Nos. 2014-1274, 2014-1277, 2014-1276, 2014-1278

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MOMENTA PHARMACEUTICALS, INC., SANDOZ INC.,
Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA INC.,
Defendant-Appellee.

Appeals from the United States District Court for the District of Massachusetts in No. 1:10-cv-12079-NMG, Judge Nathaniel M. Gorton

(Caption Continued on Inside Cover)

CORRECTED BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

DAVID J. HOROWITZ
Deputy General Counsel
ELIZABETH H. DICKINSON
Associate General Counsel, Food and Drug Division
ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation
WENDY S. VICENTE
Senior Counsel
Department of Health and Human Services

THOMAS W. KRAUSE
Acting Solicitor
SCOTT C. WEIDENFELLER
Acting Deputy Solicitor
FARHEENA Y. RASHEED
WILLIAM LAMARCA
Associate Solicitors
Patent and Trademark Office

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General

MARK R. FREEMAN
CAROLINE D. LOPEZ
(202) 514-4825
Attorneys, Appellate Staff
Civil Division, Room 7535
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530

MOMENTA PHARMACEUTICALS, INC., SANDOZ INC.,
Plaintiffs-Appellants,

v.

AMPHASTAR PHARMACEUTICALS, INC.,
INTERNATIONAL MEDICATION SYSTEMS, LTD.,
ACTAVIS, INC., ACTAVIS PHARMA, INC., FKA
WATSON PHARMA, INC.,
Defendants-Appellees.

Appeals from the United States District Court for the District of Massachusetts in No. 1:11-cv-11681-NMG, Judge Nathaniel M. Gorton

---

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page**

Statutes:

Regulations:

Rule:

Legislative Material:

Other Authorities:

INTRODUCTION AND SUMMARY

At the invitation of the Court, the United States respectfully submits this brief pursuant to Federal Rule of Appellate Procedure 29(a). In the view of the United States, defendants' routine use of a patented testing process in the commercial manufacture of a drug is not shielded from infringement liability by 35 U.S.C. § 271(e)(1).

Defendants are engaged in the commercial manufacture and sale of enoxaparin sodium ("enoxaparin"), a complex drug useful for treating blood clots. Before releasing a batch of the drug for sale, defendants must test to ensure that the drug they are about to distribute in interstate commerce has the required identity, strength, quality, and purity for FDA-approved enoxaparin—that is, to ensure that they are not engaged in the unlawful distribution of adulterated drugs. Every drug manufacturer, whether brand-name or generic, must conduct quality-control tests of this kind. The fact that defendants also must document the results of these routine tests (along with countless other manufacturing details) in records subject to FDA inspection does not mean that they are free to employ any patented testing process they wish, without regard to infringement liability.

Section 271(e)(1) provides a safe harbor "solely" for uses of a patented invention that are "reasonably related to the development and submission of information" to FDA. 35 U.S.C. § 271(e)(1). Routine quality-control testing as part of the ongoing commercial manufacture of a drug is not "reasonably related" to the

"development and submission of information" to FDA. That is true for at least two independent reasons.

First, defendants' conduct does not involve the "development . . . of information" at all. As used in section 271(e)(1), "development" refers to the deliberate cultivation of information for a specific goal, such as to establish the efficacy of a drug or the frequency of a particular side effect. Defendants are not engaged in the "development" of any information for FDA. Defendants manufacture enoxaparin in order to sell it commercially, not for the purpose of performing tests with (and thereby generating information about) the drug.

Second, even aside from "development," defendants' use of the patented testing process is not "reasonably related" to the "submission" of any information to FDA. Under a 2012 statutory amendment not cited by the parties, FDA has the power to require drug manufacturers to provide copies of their batch records to the agency. Defendants' use of the patented testing process, however, is not "reasonably related" to that possibility. Like every other significant step in their production, control, and distribution processes, defendants' quality-control tests principally advance defendants' commercial purpose of lawfully making and selling enoxaparin. Even if FDA did not require drug makers to maintain batch records at all, defendants

still would have to test to ensure that they are making and selling the drug for which they have FDA approval.[1]

Accepting defendants' contrary arguments would transform section 271(e)(1) into a royalty-free, open-ended statutory license for the use of patented inventions in commercial drug manufacturing. That result cannot plausibly be attributed to congressional design. Congress struck a careful balance in the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman amendments), enabling and encouraging prompt market-entry by generic drug makers while at the same time respecting valid patent rights. Yet on defendants' theory, if someone tomorrow patented a faster and cheaper method of analyzing a batch of enoxaparin, defendants could simply amend their applications to incorporate that patented process and reap its benefits on a commercial scale, without accounting to the patent owner. Nothing in the text or history of section 271(e)(1) suggests that Congress intended so sharp a departure from prior law.

INTEREST OF THE UNITED STATES

The questions presented here implicate the expertise and interests of a wide array of federal agencies and components, including the Department of Health and Human Services, the Patent and Trademark Office, the Department of Commerce,

[1] The Court also invited the government's views concerning the meaning of the statutory term "solely." For the reasons discussed below, we do not believe that term casts light on the question whether section 271(e)(1) encompasses defendants' conduct in this case.

the Federal Trade Commission, the Office of the U.S. Trade Representative, and the Antitrust Division of the Justice Department, among others. On May 7, 2015, this Court invited the United States to file a brief expressing its views.

QUESTIONS PRESENTED

The Court invited the United States to address the issues of "statutory interpretation" presented by this case, including in particular the "meaning of [35 U.S.C. § 271(e)(1)'s] 'submission' and 'solely' language" and "whether performing a process and retaining process records after initial FDA approval for the purposes of demonstrating compliance with FDA requirements is protected by the safe harbor of § 271(e)(1) if that activity also has a commercial purpose."[2]

SUPPLEMENTAL STATEMENT

The parties' briefs describe the factual and procedural history of this litigation, as well as the general operation of the regulatory scheme governing the approval of abbreviated new drug applications (ANDAs).[3] In several respects, however, the government wishes to clarify and supplement the parties' discussion of the relevant statutory and regulatory background.

---

[2] The United States does not address any other question presented in this case, including whether and to what extent the Court's prior decision in this case binds the panel now, or the proper interpretation of 35 U.S.C. § 271(g).

[3] Although the section 271(e)(1) safe harbor is not limited to ANDAs, we reference ANDAs throughout this brief because that is the relevant type of application in this litigation.

1. Batch Testing Requirements

The Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations require all drug manufacturers to take adequate steps in drug manufacturing to prevent the adulteration of drugs prevent the adulteration of drugs. *See* 21 U.S.C. § 351(a)(2)(B), (b); 21 C.F.R. § 211.180. These processes must be detailed in a company's ANDA, and their satisfactory completion must be documented during the subsequent manufacture of the drug. *See* 21 U.S.C. § 355(b)(1)(D); 21 C.F.R. § 211.180, *see also* 21 C.F.R. §§ 211.165(a), (e), 211.194(a)(2).

In particular, for each commercial batch of drugs, FDA requires drug manufacturers to comply with FDA's Current Good Manufacturing Practice regulations. *See* 21 U.S.C. § 351(a)(2)(B). Doing so ensures that the batch meets the standards of identity, strength, quality, and purity required by FDA for specified active ingredients—standards that, for many drugs, are set by the relevant United States Pharmacopoeia (USP) Monograph entry.[4] *See* 21 U.S.C. §§ 321(j), 351(b). Among other steps, a drug manufacturer must conduct and document regular tests of its final drug product to confirm that it conforms to the approved drug specifications. *See* 21 C.F.R. § 211.165(a) ("For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the

[4] *See generally* U.S. Pharmacopeial Convention, About USP (2015), http://www.usp.org/about-usp (last visited July 7, 2015) (describing the USP, a non-profit scientific organization). In other cases, FDA itself sets the relevant standards.

drug product, including the identity and strength of each active ingredient, prior to release."). These batch-testing requirements apply to all manufacturers of drug products approved for distribution in the United States.

To satisfy the batch-testing requirement, a manufacturer has considerable latitude to employ any test protocol that meets the requirements specific to FDA's approval of that drug, provided that the "accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm" are "established and documented." 21 C.F.R. § 211.165(e). If the manufacturer elects to use a testing method approved by the USP or other recognized references, a simple "statement indicating the method and reference will suffice." 21 C.F.R. § 211.194(a)(2); *see id.* § 211.165(e) (providing that testing methods may be validated "in accordance with § 211.194(a)(2)"). Alternatively, FDA regulations provide that a manufacturer generally can validate its testing method by attesting that it has used the method identified in its approved ANDA. *Id.* § 211.194(a)(2) (testing methodology is sufficient "[i]f the method employed is . . . detailed in an approved new drug application and the referenced method is not modified"). Whatever the testing method employed, FDA requires that drug manufacturers "maintain[]" records of these batch tests—and of many other steps of the drug-manufacturing process—and make the records available for FDA's inspection. *See id.* § 211.180(a)-(c); *see also* 21 U.S.C. § 374(a)(1), (a)(4)(A).

In anticipation of these requirements, an ANDA applicant must "submit . . . a full description of the methods used in, and the facilities and controls used for, the

manufacture, processing, and packing" of the drug as part of its application, 21 U.S.C. § 355(b)(1)(D), including the manufacturer's anticipated batch-testing methods. After approval, the manufacturer must notify FDA if it intends to change any of the "conditions" described in the ANDA. *See* 21 C.F.R. § 314.70(a). Certain changes to the manufacturing methods identified in the ANDA—including changes to quality controls—may require a supplemental application, depending on the potential consequences of the change for "the identity, strength, quality, purity, or potency of the drug product." 21 C.F.R. § 314.70(b), (c); *see also* 21 U.S.C. § 356a. Less significant changes may be made merely upon notice to FDA in an annual report. 21 C.F.R. § 314.70(d); *see also* 21 U.S.C. § 356a(d)(2). Thus, a drug manufacturer typically must follow the batch-testing methods set out in its ANDA, and must routinely document that it has done so in its batch records, unless it complies with the requirements described above.

2. Submission of Batch Records to FDA

As noted above, a drug manufacturer must "maintain[]" its batch records for possible inspection by FDA. 21 C.F.R. § 211.180(a)-(c). The parties have focused on the question of whether this maintenance requirement qualifies as a "submission" for purposes of the safe harbor in 35 U.S.C. § 271(e)(1).

In 2012, however, Congress amended the FDCA to authorize the FDA to require drug manufacturers to "provide[]" to the Secretary copies of any records that FDA has the right to inspect:

> Any records or other information that the Secretary may inspect under this section . . . shall, upon the request of the Secretary, be provided to the Secretary . . . in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person.

Pub. L. No. 112–144, tit. VII, § 706, 126 Stat. 993, 1068 (2012) (codified at 21 U.S.C. § 374(a)(4)(A)). Consequently, FDA may now require a drug manufacturer to "provide[]" to the agency any batch records, including batch-testing records, that the drug manufacturer maintains.

ARGUMENT

I. Section 271(e)(1) Does Not Protect Defendants' Commercial Use Of Momenta's Patented Invention Because That Use Is Not Reasonably Related To The Development And Submission Of Information To FDA

Every company engaged in the commercial manufacture of a drug must conduct routine quality-control tests to ensure that the drug it is selling in fact conforms to the FDA specifications for that drug. And every drug manufacturer must document its compliance with this and myriad other FDA good-manufacturing requirements on an ongoing basis. Routine quality-control testing and record-keeping of this kind is not "reasonably related" to the "development and submission of information" to FDA. To conclude otherwise would transform the limited safe harbor in section 271(e)(1) into something Congress never intended: an open-ended, royalty-free license to infringe a valid patent in commercial drug production.

A. In Enacting Section 271(e)(1), Congress Intended To Preserve Patent Rights In Commercial Competition Between Drug Companies

Any analysis of the safe harbor must start by recognizing the balance struck by Congress in the Hatch-Waxman amendments: enabling generic drug manufacturers to bring their products to market promptly, while at the same time respecting patent holders' exclusive rights. The preservation of valid patent rights between competing drug companies was an explicit goal of the legislation. Indeed, as the Supreme Court has emphasized, one of the "key features" of the Hatch-Waxman amendments was the creation of "special procedures for identifying, and resolving, related patent disputes," including the "paragraph IV" process for provoking patent litigation. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228-29 (2013). Nothing in the text or history of section 271(e) suggests that Congress intended to immunize any commercial drug-manufacturing activity from patent-infringement claims by competitors.

The safe harbor in section 271(e)(1) was meant to reinforce this careful balance. Congress enacted section 271(e)(1) in response to this Court's decision in *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), in which this Court held that a generic drug company's use of a patented drug compound during the term of the patent in order to complete the statutory and regulatory steps necessary to bring a generic version of the drug to market after expiration of the patent constituted an infringement of the patent. *Roche Products, Inc.*, 733 F.2d at 858. In so holding, the Court acknowledged the objection that, by delaying FDA approval of the generic

drug, this interpretation of the patent laws effectively awarded the brand-name manufacturer an extension of its patent term. *See id.* at 864. But the Court concluded that the matter was properly a subject for Congress. *Id.* at 864-65.

In response, Congress eliminated the effective extension of the patent term by "allow[ing] competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990); *see* H.R. Rep. 98-857, pt. 1, at 45 (1984). And by defining the activities shielded from infringement claims in terms of the "development and submission of information" to FDA, Congress ensured that patent infringement claims also would not impede drug manufacturers from conducting necessary safety studies and other supplementary research following approval of their ANDAs. *Cf. Momenta Pharms., Inc. v. Amphastar, Inc.*, 686 F.3d 1348, 1354-55 (Fed. Cir. 2012) (*Momenta I*). But Congress did not take the further step of authorizing any drug company, generic or otherwise, to infringe a competitor's patent in the commercial manufacture and sale of a drug. Rather, the legislation permitted patent holders to exclude others from the marketplace for the full term of their patents. *See* H.R. Rep. No. 98-857, pt. 1, at 45-46; *id.* pt. 2, at 8-9, 29-30; *cf. Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed Cir. 2008). Overall, the safe harbor was intended to have only a "*de minimis*" effect on the exclusive rights of patentees insofar as it authorizes only experimentation, and not marketing, during the term of a patent. *See* H.R. Rep. No. 98-857, pt. 2, at 30.

Congress thus recognized in section 271(e)(1) that non-commercial experimentation is often a necessary prelude to obtain FDA approval for commercial manufacturing and sale, and it sought to immunize such experimentation from infringement liability during the period while competitors' patents remained in force. But Congress did not seek to immunize otherwise-infringing *commercial* conduct from patent claims by competitors. Indeed, Congress explicitly juxtaposed the information-development activities immunized from infringement claims under 35 U.S.C. § 271(e)(1) with the filing of an application seeking regulatory approval for "the commercial manufacture, use, or sale of a drug" during the term of a patent, which is the subject of 35 U.S.C. § 271(e)(2).

Defendants' proposed interpretation of section 271(e)(1) would radically alter the balance that Congress struck by immunizing routine, ongoing commercial activity from patent infringement claims by competitors. FDA requires drug manufacturers to maintain records of numerous steps of the drug-manufacturing process. *See* 21 C.F.R. § 211.180(a)-(c). Indeed, Congress has authorized the FDA to inspect *all* records relating to whether adulterated, misbranded, or otherwise unauthorized prescription drugs "have been or are being manufactured, processed, packed, transported, or held" in violation of the FDCA. 21 U.S.C. § 374(a)(1)(B). An interpretation of section 271(e)(1) that encompassed the routine generation and recording of information in drug manufacturing—even limited, as defendants contend here, to tests designed to confirm the identity, strength, quality, or purity of a drug product's active

ingredients—would therefore immunize a broad range of commercial activity from infringement claims. Moreover, as Judge Dyk observed at oral argument, because a generic manufacturer is required to document on an ongoing basis that it is adhering to the manufacturing and control processes proposed in its ANDA, endorsing defendants' arguments would have the peculiar "boot-strapping" effect of allowing generic drug makers to grant themselves royalty-free licenses simply by proposing in their ANDAs to employ the patented inventions. *See Momenta Pharmaceuticals, Inc. et al v. Amphastar Pharmaceuticals et al.*, Nos. 2014-1274, 2014-1276 (Oral Argument), at 48:30–48:59 (Judge Dyk); *see also* 21 C.F.R. § 211.165(a), (d)-(e), 211.194(a)(2).

In sum, if defendants' interpretation of section 271(e)(1) were correct, it would mean that Congress enacted—indirectly, and without a whisper of discussion in the legislative history—the first and only mandatory, royalty-free license for ordinary commercial activity in the Patent Act. As we explain below, that interpretation cannot be reconciled with the statutory text, which encompasses "solely" uses of a patented invention that are "reasonably related to the development and submission of information" to FDA. 35 U.S.C. § 271(e)(1).

B. Defendants' Conduct Does Not Constitute The "Development" Of Information For FDA

Section 271(e)(1) only immunizes uses of patented inventions that are "reasonably related to *the development* and submission of information" under a federal law that regulates drugs. 35 U.S.C. 271(e)(1) (emphasis added). Defendants are not

engaged in the "development . . . of information" for FDA when they manufacture enoxaparin for ordinary, commercial purposes, merely because they conduct routine, confirmatory tests on each batch and record the results.

As used in section 271(e)(1), "development" requires more than the simple collection of information. The statutory phrase "development . . . of information" connotes the purposeful cultivation of information for a specific goal, such as a controlled experiment designed to produce drug-safety data that would not otherwise exist. *Cf. American Heritage Dictionary* 389 (2d college ed. 1982) (defining "develop" to mean, *inter alia*, "[t]o elaborate or enlarge: *develop an idea*" or "[t]o bring into being; make active: *develop industry*"); *Webster's Ninth New Collegiate Dictionary* 347 (1985) ("to work out the possibilities of," "to make active," or "to promote the growth of"). At a minimum, "development" implies more than the mere collection of information that is generated incidental to commercial activity, even if that information may reflect or relate to an FDA regulatory requirement (as nearly all information generated in the commercial manufacture of a drug will). *Cf.* U.S. Amicus Br. at 18, *GlaxoSmithKline v. Classen Immunotherapies, Inc.,* No. 11-1078 (U.S. Dec. 13, 2012), 2012 WL 6206566, at *18 (U.S. *Classen* Br.).

Here, defendants routinely use a patented quality-control testing process owned by their competitor, Momenta Pharmaceuticals, Inc., and licensed to Sandoz Inc. (collectively, Momenta) to select appropriate batches of enoxaparin for commercial

sale.[5] *Momenta I*, 686 F.3d at 1351. Defendants are not manufacturing enoxaparin to "develop[]" information for FDA; they are engaged in the straightforward, commercial manufacture of a generic drug. In doing so, defendants conduct routine batch tests and record the results, together with myriad other information, in records that FDA may one day elect to review. But defendants are not in any meaningful sense engaged in the "development" of information for FDA.

Because defendants' alleged use of Momenta's patented process is not directed to the "development" of information for FDA, it is not protected by the safe harbor. By contrast, defendants *would* be covered by the safe harbor if, for example, they used Momenta's patented process to perform a post-approval study or clinical trial of enoxaparin to "assess a known serious risk related to the use of the drug involved" or to "identify an unexpected serious risk when available data indicates the potential for a serious risk," 21 U.S.C. § 355(o)(3). Such studies, even though conducted after initial FDA approval, would involve the "development . . . of information" for FDA.

As this Court recently made clear, moreover, if defendants were engaged in conduct legitimately protected by section 271(e)(1), they could use the information thereby generated for commercial purposes as well: the mere fact that immunized conduct yields commercially useful information does not negate application of the

[5] For purposes of this brief, the government accepts as true the well-pleaded factual allegations in Momenta's complaint. We express no view on whether defendants' conduct in fact constitutes infringement.

safe harbor, provided that the commercial use is not itself an act of infringement. *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 898 (Fed. Cir. 2015) (citing *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1523–24 (Fed Cir. 1992)). But that does not mean that defendants can infringe a patented invention in routine, ongoing commercial activity, without accounting to the patent owner, merely because they retain quality-control information related to those commercial activities in records that might be reviewed by FDA. That is not the sort of "development . . . of information" that Congress intended section 271(e)(1) to reach.

C. Defendants' Conduct Is Not "Reasonably Related" To The "Submission" Of Information To FDA

Defendants also are ineligible for the statutory safe harbor for the additional reason that their conduct is not "reasonably related" to the "submission" of information to FDA.

1. FDA May Require The "Submission" Of Batch Records

Momenta has argued that the FDCA and FDA's implementing regulations distinguish between the affirmative submission of information to FDA, on the one hand, and passive record-keeping requirements on the other. *See generally* Momenta Opening Br. (Nos. 14-1274, 14-1277) 39-44; Momenta Opening Br. (Nos. 14-1276, 14-1278) 38-44. The United States agrees that, in general, a simple requirement to maintain records for possible inspection is not the same as an affirmative

"submission" of information to FDA. If Congress had meant to encompass the mere maintenance of records in section 271(e)(1), it easily could have so provided.

In 2012, however, in a provision not cited by the parties, Congress amended the FDCA to authorize the FDA to require that copies of "[a]ny records or other information that the Secretary may inspect" be "provided to the Secretary." *See* Pub. L. No. 112–144, tit. VII, § 706, 126 Stat. 993, 1067 (2012) (codified at 21 U.S.C. § 374(a)(4)(A)). Consequently, it is now at least theoretically possible that a drug manufacturer could be required to "provide[]" to FDA copies of its batch-testing records documented under 21 C.F.R. § 211.165(a), which are among the many types of records "that the Secretary may inspect," 21 U.S.C. § 374(a)(1)(B), (a)(4)(A). Under the plain language of section 271(e)(1), that affirmative act would constitute a "submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."[6]

[6] The 2012 amendment at 21 U.S.C. § 374(a)(4)(A) uses the verb "provide[]," not "submit." But there is no sound reason to construe the term "submission" in section 271(e)(1) to exclude the provision of information to FDA pursuant to the 2012 amendment. Indeed, the FDCA and its implementing regulations at times use the words "submit" and "provide" interchangeably. For example, the FDCA instructs tobacco manufacturers to "provide" to FDA the same type of information for new products that they are required to "submit" for existing tobacco products. *See* 21 U.S.C. § 387d(a) (for existing tobacco products, "[e]ach tobacco product manufacturer . . . shall *submit* to the Secretary" certain health-related information) (emphasis added); *id.* § 387d(c) (when introducing a new tobacco product, "the manufacturer of such product shall *provide* the information required under subsection (a)") (emphasis added); *see also*, *e.g.*, 21 C.F.R. § 803.56 (specifying, with respect to medical device manufacturers, that "when you obtain information required under this

Continued on next page.

2. Defendants' Conduct Is Not "Reasonably Related" To The "Submission" Of Information

Although FDA may now require the submission of manufacturing batch records, defendants' "use" of the patented invention is not "reasonably related" to the possibility of such a submission. Section 271(e)(1) does not immunize *all* uses of patented inventions that happen to yield information that is submitted to FDA, but "solely" those uses that are "reasonably related" to that statutory end. Defendants' ongoing use of Momenta's patented quality-control testing process to select batches of enoxaparin for commercial distribution is not "reasonably related" to the attenuated prospect of an FDA request for the submission of batch records.

Congress carefully defined the "uses" of patented inventions that would fall within the safe harbor. Recognizing that experimentation requires room for failure, *see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206-07 (2005), Congress did not limit the safe harbor to only those uses of patented inventions that actually yield submissions to FDA. At the same time, Congress recognized that extending the safe harbor to every "use" of a patented invention that is in some sense causally related to an FDA submission would potentially immunize a vast range of conduct from infringement liability. Accordingly, intending to craft a safe harbor that would have only a "*de minimis*" effect on the exclusive rights of patent owners, *see* H.R. Rep. No.

---

part that you did not *provide* because it was not known or was not available when you *submitted* the initial report, you must *submit* the supplemental information to us within 1 month of the day that you receive this information") (emphasis added).

98-857, pt. 2, at 30, Congress specified that only those uses of patented inventions that are "reasonably related" to the development and submission of information to FDA would be shielded from infringement claims.

The phrase "reasonably related" in section 271(e)(1) requires a substantial, proximate relationship between a defendant's use of a patented invention and the development and submission of information to FDA. That predicate ordinarily will be satisfied when, for example, a drug maker uses a patented invention in the course of preparing a new drug application or an ANDA, or when a drug company conducts post-approval studies to investigate new safety concerns at FDA's request. But the exploitation of another's patented invention in the ordinary commercial production of a drug will not normally bear the same sort of substantial, proximate relationship to the development and submission of information to FDA. For example, a drug maker's use of a patented invention in routine commercial activity is not immune from infringement liability merely because the company also might report adverse reactions to FDA pursuant to 21 C.F.R. §§ 314.80, 600.80. *Cf.* U.S. *Classen* Br. 18.

Likewise, here, defendants' use of Momenta's patented invention in the routine commercial manufacture of enoxaparin incidentally generates information that may at some point be shared with FDA—*i.e.*, to verify that defendants complied with FDA's Current Good Manufacturing Practice requirements by following the testing procedure that defendants described in their ANDAs. But that does not mean that defendants' use of the patented invention is "reasonably related" to that hypothetical

submission. Unlike the drug company in *Merck*, defendants are not hoping or intending to incorporate their test results into any proximately related, affirmative submission to FDA. Defendants would presumably be content if FDA never asked to see their batch records.

Instead, defendants' quality-control tests are simply a necessary corollary of their commercial manufacture of enoxaparin. Indeed, defendants would have to conduct some version of the testing at issue in this case even absent any FDA requirement to prepare or maintain batch records. Defendants' use of Momenta's patented process allows defendants to ensure that the generic drug they are distributing in interstate commerce in fact conforms to FDA's specifications for enoxaparin—*i.e.*, that they are not engaged in the illegal manufacture and distribution of adulterated drugs. *See* 21 U.S.C. § 331(a)-(b) (prohibition on manufacture and sale of adulterated drugs); *id.* § 333(a) (criminal penalties); *id.* § 351(a)(2)(B) (drug is adulterated if manufacturing does not comply with the Good Manufacturing Practice requirements); *id.* § 351(b) (drug is adulterated if it "purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium," unless plainly stated on the label). Absent use of Momenta's patented process or another similar method, batches of defendants' commercial product might be adulterated because the appropriate enoxaparin lots might not be selected. *Every* drug manufacturer must conduct quality-control tests of this kind, wholly apart from

any informational or record-keeping requirement, if it wishes to remain in business. *See*, *e.g.*, 21 U.S.C. §§ 331(a)-(b), 333(a), 351(a)(2)(B). Routine testing for that purpose is not "reasonably related to the development and submission of information" to FDA.

It is no answer to say that federal law requires drug makers to take steps to avoid adulteration. Section 271(e)(1) is not a general license for the infringement of patents when necessary to comply with the FDCA or FDA regulations. Although FDA does not, in fact, require defendants to use Momenta's patented invention to meet the USP standard, *see* USP Revision Bulletin, Enoxaparin Sodium and Enoxaparin Sodium Injection,[7] the safe harbor would not protect defendants even if use of that invention were unavoidable. The Patent Act's prohibition on the unauthorized use of patented inventions applies even where the use of a particular invention is legally or practically essential to the commercial manufacture of a beneficial product. Indeed, one premise of the paragraph IV certification provisions of the Hatch-Waxman amendments is that patent owners are entitled to exclude generic competition if their patents are judged to be valid and infringed. Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1586 (codified at 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). The

[7] Available at http://www.usp.org/usp-nf/official-text/accelerated-revision-process/accelerated-revision-history/enoxaparin-sodium-and-enoxaparin-sodium-injection (last visited July 7, 2015). Indeed, Momenta represents in its briefing that FDA approved its ANDA even though Momenta listed a different procedure to meet the requirements of the USP Monograph. *See, e.g.*, Momenta Opening Br. (Nos. 14-1274, 14-1277) 36; Momenta Opening Br. (Nos. 14-1276, 14-1278) 34.

availability of the section 271(e)(1) safe harbor turns, not on whether particular conduct is necessary to achieve compliance with the substantive requirements of the federal drug laws, but on whether that conduct is "reasonably related to the development and submission of information" to FDA. 35 U.S.C. § 271(e)(1). Defendants' routine use of Momenta's patented testing process in connection with the commercial manufacture of enoxaparin is not "reasonably related" to any such development or submission.

Defendants also have contended that their use of the particular testing method at issue here is reasonably related to the development and submission of information to FDA because Momenta's test yields information relevant to the specific measure that the USP endorses as the standard of identity for enoxaparin—*i.e.*, that the product contains a 1,6 anhydro ring structure at the reducing ends of between 15-25% of its oligosaccharide chains. But that is no meaningful limitation at all. The USP sets forth standards of identity for thousands of drugs. And it is not merely "identity" that a drug maker must show; a drug also is adulterated if it fails to adhere to the requirements of "strength, quality, [and] purity" prescribed in the official compendium. *See* 21 U.S.C. § 351(b); *see also* 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. § 211.165(a). Defendants' interpretation of section 271(e)(1) would thus sweep within the safe harbor any patented method (or, presumably, apparatus) useful for establishing that a manufactured drug has the identify, strength, quality, or purity

required by the USP. And there is no reason why defendants' theory would not apply beyond the drug context as well. *Cf. Eli Lilly*, 496 U.S. at 673-74.

Similarly, defendants have argued that their interpretation of section 271(e)(1) would affect only those patented methods, like Momenta's process of analyzing enoxaparin, designed to generate information. *See* Oral Argument at 54:35-55:39 (counsel for Amphastar). The FDA recordkeeping requirements on which defendants rely, however, do not distinguish between testing patents and other manufacturing patents. Rather, they encompass a broad swath of information in "any" and "all" records that could pertain to adulteration, misbranding, drug components, drug product containers, or any other information "otherwise bearing on violation of this chapter." *See* 21 C.F.R. § 211.180(a); *see also* 21 U.S.C. § 374(a)(1)(B), (a)(4)(A). Thus, the "information" that defendants contend is "develop[ed] and submit[tted]" as part of a manufacturer's batch records is not limited to the type of test results at issue here, but also would include information demonstrating that, for each batch of drugs, the manufacturer followed all other manufacturing protocols in its ANDA. *Cf.* 21 C.F.R. §§ 211.165(a), 314.70(a)(1)(i).

Finally, there is no evident limit under defendants' reading to the ability of a drug maker to adjust its commercial manufacturing and testing methods to exploit new patented technologies. On defendants' theory, if someone tomorrow patented a faster and cheaper method of analyzing a batch of enoxaparin, defendants could simply amend their ANDAs to incorporate that patented process and reap its benefits

on a commercial scale, without accounting to the patent owner. That result cannot plausibly be attributed to congressional design.

II. Momenta Erroneously Relies On The "Solely" Limitation In Section 271(e)(1)

For the foregoing reasons, defendants are not entitled to the protection of section 271(e)(1)'s safe harbor. Momenta is mistaken, however, in relying on the term "solely" in seeking reversal of the district court's decision. *See*, *e.g.*, Momenta Opening Br. (Nos. 14-1274, 14-1277) 46-48; Momenta Opening Br. (Nos. 14-1276, 14-1278) 45-48.

Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention "*solely* for uses reasonably related to the development and submission of information" under a federal law that regulates drugs. 35 U.S.C. 271(e)(1) (emphasis added). Congress thereby made clear that the only "uses" of a patented invention to which the safe harbor's protection extends are those that are "reasonably related to the development and submission of information" to FDA. Thus, if a generic drug company makes multiple, independent uses of a patented invention, (*e.g.*, by selling a patented drug commercially, while also administering it to research subjects during a controlled study), one use might provide a basis for infringement liability, even though the other is eligible for the safe harbor. *Cf.* U.S. *Classen* Br. 17. In this way, the term "solely" operates as an important limitation on the reach of section 271(e)(1). *Cf.* Oral Argument at 44:00-44:34 (Judge Moore).

In this case, Momenta relies on the fact that defendants employ the results of the patented testing method in two distinct ways: to determine whether each tested batch of enoxaparin should be sold commercially or instead discarded, and to document the test results in the company's batch records for possible FDA inspection. Characterizing each of these applications as a separate "use," Momenta argues that, because the first of these "uses" is unrelated to the submission of information to FDA, the word "solely" renders the section 271(e)(1) safe harbor inapplicable. *See*, *e.g.*, Momenta Opening Br. (Nos. 14-1274, 14-1277) 36; Momenta Opening Br. (Nos. 14-1276, 14-1278) 34; Momenta Reply Br. (Nos. 14-1276, 14-1278) 18-19. That argument is misplaced, however, because the "uses" with which section 271(e)(1) is concerned are uses *of the patented invention—i.e.,* discrete infringing acts. Here, defendants conduct the patented testing method only once for each batch of enoxaparin, the results of which they both exploit for commercial purposes and record in batch records. There is, consequently, only a single relevant "use" in the sense of section 271(e)(1) in this case. The relevant question is whether that use is "reasonably related to the development and submission of information" to FDA. For the reasons already discussed, it is not.

CONCLUSION

For the foregoing reasons, the safe harbor in 35 U.S.C. § 271(e)(1) does not immunize defendants' conduct.

Respectfully submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General

MARK R. FREEMAN

s/ Caroline D. Lopez
CAROLINE D. LOPEZ
(202) 514-4825
Attorneys, Appellate Staff
Civil Division, Room 7535
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530

DAVID J. HOROWITZ
Deputy General Counsel

ELIZABETH H. DICKINSON
Associate General Counsel, Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

WENDY S. VICENTE
Senior Counsel
Department of Health and Human Services

THOMAS W. KRAUSE
Acting Solicitor
SCOTT C. WEIDENFELLER
Acting Deputy Solicitor
FARHEENA Y. RASHEED
WILLIAM LAMARCA
Associate Solicitors
Patent and Trademark Office

JULY 2015

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing amicus brief complies with the requirements of Fed. R. App. P. 32(a)(5) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) and 29(d) because it contains **5,911 words**, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/ Caroline D. Lopez
CAROLINE D. LOPEZ

CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2015, I electronically filed the foregoing corrected amicus brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

s/ Caroline D. Lopez
CAROLINE D. LOPEZ