicated that Congress did not intend to include research tool patents within the scope of the safe harbor.[30]

On remand,[31] the research tool issue was not discussed by the majority.[32] Judge (now Chief Judge) Rader, dissenting-in-part and concurring-in-part,[33] however, again focused on research tools. As one example, Judge Rader stated:

> These purified cell receptors [*i.e.*, the subject of the research tool patents] do not operate as "patented compounds" for FDA approval themselves, but rather as experimental targets to test for attachment characteristics…. As such, this method of isolating cell surface receptors is only a tool to conduct research on biological and chemical systems.[34]

Judge Rader did not mention any symmetry between §156(a) and §271(e)(1) as the basis of his decision. In his view, §271(e)(1) applied only where the research was directed to products that were potentially subject to FDA review and approval. Despite Judge Rader's dissent, it would appear that research tool patents, despite their non-extendibility, can, under appropriate circumstances, be subject to §271(e)(1) in view of the earlier decisions in *Abtox* and *Chartex*.[35] This was abruptly changed by the Federal Circuit's decision in *Proveris Scientific Corp. v. Innovasystems, Inc.*[36]

In *Proveris*, the patent-in-suit covered a system and apparatus for characterizing aerosol sprays used in testing drug-delivery systems. The apparatus itself was not subject to FDA approval. Defendant Innovasystems had sold patented instruments to three companies for the sole use of gathering information for FDA submission. The district court found that §271(e)(1) did not apply.

On appeal, Proveris argued that §271(e)(1) did not apply to research tool patents because such patents could not be extended under §156(a). Additionally, because Innovasystems did not itself gather the data for FDA submission, §271(e)(1) did not apply. Innovasystems argued that §271(e)(1) applied to all "patented inventions" without limitation and that "sales" by third parties (*e.g.,* Innovasystems) were contemplated by §271(e)(1) because "sales" are specifically exempted by the statute. Thus, according to Innovasystems, §271(e)(1) is not limited to organizations that

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[23]*Id.* at 672 n.4.
[24]331 F.3d 860 (Fed. Cir. 2003).
[25]*Id.* at 867. *See* H.R. Rep. No. 98-857 at 8 (1984), reprinted in 1984 U.S. C.C.A.N. 2692.
[26]331 F.3d at 867.
[27]*Id.* at 878 n.10.
[28]*Id.*
[29]*Merck KGaA v. Integra Life Sciences I, Ltd.*, 125 S.Ct. 2372, 2382 n.7 (2005).
[30]Brief for the United States as *Amicus Curiae* Supporting Petitioner at 29–30 n.12.
[31]*Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334 (Fed. Cir. 2007).
[32]*Id.* at 1347–48.
[33]*Id.* at 1348.
[34]*Id.* at 1351.
[35]*See also Amgen, Inc. v. Hoescht Marion Roussel*, 3 F. Supp. 2d 104 (D. Mass. 1998), where the patents covered erythropoietin, which had, *inter alia*, been used as a "standard reference." This use was held to be subject to §271(e)(1). There was no mention of symmetry between §§156(a) and 271(e)(1).
[36]536 F.3d 1256 (Fed. Cir. 2008).

themselves gather data for FDA submission. In the author's opinion, the second issue was never decided by the court, although advocates have attempted to distinguish *Proveris* on this basis. Indeed, as discussed below, one court has recently accepted this distinction.

The Federal Circuit, relying on *Eli Lilly*, seemed to decide that the term "patented invention" in §271(e) included *only* those patents extendable under §156(a), and that this approach produced a "perfect fit" between the two sections.[37] Simply put, the *Proveris* Court held that if a patent could not be extended under §156(a), it was not a "patented invention" under §271(e)(1). This reasoning disregards the Federal Circuit's earlier decisions in *Abtox* and *Chartex*. Moreover, the *Eli Lilly* Court recognized possible exceptions to the symmetry approach.

Continuing its discussion, the Federal Circuit addressed the supposed distortion rectified by §271(e)(1):

> Innova's OSA device is not subject to FDA premarket approval…. In short, Innova is not a party seeking FDA approval for a product in order to enter the market to compete with patentees. Because the OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry before patent expiration, Innova is not a party who, prior to the enactment of the Hatch-Waxman Act, could be said to have been adversely affected by [the distortion rectified by §271(e)(1)]… Put another way, insofar as its OSA device is concerned, Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief.[38]

Under *Proveris*, is it necessary that the patent-in-suit be extendable under §156(a) *and* the accused product be subject to FDA approval before §271(e)(1) applies? For research tools, both elements would seemingly not be satisfied. At a minimum, however, according to *Proveris*, if a patented invention "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)."[39] While research tools do not satisfy this requirement, this standard ignores both *Abtox* and *Chartex*.

The *Proveris* reasoning was followed by various district courts.[40] In *PSN Illinois*, the patent covered a protein receptor. The district court held that the patented receptor had been used as a research tool to perform tests on potential drug candidates. In its decision, the court emphasized the legislative history of §271(e)(1) and the *Proveris* holding that an invention that did not require regulatory approval was not a "patented invention" within §271(e)(1). This decision, like Chief Judge Rader's dissent in *Integra*, stressed the specific use of the patented invention. Thus, even though a particular patent may be theoretically extendable under §156(a), if the invention is used as a research tool, §271(e)(1) may not apply, at least according to *Proveris*.

Two recent Federal Circuit decisions bear on this issue: *Classen Immunotherapies, Inc. v. Biogen Idec*[41] and *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*[42]

In *Classen*, the patents-in-suit covered methods of evaluating and improving the safety of immunization schedules. The defendant alleged its use of the patented inventions to gather information for FDA submission was exempt under §271(e)(1). Although the patents were not extendable, and their use was not subject to FDA approval, the case did not turn on these factors. Rather, because the information was not required by the FDA, and further, because the information was acquired *post*-FDA approval, §271(e)(1) did not apply. The case could easily have been decided the same way if *Proveris* were followed because the patented inventions were essentially research tools.

In *Momenta*, the patent covered methods for analyzing heterogeneous populations of various compounds, including heparin. This patent—a research tool patent—was not extendable under §156(a). The defendant used the patented method to determine the molecular weight of its generic heparin. Even though the ANDA had been approved, the molecular weight of each commercial batch had to be tested before the batch could be marketed. Thus, the alleged infringing conduct occurred *after* FDA approval. Despite *Classen*, the *Momenta* majority held that such conduct—because it was regulated and required by the FDA—was protected by §271(e)(1). As pertinent here, the majority dismissed plaintiff's argument (noted by the dissent) that §271(e)(1) is not available unless the patent is extendable under §156(a). The court held that the Supreme Court in *Eli Lilly* recognized that this symmetry was not always achievable.[43] In this regard, the Federal Circuit stated:

> 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

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[37] *Id.* at 1262, 1265–66.
[38] *Id.* at 1265. *But see Monsanto Co. v. E.I. DuPont De Nemours & Co.*, 2010 U.S. Dist. LEXIS 77877 (E.D. Mo. 2010)(stating that pre-market approval is not required for §271(e)(1) to apply).
[39] 536 F.3d at 1266.
[40] *See, e.g., Isis Pharmaceuticals, Inc. v. Santaris Pharma A/S Corp.*, 2012 WL 4111157 (S.D. Cal. 2012); *PSN Illinois, LLC v. Abbott Labs.*, 2011 WL 4442825 (N.D. Ill 2011).
[41] 659 F.3d 1057 (Fed. Cir. 2011).
[42] 686 F.3d 1348 (Fed. Cir. 2012).
[43] *Id.* at 1361.

> 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).[44]

Accordingly, under *Momenta*, research tool patents could be subject to §271(e)(1). In dissent, Chief Judge Rader stated that the majority ignored the binding precedent of *Classen* on *post*-approval testing and, as relevant here, the result rendered manufacturing test method patents "worthless."[45] To explain his reasoning, Chief Judge Rader stated:

> The 1984 Act enacted the two sections to create a balance. The Supreme Court rejected the party's attempt to create a "disequilibrium" between the two sections.
> This Court's new interpretation in this case would apply the disadvantage of §[271(e)(1)] to a patentee who would not be able to obtain the benefits of §[156]. The patentee of a manufacturing patent does not obtain the patent extension created in §[156(a)], yet this court's new expansion of §[271(e)(1)] would allow its competitors to infringe during the life of its patent. The Supreme Court rejected this sort of disequilibrium.[46]

As noted above, the Supreme Court in *Eli Lilly* did *not* require symmetry between §156(a) and §271(e)(1) and, indeed, specifically recognized that instances of non-symmetry could occur. Certainly, in *Abtox*, the Federal Circuit did not require symmetry between the two sections.[47] Significantly, on June 25, 2013, the Supreme Court denied the petition for *certiorari* filed in the *Momenta* case. Thus, despite their differences in *pre-* vs. *post*-approval testing, both decisions (particularly *Momenta*) would support the applicability of §271(e)(1) to research tool patents.[48]

Two recent cases highlight the conflicting views of §271(e)(1) as it applies to research tools. In these cases, Teva sued Sandoz[49] and Mylan[50] alleging that their use of Teva's patented polypeptides as "molecular weight markers" in the development of their own generic versions of copaxone infringed.

Significantly, the patents-in-suit covered the use of the peptides as therapeutics and markers. Both Sandoz and Mylan moved to dismiss and argued that §271(e)(1) applied because the results of the tests were included in their respective ANDAs. In particular, Sandoz contended that its use of the patented peptides paralleled the use of the patented peptides in *Integra* and the use of erythropoietin sanctioned in *Amgen,* where one of the patented peptides was used as a "reference standard." Sandoz distinguished *Proveris* because Innovasystems—unlike Sandoz—did not itself gather information for FDA submission. As noted earlier, this distinction did not factor into the *Proveris* decision. Moreover, according to Sandoz, unlike the laboratory equipment in *Proveris*, the accused peptides had *theoretical* uses as therapeutic agents. Lastly, citing *Eli Lilly* and *Momenta*, Sandoz argued that symmetry between §156(a) and §271(e)(1) is not required.

In its motion to dismiss, Mylan argued that the *Eli Lilly* Court held that the term "patented inventions" includes "*all* inventions" and did not hold that a patent must be extendable under §156(a) before the §271(e)(1) exemption could apply. Mylan also noted that *Proveris* could not overturn the Federal Circuit's holding in *Abtox,* and that the patented, non-extendable testing methods in *Momenta* were subject to the §271(e)(1) exemption. Like Sandoz, Mylan argued that *Proveris* was not applicable because the defendant there did not itself gather information for FDA submission.

In opposing the motions, Teva argued that the patented polypeptides were not "drug products," as they had not been approved by the FDA. Indeed, even though such products had potential therapeutic uses, neither Sandoz nor Mylan was using the peptides in that way, but only as analytical tools in characterizing the products they intended to sell as pharmaceuticals. Citing the *Proveris* symmetry requirement, as well as the decisions in *Isis* and *PSN Illinois*, Teva contended that the peptides were not "patented inventions" under §271(e)(1).

Judge Forrest, in one written opinion, granted both Mylan's and Sandoz' motions to dismiss.[51] In her decision, she construed the term "patented invention" in §271(e)(1), as defined in 35 U.S.C. §101: "'When used in this title, unless the context otherwise indicates… [t]he term "invention" means invention or discovery.' *See Eli Lilly* 496 U.S. at 665."[52] Accordingly,

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[44] *Id.*
[45] *Id.* at 1362.
[46] *Id.* (citations omitted).
[47] *Id.* at 1371. *See also Classen Immunotherapies, Inc. V. Kung Pharmaceuticals, Inc.,* Civil Action No. WDQ-04-352; slip. op. at 12–13 (Oct. 31, 2013 D. Md.) (Even if FDA does not "require" information to be submitted as in *Momenta*, safe harbor can still apply so long as the information is not "routine" as in *Classen*.)
[48] In a related case with the same facts as *Amphstar*, *Momenta Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc*., Civil Action No. 10-12079-NMG, slip. op. (July 19, 2013), the district court granted Teva's motion for summary judgment based on the Federal Circuit's decision in the Momenta action against Amphstar.
[49] *Teva Pharmaceuticals USA, Inc. v. Sandoz Inc*., Civil Action No. 09-cv-10112 (KBF).
[50] *Teva Pharmaceuticals USA, Inc. v. Mylan Pharmaceuticals Inc*., Civil Action No. 10-cv-7246 (KBF).
[51] Civil Action No. 09-cv-10112 (KBF) and 10-cv-7246 (KBF), slip. op. (July 15, 2013 S.D.N.Y.).
[52] *Id.* at 9.

she held that *Proveris'* interpretation of that term was wrong. Moreover, the court held that *Proveris'* narrow interpretation could not conflict with the Federal Circuit's earlier *Abtox* decision, which held that patents that cannot be extended under §156(a) are still subject to §271(e)(1).[53]

The court also held that the *Proveris* decision was based on the fact that the defendant Innovasystems did not itself gather the information for FDA submission. This, in turn, was based on the statement in *Proveris* that "[I]nsofar as its *OSA device* is concerned, Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief."[54] Yet, this statement in *Proveris* was preceded by the following:

> Because the OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration, Innova is not a party who, prior to enactment of the Hatch-Waxman Act, could be said to be adversely affected by the [pre-market approval] distortion….
>
> Put another way, insofar as its OSA device is concerned, Innova is not within the category of entities for whom the safe harbor was designed to provide relief.[55]

Accordingly, despite Judge Forrest's ruling, the *Proveris* decision would not appear to be based on whether the defendant itself gathered the data for FDA submission. Regardless, both the Federal Circuit's *Momenta* decision and this decision clearly support the opinion that research tool patents can be subject to §271(e)(1).

Regardless of the implications of the Act's legislative history, §271(e)(1) was apparently not limited to those patents extendable by §156(a). This result is confirmed by the Supreme Court's decision in *Eli Lilly* and the Federal Circuit's decisions in *Abtox* and *Momenta*. Rather, as the *Eli Lilly* Court stated, §271(e)(1) covers "all inventions." The recent *Teva* district court decision holds similarly.

Other portions of the legislative history would indicate a different outcome. Under §271(e)(1), the "nature of the interference" with a patentee's rights was not intended to be "substantial," but only "*de minimis*." Certainly, the post-approval use of a patented invention sanctioned by the Federal Circuit in *Momenta* or the use sanctioned by the Southern District of New York in *Teva* is not *de minimis*. Moreover, the use of a research tool (*e.g*., an assay) to discover or develop a commercial product would not seem to be *de minimis*, as the making, using, or selling of the resulting product—"the fruit of the poisonous tree"—would not infringe the research tool patent. Thus, if §271(e)(1) were applicable, the patent holder would never have a claim against an "infringer," and the patent, as Chief Judge Rader has observed, would become essentially worthless.

This portion of the legislative history, however, was directed to the use—probably insubstantial—of a patented product to develop a generic equivalent. Congress was certainly not concerned with the impact of §271(e)(1) on research tool patents. If one were to incorporate this concept into the statute, as Chief Judge Rader seemingly advocates, §271(e)(1) would not cover research tools. The statute is not written in that way, however, and the cases hold otherwise.

In conclusion, one must await clearer guidance from the Federal Circuit on this issue. If, however, a research tool is used to gather information to submit to the FDA seeking approval, §271(e)(1) should apply. Moreover, if the FDA requires certain information, gathering such information using a research tool should also be subject to §271(e)(1), pre- or post-approval. Alternative options to obtain the information do not alter this conclusion. However, whether the use of a research tool in experiments leading up to an FDA submission is subject to §271(e)(1) will still be hotly contested. Although in *Merck v. Integra,* certain patented peptides were used as positive controls, each peptide was considered as a possible drug candidate. The use of a research tool to evaluate potential candidates or to select a candidate for further development would seem to present a different situation.

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[53] *Id*. at 14–16.
[54] *Id*. at 15 (citation omitted).
[55] *Proveris*, 536 F.3d at 1265.