

Survey of the Safe Harbor in the United States and Europe



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SURVEY OF THE SAFE HARBOR IN THE UNITED STATES AND EUROPE

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On October 3, 2016, the United States Supreme Court denied Amphastar Pharmaceutical's petition for certiorari regarding the so-called "safe harbor," 35 U.S.C. § 271(e)(1), which shields activities done, *inter alia*, to secure regulatory approval of generic and biosimilar drugs (the "Safe Harbor").² This decision left undisturbed the Federal Circuit's holding in *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.* ("*Momenta II*") that implemented a heightened standard of scrutiny on whether post-approval activities are covered by the Safe Harbor.³ After examining the decisions that led to *Momenta II*, it seems clear that a broad range of pre- and post-approval activities — including supplying active ingredients, using research tools, and stockpiling drug inventory — may be protected under the Safe Harbor as long as they are clearly linked to efforts to secure regulatory approval. Appreciating the scope of protection afforded by the Safe Harbor is vital to pharmaceutical and biotech firms.

Understanding the so-called Bolar Exception and Bolar Exemption, the Canadian and European analogs of the U.S. Safe Harbor, respectively, as well as the broad research exemption that exists in Europe is critically important to allow multinational organizations to conduct their research and development efforts and take advantage of these differing, world-wide protections. We begin with the genesis of the Safe Harbor.

¹ The purpose of this article is to provide educational and informational content and is not intended to provide legal services or advice. The opinions, views and other statements expressed by the authors are solely those of the authors and do not necessarily represent those of Fish & Richardson P.C.

² *Amphastar Pharm. Inc. v. Momenta Pharm., Inc.* (S. Ct. Dkt. No. 15-1402), https://www.supremecourt.gov/orders/courtorders/100316zor_9ol1.pdf.

³ 809 F.3d 610 (Fed. Cir. 2015), *cert. denied sub nom., Amphastar Pharm., Inc. v. Momenta Pharm., Inc.* (U.S. Oct. 3, 2016).

I. THE SAFE HARBOR AROSE TO ADDRESS THE *LIMITED* RESEARCH EXEMPTION IN THE U.S.

The Safe Harbor was enacted to broaden the narrow U.S. research exception which, in contrast to the European approach, provides little protection to drug developers. A patentee's competitors typically can begin selling an otherwise infringing product on the day a 'blocking' patent expires.⁴ The marketing of pharmaceuticals, however, is strictly regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act,⁵ which requires that drug manufacturers comply with various statutes, regulations, and guidelines before market approval is granted. This approval process, which usually takes years, was further delayed by the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, where the Federal Circuit held that a manufacturer could not even begin the testing required to obtain FDA approval without infringing any blocking patents. Under U.S. precedent, the "truly narrow" experimental use exception is limited to experiments "to satisfy idle curiosity, or for strictly philosophical inquiry."⁶ In essence, *Roche* further delayed the availability of generic drugs by allowing a patentee to maintain market exclusivity long *after* its blocking patent(s) expired. Shortly thereafter, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or the "Act")⁷ and created the Safe Harbor to specifically overrule *Roche*.⁸

II. CONGRESS ENACTED THE SAFE HARBOR TO EXPEDITE THE *APPROVAL* OF GENERIC DRUGS

A key purpose of the Hatch-Waxman Act, including the Safe Harbor, was to expedite FDA approval of generic drugs⁹ and get those drugs to market immediately following expiration of any blocking patents.¹⁰

⁴ The Patent Act provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

⁵ See generally Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

⁶ 733 F.2d 858, 863 (Fed. Cir. 1984). The court found that Bolar infringed when it used Roche's patented substance prior to expiration of the blocking patent to prepare an FDA submission to enable Bolar to market its own version of the drug after the Roche patent expired. *Id.* at 863.

⁷ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. §§ 156 and 271e).

⁸ The legislative history shows that "[t]he purpose of [§ 271(e)(1)] is to overturn the ruling in *Roche* . . ." H.R. Rep. No. 857, 98th Congress, 2d Sess., pt. 2, at 27, reprinted in 1984 U.S. Code Cong. & Admin. News 2647, 2711 n.18.

⁹ As used herein, the term "generic drugs" includes Section 505(b)(2) filings ("paper NDAs") and follow-on biologics.

¹⁰ The legislative history notes that "[i]t is the [Energy & Commerce] 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 preventing of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date." H.R. Rep. No. 98-857, pt. 1, at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679. Similarly, the same Committee "reasoned that without [§ 271(e)(1)] generic manufacturers would be required to engage in . . . 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." H.R. Rep. No. 98-857, pt. 2, at 8-9 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2692-93.

To effectuate this goal, the Act overruled *Roche* and created the Section 271(e)(1) Safe Harbor, which insulates certain activities from patent infringement. In relevant part, the statute reads:

It 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.¹¹

To compensate patentees for exempting this otherwise infringing conduct and for the loss in patent term while awaiting FDA approval of their own patented products, Congress also enacted 35 U.S.C. § 156, which permits patentees to extend the life of patents claiming an FDA-approved product or a method of making or using the product.¹² Section 156, together with the Safe Harbor, sought to balance the rights of patentees and generic manufacturers and foster the Act’s goal of quickly bringing generic drugs to market. Importantly, research tools — patented inventions that are used in drug development, testing, and screening¹³ — are not subject to regulatory approval and thus are not extendable under Section 156. As discussed in Part V, *infra*, because these two sections were simultaneously enacted, some courts have cited the lack of symmetry between them to exclude research tools from the Safe Harbor.

Courts have interpreted the scope of the Safe Harbor broadly, exempting activities with an ultimate commercial benefit as long as the conduct is reasonably related to gaining information relevant to the FDA approval process. In a series of decisions culminating in *Momenta II*, the Federal Circuit clarified that although the Safe Harbor could exempt both pre- and post-approval activity, a “more critical analysis [was required] in the post-approval context.” Various aspects of the Safe Harbor are discussed in Parts III–V, *infra*.

III. *MOMENTA I AND II* DEFINE THE SCOPE OF PRE- AND POST-APPROVAL ACTIVITIES UNDER THE SAFE HARBOR

In *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* (“*Momenta I*”), the Federal Circuit found that Amphastar’s use of Momenta’s patented assay in its process for manufacturing the approved drug was protected by the Safe Harbor because the resulting information was “necessary both to the continued approval of [the] ANDA and to [Amphastar’s] ability to market the generic drug.”¹⁴ In particular, the FDA had required Amphastar to test each commercial batch to ensure that the product met rigid specifications. Although other testing regimens were available, Amphastar used Momenta’s patented assay to conduct these tests.¹⁵ In its decision, the Federal Circuit distinguished its earlier holding in *Classen*

¹¹ 35 U.S.C. § 271(e)(1) (emphasis added). The Safe Harbor does not cover new animal drugs or certain veterinary biological products involving site specific genetic manipulation techniques. *Id.* The Safe Harbor also did not impact the U.S. experimental use doctrine, which continues to be very narrowly interpreted. See Part VII, *infra*.

¹² 35 U.S.C. § 156(a). Section 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. The extension may not exceed five years. 35 U.S.C. § 156(i).

¹³ A research tool has been described as “a product or method whose purpose is use in the conduct of research, whether the tool is an analytical balance, an assay kit, a laser device . . . or a biochemical method such as the PCR (polymerase chain reaction).” *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., dissenting).

¹⁴ 686 F.3d 1348, 1358 (Fed. Cir. 2012).

¹⁵ *Id.* at 1352, 1359 (noting that there were FDA approved non-infringing alternatives available to Amphastar).

Immunotherapies, Inc. v. Biogen Idec., which held that the Safe Harbor “does not apply to information that may be *routinely* reported to the FDA, long after marketing approval has been obtained.”¹⁶ Rather, the *Momenta I* Court explained that Amphastar’s post-approval activities were sheltered because they were conducted to satisfy the FDA’s specific requirements and thus were “anything but ‘routine.’”¹⁷ In doing so, the *Momenta I* Court found that the broad language of Section 271(e)(1) unambiguously applied to *all* uses of patented compounds “reasonably related” to the process of developing information for FDA submission and was not limited to information actually submitted to the FDA.¹⁸

In his dissent, former Chief Judge Rader, noting that the Supreme Court in *Eli Lilly & Co. v. Medtronic, Inc.* had observed that the text of Section 271(e)(1) was “not plainly comprehensible,” contended that the Act’s legislative history showed that the Safe Harbor only permitted a limited amount of *pre-approval* testing to obtain FDA authorization.¹⁹ He noted that Section 271(e)(1) had won approval from a diverse group of stakeholders with competing interests because it was limited in time and only applied to experimentation and not commercial sales:

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.²⁰

In an earlier dissent in *Integra Lifesciences I, Ltd. v. Merck KGaA*, which also addressed research tools (the subject of *Momenta*’s patent), Chief Judge Rader argued that research tools should not be covered under the Safe Harbor and further opined that when deciding whether something is a research tool, the focus should be on how a patented compound or method is being used, not how it is claimed.²¹ The Chief Judge’s views are instructive because he was involved in the legislative history of the Act during his tenure on Senator Orrin Hatch’s staff. Thus, as discussed in Section V.B, *infra*, the legislative history may indicate that Congress never intended that the Safe Harbor would protect Amphastar’s ongoing post-approval use of the patented assay (*i.e.* a research tool) in support of commercial sales.

¹⁶ 659 F.3d 1057, 1070 (Fed. Cir. 2011).

¹⁷ *Momenta I*, 686 F.3d at 1358. *Classen* involved post-approval studies that monitored the effectiveness of vaccines. The studies were not required by the FDA, but once performed, the results were necessarily reported to the FDA. *Id.* at 1358-59.

¹⁸ *Id.* at 1356.

¹⁹ *Momenta I*, 686 F.3d at 1362 (Fed. Cir. 2012) (Rader, C.J., dissenting). The Supreme Court ultimately found that the legislative history “shed [] no clear light” on whether medical devices were covered by the Safe Harbor because the argument “that the legislative history of [the section] mentions only drugs—which is quite different, of course, from its saying (as it does not) that only drugs are included” since a statute can have effects that are not explicitly mentioned in its legislative history. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 & n.2 (1990).

²⁰ *Momenta I*, 686 F.3d at 1366.

²¹ 496 F.3d 1334, 1352 (Fed. Cir. 2007) (Rader, J., dissenting).

A. PRE-APPROVAL CONDUCT WITH A COMMERCIAL BENEFIT IS EXEMPTED AS LONG AS IT IS REASONABLY TIED TO THE FDA APPROVAL PROCESS

Pre-approval conduct is within the Safe Harbor as long as it is “reasonably related to the development and submission of information to FDA, regardless of the attendant consequences of the activity.”²² For instance, pre-approval studies that are submitted to the FDA and reflected in the drug label are within the Safe Harbor, even though the label is distributed post-approval.²³ The Safe Harbor also protects parties that supply an active pharmaceutical ingredient (API) to a generic filer. Thus, in *Shire LLC v. Amneal Pharm.*, the Federal Circuit held that the Safe Harbor protected Johnson Matthey, a pre-approval supplier of the active ingredient to the generic filer:

Johnson Matthey is correct that it cannot be liable for the API it sold the ANDA defendants up to this point. Johnson Matthey, as an API supplier, has thus far done nothing more than provide material for use by the ANDA defendants in obtaining FDA approval.²⁴

One that will supply commercial quantities of the API after approval, however, may be liable for inducing infringement by the ANDA filer under Section 271(b). For example, in *Smithkline Beecham Corp v. Geneva Pharmaceuticals, Inc.*, the court permitted Smithkline to sue third party Sumika, which had filed a Drug Master File with the FDA and authorized Geneva to rely on it, but only because Sumika would manufacture and sell the generic product *after* FDA approval.²⁵

Importantly, the subsequent use of information obtained under the exemption, even for purposes other than regulatory approval, does not forfeit the Safe Harbor protection, unless the subsequent conduct is itself a separate act of infringement.²⁶ For example, the filing of patent applications based on data derived from clinical trials²⁷ and the presentation of clinical trial data to investors, analysts and journalists to secure funding²⁸ are both protected by the Safe Harbor.

²² *Momenta II*, 809 F.3d at 621 (quoting *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir.), *op. am. on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997) (holding that alleged infringer could use its data from tests conducted on patent for plasma sterilizer for more than FDA approval purposes)); *see also id.* at 621 n.6 (listing cases).

²³ *Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals*, 2:12-cv-06643-GAF-PLA at *6 (C.D. Cal. 2013), *aff'd per curiam without op.*, 2014 WL 185171 (Fed. Cir. 2014).

²⁴ 802 F.3d 1301, 1310 (Fed. Cir. 2015). Third parties who provide assistance to ANDA filers by supplying an API are not direct infringers under § 271(e)(2)(A) because they did not “submit” the ANDA. *See generally* Brian Coggio and Ron Vogel, *Safe Harbor Protects Supplier of Active Ingredient for ANDA*, Law360 (Sep. 29, 2015) (citing *Smithkline Beecham Corp. v. Geneva Pharmaceuticals, Inc.*, 287 F. Supp. 2d 576, 585-86 (E.D. Pa. 2002); *SmithKline Beecham Corp. v. Pentech Pharmaceuticals, Inc.*, 2001 WL 184804 at *3 (N.D. Ill. Feb. 20, 2001)).

²⁵ 287 F. Supp. at 585; *see also Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F. Supp. 2d 338, 349-50 (D. Del. 2009); *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 308 (D. Md. 2007); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 495 (E.D. Va. 2005).

²⁶ *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1523–24 (Fed. Cir. 1992).

²⁷ *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, No. RDB-04-3521, 2016 WL 5390803, at *5 (D. Md. Sept. 27, 2016) (“Following the Federal Circuit’s guidance, it is clear that Elan’s alleged ‘reanalyzing the clinical data to identify patentable information and filing patent applications,’ . . . fall[s] squarely within the safe harbor of § 271(e)(1).”).

²⁸ *Telectronics*, 982 F.2d at 1523–24.

B. MOMENTA II APPLIED GREATER SCRUTINY TO POST-APPROVAL ACTIVITIES

In *Momenta II*, the Federal Circuit reconsidered its *Momenta I* decision and held that while post-approval studies can fall within the safe harbor, whether such conduct is “reasonably related” to an FDA submission requires “more critical analysis in the post-approval context.”²⁹ In doing so, the *Momenta II* Court held that because Amphastar’s quality control assay was a “habitual” or “regular” part of the production process and not related to obtaining FDA approval, it was not exempt.³⁰ The court stressed that the Safe Harbor was directed to seeking FDA approval and would only cover limited types of post-approval conduct:

The routine record retention requirements associated with testing and other aspects of the commercial production process contrast with non-routine submissions that may occur both pre- and post-approval, such as the submission of investigational new drug applications (“INDs”), new drug applications (“NDAs”), supplemental NDAs, or other post-approval research results. . . . The routine quality control testing of each batch of generic enoxaparin as part of the post approval, commercial production process is therefore not “reasonably related to the development and submission of information” to the FDA, and it was clearly erroneous to conclude otherwise.³¹

Although no pre/post approval dichotomy exists under the statute, it appears that post-approval conduct will only be exempted if it is truly “required” by the FDA — for instance, studies to obtain or supplement an existing filing or to modify an existing drug label. Pre-*Momenta* decisions support this reasoning. For example, in *Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc.*, the district court held that post-approval studies on the effect of food on the drug’s bioavailability resulting in a change to its drug label were exempt because the studies “expedit[ed] development of information for regulatory approval” and therefore, were not “routine.”³² Thus, post-approval conduct undertaken to modify a drug label may be protected, even if not technically “required.”³³

Since the testing in *Momenta* was in fact required by the FDA before a batch could be marketed, the “FDA-required-versus-not-required” test is not particularly helpful.

²⁹ *Momenta II*, 809 F.3d at 621. See generally Brian Coggio and Ron Vogel, *Federal Circuit Limits Safe Harbor for Post-Approval Conduct*, LAW360 (Nov. 17, 2015).

³⁰ *Momenta II*, 809 F.3d. at 620.

³¹ *Id.*; see also *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 897 (Fed. Cir. 2015) (noting that “in the post-approval context it may be less straightforward to determine whether an accused infringer’s use of a patented invention was ‘solely for uses reasonably related to the development and submission of information’ under the FDCA.”) (emphasis in original). The *Classen* Court held that post-approval studies conducted to secure changes to a drug label were subject to the Safe Harbor. See *id.* at 897-98.

³² 981 F. Supp. 2d 415, 421 (D. Md. 2013); see also *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, No. RDB-04-3521, 2016 WL 5390803, at *5 (D. Md. Sept. 27, 2016) (holding that sales of a drug with revised label containing information derived from clinical trials are within the Safe Harbor); *Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc.*, 466 F. Supp. 2d. 621 (D. Md. 2006).

³³ *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569 (D. Md.), *aff’d*, 586 F. App’x 585 (Fed. Cir. 2014).

IV. STOCKPILING INVENTORY, WITHOUT ACTUAL SALES, MAY BE COVERED UNDER THE SAFE HARBOR, AND MAY ALSO BE INSUFFICIENT TO SHOW PATENTEE HARM

Given the uncertainty of FDA requirements in evaluating a generic application, stockpiling commercial quantities of product may fall under the Safe Harbor. The limited case law suggests that products that are stockpiled can be protected under the Safe Harbor if there is a direct nexus to the FDA approval process.³⁴ Moreover, even if not covered under the Safe Harbor, stockpiling may be insufficient to show a patentee has suffered economic harm, at least where the stockpiled product is never marketed.

A. THE PURPOSE OF THE ACT SUPPORTS STOCKPILING

The legislative history of the Act generally indicates that stockpiling may be protected by the Safe Harbor. Indeed, the two decisions condemning stockpiling as infringement are unique — and thus less persuasive — because in both cases the alleged infringers — the parties that typically benefit from Section 271(e)(1) — did not rely on the Safe Harbor to excuse their conduct. In *Biogen, Inc. v. Schering AG*, Biogen, the alleged infringer opposed the patentee’s motion to dismiss and argued that its conduct was infringing because the Safe Harbor did not apply; therefore the court had jurisdiction to hear its declaratory judgment suit.³⁵ The district court agreed and held that Biogen’s “substantial and expensive effort” — including more than \$24 million spent stockpiling its drug in anticipation of FDA approval and expiration of the blocking patent — was not protected by Section 271(e)(1).³⁶ The alleged infringer, however, did not argue that its activities were tied to the approval process because it wanted to avoid the Safe Harbor and have its case proceed.

Several other cases, while not addressing stockpiling *per se*, show the liberal scope of Section 271(e)(1) applies when there is a nexus to the FDA approval process. As one example, in *Intermedics, Inc. v. Ventritex, Inc.*, the court held that the manufacturing of alleged infringing medical devices and their sales to hospitals and international distributors to support clinical trials were protected by the Safe Harbor because parties seeking FDA approval often do not know what kind and quantity of information will be needed to secure FDA approval.³⁷ The court essentially held that the type of protected conduct is flexible, given the unpredictable nature of the FDA approval process.³⁸

Applying the *Intermedics* test, courts have found that excess production batches, which could be stockpiled, fell under the Safe Harbor. In *NeoRx Corp. v. Immunomedics, Inc.*,³⁹ the New Jersey district court held that Immunomedics’ manufacturing and stockpiling of “launch-quantity inventory” from a fourth

³⁴ See generally Brian Coggio and Ron Vogel, *Is Stockpiling Protected By Hatch-Waxman Safe Harbor?*, LAW360 (Nov. 21, 2014).

³⁵ 954 F. Supp. 391, 395-96 (D. Mass. 1996). See also *Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 695 F. Supp. 2d 21 (S.D.N.Y. 2010), discussed *infra*.

³⁶ *Biogen*, 954 F. Supp. at 396.

³⁷ 775 F. Supp. 1269, 1280, 1289-90 (N.D. Cal. 1991), *aff’d sub nom*, *Intermedics, Inc. v. Ventritex Co.*, 991 F.2d 808 (Fed. Cir. 1993).

³⁸ *Id.* at 1280-81. The court noted that the proper test is both prospective — it evaluates the potential infringer’s activities at the time they were undertaken — and objective, because it does not consider the potential infringer’s state of mind. *Id.*

³⁹ 877 F. Supp. 202 (D.N.J. 1994).

commercial-scale lot — in excess of the three lots necessary to secure FDA approval — were protected by the Safe Harbor because the FDA’s information demands were unpredictable. This finding made the increased production “reasonably related” to regulatory approval.⁴⁰ The court, citing *Intermedics*, adopted a liberal reading of Section 271(e)(1) and reasoned that the statute would never be available if a party were to lose the exemption every time a business purpose was detectable in otherwise protected activities.⁴¹ Similarly, in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, the Massachusetts district court that had earlier decided *Biogen* held that the production of commercial batches that were neither regulated by nor submitted to the FDA fell under Section 271(e)(1) because “they were objectively likely to generate useful information, even if the results were later discarded or abandoned for reasons unrelated to FDA approval.”⁴² The *Amgen* Court reasoned that other courts, including the *Biogen* Court, had applied the Safe Harbor too narrowly:

The exemption is not so ephemeral that it will be lost as a result of conduct which postdates the making, using, or selling of the patented product. The retention of the [not yet approved generic] following its manufacture is not an activity that could constitute infringement under section 271(a).⁴³

Indeed, a limited view of the scope of the Safe Harbor — which could possibly exclude stockpiling — was rejected in *Merck KGaA v. Integra Life Sciences*, where the Supreme Court held that Section 271(e)(1) provides a “wide berth” of protection.⁴⁴ Thus, despite *Biogen*, one can argue that stockpiling is protected by the Safe Harbor in view of the overriding purpose of the Act, as discussed *infra*.

B. STOCKPILING, WITHOUT INFRINGING SALES, IS LIKELY INSUFFICIENT TO SUPPORT A DAMAGES CLAIM BECAUSE THE PATENTEE IS NOT ECONOMICALLY HARMED

Even if stockpiling were not covered under the Safe Harbor, the accumulation of pre-launch inventory, without actual sales, may be insufficient to support a damages award. The generic manufacturer in *Aktiebolag v. Andrx Pharmaceuticals, Inc.*, like the one in *Biogen*, did not seek to exempt its stockpiling activities under the Safe Harbor; instead, it sought to avoid damages by excluding the patentee’s expert damages report because the report ignored the absence of infringing sales.⁴⁵

Astra had sued Andrx alleging that its ANDA filing infringed several of Astra’s omeprazole patents.⁴⁶ In the year before trial, Andrx produced ten validation batches followed by seventy-eight “commercial” batches worth over \$400 million. It intended to enter the market soon after a district court finding of non-infringement, but the court, however, found that Andrx’s product infringed and began the damages phase.⁴⁷

⁴⁰ *Id.* at 206-07.

⁴¹ *Id.* at 205-06.

⁴² 3 F. Supp. 2d 104, 108, 110 (D. Mass. 1998).

⁴³ *Id.*

⁴⁴ 545 U.S. 193, 202 (2005). See also *Eli Lilly*, 496 U.S. at 665 (holding that the term “drugs” in § 271(e)(1) includes medical devices).

⁴⁵ 695 F. Supp. 2d 21 (S.D.N.Y. 2010).

⁴⁶ *Id.* at 23-24.

⁴⁷ Transcript of Proceedings re: Conference held on 9/20/2013 before Judge Denise L. Cote at 12, 21, *Aktiebolag v. Andrx Pharm., Inc.*, No. 1:99-cv-09887 (S.D.N.Y. 2010) (Dkt. 239) [hereinafter *Transcript of Proceedings*]; *Andrx*, 695 F. Supp. 2d at 24.

The court, however, deferred Andrx's claim that the seventy-eight "commercial" batches were protected under the Safe Harbor.⁴⁸ In the interim, Andrx destroyed all the commercial batches it had manufactured.⁴⁹

In the damages phase, Andrx moved for summary judgement and conceded that the seventy-eight batches were not exempted by the Safe Harbor; rather, Andrx argued that damages were barred because the manufacture, without sale, did not qualify as "commercial manufacture" within the meaning of the Hatch-Waxman damages provision, Section 271(e)(4)(C).⁵⁰ The court denied Andrx's motion and held that liability for "commercial manufacture" did not require actual sales.⁵¹ The court, however, subsequently excluded the testimony of Astra's damages expert because the expert improperly derived her conclusions from projected sales — not actual sales — and awarded no damages because Astra was not economically harmed:

[Astra's expert's] analysis suffers from several flaws. First and foremost, it does not calculate a reasonable royalty based on manufacture alone, which is the sole act of infringement here. . . . [Astra's expert also] does not suggest any harm to Astra from Andrx's manufacture of product alone. [The] report, being wholly divorced from events subsequent to the hypothetical negotiation date, particularly the fact that Astra concededly suffered no harm as a result of the infringement, is thus properly excluded under Rule 702.⁵²

In indirectly sheltering Andrx's stockpiling efforts, the court noted that a finding of infringement (via removal of the stockpiling activities from the Safe Harbor) did not absolve the patentee of its burden of proof on damages.⁵³

It is not clear what damages — if any — the court would have awarded had Astra's expert properly addressed "damages" or if the stockpiled products had not been destroyed, but actually sold.

C. THE HATCH WAXMAN ACT'S LEGISLATIVE HISTORY SHOWS THAT STOCKPILING FURTHERS CONGRESS' GOAL TO GET GENERIC DRUGS TO MARKET IMMEDIATELY FOLLOWING PATENT EXPIRATION

The Act's legislative history demonstrates that Congress' primary concern in enacting the Safe Harbor was to immunize the testing needed to secure FDA approval of generic drugs to give the public *immediate* access to these products after patent expiration.⁵⁴ It could be argued that the best way to achieve

⁴⁸ *Id.* at 12.

⁴⁹ *Id.* at 26, 37.

⁵⁰ Andrx Pharmaceuticals, Inc.'s Memorandum of Law in Support of its Motion For Summary Judgment On Damages at 2, 12 n.6, *Aktiebolag v. Andrx Pharm., Inc.*, No. 1:99-cv-09887 (S.D.N.Y. 2010) (Dkt. 83).

⁵¹ *Andrx*, 695 F. Supp. 2d at 29.

⁵² Transcript of Proceedings, at 35, 38; see also Consent Order and Final Judgment at ¶¶ 5-6, *Aktiebolag v. Andrx Pharm., Inc.*, No. 1 99-cv-09887 (S.D.N.Y. 2010) (Dkt. 259).

⁵³ Transcript of Proceedings, at 33-34 ("At all times the Federal Circuit has noted that damages inquiry must concentrate on compensation for the economic harm caused by infringement of the claimed invention. Thus, while there is a presumption of damages when infringement is proven, the burden of proving damages is on the patentee and the patentee is entitled to no less than a reasonable royalty under the patent act, does not absolve him of the duty to prove damages.") (internal citations omitted).

⁵⁴ See Allan M. Fox & Allan R. Bennett, *The Legislative History of the Drug Price Competition And Patent Term Restoration Act of 1984*, 187-200 (FDLI 1987).

this goal would be to allow a generic manufacturer to prepare to enter the commercial market immediately after any blocking patent expires by stockpiling the product. The legislative history supports this view:

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 preventing of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.⁵⁵

* * *

[The Committee on Energy and Commerce] reasoned that without [§ 271(e)(1)] generic manufacturers would be required to engage in . . . 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.⁵⁶

Thus, stockpiling allows undelayed market entry to achieve Congress' goal of assuring prompt public access to generic products. Moreover, the two decisions condemning stockpiling are distinguishable because: (i) *Biogen* is a procedural outlier in which the alleged infringer sought to avoid the protections of the Safe Harbor; and (ii) under somewhat unusual circumstances, *Andrx* found that a patentee suffered no harm as a result of the infringing stockpiling. A different result, however, might have resulted in *Andrx* had the stockpiled product been marketed after patent expiration.

The authors are not aware of any decision that evaluates stockpiling under the Safe Harbor in view of the overriding purpose of the Act.

V. UNDER *MOMENTA II*, RESEARCH TOOLS MAY STILL FALL UNDER THE SAFE HARBOR

The Federal Circuit's holding in *Momenta II* may allow research tools to be covered under the Safe Harbor. In this regard, the *Momenta II* Court, in explaining the breadth of the exemption, stated:

Despite the broad contours of the [Safe Harbor] exemption, some activities are outside its protection. . . . [R]esearch tools or devices that are not themselves subject to FDA approval may not be covered. *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008).⁵⁷

Some uncertainty exists because the Court's use of the word "may" is at odds with its citation of *Proveris*, where the Federal Circuit seemingly held that research tools are *not* covered by the exemption because of the lack of symmetry between Sections 271(e)(1) and 156. That is, since research tool patents cannot be extended under Section 156, they are not subject to Section 271(e)(1). However, if the *Momenta II* Court believed that research tools were *never* covered under the Safe Harbor, it could have said so and ended its analysis. But the Court did not; instead, it excluded Amphastar's quality control tests from the Safe Harbor because they were a "habitual" or "regular" part of the production process.⁵⁸ Thus, the Court

⁵⁵ H.R. Rep. No. 98-857, pt. 1, at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.

⁵⁶ H.R. Rep. No. 98-857, pt. 2, at 8-9 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2692-93.

⁵⁷ *Momenta II*, 809 F.3d at 619 (emphasis added).

⁵⁸ *Id.* at 620.

implicitly acknowledged that research tools “may” fall under the Safe Harbor because it decided the case on different grounds:

The conclusion in *Momenta I* that Amphastar's commercial use of Momenta's patented method falls within the safe harbor of § 271(e)(1) would result in manifest injustice. Amphastar points to no case, until *Momenta I*, extending immunity under § 271(e)(1) to encompass activities related to ongoing commercial manufacture and sale.⁵⁹

The *Momenta II* Court's citation of *Proveris* is further evidence of the confusion on this issue because *Proveris* is contravened by the earlier and binding Federal Circuit holding in *Abtox, Inc. v. Exitron Corp.*, which held — contrary to *Proveris* — that statutory symmetry between Sections 271(e)(1) and 156 for research tools was *not* required before the Safe Harbor applies.⁶⁰

A. SOME COURTS EXCLUDE RESEARCH TOOLS FROM THE SAFE HARBOR UNDER THE STATUTORY SYMMETRY APPROACH, SEEMINGLY AGAINST SUPREME COURT AND FEDERAL CIRCUIT PRECEDENT

The symmetry approach was first recognized in *Eli Lilly and Co. v. Medtronic, Inc.*, where the Supreme Court suggested that only those patents whose terms were extendable under Section 156 were covered by the Safe Harbor.⁶¹ The Supreme Court, however, recognized, in contrast to *Proveris* (and possibly *Momenta II*) that exceptions could exist where research tool patents would be subject to Section 271(e)(1), even though the controlling patent was not extendable under Section 156:

[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.⁶²

The use of research tools in the biotech and pharmaceutical industries is certainly not “relatively rare.”

The first two Federal Circuit panels to address *Eli Lilly's* symmetry approach — *Abtox* and *Chartex Int'l PLC v. M.D. Personal Prods. Corp.*⁶³ — did not read the limitations of Section 156 into Section 271(e)(1). In *Abtox*, a Federal Circuit panel explicitly stated that in *Eli Lilly* “the Supreme Court command[ed] that statutory symmetry is preferable *but not required*” and held that a patented device that was not eligible for a patent term extension under Section 156 was still protectable under the Safe Harbor.⁶⁴ Years later,

⁵⁹ *Id.* at 621 (emphasis added).

⁶⁰ 122 F.3d 1019, 1030 (Fed. Cir.), *op. amended on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997).

⁶¹ 496 U.S. 661 (1990). Although *Eli Lilly* examined patents covering Class III medical devices (which can be extended) and patents covering Class I and Class II devices (which cannot be extended), the holding suggests that research tools may not be covered under the Safe Harbor because they are not themselves subject to FDA approval and therefore not extendable under § 156. *Id.*; see also Brian Coggio, *Research Tools and the Hatch-Waxman Safe Harbor*, 22 BIOTECHNOLOGY LAW REPORT 1 (November 1, 2014).

⁶² *Eli Lilly*, 496 U.S. at 671-72.

⁶³ 5 F.3d 1505, at *2 n.2 (Fed. Cir. 1993).

⁶⁴ *Abtox*, 122 F.3d at 1030 (emphasis added).

the panel in *Proveris* held differently and found that research tools were not subject to the Safe Harbor because they were not eligible for Section 156 extensions.⁶⁵ But the earlier *Abtox* decision should control because when two Federal Circuit decisions conflict, the earlier precedent controls until overruled *en banc*.⁶⁶ Significantly, *Abtox* has never been overruled. Thus, both the Supreme Court (in *Eli Lilly*) and the Federal Circuit (in *Abtox*) agree that research tools may be protected because statutory symmetry is not required. Some district court decisions reinforce these holdings,⁶⁷ but other courts require symmetry between the two sections.⁶⁸

B. THE HATCH WAXMAN ACT'S LEGISLATIVE HISTORY DOES NOT ADDRESS THE USE OF RESEARCH TOOLS TO SUPPORT COMMERCIAL SALES

As discussed in Part IV.C, *supra*, the Act's legislative history shows that Congress did not intend that the Safe Harbor have an adverse economic impact on a patentee before its patent expired.⁶⁹ The *Momenta II* Court's decision to remove Amphastar's conduct from the Safe Harbor could align with the legislative history if, as discussed in Part IV.B, *supra*, the Court acted to protect Momenta from the impact of lost sales (through Amphastar's royalty-free use of the assay) before its patent expired.⁷⁰ Although the *Momenta II* decision on research tools could support the overriding purpose of the Act, as mentioned *supra*, the authors are not aware of any controlling decision that explicitly evaluates Safe Harbor protection of research tools in view of the Act's legislative history. Moreover, the Federal Circuit has not yet addressed what would happen if FDA mandated that a generic manufacturer use a specific patented method or no alternative, non-patented methods were available. Thus, the scope of the protection for the use of research tools under the Safe Harbor, if any, awaits further resolution.

VI. THE BOLAR EXEMPTION — THE EUROPEAN UNION'S REGULATORY SAFE HARBOR — VARIES GREATLY AMONG MEMBER STATES

The EU's version of the Safe Harbor provides a regulatory approval exemption that varies from country to country. The EU Parliament and Council adopted a Directive on the Community Code relating to medicinal products for human use ("CCMP") that is similar to the Safe Harbor.⁷¹ Article 10(6) of the Directive, known as the Bolar Exemption, protects activities carried out to support drug marketing approval:

Conducting the necessary studies and trials . . . and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary

⁶⁵ 536 F.3d 1256, 1265 (Fed. Cir. 2008).

⁶⁶ *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988). *Abtox* and *Proveris* are panel decisions, and another earlier decision that agrees with *Abtox*, *Chartex Int'l PLC v. M.D. Pers. Prod. Corp.*, was unpublished and thus not precedential. 5 F.3d 1505 (Fed. Cir. 1993).

⁶⁷ See, e.g., *Teva Pharm. USA, Inc. v. Sandoz Inc.*, No. 09 CIV. 10112, 2013 WL 3732867, at *7 (S.D.N.Y. July 16, 2013), appeal dismissed (Sept. 5, 2013), appeal dismissed (Nov. 20, 2013).

⁶⁸ See, e.g., *Isis Pharm., Inc. v. Santaris Pharma A/S Corp.*, No. 3:11-CV-2214-GPC-KSC, 2014 WL 794811, at *11-*12 (S.D. Cal. Feb. 27, 2014), reconsideration denied, No. 3:11-CV-2214-GPC-KSC, 2014 WL 2212114 (S.D. Cal. May 28, 2014); *PSN Illinois, LLC v. Abbott Labs.*, No. 09 C 5879, 2011 WL 4442825, at *5 (N.D. Ill. Sept. 20, 2011).

⁶⁹ H.R. Rep. No. 98-857, pt. 1, at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.

⁷⁰ *Momenta II*, 809 F.3d at 621.

⁷¹ Council Directive 2004/27, 2004 O.J. (L136) (EC) (amending Council Directive 2001/83, 2001 O.J. (L 311) (EC)).

protection certificates for medicinal products.⁷²

Each EU member state implemented a version of CCMP into its own national law. As a result, the Bolar Exemption varies considerably among the largest EU markets, including Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Spain, Switzerland, and the United Kingdom (UK).⁷³

Practitioners agree that the Bolar Exemption is limited to studies and trials necessary for obtaining generic EU marketing approval in Belgium, Germany, Ireland and the Netherlands, while a broader scope of trials — for originator and generic approval — should be exempted in Denmark, France, Italy, the UK, and Spain.⁷⁴ All Phase 4 (post-marketing) trials are exempted in Italy, whereas only Phase 4 trials necessary to obtain or maintain marketing approval are exempted in Belgium, France, Germany, the Netherlands, Spain, and the UK.⁷⁵

The geographical scope of protection also varies across the continent: trials to obtain marketing authorizations outside the EU do not constitute patent infringement in Denmark, France, Germany, Italy, Spain, Switzerland, or the UK, whereas the exemption is limited to trials for EU-wide approval in Belgium, Ireland, and the Netherlands.⁷⁶ Regarding post-approval conduct, the French High Court has held that the Bolar Exemption can apply to such activities when tied to agency approval.⁷⁷ The issue is not otherwise settled. Further complicating matters, as discussed *infra*, many European countries, unlike the U.S., have an exemption protecting basic research.

Legal uncertainty about the scope and interpretation of Bolar Exemption across the EU remains given the limited national case law and lack of guidance from the European Court of Justice, which interprets all EU Directives. As one example, no case law exists on whether a third-party supplier of an API can benefit from the Bolar Exemption.⁷⁸

The establishment of the Unified Patent Court (UPC) will help harmonize the Bolar Exemption across the EU.⁷⁹ Progress toward implementation of the UPC slowed following the June 2016 UK Referendum where voters favored leaving the EU (“Brexit”) because of uncertainty over the UK’s role in the

⁷² *Id.*

⁷³ See Kupecz et al., *Safe Harbors in Europe: An Update on the Research and Bolar Exemptions to Patent Infringement* at 712, *NATURE BIOTECH.*, vol. 33 No. 7 (July 2015) (discussing the research and Bolar exemptions in Belgium, France, Germany, Italy, Spain, the Netherlands and the UK) [hereinafter *Kupecz*]; see also Isabelle Romet and Bert Oosting, *Bolar and Research Exemptions*, Biotech and Pharmaceutical Patenting Conference 2015 (Feb. 24, 2015), available at http://www.veron.com/publications/Colloques/2015-02-24_Bolar_and_Research_Exemption_presentation_Munich1.pdf?card=1296 [hereinafter *Romet*].

⁷⁴ Kupecz, *supra* note 72, at 715; see also Romet, *supra* note 72.

⁷⁵ Kupecz, *supra* note 72, at 713-15.

⁷⁶ *Id.*; see also Romet, *supra* note 72.

⁷⁷ *Sanofi-Aventis Deutschland v. Lilly France*, No. 14/58023, High Court of Paris, Order of December, 15 2014 at 7.

⁷⁸ Romet, *supra* note 72.

⁷⁹ Article 27 of the UPC Agreement includes the CCMP’s Bolar provisions, and its wording appears to restrict the exemption to generic medicines, bioequivalents and biosimilars. Kupecz, *supra* note 72, at 715.

UPC.⁸⁰ However, the UK government has said that it plans to ratify the agreement while the UK is still part of the EU. That would allow the court to begin operations in 2017.⁸¹

In Canada, the Bolar Exception shields activities done to generate information reasonably related to the development and submission of information required for regulatory approval — including, but not limited to, drug approvals — in both Canada and other countries.⁸² The Bolar Exception can protect both pre- and post-approval activities as long as there is no commercial aspect to the work.⁸³ For example, the Bolar Exception will not apply if drug samples were sold subsequent to their use for regulatory purposes.⁸⁴

VII. THE BASIC RESEARCH EXEMPTION IS MUCH BROADER IN THE EUROPEAN UNION THAN IN THE UNITED STATES

In the United States, the research exemption is a “very narrow and strictly limited experimental use defense” that shelters acts done for “amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”⁸⁵ In *Madey v. Duke University*, the Federal Circuit held that the defense does not protect any conduct that furthers the alleged infringer’s legitimate business, including educating students or securing research grants, regardless of commercial implications or the infringer’s profit or non-profit status:

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.⁸⁶

As discussed *supra*, Section 271(e)(1) is a statutory exemption for research to support regulatory approval. Thus, in the United States, basic pharmaceutical research would only be exempted under the Safe Harbor, if at all.

Many EU countries, however, have a stand-alone basic research exemption. This exception is permitted under Article 30 of the WTO’s TRIPs Agreement, which states that members may weigh third-party interests when limiting patent rights so long as these limits do not unreasonably prejudice patent owners:

Members may provide limited exceptions to the exclusive rights conferred by a

⁸⁰ See <http://www.fr.com/news/legal-alert-a-path-to-the-upc/>.

⁸¹ Clive Cookson, *Britain to Ratify Single European Patent System*, FINANCIAL TIMES (Nov. 29, 2016), <https://www.ft.com/content/6a07fdb5-b56f-11e6-ba85-95d1533d9a62>. The UK’s continued participation after it leaves the EU will likely be subject to the Brexit negotiations between the UK and the EU.

⁸² Patent Act, R.S.C., ch. P-4, § 55.2(1) (2001) (Can.) (“It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.”).

⁸³ *Merck & Co., Inc. v. Apotex Inc.*, 2006 FC 524, aff’d 2006 FCA 323.

⁸⁴ *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186.

⁸⁵ *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

⁸⁶ *Id.*

patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.⁸⁷

The breadth of the basic research exemption varies considerably among the larger EU member states.⁸⁸ In many countries, including France, Germany, the Netherlands, Spain, and the UK, only research 'on' patented subject matter (*i.e.*, to understand or improve the invention) is protected. In Italy and Belgium, the research exemption is broader and permits both research 'on' patented subject matter as well as research 'with' patented subject matter (*i.e.*, using the invention for commercial-type activities). Thus, the use of research tools may be protected in these two countries and in the UK, where the Bolar Exemption allows the use of a patented research tool in trials to support regulatory approval.⁸⁹

In the U.S., Judge Newman, in her dissent in *Integra Lifesciences I, Ltd. v. Merck KGaA*, argued for a similar distinction between research into the science and technology disclosed in patents [*i.e.*, research 'on'] and the use of tools in research with patented products or methods [*i.e.*, research 'with'].⁹⁰ Judge Newman reasoned that a patentee's permission is not required whenever a patented invention is investigated because the "[s]tudy of patented information is essential to the creation of new knowledge, thereby achieving further scientific and technologic progress."⁹¹ Her approach was rejected, and little remains of the U.S. research exception after *Madey*.

In Canada, the experimental use exemption is narrowly defined to cover research on the subject matter of an invention, where the research does not have a commercial purpose.⁹² No case law exists regarding the use of research tools in Canada.

VIII. CONCLUSION

Although the *Momenta II* decision requires a greater scrutiny of post-approval conduct, a wide variety of activities, including supplying active ingredients, using research tools, and stockpiling drug inventory, may still be protected under the Safe Harbor as long as there is clear link between such conduct and efforts to secure regulatory approval. The latter two categories are subject to some debate, and the boundaries will not become any clearer until further decisions are rendered. Similarly, the scope of the Bolar Exemption, the EU analog to the Safe Harbor, will be clearer after the implementation of the UPC.

Understanding the scope of the Safe Harbor in the U.S. and the regulatory and research safe harbors in the EU and Canada will allow companies to take advantage of the best geographical locations in order to avoid infringement accusations in researching and developing pharmaceutical products.

⁸⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197, art. 30 (1994).

⁸⁸ Kupecz, *supra* note 72, at 710-12. Although the research exemption varies, some commentators believe that it may be limited to studies and trials for generic drugs for obtaining marketing approval in Europe once the unitary patent system and the Unified Patent Court (UPC) system come into force. *Id.* at 715.

⁸⁹ *Id.* at 713-14. In the UK the Bolar exemption allows the use of a patented research tool in trials to support regulatory approval.

⁹⁰ 331 F.3d 860, 877-78 (Fed. Cir. 2003) (Newman, J., dissenting).

⁹¹ *Id.* at 875-76.

⁹² Patent Act, R.S.C., ch. P-4, § 55.2(6) (2001) (Can.).