United States Court of Appeals for the Federal Circuit

MOMENTA PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

and

SANDOZ, INC.,
Plaintiff-Appellee,

v.

AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., WATSON PHARMACEUTICALS, INC., AND WATSON PHARMA, INC.,
Defendants-Appellants.

2012-1062, -1103, -1104

Appeals from the United States District Court for the District of Massachusetts in case no. 11-CV-11681, Judge Nathaniel M. Gorton.

Decided: August 3, 2012

ROBERT S. FRANK, JR., Choate Hall & Stewart LLP, of Boston, Massachusetts, argued for both plaintiffs-appellees. With him on the brief was ERIC J. MARANDETT. Of counsel on the brief for plaintiff-appellee for Sandoz,

Inc., was THOMAS P. STEINDLER, McDermott, Will & Emery LLP, of Washington, DC.

PATRICIA A. MILLETT, Akin Gump Strauss Hauer & Feld LLP, of Washington, DC, argued for plaintiffs-appellants. With her on the brief were ANTHONY T. PIERCE, MARK MANSOUR, EMILY C. JOHNSON and JAMES E. TYSSE; and L. RACHEL LERMAN, of Los Angeles, California.

Before RADER, *Chief Judge*, DYK and MOORE, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* MOORE.
Dissenting opinion filed by *Chief Judge* RADER.

MOORE, *Circuit Judge*.

Amphastar Pharmaceuticals, Inc., International Medication Systems, Ltd., Watson Pharmaceuticals, Inc., and Watson Pharma, Inc. (collectively, Amphastar) appeal the district court's order denying the Emergency Motion to Dissolve or Stay the preliminary injunction entered in this case. Because the district court applied an unduly narrow interpretation of the Hatch-Waxman safe harbor, 35 U.S.C. § 271(e)(1), we vacate the grant of a preliminary injunction and remand for further proceedings consistent with this opinion.

BACKGROUND

This case is a patent litigation involving a generic version of Lovenox (enoxaparin), a drug that prevents blood clots. Enoxaparin is a low molecular weight version of heparin, a naturally occurring molecule. Heparin is a polymer, known as a polysaccharide, made up of long chains of sugar molecules. Heparin is not a single defined molecule. Instead, heparin molecules have considerable

diversity in (1) the length of the polysaccharide chain and (2) in the component disaccharide units and the corresponding distribution of disaccharide unit sequences in the polysaccharide chains. FDA Letter to Aventis Pharmaceuticals, Inc., July 23, 2010, FDA Docket No. FDA-2003-P-0273 (FDA Letter), J.A. 291. For example, the molecular weight of heparin molecules varies between 5,000 and 40,000 daltons. *Id.* Likewise, the disaccharide units can vary between two different uronic acid components, and each of four positions on the disaccharide unit can be modified. *Id.*, J.A. 291-92. The natural diversity inherent to heparin stems from the biosynthetic pathway used to produce the molecule. *Id.*, J.A. 292.

Enoxaparin is produced by breaking the heparin polysaccharide into smaller pieces, called oligosaccharides. Because the heparin starting material is a diverse set of molecules, enoxaparin is also made up of different chain lengths and disaccharide units corresponding to the diversity in the original mix of heparin molecules. *Id.* Additional diversity is introduced based on the way in which the heparin molecule is broken down into the low molecular weight heparin product. *Id.*, JA 292-93. Thus, unlike a typical small molecule drug like penicillin, enoxaparin is made up of a range of different molecules.

This molecular diversity raises a potential problem in light of the Food and Drug Administration's (FDA's) abbreviated new drug application (ANDA) approval process. ANDAs are typically used by generic companies to obtain approval to market a generic version of an existing drug. Unlike a new drug application (NDA), an ANDA applicant is not required to submit the same extensive clinical studies typically needed to prove the drug's safety and efficacy. Instead, the ANDA applicant must submit studies to establish that its drug is bioequivalent to the reference drug. The ANDA must also

include sufficient information to establish that the generic drug has the same active ingredients as the reference drug.

The obvious complication with using an ANDA application to gain approval for enoxaparin is that it is a mixture of a number of different low molecular weight heparin molecules. In fact, Aventis, which marketed Lovenox, asked the FDA to deny approval for a generic version of enoxaparin via an ANDA unless the applicant either (1) completely characterized enoxaparin by isolating, purifying, and sequencing each of its unique polysaccharide chains, which Aventis claimed was impossible; (2) used Aventis's manufacturing process; or (3) conducted clinical trials to prove safety and efficacy (the very type of duplicative studies the ANDA approval process was designed to avoid). FDA Letter, J.A. 286. The FDA rejected Aventis's arguments, and instead explained that the ANDA "statutory provisions do not describe the type or amount of information that an ANDA applicant must submit to demonstrate that the active ingredient in the generic drug product is the same as the active ingredient in the [reference drug]." *Id.*, J.A. 294. As a result, the FDA concluded that Congress recognized that the FDA has "broad discretion with respect to the information [it] may consider in making a finding on the 'sameness' of an active ingredient." *Id.*

Consistent with this discretion, the FDA identified five criteria, or "standards for identity," that "together provide sufficient information to conclude that generic enoxaparin has the 'same' active ingredient as Lovenox." *Id.*, J.A. 295. These criteria included, *inter alia*, "[e]quivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species." *Id.* The FDA explained that such equivalence is proven by "exhaustive digestion of enoxaparin with purified heparin

digesting enzymes (heparinases I, II, III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin." *Id.*, J.A. 300. These disaccharides can then potentially be "separated and quantified" by a number of techniques, including capillary electrophoresis (CE), reverse phase high performance liquid chromatography (RP-HPLC), and strong anion exchange high performance liquid chromatography (SAX-HPLC). *Id.*

The FDA also suggested the identity of the disaccharides could be determined via standard techniques, including mass spectroscopy, NMR spectroscopy, modifying reagents, or modifying enzymes. These techniques identify the nature of the constituent sugars and their substitution patterns, including the sulfation and acetylation patterns, as well as "whether the disaccharide possesses, among other structures, a . . . 1,6 anhydro ring" structure. *Id.*, J.A. 300-01. Detecting the presence of a 1,6 anhydro ring structure is particularly important for proving equivalence because "[e]quivalence in disaccharide building blocks together with equivalence in molecular weight distribution shows that generic enoxaparin contains the 1,6 anhydro ring structure at the reducing ends of between 15 percent and 25 percent of its poly(oligo)saccharide chains." *Id.* n.68, J.A. 301.

Amphastar was the first company to file an ANDA for a generic version of enoxaparin. It submitted its ANDA to the FDA in March 2003, and subsequently engaged in a lengthy patent litigation with Sanofi-Aventis. Amphastar received FDA approval to market its generic enoxaparin on September 19, 2011. Despite the fact that Amphastar was the first company to file an ANDA, Momenta Pharmaceuticals, Inc. and Sandoz, Inc. (collectively Momenta), who collaborated to develop a generic enoxaparin product, were the first to bring generic enoxaparin to the market-

place. Momenta received FDA approval to market enoxaparin in July 2010, more than a year before Amphastar's approval. Being the only generic version of enoxaparin has it benefits: its sales generated revenues of $260 million *per quarter*. J.A. 189. The approval of Amphastar's version of enoxaparin, and the resultant ruinous competition of another generic version of the drug, threatened this unique market position. Understandably unwilling to give up a billion dollars in yearly revenue, Momenta initiated the present litigation two days after Amphastar received final FDA approval to market its generic enoxaparin.

Momenta is the assignee of United States Patent No. 7,575,886 ('886 patent). The '886 patent generally relates "to methods for analyzing heterogeneous populations of sulfated polysaccharides, e.g. heparin [and] . . . LMWH [e.g., enoxaparin.]" '886 patent col.4 ll.53-55. Claim 6 is typical. It is a method for analyzing an enoxaparin sample "for the presence or amount of a non naturally occurring sugar . . . that results from a method of making enoxaparin that included ß-eliminative cleavage with a benzyl ester and depolymerization." *Id.* col.64 ll.35-39. Momenta also asserted independent claims 15, which assesses the level of non-naturally occurring sugar, and 53, which allows selection of an appropriate batch. These claims are similar to claim 6. The asserted claims generally require digestion of an enoxaparin sample with a heparin degrading enzyme, followed by the use of a separation method to detect the presence of the non-naturally occurring sugar resulting from the ß-eliminative cleavage. The signal corresponding to the non-naturally occurring sugar can then be used to analyze the test sample based on a comparison with a reference standard. *Id.* col.64 ll.40-57.

Momenta alleged that Amphastar infringed the '886 patent by "manufacturing generic enoxaparin for commercial sale" using the claimed methods. J.A. 58. Momenta asserted that Amphastar "included in their process for manufacturing batches of enoxaparin sodium . . . a method for determining that a defined percentage of the oligosaccharide chains that make up enoxaparin include . . . a non-naturally occurring sugar that includes a 1,6-anhydro ring structure, which method infringes the '886 patent." J.A. 57. Momenta also alleged that this infringing testing was necessary because the "FDA requires a generic manufacture to include in its manufacturing process the analysis of each batch of its enoxaparin drug substance to confirm that . . . [it] includes a 1,6-anhydro ring structure." J.A. 56. Momenta moved for and received a temporary restraining order to prevent the irreparable harm of additional generic entry from Amphastar. J.A. 4. The district court subsequently granted Momenta a preliminary injunction based on its belief that Amphastar's quality control batch testing infringed the '886 patent. J.A. 30. Amphastar later filed two emergency motions for relief from the preliminary injunction, which the district court denied.

Amphastar sequentially appealed the preliminary injunction and the two denials for relief from the preliminary injunction. These three appeals were consolidated. We have jurisdiction to hear these appeals pursuant to 28 U.S.C. § 1292. After hearing oral argument in this case, we stayed the preliminary injunction. This stay, however, was not a final decision on the merits of Amphastar's appeal. We now explain why the district court incorrectly concluded that Momenta was likely to succeed on the merits of its infringement claim, and conclude that the preliminary injunction must be vacated.

ANALYSIS

"The issuance of a preliminary injunction . . . is a matter of discretion for a district court. That discretion, however, is not absolute and must be reviewed in light of the equitable standards governing the issuance of injunctions." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). To determine whether a preliminary injunction is appropriate, the district court weighs factors including "(1) whether the movant has sufficiently established a reasonable likelihood of success on the merits; (2) whether the movant would suffer irreparable harm if the injunction were not granted; (3) whether the balance of hardships tips in the movant's favor; and (4) the impact, if any, of the injunction on the public interest." *Id.* The grant of a preliminary injunction can be overturned "by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997). As the party seeking the injunction, the burden is on Momenta to establish it is entitled to this extraordinary relief. *Id.* In order to prove a likelihood of success on the merits, Momenta must prove that Amphastar likely infringes its patent. *Id.* Conversely, if Amphastar establishes that Momenta is unlikely to succeed on its claim of infringement, a preliminary injunction is likely not appropriate. *Id.*

In its opposition to the preliminary injunction, Amphastar argued, among other things, that its testing falls within the scope of the Hatch-Waxman safe harbor, 35 U.S.C. § 271(e)(1). Section 271(e)(1) indicates that "[i]t shall not be an act of infringement to . . . use . . . 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 . . . ." The district court found that "the alleged infringing activity involves the use of plaintiffs' patented quality control testing methods on each commercial batch of enoxaparin that will be sold after FDA approval." J.A. 31; *see also* J.A. 56 (Momenta's complaint alleging that the "FDA requires" the testing). While acknowledging that Amphastar's use of the patented method was for the purpose of developing information to submit to the FDA, the district court nevertheless concluded that the safe harbor does not apply to Amphastar's testing: "although the safe harbor provision permits otherwise infringing activity that is conducted to obtain regulatory approval of a product, it does not permit a generic manufacturer to continue in that otherwise infringing activity after obtaining such approval." J.A. 23. In reaching this conclusion, the district court focused primarily on the legislative history of the safe harbor, as quoted in one of our prior cases, *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011). J.A. 23.

On appeal, Amphastar argues that the district court took an unduly restrictive view of the safe harbor, and that its activities fall within the plain language of 35 U.S.C. § 271(e)(1). Momenta counters that the district court correctly held that the safe harbor does not apply to Amphastar's testing for two reasons. First, Momenta argues that that the safe harbor does not apply to post-approval activity: "In *Classen*, this court squarely held that '[t]he [safe harbor] does not apply to information that may be routinely reported to the FDA long after marketing approval has been obtained.'" Appellee's Br. at 43 (quoting *Classen*, 659 F.3d at 1070, alterations made by Momenta)). Because Amphastar's batch testing is carried out as a condition for the post-FDA approval sale of enoxaparin, Momenta argues it falls outside the scope of the safe harbor.

Second, despite its allegations and concessions, Momenta asserts the safe harbor does not apply because "the FDA does not require the use of the particular procedure that is claimed in the '886 patent." *Id.* at 41. Instead, Momenta claims that the FDA's interpretation of its statutory mandate in its letter response to Aventis's petition, J.A. 300-01, allows a variety of testing methods to be used to establish equivalence, both for the submission of an ANDA and for the undisputedly required batch testing. Appellee's Br. at 41. Momenta argues that the availability of other acceptable testing methods means that Amphastar's alleged use of the patented method is not required by the FDA, and is therefore outside of the safe harbor provision.

The parties thus present us with conflicting views about the scope of the safe harbor. If Amphastar is correct that its post-approval activities actually fall within the scope of 35 U.S.C. § 271(e)(1), Momenta is unlikely to succeed on its claim of infringement and the preliminary injunction is likely inappropriate. *Genentech*, 108 F.3d at 1364. In order to determine whether the preliminary injunction was appropriate in this case, we must first ascertain the scope of the Hatch-Waxman safe harbor provision, 35 U.S.C. § 271(e)(1).

I.

"[A]ll statutory construction cases . . . begin with the language of the statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002). The "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997). 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.'" *Id.* (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240 (1989)). 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." *Id.* at 341.

The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), Public Law No. 98-417 (1984) (codified in relevant part at 35 U.S.C. § 271(e)) set up a statutory system to "balance the need to stimulate innovation against the goal of furthering the public interest." H.R. Rep. 98-857, pt. 2, at 2714 (Aug. 1, 1984). This balance is embodied, in part, in the "safe harbor" provision of 35 U.S.C. § 271(e)(1), which provides (with emphasis added) that:

> 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 (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.

Congress could not have been clearer in its choice of words: as long as the use of the patented invention is solely for uses "reasonably related" to developing and submitting information pursuant to "a Federal law"

regulating the manufacture, use, or sale of drugs, it is not "an act of infringement."

Although the Hatch-Waxman safe harbor provision was enacted in the context of the then-novel ANDA approval process, 35 U.S.C. § 271(e)(1) does not reference the portion of the Federal Food, Drug, and Cosmetic Act describing the ANDA requirements, e.g., 21 U.S.C. § 355(j). Instead, Congress used more flexible and expansive language to define the scope of § 271(e)(1), referring generally to "the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." This broad language unambiguously applies to submissions under any federal law, providing that the law "regulates the manufacture, use, or sale of drugs." Limiting the scope of 35 U.S.C. § 271(e)(1) to just the submission of information pursuant to the Federal Food, Drug, and Cosmetic Act generally, or to the ANDA provision of the Federal Food, Drug, and Cosmetic Act in specific, would read words into the statute in violation of the express language chosen by Congress.

This interpretation is also consistent with the rest of the statutory scheme. When Congress wanted to impose a limitation based on the Federal Food, Drug, and Cosmetic Act, it expressly referenced the Act. For example, in the safe harbor provision, Congress excluded "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)" made using certain genetic techniques. 35 U.S.C. § 271(e)(1) (emphasis added). Likewise, when Congress wanted to limit the statute to just a certain kind of submission, for example the submission of an ANDA application under 21 U.S.C. § 355(j), it specifically referenced the statutory section governing those submissions. For example, in the subsec-

tion immediately following the safe harbor, Congress defined as an act of infringement the submission of "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [codified at 21 U.S.C. § 355(j)] or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

Unlike the closely related infringement provision, 35 U.S.C. § 271(e)(2), Congress did not link the safe harbor to the submission of an application for approval under the Federal Food, Drug, and Cosmetic Act. *Compare* 35 U.S.C. § 271(e)(1) (not an act of infringement when used for "the development and submission of information under a Federal law") *with* 35 U.S.C. § 271(e)(2)(A) (it is an act of infringement to submit "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act"). We cannot change the statutory language. We will not import the limitation of § 271(e)(2) into § 271(e)(1). "[O]ur obligation is to take statutes as we find them." *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980); *see also*, *e.g.*, *Reiter v. Sonotone Corp.*, 442 U.S. 330, 344 (1978) ("We must take the statute as we find it."). The statute here applies to *any* use of a patented invention as long as the use is "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).

In light of these provisions, the only coherent and consistent interpretation of "a Federal law which regulates the manufacture, use, or sale of drugs" is that it must be broad enough to encompass submissions made pursuant to the Federal Food, Drug, and Cosmetic Act. Since 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. *Robinson*, 519 U.S. at 340. 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. *Id.* The scope of the Hatch-Waxman safe harbor does not stop at activities reasonably related to development of information submitted in an ANDA. Instead, the safe harbor applies "to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." As 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 law.

This analysis is not groundbreaking: the Supreme Court came to essentially the same conclusion 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 *an entire statutory scheme of regulation*," and not just a particular provision of the law. 496 U.S. 661, 666 (1990) (emphasis added). Although the legislative history of the safe harbor only mentioned drugs, *id.* at 669 n.2, the Court nevertheless concluded that the safe harbor also extended to medical devices, which were also part of "a Federal law which regulates the manufacture, use or sale of drugs," namely the Federal Food, Drug, and Cosmetic Act, *id.* at 674.

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 I, Ltd.*, 545 U.S. 193,

202 (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. 545 U.S. at 202 n.6. 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*." *Id.* at 202 (emphasis added). 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*." *Id.* (emphasis added). The use of the word "under" in the statute is expansive. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. __, 132 S. Ct. 1670, 1683-84 (2012). "Under 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." *Id.*

While 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). "Reasonably related," however, 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." *Merck KGaA*, 545 U.S. at 206. Instead, the Court explained that the safe harbor "exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing

information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Id.* (emphasis in original). Thus, the Court explicitly rejected the notion that § 271(e)(1) was limited "to the activities necessary to seek approval of a generic drug." *Id.* 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.'" *Id.* at 207.

II.

At the outset we are met with the contention that the information in question was not "submitted" to the FDA, *see* 35 U.S.C. § 271(e)(1) (". . . solely for uses reasonably related to the development and *submission* of information . . ."), but rather was retained by the ANDA holder. We do not agree. Amphastar, as a generic drug manufacturer under an ANDA, cannot sell a batch of enoxaparin unless it has established that its strength and quality is consistent with the standards set forth in the relevant official compendium. *See* 21 U.S.C. §§ 331(a), 351(b). FDA regulations require that all records associated with a produced batch of drugs, including these batch records, "be retained for at least 1 year after the expiration date of the batch." 21 C.F.R. § 211.180(a). These records "shall be readily available for authorized inspection" by the FDA at any time. 21 C.F.R. § 211.180(c). We 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.*, 545 U.S. 193 (2005), 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. *Id.* at 208. The Court explained that

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

Id. at 206. Thus, it was not an act of infringement to use patented compounds in preclinical studies which were not ultimately submitted to the FDA where "there [was] a reasonable basis for believing that the experiments [would] produce the types of information that are relevant to an IND or NDA." *Id.* at 208.

However, in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011), 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." At issue in *Classen* were studies to evaluate the association between the timing of childhood vaccinations and the risk of developing certain immune-mediated disorders. The studies themselves were not mandated by the FDA, but any vaccine license holder was required to report to the FDA "adverse experience information," such as adverse side effects, it acquired as a result of vaccine studies. *See* 21 C.F.R. § 600.80. We found that the studies conducted by the vaccine license holder according to patented methods were not insulated by the safe harbor because the studies did not facilitate marketing a generic drug by "expedit[ing] development of information for regulatory approval." *Classen*, 659 F.3d at 1070. We, of course, are bound by the *Classen* decision unless it is overruled en banc or by the Supreme Court. Accordingly, the scope of the safe harbor provision does not extend to "information that may be routinely reported to the FDA, long after marketing approval has been obtained."

This case, however, 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. Amphastar is required to conduct a laboratory determination of identity and strength of the active ingredient for each batch of enoxaparin. *See* 21 C.F.R. § 211.165(a). This test must be done according to the patented methods described in an official compendium, in this case the United States Pharmacopeia (USP). *See* 21 U.S.C. § 351(b) (Any "determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set

forth in such compendium."). Moreover, as described above, FDA regulations require that all such batch records "be retained for at least 1 year after the expiration date of the batch," 21 C.F.R. § 211.180(a), and that such records "shall be readily available for authorized inspection" by the FDA at any time, 21 C.F.R. § 211.180(c); *see also* 21 C.F.R. §§ 211.186, 211.188, 211.194 (requiring "master production and control records," "batch production and control records," and "laboratory records"). Failure to comply with these requirements could result in suspension or revocation of Amphastar's ANDA approval to market the drug. *See* 21 U.S.C. §§ 335a(g), 355(e). Furthermore, such testing is "a condition for [the drug's] approval and release" into commerce, 21 C.F.R. § 211.165(d), thus acting as a predicate to the ability to market the ANDA-approved drug to the public.

The 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 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. While 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.[1] We therefore hold that post-approval studies that are "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" fall within the scope of the § 271(e)(1) safe harbor.

In this case, Momenta concedes that Amphastar's tests "are conducted *in order to satisfy the FDA's requirements* that each batch of enoxaparin that is sold commercially after FDA approval is actually the same as the brand name drug." Appellee's Br. at 40-41 (emphasis added); *see also* J.A. 56 (allegation that the "FDA requires" the accused testing). 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 dispute in this case that Amphastar's allegedly infringing activities are carried out to "satisfy the FDA's requirements." The district court's interpretation of § 271(e)(1) was erroneous. Under the correct construction, Momenta cannot establish a likelihood of success on infringement and the preliminary injunction must be vacated. *Genentech, Inc.*, 108 F.3d at 1364.

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[1] We are puzzled by the dissent's claim that the use of the words "solely" and "submitted" require us to limit the statute to pre-approval activities. This is not the plain meaning of those words. For example, if the FDA required post-approval testing with subsequent submission of those test results, those test results were clearly generated "solely" for an FDA submission and equally clearly were "submitted" to the agency. "Solely" and "submitted" in no manner limit § 271(e)(1) to "pre-approval testing."

Momenta also argues 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. The safe harbor, however, does not mandate the use of a non-infringing 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." 35 U.S.C. § 271(e)(1). 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." This makes good sense because it eliminates liability for infringement when that act of infringement is, in effect, required by the federal government as part of the continuing safety and efficacy monitoring of an approved drug. It also avoids the situation here, where a drug has received approval, but is nevertheless kept from the market based on an FDA mandated testing requirement.

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. This 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 205-206. 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.[2]

Even if Momenta's strained reading of the statute was supportable, Amphastar's allegedly infringing activities are clearly carried out according to the dictates of the Federal Food, Drug, and Cosmetic Act. Under the Act, Amphastar is prohibited from selling a drug if it is adul-

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[2] Although the parties do not argue that FDA-mandated quality control testing during manufacturing is not done "solely" for purposes of developing and submitting information to the FDA, the dissent suggests that because Amphastar uses the patented method while manufacturing a product to sell in commerce its infringing activity does not meet the "solely" limitation in the statute. This is not a tenable reading of the statute, and is indeed contrary to precedent. The Supreme Court cases interpreting the safe harbor make clear that the safe harbor is not limited to acts which only produce information for the FDA but protects *all* acts, even interim research steps and acts that might produce other useful data, "as long as there is a reasonable basis for believing that the [act] will produce the types of information that are relevant to [a submission to the FDA]." *Merck*, 545 U.S. at 208. We have interpreted this 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").

terated. 21 U.S.C. § 331(a). A drug is adulterated if it purports to be a drug listed in an official compendium, for example the USP, but in actuality differs in composition. 21 U.S.C. § 351(b); *see also* 21 U.S.C. § 321(j) (defining "official compendium"). In order to demonstrate that a drug is not adulterated, testing must be carried out pursuant to the methods articulated in the compendium, in this case the USP. *See* 21 U.S.C. § 351(b) (Any "determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium."). "For each batch of drug product, there shall be appropriate laboratory determination of . . . the identity and strength of each active ingredient . . . ." 21 C.F.R. § 21.165(a). FDA regulations characterize this testing as "a condition for [the drug's] approval and release" into commerce. 21 C.F.R. § 211.165(d). The FDA also mandates maintenance of appropriate records related to this type of testing. *See* 21 C.F.R. § 211.180(a) (production, control, and distribution records associated with a batch of drug must be retained for at least one year after the expiration date of the batch); *see also* 21 C.F.R. §§ 211.186, 211.188, 211.194 (requiring "master production and control records," "batch production and control records," and "laboratory records").

The USP entry for enoxaparin, the drug at issue in this litigation, states: "About 20 percent of the materials contain a 1,6-anhydro derivative on the reducing end of the chain, the range being between 15 and 25 percent." J.A. 365 (USP Revision Bulletin, Official December 1, 2008). Thus, in order to be "enoxaparin" as defined in the USP entry, the marketed drug product must contain between 15 and 25 percent of the 1,6-anhydro derivative. *Id.*; *see also* 21 U.S.C. § 351(b) (drug adulterated if purports to be a drug in an official compendium but its strength, quality, or purity differs from the standard set

forth in the compendium). The USP also includes a specific test for the 1,6-anhydro derivative, which "involves HPLC analysis of a depolymerized enoxaparin sodium solution by a mixture of heparinases." J.A. 369 (USP Method <207>). As the district court explained: "Claims 6, 16, and 53 of the '886 patent describe how to analyze a sample of enoxaparin to ensure its conformity to the USP Monograph standard." J.A. 8. Amphastar is required by the FDA to use this test in order to ensure its enoxaparin is not adulterated. 21 U.S.C. § 351(b). This testing, which generates information for submission pursuant to the Food, Drug, and Cosmetic Act, therefore falls squarely within the scope of the safe harbor.

Finally, 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. Dissenting Op. at 19-20. This is not correct. The Supreme Court in *Eli Lilly* noted that equilibrium was not always achieved. *See Eli Lilly*, 496 U.S. at 671-72. 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).

III.

Under the correct interpretation of 35 U.S.C. § 271(e)(1), Momenta's admission that Amphastar's testing is carried out to "satisfy the FDA's requirements," Appellee's Brief at 40-41, makes it unlikely that Momenta will succeed on the merits of its infringement claim. The district court's findings with respect to the irreparable

harm, balance of the hardships, and public interest factors were all, to some extent, predicated on its erroneous conclusion that Momenta's patent was likely infringed by Amphastar's product. *See* J.A. 24 (applying a presumption of irreparable harm in view of Momenta's "showing of infringement and validity"); J.A. 29 (explaining that in light of the "showing of likelihood of success on the merits, the balance of hardship tips in [Momenta's] favor"); J.A. 30 (public interest favors protection of patent rights secured by valid patents). Because Momenta has not established a likelihood of success on its claim of infringement, the preliminary injunction must be vacated.

On remand, the district court may want to consider whether Momenta's admission that Amphastar's use of the patented invention is to "satisfy the FDA's requirements" makes this case amenable to summary judgment of non-infringement in favor of Amphastar. Because the safe harbor issue is dispositive, we need not reach the other arguments on appeal.

VACATED AND REMANDED

COSTS

Costs to Appellants.

United States Court of Appeals for the Federal Circuit

MOMENTA PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

and

SANDOZ, INC.,
Plaintiff-Appellee,

v.

AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., WATSON PHARMACEUTICALS, INC., AND WATSON PHARMA, INC.,
Defendants-Appellants.

2012-1062, -1103, -1104

Appeals from the United States District Court for the District of Massachusetts in Case No. 11-CV-11681, Judge Nathaniel M. Gorton.

RADER, *Chief Judge*, dissenting.

By definition, a patent defines a right to exclude. Consistent with property principles, an infringer of a valid patent is an unlawful trespasser. The remedy for trespassing, in this area of property law as well as others, is removal of the trespasser. Indeed even the Constitution acknowledges the patent owner's right to exclude

trespassers. U.S. Const. art. I, § 8, cl. 8. Thus, exceptions to the traditional property remedy amount to a get-out-of-jail-free card for the trespasser. Accordingly, such exceptions must occur only sparingly with awareness that this license allows the wrongdoer free reign to continue trespassing.

The public readily applauds the role of patents in the development and delivery to the marketplace of life-saving drugs or modern technology products like smartphones. At the same time, many incremental advances contribute to these monumental advances or, as in this case, enhance their delivery to the public. These incremental inventions also represent difficult and expensive advances in technology. For example, in this case, Amphastar had a strong incentive to invent this patented manufacturing method. As the first-filer, it would have obtained 180 days of market exclusivity as the only seller of the generic drug — a right worth $260 million per quarter. Nevertheless, Amphastar could not make that invention. Instead, the patentee Momenta made the investment, did the research, and engineered the new method disclosed in the '886 patent.

At that point, Amphastar stepped in and took Momenta's patented invention without permission and used it to manufacture each commercial batch it sells on the market. Indeed Amphastar continues to trespass and promises to trespass for years to come. In fact, as the court repeatedly acknowledges, 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*, 659 F.3d 1057 (Fed. Cir. 2011). Sadly this result will render worthless manufacturing test method patents. Accordingly, I must respectfully dissent.

I.

The Supreme Court has observed that the text alone of § 271(e)(1) can be "not plainly comprehensible." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). The purpose of this text, which ought to inform its application, however, is evident from the legislative history. The legislative history of § 271(e)(1) includes more than 2 House reports, 25 statements and letters, and many pages of Congressional testimony. A review of this extensive material 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.*, 733 F.2d 858 (Fed. Cir. 1984). In particular, § 271(e)(1) applied only in limited situations, namely pre-approval experiments to obtain FDA approval:

> 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.*, 733 F.2d 858 (Fed. Cir. 1984), the Court of Appeals for the Federal Circuit held that the **ex-**

> **perimental 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.

H.R. REP. NO. 98-857, pt. 1, at 45-46 (1984) (emphases added).

> 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.*, 733 F.2d 858 (Fed. Cir. 1984).

H.R. REP. NO. 98-857, pt. 2, at 27 (1984). *See also Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 742 (1984) (statement of Laurence H. Tribe, Professor of Law, Harvard Law School) ("Section 202, the thrust of which is to overturn *Roche v. Bolar* legislatively"); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 826 (1984) (letter from Bernarr R. Pravel, President, American Intellectual Property Law Association) ("Section 202 is intended to reverse the April 23, 1984, decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984)."); Memorandum from Congressional Research

Service, The Library of Congress, American Law Division to House Judiciary Committee, *located at* H.R. REP. NO. 98-857, pt. 2, at 27 n.18 (1984).

Roche v. Bolar held that the limited pre-approval experiments to obtain FDA approval still infringed a valid patent. *See* 733 F.2d at 861 ("The district court correctly recognized that the issue in this case is narrow: does the **limited** use of a patented drug **for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent** constitute a use which, unless licensed, the patent statute makes actionable?" (emphasis added)). In overturning *Roche v. Bolar*, § 271(e)(1) allowed pharmaceutical companies to conduct such experiments to obtain FDA approval. The new section enabled those companies to begin the approval process while the patent is still in force, so that they can obtain FDA approval and begin selling immediately *after* the patent's life. Otherwise, the safety testing processes would have to wait until after the patent's life ends thus creating a lag in time when the patent would not be in force yet the companies could not enter the market pending FDA approval:

> **In order to complete this application** the generic manufacturer must conduct certain drug tests. In order to facilitate this type of testing, section 202 of the bill creates general exception to the rules of patent infringement. Thus, a generic manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product **if the purpose of those tests is to submit an application to FDA for approval**.

130 CONG. REC. 23060 (1984) (statement of Rep. Robert W. Kastenmeier, Chairman of the Subcommittee on

Courts, Civil Liberties and the Administration of Justice, Committee on the Judiciary) (emphases added).

The Pharmaceutical Manufacturers Association echoed the Chairman's analysis of the purpose of the bill:

> The sponsors and supporters of the legislation have agreed from the beginning that generic products should not be approved for marketing prior to the expiration of a valid patent as extended under the legislation. In return, there has been a compromise agreement that **preapproval testing** could be conducted prior to the expiration of the patent, as extended, so that marketing could begin immediately thereafter. Therefore, the bill reverses the *Roche v. Bolar* decision to permit a generic company to "use" a patented product **for the limited purpose of completing the testing necessary for FDA approval.**

Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary, 98th Cong. 696 (1984) (letter from Pharmaceutical Manufacturers Association) (emphases added).

On the other side of the industry, the Generic Pharmaceutical Industry Association agreed that section 202 is only for limited pre-approval experiments:

> The purpose of the foregoing provision is to permit a generic drug manufacturer to engage in **the limited experimental activities which are necessary to obtain FDA pre-marketing approval** before a patent expires so that actual competition between the generic drug and the original drug can begin immediately after the patent covering the original drug expires. **Section**

> **202 does not authorize any activity which would deprive the patent owner of the sale of a single tablet during the life of a valid patent. In fact, the limited testing activity required to obtain FDA approval of a generic drug would not normally result in the use of even a single generic tablet for its therapeutic purpose during the life of a valid patent.**

Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary, 98th Cong. 926 (1984) (memorandum of Alfred B. Engleberg, Patent Counsel, Generic Pharmaceutical Industry Association) (emphases added).

The executive branch favored an even more limited exception than the one proposed in section 202 and enacted as § 271(e)(1). Nevertheless, it clearly understood the boundaries of section 202 to be pre-approval experimental use.

> This letter sets forth the Administration's views on H.R. 3605 … First, section 202 of title II should be amended to permit experimental use of a drug by a non-patentee only during the period in which the affected patent is in restoration period. Existing patentees have relied upon accepted doctrine indicating that use of a patented invention **for the purpose of obtaining regulatory approval** infringes that patent. Upsetting expectations of this sort could only inhibit future innovation and investment, which depend upon the integrity of the patent laws.

Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the

Admin. of Justice of the H. Comm. on the Judiciary, 98th Cong. 812 (1984) (letter from David A. Stockman, Director, Office of Management and Budget, to Rep. Edward R. Madigan, Subcomm. on Health and the Environment, H. Comm. on Energy and Commerce) (emphasis added).

The pharmaceutical industry expressed concern about permitting trespass on exclusive rights, but 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***.

Id. at 30 (emphases added).

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. 130 CONG. REC. 23060 (1984) (statement of Rep. Robert W. Kastenmeier, Chairman of the Subcommittee on Courts, Civil Liberties and the Administration of Justice, Committee on the Judiciary) (see block quote above); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 696 (1984) (letter from Pharmaceutical Manufacturers Association) (see block quote above); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 742 (1984) (statement of Laurence H. Tribe, Professor of Law, Harvard Law School) ("Section 202, the thrust of which is to over-

turn *Roche v. Bolar* legislatively, so as to provide that it is *not* an infringement to make, use, or sell a patented invention for purposes 'reasonably related' to the development and submission of information to obtain FDA's **premarketing approval** to engage in the commercial manufacture, use, or sale of the drug after patent expiration") (emphasis added); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 926 (1984) (memorandum of Alfred B. Engleberg, Patent Counsel, Generic Pharmaceutical Industry Association) (see block quote above); Memorandum from Congressional Research Service, The Library of Congress, American Law Division to House Judiciary Committee, *located at* H.R. REP. NO. 98-857, pt. 2, at 27 n.18 (1984) ("In § 202, Congress would provide that it is not an infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information **for the purpose of obtaining FDA premarketing approval of a drug**.").

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. H.R. REP. NO. 98-857, pt. 1, at 45-46 (1984) (see block quote above); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 696 (1984) (letter from Pharmaceutical Manufacturers Association) (see block quote above); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 742 (1984) (statement of Laurence H. Tribe, Professor of Law, Harvard Law

School) (quoted above); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 926 (1984) (memorandum of Alfred B. Engleberg, Patent Counsel, Generic Pharmaceutical Industry Association) (see block quote above).

In particular, the authors made 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. H.R. REP. NO. 98-857, pt. 1, at 45 (1984) ("This section **does not permit the commercial sale** of a patented drug by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredients to such party.") (emphasis added); *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 932 (1984) (memorandum of Alfred B. Engleberg, Patent Counsel, Generic Pharmaceutical Industry Association) ("The **limited 'experimental use'** permitted by Section 202 does not, in any way, impinge on the exclusive right of the patent owner to make, use and sell the patented invention for all commercial purposes during the life of the patent. **The permitted experimental use would not result in competitive commercial activity until all valid patents expired**.") (emphases added).

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. As discussed below, Amphastar has already obtained FDA regulatory approval, and today this court rewrites the law to allow Amphastar to infringe Mo-

menta'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.

Of course, this court proclaims that it finds no ambiguity requiring it to find out the purpose of the section it distorts. To the contrary, the Supreme Court found the statute can be ambiguous and "not plainly comprehensible." *See Eli Lilly*, 496 U.S. at 669. Moreover the court strains to avoid ambiguity by discounting critical statutory phrases, namely "solely" and "submission."

To 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." *See* Majority Op. 13, 14, 15, 16, 20, 21. 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.

Second, 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.

Specifically, 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. Majority Op. 16 ("We 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. Thus, we consider this information 'submitted' for purposes of the statute." (emphasis added)), 19. 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.

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. *See* 21 U.S.C. § 374. 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."

Therefore, 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. Thus, the statute limits the exception to "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."

II.

This 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." 659 F.3d at 1070 (emphasis added). As support, *Classen* looked to the legislative history: "The Report is replete with statements that the legislation concerns **premarketing approval** of generic drugs. The Report emphasizes that 'The information which can be developed under this provision is the type which is required **to obtain approval** of the drug.'" *Id.* at 1071 (emphases added).

Classen also looked to Supreme Court precedent, such as *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 1047 (1990) and *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005): "Every decision examining the statute has appreciated that § 271(e)(1) is directed to **premarketing approval** of generic counterparts before patent expiration." *Id.* at 1071 (emphasis added). In particular, *Classen* stated:

> 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,' [659 F.3d at 1083 (Moore, J., dissenting)] (emphasis in dissent), 'including information regarding **post-approval** uses.' *Id.* Such a massive enlargement of the statutory exemption is incorrect.

Id. at 1072 n.4 (bold emphasis added).

Here, Amphastar uses Momenta's patented method in the manufacture of each commercial batch it sells. By definition, its use is not to obtain FDA approval. One can only market a drug that the FDA has already approved. Amphastar is not using Momenta's patented method for pre-approval, limited experimental use. It is not *pre-approval* because Amphastar has already obtained approval. *See* Appellant Br. 7 (Amphastar received FDA approval on September 19, 2011.); Majority Op. 21 ("It also avoids the situation here, where a drug has received approval …"). Thus, its activity is post-approval. It is not *limited* because Amphastar uses Momenta's invention on a continuous basis in the manufacture of each commercial batch and during the life of Momenta's patent. It is not *experimental* because Amphastar uses Momenta's invention in manufacturing each commercial batch of its product for contemporaneous sale on the market (in commerce) to obtain profits and to compete with Momenta. This is a commercial use of an invention by a competitor to compete and trespass on the inventor's exclusive right. Amphastar's use is not for premarketing FDA approval and therefore *Classen* definitively holds that § 271(e)(1) does not apply here.

To come out the exact opposite way, the court first claims *Classen* did not turn on the pre-/post-approval distinction. Majority Op. 19. Second, the court claims

Classen merely held that § 271(e)(1) does not apply to "routine" submissions. Therefore, this court opines: "This case, however, 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." Majority Op. 18.

At the outset, this court must stretch too far to claim *Classen* did not turn on a pre-/post-approval distinction. The dissent actually helps identify the holding in *Classen*. The *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**. …" 659 F.3d at 1083 (emphases added).

Further, the parties and the amici certainly thought *Classen* turned on a pre-/post-approval distinction. *See, e.g.*, Classen's Opposition to Petition for Rehearing En Banc, at *1 ("Plaintiff-Appellant agrees with Hatch-Waxman, The United States Supreme Court and the Federal Circuit: 35 USC §271(e)(1) applies only to **pre-market development activities**, there is no safe harbor after the commencement of commercial sales of a drug. An extension of 271(e)(1) into the **post-approval/post-commercialization period** is outside the scope of the Drug Price Competition and Patent Term Restoration Act and would present unworkable difficulties in its application.") (emphases added).

Moreover, 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." Majority Op. 18. Indeed, this post-approval, continuous, commercial use is the exact opposite of the *Classen* rule. *Classen* rested its holding on "premarketing approval," 659 F.3d at 1070, 1071, "limited amount of testing," *id.* at 1071, and "experimentation," *id.*

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* ("post-approval"; "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"). This decision should instead request the entire court to resolve the issue *en banc*.

The court distinguishes *Classen* by characterizing the activities in that case as not "mandated by the FDA," while the activities here are. Some context is in order. The patented method here is "mandated" only in that Momenta thus far has created and developed the only successful method by which one can show the FDA's requirement has been met. Amphastar is free to invent its own method to satisfy these requirements. Instead it chooses to trespass. Because it has not ventured to find another way to perform these tests, it is unfair to suggest that Amphastar's hands are tied. Indeed, to the extent the court is creating a new expansion of the statute that covers anything "mandated" by the FDA, this would unfairly attack inventors of the newest and most successful method. Such a method would be adopted or "mandated" by the FDA and then trigger the court's new infringement exception. Needless to say, that would be

the exact opposite from a system that incentivizes creation and improvement.

III.

This court's interpretation of § 271(e)(1) would essentially render manufacturing method patents worthless. This court repeatedly states that the FDA's adoption of Momenta's patented method as a standard means that § 271(e)(1) should apply. Majority Op. 19 ("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"), 21 ("that act of infringement is, in effect, required by the federal government as part of the continuing safety and efficacy monitoring of an approved drug"), *id.* ("where a drug has received approval, but is nevertheless kept from the market based on an FDA mandated testing requirement"), 20 ("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"), 22 ("Amphastar's allegedly infringing activities are clearly carried out according to the dictates of the Federal Food, Drug, and Cosmetic Act").

In essence, this reasoning repeals the incentives and protections of the patent act in this area. A patentee invents the first and (at the time) best method. Because of the success and utility of the inventive method, the FDA adopts that method as a standard. Because that method is "required by the FDA," this court would permit copiers to infringe. What incentive remains to invest in inventing a better test? Imagine a teacher who rewards the top student by allowing her peers to copy her exam answers. Needless to say, this approach does violence to patent law and future research incentives in this field.

And what happens if a second, less effective (patented) method appears? Will copiers be allowed to infringe that method, too? Or, instead, because it is not as good and the FDA does not adopt it as the standard, then the court's new interpretation of § 271(e)(1) does not apply and copiers can infringe the first, best method but not the second, less effective method?

IV.

The Supreme Court cases *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 1047 (1990) and *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) support the holding in *Classen* and do not support this decision. Both 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. Nevertheless, the court takes phrases from those opinions out of context to allege that its new interpretation of § 271(e)(1) is consistent with those cases.

In *Eli Lilly*, the Supreme Court addressed whether § 271(e)(1) applies to medical devices in addition to drugs. 496 U.S. at 663-64 ("This case presents the question whether 35 U.S.C. § 271(e)(1) renders activities that would otherwise constitute patent infringement noninfringing if they are undertaken for the purpose of developing and submitting to the Food and Drug Administration (FDA) information necessary to obtain marketing approval for a medical device under § 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), 90 Stat. 552, 21 U.S.C. § 360e.").

The Supreme Court described how §§ 201 and 202 should be read together. Section 201 concerns activity in the early years of a patent's life. Section 202 concerns the

latter years. Each section is a reciprocal counter to the other. Importantly, Congress intended the sections to deal with "premarket regulatory approval":

> The parties agree that the 1984 Act was designed to respond to two unintended distortions of the 17-year 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. … 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 Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, see § 271(a), even if it was for the sole purpose of conducting tests and developing information necessary **to apply for regulatory approval**. *See Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984). 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.

496 U.S. at 669-670 (emphases added). Therefore:

> 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. … Section 201 provides that patents relating to these products can be extended up to five years … The distortion at the other end of the patent period was addressed by § 202 of the Act. … This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary **to obtain regulatory approval**."

Id. at 670-71 (emphasis added).

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. *Id.* at 672.

This court's new interpretation in this case would apply the disadvantage of § 202 to a patentee who would not be able to obtain the benefits of § 201. The patentee of a manufacturing patent does not obtain the patent extension created in § 201, yet this court's new expansion of § 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) (relying on *Merck* to hold that § 271(e)(1) does not apply to infringement of patented product not eligible to obtain patent extension).

This court's new interpretation does not reserve § 202 for the "end of the patent term." Instead, its interpreta-

tion allows infringing activity continuously throughout the life of the patent, including the "early years" reserved for § 201. If, as the court claims, § 202 was meant to cover the continuous, commercial use throughout the life of the patent, there would be no balance between § 201 and § 202. This decision improperly cuts short the life of Momenta's patent.

And, as already discussed, this new interpretation expands beyond "premarket regulatory approval." *See* 496 U.S. at 669-670. Its interpretation allows infringing activity after the product has already been approved for sale on the market.

Surprisingly, the court claims that its "analysis is not groundbreaking: the Supreme Court came to essentially the same conclusion in 1990" and cites *Eli Lilly*. Majority Op. 14. It has been quoted that "Words are easy, like the wind." Saying that something "is not groundbreaking" does not make it so.

Nowhere in *Eli Lilly* does the Supreme Court come to "essentially the same conclusion" as the majority here. The Supreme Court does not say that the mere maintenance or retention of records — with no intention to submit to the FDA but that only could potentially be viewed by the FDA if the FDA requested it — would satisfy as a "submission" to the FDA. The Supreme Court does not sanction post-approval activity. The Supreme Court does not read the word "solely" out from the statute.

It is more telling what the court's reasoning omits than what it cites. The court only relies on a single sentence from *Eli Lilly*, which it quotes out of context. 496 U.S. at 666 ("But the phrase 'a Federal law which regulates the manufacture, use, or sale of drugs' more naturally summons up the image of an entire statutory

scheme of regulation."). The Supreme Court was not even referencing the same phrase that is at issue here: "a Federal law," not "submission." In fact, that sentence is not even in the section in the Supreme Court's opinion that discusses the basis on which the Court decided the case. Instead, that sentence is in a prior section discussing the text of the statute, which the Supreme Court found "somewhat more naturally reads as the Court of Appeals determined, but that is not plainly comprehensible on anyone's view." *Id.*

The sentence cited by this court is not even a definitive holding of the Supreme Court but instead a discussion of the parties' arguments. In looking at the paragraphs following the one cited by this decision, the Supreme Court states the case for the opposing side: "On the other side of the ledger, however, one must admit that while the provision more naturally means what respondent 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, in any of its provisions, not necessarily the one at issue, regulates drugs?" *Id.* at 668. On other occasions, the Federal Circuit advises against this type of slanted wordsmithing.

In *Merck*, the Supreme Court addressed whether § 271(e)(1) applies to research intended for submission for FDA approval but ultimately not submitted to the FDA. 545 U.S. at 195 ("This case presents the question whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U.S.C. § 271(e)(1)."). In other words, the case presented an instance of limited

experiments performed in the pre-approval stage of drug development.

Nowhere does *Merck* suggest that post-approval, commercial, continuous infringing use would be permitted. Indeed, *Merck* clearly lays out that § 271(e)(1) is intended for pre-approval, experimental, limited use.

> Basic 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. It does not follow from this, however, that § 271(e)(1)'s exemption from infringement categorically excludes either (1) **experimentation** on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in **experiments** that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations." [205-06 (emphasis added)] "Moreover, many of the uncertainties that exist with respect to **the selection of a specific drug** exist as well with respect to the decision of **what research to include** in an IND or NDA. 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**.' *Intermedics, Inc. v. Ventritex, Inc.*, 775 F.Supp. 1269, 1280 (N.D.Cal. 1991), aff'd, 991 F.2d 808 (Fed. Cir. 1993). This is especially true at the preclinical stage of drug approval."

545 U.S. at 207 (emphases added).

This 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. This context is apparent in the sentences *next to* the sentence quoted by the majority, which state:

> We 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**: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under ... Federal law." § 271(e)(1).

Id. at 207 (emphases added).

Merck does not reduce the importance of the limitation that § 271(e)(1) is reserved "**solely** for uses reasonably related to the development and submission of information." Holding that preclinical research reasona-

bly 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, *id.* at 206-07, 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. Here, Amphastar's use of the patented method is primarily for production of a commercial product; it is not "solely for uses reasonably related to" development of information.

As another point, this 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.'" Majority Op. 16. 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." Imagine ordering a computer and stating that "I do not want it delivered to my house on Wednesday." Then, the post office delivered it to your neighbor's house on Thursday. Obviously, you meant to emphasize "Wednesday," not "my house." Similarly, this court must read the Supreme Court's cases as a whole and in context.

Just 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 retention of documents as part of a company's records could be considered a "submission" to the FDA. In other words, if a house owner allows a hired painter to paint his house *any*

and *all* shades of brown, that is not permission to choose neon orange or turquoise.

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."

V.

The safe harbor provision at issue in this case, due to its origin and purpose in reversing *Roche v. Bolar*, receives attention as an exception that permits experimentation. This link to experimentation and its role in advancing the progress of technology requires some commentary as well. Too often patent law is misunderstood as impeding more than promoting innovation. This academic proposition, called the tragedy of the Anticommons in some scholarly presentations, suggests that exclusive rights impede the flow of information and limit experimentation that might lead to the next generation of technological advance. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

In the first place, in an era of empirical research, one might ask the reason that this academic notion has never actually been verified. Although studied, no research has substantiated this alleged attack on the patent system. In fact, "the effects predicted by the anti-commons hy-

pothesis are not borne out in the available data." Timothy Caulfield, *Human Gene Patents: Proof of Problems?*, 84 Chi.-Kent L. Rev. 133, 137 (2009); *see also* American Association for the Advancement of Science, INTERNATIONAL INTELLECTUAL PROPERTY EXPERIENCES: A REPORT OF FOUR COUNTRIES 12 (2007) (finding the results of a 2006 survey of U.S. and Japanese researchers "offer very little evidence of an 'anticommons problem'" and that "IP-protected technologies remain relatively accessible to the broad scientific community"). Surveys of academic researchers have revealed that "only 1 percent . . . report having to delay a project, and none abandoned a project due to others' patents." Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, *in* 8 INNOVATION POLICY AND THE ECONOMY 1, 10-11 (Adam B. Jaffe, Josh Lerner, & Scott Stern eds. 2008), *available at* http://www.nber.org/~marschke/mice/Papers/cohenwalsh.pdf (citing John P. Walsh et al., *The View from the Bench: Patents, Material Transfers and Biomedical Research*, 309 SCIENCE 2002 (2005)). In other words, patents on research tools and biomedical innovations do not significantly slow the pace of research and do not deter researchers from pursuing promising projects.

The reason that patents have not been proven to impede more than stimulate technological advance is simple: it does not happen. It does not happen for several reasons. First, experiments advancing technology rarely, if ever, generate commercial value. Thus patent owners have little, if any, incentive to license or inhibit research. Stated otherwise, even if a patent owner wanted to sue or license potential researchers, experiments do not produce income or a source of damages. *See id.* at 12.

Second, in the modern age of technology, the character of technological advance has changed. The era when

the Bell Labs or some other tech center could hire the most promising engineers and essentially invent everything for the world has passed. With the vast specialization of all fields of research, advances in technology require great cooperation. A new product or a new direction in biotechnology or electronics will be produced by cooperation between a professor in Chengdu, China, a young programmer in Bangaluru, India, an engineer at a large corporation in Munich, Germany, a graduate student at Tokyo University, and a team at a small start-up company in Silicon Valley. The patent system can help inform each of them of the other and bring together their incremental advances to achieve the next generation of progress in some tiny corner of human progress.

Thus, patents 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. *See JEM Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001). 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. Even academic researchers may delay publication of results in order to maintain an edge over the competition, Cohen & Walsh, *supra* at 14, and the race to the patent office helps counteract this tendency toward secrecy by rewarding earlier disclosure. "The information in patents is added to the store of knowledge with the publication/issuance of the patent. . . . [It] is not insulated from analysis, study, and experimentation for the twenty years until patent expiration." *Classen*, 659 F.3d at 1072. Rather, information shared through patent applications is immediately avail-

able for others to build upon. It speeds the progress of scientific endeavor. In other words, the patent system's modern benefits facilitate experimentation far more than any hypothetical inhibition.

VI.

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 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.