809 F.3d 610
United States Court of Appeals,
Federal Circuit.

MOMENTA PHARMACEUTICALS, INC., Sandoz Inc., Plaintiffs–Appellants
v.
TEVA PHARMACEUTICALS USA INC., Defendant–Appellee.
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.

Nos. 2014–1274, 2014–1277, 2014–1276, 2014–1278.
|
Nov. 10, 2015.

Synopsis
Background: Drug manufacturer brought patent infringement action against generic drug manufacturers. The District Court for the District of Massachusetts, Nathaniel M. Gorton, J., 882 F.Supp.2d 184, denied generic manufacturers' emergency motion to dissolve or stay a preliminary injunction previously entered in the case, and manufacturers appealed. The United States Court of Appeals for the Federal Circuit, Moore, Circuit Judge, 686 F.3d 1348, vacated and remanded. On remand, the District Court, Nathaniel M. Gorton, J, 962 F.Supp.2d 348, entered summary judgment in generic manufacturer's favor. Drug manufacturer appealed.

Holdings: The Court of Appeals, Wallach, Circuit Judge, held that:

[1] generic manufacturer's generic versions of drug were not "made by" drug manufacturer's patented process, and

[2] generic drug manufacturer's use of drug manufacturers's patented method was not protected by safe harbor statute.

Affirmed in part, vacated in part, and remanded.

Dyk, Circuit Judge, concurred in part and dissented in part, and filed opinion.

West Headnotes (15)

[1] Courts
Particular questions or subject matter

Court of Appeals for the Federal Circuit reviews summary judgment decisions under the law of the regional circuit.

5 Cases that cite this headnote

[2] Patents
Importation and sale or use of imported article

Generic drug manufacturers' generic versions of drug that prevented blood clots were not "made by" drug manufacturer's patented process, and thus did not infringe patent under statute prohibiting the unauthorized importation into the United States, or sale or use within the United States of a "product which is made by a process patented in the United States," where patented process that generic manufacturer used was method to analyze generic drug samples, rather than to manufacture drugs. 35 U.S.C.A. § 271(g).

1 Cases that cite this headnote

[3] Patents
Plain, ordinary, or customary meaning in general

In patent law, as in all statutory construction, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.

[4] Patents
Importation and sale or use of imported article

Word "made" as used in statute prohibiting the unauthorized importation into the United

States, or sale or use within the United States of a "product which is made by a process patented in the United States," meant manufacture, and extended to the creation or transformation of a product, such as by synthesizing, combining components, or giving raw materials new properties, but did not extend to testing to determine whether an already-synthesized drug substance possessed existing qualities or properties. 35 U.S.C.A. § 271(g).

1 Cases that cite this headnote

[5] Patents

Importation and sale or use of imported article

A product is not "made by" a patented process within the meaning of the statute prohibiting the unauthorized importation into the United States, or sale or use within the United States of a "product which is made by a process patented in the United States," if it is used merely to determine whether the intended product of a separate and perhaps separately-patented process has in fact already been manufactured. 35 U.S.C.A. § 271(g).

1 Cases that cite this headnote

[6] Patents

Safe harbor for drug development

Purpose of safe harbor statute providing that it is not an act of patent infringement for a generic drug maker to import or test a patented drug in preparation for seeking Food and Drug Administration (FDA) approval if marketing of drug would occur after expiration of patent is to facilitate market entry upon patent expiration. 35 U.S.C.A. § 271(e)(1).

[7] Patents

Safe harbor for drug development

The safe harbor statute providing that it is not an act of patent infringement for a generic drug maker to import or test a patented drug in preparation for seeking Food and Drug Administration (FDA) approval if marketing of drug would occur after expiration of patent applies to medical devices, and is not restricted to pre-approval activities. 35 U.S.C.A. § 271(e)(1).

3 Cases that cite this headnote

[8] Patents

Safe harbor for drug development

The safe harbor statute providing that it is not an act of patent infringement for a generic drug maker to import or test a patented drug in preparation for seeking Food and Drug Administration (FDA) approval if marketing of drug would occur after expiration of patent does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained. 35 U.S.C.A. § 271(e)(1).

3 Cases that cite this headnote

[9] Courts

Previous Decisions in Same Case as Law of the Case

Whether to apply the "law of the case doctrine," under which a court will not generally revisit an issue once decided in the litigation, is a matter which rests on discretion.

[10] Courts

Previous Decisions in Same Case as Law of the Case

For the law of the case doctrine, under which a court will not generally revisit an issue once decided in the litigation, to apply, the issue must have actually been decided; findings of fact and fact-intensive conclusions of law made by a court in the preliminary injunction context are not binding.

[11] Federal Courts

Former decision as law of the case

Law of the case doctrine, under which a court will not generally revisit an issue once decided in the litigation, did not apply to issue of generic drug manufacturer's eligibility for protection

from liability for patent infringement under safe harbor statute providing that it is not an act of patent infringement for a generic drug maker to import or test a patented drug in preparation for seeking Food and Drug Administration (FDA) approval if marketing of drug would occur after expiration of patent, in drug manufacturer's patent infringement action against generic manufacturer, since drug manufacturer was not seeking to relitigate an issue that was conclusively decided on prior appeal. 35 U.S.C.A. § 271(e)(1).

[12] Courts

Previous Decisions in Same Case as Law of the Case

Under law of the case doctrine, it is not improper for a court to depart from a prior holding if convinced that it is clearly erroneous and would work a manifest injustice.

[13] Patents

Safe harbor for drug development

Generic drug manufacturer's use of drug manufacturer's patented method of quality control testing its generic drugs within the United States as part of the post-approval, commercial production process was routine and not reasonably related to the development and submission of information to the Food and Drug Administration (FDA), and thus was not protected by safe harbor statute providing that it is not an act of patent infringement for a generic drug maker to import or test a patented drug in preparation for seeking FDA approval if marketing of drug would occur after expiration of patent, in drug manufacturer's patent infringement action against generic manufacturer, where information generated as each batch of drug substance was tested was habitually, regularly, and repeatedly recorded and retained as required by regulation. 35 U.S.C.A. § 271(e)(1); 21 C.F.R. §§ 211.165, 211.180, 211.186, 211.188, 211.194.

5 Cases that cite this headnote

[14] Courts

Particular questions or subject matter

Decisions of Court of Appeals for the Federal Circuit whether to allow an amendment to pleadings after the scheduling order deadline are reviewed under the law of the regional circuit.

1 Cases that cite this headnote

[15] Patents

In general; utility

US Patent 7,575,886. Cited.

Attorneys and Law Firms

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Before DYK, MOORE, and WALLACH, Circuit Judges.

Opinion

Opinion concurring in part and dissenting in part filed by Circuit Judge DYK.

WALLACH, Circuit Judge.

Plaintiffs-appellants Momenta Pharmaceuticals, Inc. and Sandoz Inc. (collectively, "Momenta") appeal the district court's decision finding Teva Pharmaceuticals USA Inc. ("Teva") does not infringe U.S. Patent No. 7,575,886 ("the '886 patent"). In a companion case, Momenta appeals the district court's decision finding Amphastar Pharmaceuticals, Inc., International Medication Systems, Ltd., Actavis, Inc., and Actavis Pharma, Inc. (collectively, "Amphastar") do not infringe the '886 patent.

For the reasons set forth below, this court affirms the district court's holdings that neither Teva nor Amphastar infringes under 35 U.S.C. § 271(g) (2012). However, this court vacates the district court's grant of summary judgment in favor of Amphastar to the extent it was based on the erroneous determination that Amphastar's activities fall within the § 271(e)(1) safe harbor and therefore do not infringe under 35 U.S.C. § 271(a). We accordingly remand as to Amphastar for further proceedings consistent with this opinion.

BACKGROUND

Enoxaparin is an anticoagulant that helps to prevent blood clots that was first approved for marketing in the United States in 1993 under the trade name Lovenox. In 2010, Momenta became the first company to market a generic version of enoxaparin. Momenta is also the assignee of the '886 patent, which is directed to a process used to ensure each batch of generic ***614** enoxaparin meets certain quality standards.

Teva, another generic manufacturer, sought to enter the enoxaparin market. It does not manufacture enoxaparin itself, but sources the product from Chemi S.p.A., an Italian company that manufactures, analyzes, tests, packages, and labels Teva's generic version of enoxaparin, which Teva then imports into the United States. Momenta sued Teva for infringement of the '886 patent on the grounds it intended to market in the United States an enoxaparin product that was manufactured using a process covered by the '886 patent.

The district court found Teva's conduct did not infringe because it fell within the safe harbor from infringement provided by 35 U.S.C. § 271(e)(1), which states it is not infringement for a party 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." 35 U.S.C. § 271(e)(1). [1] The district court also rejected Momenta's contention that Teva's sales in the United States constitute infringement under § 271(g), which prohibits selling "within the United States a product which is *made by* a process patented in the United States." *Id.* § 271(g) (emphasis added). The district court reasoned that the patented process related to "quality control release testing" and was "not a method of making enoxaparin." J.A. (–1274, –1277) 7.

Amphastar is also a generic manufacturer of enoxaparin. Unlike Teva, however, Amphastar manufactures its enoxaparin product within the United States. Momenta asserts the district court erred in granting summary judgment of non-infringement of the '886 patent in favor of Amphastar. According to Momenta, Amphastar's use of the patented method in the United States as part of the manufacture of enoxaparin infringes the '886 patent, and this infringement does not fall within the safe harbor of 35 U.S.C. § 271(e)(1). It further argues Amphastar's sale of enoxaparin in the United States infringes under 35 U.S.C. § 271(g).

In a prior appeal by Amphastar at the preliminary injunction phase, this court held that it was "unlikely that Momenta will succeed on the merits of its infringement claim." *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.* (*Momenta I*), 686 F.3d 1348, 1361(Fed.Cir.2012). On remand from *Momenta I,* the district court found "[Amphastar's] activities are ... protected by the safe harbor" of § 271(e)(1), which decision forms the basis of the present appeal. J.A. (–1276, –1278) 9.

Momenta appeals the district court's grants of summary judgment in favor of Teva and Amphastar. This court has jurisdiction under 28 U.S.C. § 1295(a) (2012). [2]

DISCUSSION

I. Standard of Review

[1] This court reviews summary judgment decisions under the law of the regional circuit. *MicroStrategy Inc. v. Bus.* ***615** *Objects, S.A.,* 429 F.3d 1344, 1349 (Fed.Cir.2005). The First Circuit reviews such decisions de novo. *Adamson v. Walgreens Co.,* 750 F.3d 73, 78 (1st Cir.2014).

II. Teva's and Amphastar's Enoxaparin Products Are Not "Made By" Momenta's Patented Process [3]

[2] Section 271(g) prohibits the unauthorized importation into the United States, or sale or use within the United States, of a "product which is *made by* a process patented in the United States." 35 U.S.C. § 271(g) (emphasis added). A key issue on appeal is therefore whether Teva's and Amphastar's enoxaparin products are "made by" Momenta's patented process within the meaning of § 271(g). We conclude they are not.

Momenta argues that "made" means "manufactured," and that its patented method is "a crucial interim step used directly in the manufacture of [Teva's] product [s]." Appellants' Br. (–1274, –1277) 59 (internal quotation marks and citation omitted); *see also* Appellants' Br. (–1276, –1278) 54 ("Amphastar uses Momenta's method as an intermediate step in the multi-step process of manufacturing its drug."). Specifically, Momenta asserts its "method is used [by Teva] to select and separate batches of intermediate drug substance that conform to [United States Pharmacopoeial Convention] requirements for enoxaparin from batches that do not," and that selected batches are then "further process[ed]." Appellants' Br. (–1274, –1277) 59, 62; *see also* Appellants' Br. (–1276, –1278) 54 ("Amphastar uses Momenta's method ... to select the individual batches of interim enoxaparin preparation it will further process into final drug product."). Momenta also notes "[t]he [U.S. Food and Drug Administration's ('FDA')] Good Manufacturing Practice ['GMP'] regulations define '[m]anufacture' and 'processing' of drug products as including 'testing [ ] and quality control of drug products.' " Appellants' Br. (–1274, –1277) 59 (quoting 21 C.F.R. § 210.3(b)(12)); *see also* Appellants' Br. (–1276, –1278) 54.

[3] Although Momenta's arguments are not without merit, it is more consonant with the language of the statute, as well as with this court's precedent, to limit § 271(g) to the actual "ma[king]" of a product, rather than extend its reach to methods of testing a final product or intermediate substance to ensure that the intended product or substance has in fact been made. *See* 35 U.S.C. § 271(g) ("made by"). "In patent law, as in all statutory construction, [u]nless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning." *Bilski v. Kappos,* 561 U.S. 593, 603, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010) (alteration in original) (internal quotation marks and citations omitted). Dictionaries define the verb forms of "make" to involve the creation or bringing into existence of something. *See, e.g., Make,* Webster's Third New International Dictionary of the English Language Unabridged (Philip ***616** Babcock Gove et al. eds., 1986) ("Webster's") ("to bring (a material thing) into being by forming, shaping, or altering material: FASHION, MANUFACTURE"); *Make,* The American Heritage Dictionary (2d college ed. 1982) ("The American Heritage Dictionary") ("To cause to exist or happen; create;" "To bring into existence by forming or modifying materials;" "To create by putting together component parts"); *see also Make,* Black's Law Dictionary (10th ed. 2014) ("To cause (something) to exist").

This court has previously equated the word "made" in § 271(g) with "manufacture." *Bayer AG v. Housey Pharm., Inc.,* 340 F.3d 1367, 1373 (Fed.Cir.2003) ("[T]he statute clearly contemplates that 'made' means 'manufactured.' "). As with the word "make," dictionaries define the verb form of "manufacture" to involve the creation or bringing into existence of something. *See, e.g., Manufacture,* Webster's ("to make (as raw material) into a product suitable for use"); *Manufacture,* The American Heritage Dictionary ("To make or process (a raw material) into a finished product"). In *American Fruit Growers, Inc. v. Brogdex Co.,* the Supreme Court quoted with approval the definition of "manufacture" provided in the Century Dictionary, namely, "*giving* [raw or prepared materials] *new* ... qualities [or] properties." 283 U.S. 1, 11, 51 S.Ct. 328, 75 L.Ed. 801 (1931) (emphases added).

[4] In light of the foregoing, the ordinary meaning of "made" as used in § 271(g) means "manufacture," and extends to the creation or transformation of a product, such as by synthesizing, combining components, or giving raw materials new properties. However, "ma[king]" does not extend to testing to determine whether an already synthesized drug substance possesses existing qualities or properties. *See Phillip M. Adams & Assocs., LLC v. Dell Comput. Corp.,* 519 Fed.Appx. 998, 1005 (Fed.Cir.2013) (unpublished) ("[E]ven assuming the certification testing constituted infringement ..., the motherboards were not 'made by' the certification testing pursuant to 35 U.S.C. § 271(g)."); *see also Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.,* 956 F.Supp.2d 295, 229

(D.Mass.2013) (J.A. 1–9) ("[W]hile ... quality control release testing is a regulatory requirement for sale of enoxaparin in the United States, it is not a method for making enoxaparin [within the meaning of § 271(g)]."); *Sharafabadi v. Univ. of Idaho,* No. C09–1043JLR, 2009 WL 4432367, at *1, *5 (W.D.Wash. Nov. 27, 2009) (finding the plaintiff failed to state a claim under § 271(g) when he alleged the defendant used the patented process "[d]uring various stages of productions and processing of IdaGold yellow mustard seeds ... to produce [sufficient mustard gum] for measuring its viscosity as a means to ensure the quality characteristics of the ... seeds"); David L. Hitchcock & Craig Allen Nard, *The Process Patent Amendments Act: The Labyrinth,* 3 Fordham Ent. Media & Intell. Prop. L.F. 441, 446 (1993) ("[I]t follows from the terms of the [Process Patent Amendments Act of 1988]" that products subjected to a patented method of quality control are "*not* ... worthy of ... protection" under § 271(g).).

The samples of enoxaparin that are the subject of testing are "exhaustively digest[ed]" into "sub-chains" and the sub-chains are then separated. Appellants' Br. (–1274, –1277) 9. Based on the test performed on this sample, an enoxaparin batch from which the samples were extracted may be selected for incorporation into the finished product. No assertion is made, however, that the enoxaparin samples on which tests are performed are themselves incorporated into the finished product or imported into the United ***617** States, [4] nor do the tests create or give new properties to the enoxaparin substance in batches that are selected for further processing.

Our conclusion finds support in this court's precedent. In *Housey,* we held a product was not "made by" a process patented in the United States for purposes of § 271(g) where "the patented process [was] not used in the *actual synthesis* of the drug product." 340 F.3d at 1377 (emphasis added). *Housey* involved patents directed to "a method of screening for substances which specifically inhibit or activate a particular protein." *Id.* at 1369 (internal quotation marks and citation omitted). The screening method enabled the identification of a particular drug as "useful," which drug could then be manufactured. *Id.* at 1377. The court determined the process was too far removed from the actual making of the product. *Id.* at 1378 ("[T]he process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured.").

[5] Similarly, a product is not "made by" a patented process within the meaning of § 271(g) if it is used merely to determine whether the intended product of a separate and perhaps separately-patented process has in fact already been manufactured. *Compare Housey,* 340 F.3d at 1377 ("[P]rocesses of *identification* and generation of data are not steps in the manufacture of a final drug product." (emphasis added) (internal quotation marks and citation omitted)), *with* Dissent at 8 ("after the *identity* of the drug substance is confirmed" (emphasis added)); *see also Housey,* 340 F.3d at 1378 ("A drug product, the characteristics of which were studied using the claimed research processes ... is not a product 'made by' those claimed processes."). All of the asserted claims of the '886 patent are directed to "[a] method for *analyzing* an enoxaparin sample." *See, e.g.,* '886 patent col. 63 l. 51, col. 64 ll. 10, 35, 58 (emphasis added). Use of the word "analyzing" indicates practicing the claimed invention requires that the enoxaparin already be "made."

It is true the FDA's GMP regulations "define '[m]anufacture' and 'processing' of drug products as including 'testing[ ] and quality control,' " as Momenta asserts. Appellants' Br. (–1274, –1277) 59 (quoting 21 C.F.R. § 210.3(b)(12)). However, § 210.3 explicitly states that its definitions apply when the terms are used in parts 210, 211, 225, and 226 of Chapter 1 of Title 21 ("Food and Drugs") of the Code of Federal Regulations. 21 C.F.R. § 210.3(a). They do not control the interpretation of 35 U.S.C. § 271(g), which is part of a ***618** separate statutory scheme directed to patented inventions. *See Davis v. Mich. Dep't of Treasury,* 489 U.S. 803, 809, 109 S.Ct. 1500, 103 L.Ed.2d 891 (1989) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."). This is not a case where the FDA has interpreted § 271(g) or *Chevron* deference is owed. *See Chevron, U.S.A. Inc. v. Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 844, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984) ("[C]onsiderable weight should be accorded to an executive department's construction of a statutory scheme *it is entrusted to administer.*" (emphasis added)). The ordinary meaning of the term "made by"—rather than an FDA definition of "manufacture" crafted for purposes unrelated to incentivizing invention—therefore controls. [5]

For these reasons, Teva's and Amphastar's enoxaparin products are not "made by" Momenta's patented process for purposes of § 271(g). Because Momenta's infringement claims against Teva are based on § 271(g), the district court's grant of summary judgment in favor of Teva is affirmed.

III. The § 271(e)(1) Safe Harbor Does Not Shield the Accused Use by Amphastar

Unlike Teva, Amphastar does not assert it manufactures its enoxaparin product abroad. Momenta argues Amphastar's use of the patented method within the United States infringes under 35 U.S.C. § 271(a) and is not protected by the § 271(e)(1) safe harbor.

[6] Section 271(e)(1) provides that it is not infringement for a party 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." 35 U.S.C. § 271(e)(1). "Though the contours of [§ 271(e)(1)] are not exact in every respect," *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193, 202, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005), "[t]here is no dispute as to the statutory purpose," namely, "to facilitate market entry upon patent expiration," *Classen Immunotherapies, Inc. v. Biogen IDEC,* 659 F.3d 1057, 1072 (Fed.Cir.2011). The legislative history makes this purpose clear:

> [Section 271(e)(1)] provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent.... This section does not permit the commercial sale of a patented drug by the party using the drug to develop such information.... The information which can be developed under this provision is the type which is required to obtain approval of the drug.... *The purpose of sections 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.*

H.R.Rep. No. 98–857(I), at 15, 45 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2648 (emphasis added) (capitalization omitted).

***619** **[7]** The language of § 271(e)(1) is "sufficiently broad" to "leave[ ] adequate space for experimentation and failure on the road to regulatory approval." *Merck,* 545 U.S. at 206–07, 125 S.Ct. 2372. The breadth of the exemption extends even to activities the "actual purpose" of which may be "promot[ional]" rather than regulatory, at least where those activities are "consistent with the collection of data necessary for filing an application with the [FDA] ... for approval." *AbTox, Inc. v. Exitron Corp.,* 122 F.3d 1019, 1027 (Fed.Cir.1997). Moreover, notwithstanding the legislative focus on activities occurring prior to the approval of generic drugs, the § 271(e)(1) exemption applies to medical devices, *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990), and "is not restricted to pre-approval activities," *Momenta I,* 686 F.3d at 1358–59. Section 271(e)(1) thus "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process." *Merck,* 545 U.S. at 202, 125 S.Ct. 2372.

[8] Despite the broad contours of the exemption, some activities are outside its protection. For example, § 271(e)(1) "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." *Classen,* 659 F.3d at 1070. In addition, research tools or devices that are not themselves subject to FDA approval may not be covered. *Proveris Sci. Corp. v. Innovasystems, Inc.,* 536 F.3d 1256, 1265–66 (Fed.Cir.2008).

We preliminarily addressed the issue of Amphastar's eligibility for the § 271(e)(1) safe harbor in *Momenta I,* holding that, in light of the safe harbor and for purposes of granting a preliminary injunction, "the district court incorrectly concluded that Momenta was likely to succeed on the merits of its infringement claim." *Momenta I,* 686 F.3d at 1352. Amphastar argues this court in *Momenta I* "already decided that Amphastar's safety testing is protected by the Section 271(e)(1) safe harbor" and that this determination is law of the case. Appellees' Br. (–1276, –1278) 24.

[9] According to the law of the case doctrine, "[a] court will not generally revisit an issue once decided in the litigation." *Mendenhall v. Barber–Greene Co.,* 26 F.3d 1573, 1582 (Fed.Cir.1994). However, whether to apply law of the case doctrine is "a matter which rests on discretion." *Id.* at 1583. "Although courts are often eager to avoid reconsideration

of questions once decided in the same proceedings, it is clear that all federal courts retain power to reconsider if they wish." *Hughes Aircraft Co. v. United States,* 86 F.3d 1566, 1581 (Fed.Cir.1996) (internal quotation marks and citation omitted), *vacated on other grounds, United States v. Hughes Aircraft Co.,* 520 U.S. 1183, 117 S.Ct. 1466, 137 L.Ed.2d 680 (1997).

[10] **[11]** For the doctrine to apply, the issue must have actually been decided. Findings of fact and fact-intensive conclusions of law made by a court in the preliminary injunction context are not binding. *See generally Belgium v. United States,* 452 F.3d 1289, 1294 (Fed.Cir.2006) ("On review of the denial of a preliminary injunction, our judgment as to the merits of the plaintiff's case is necessarily tentative."); *Glaxo Grp., Ltd. v. Apotex, Inc.,* 376 F.3d 1339, 1346 (Fed.Cir.2004) ("An appellate court's preliminary injunction opinion ... is not binding on a subsequent panel."); *see also Univ. of Tex. v. Camenisch,* 451 U.S. 390, 395, 101 S.Ct. 1830, 68 L.Ed.2d 175 (1981) ("[T]he findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits."); *Indus. Bank of Wash. v. Tobriner,* 405 F.2d 1321, 1324 (D.C.Cir.1968) ("In reviewing [a preliminary ***620** injunction] determination, this court ordinarily will not consider the merits of the case further than necessary to determine whether the District Court abused its discretion." (internal quotation marks and citation omitted)). Because Momenta is not seeking to relitigate an issue that was already conclusively decided in *Momenta I,* law of the case does not apply.

[12] **[13]** Moreover, "it is not improper for a court to depart from a prior holding if convinced that it is clearly erroneous and would work a manifest injustice." *Arizona v. California,* 460 U.S. 605, 618 n. 8, 103 S.Ct. 1382, 75 L.Ed.2d 318 (1983); *see also Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.,* 776 F.3d 837, 842 (Fed.Cir.2015) ("[T]here are exceptional circumstances in which a panel may not adhere to the decision in a prior appeal in the same case," such as when "the earlier ruling was clearly erroneous and would work a manifest injustice."). The court in *Momenta I* described Amphastar's submissions as "anything but 'routine,' " 686 F.3d at 1358, a reference to *Classen* 's statement that § 271(e)(1) "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). With the benefit of additional briefing in the current appeals, which reflects the full district court record developed by all parties after the preliminary injunction phase, we conclude Amphastar's submissions are appropriately characterized as "routine."

Webster's defines the adjective form of "routine" as "of a commonplace or repetitious character." *Routine,* Webster's. The American Heritage Dictionary similarly offers a definition of "routine" as "[h]abitual; regular." *Routine,* The American Heritage Dictionary. These definitions aptly describe the patented quality control method. "[T]he '886 patent ... is directed at a set of manufacturing control processes that ensure that *each batch* of generic enoxaparin" meets quality standards. *See* J.A. (–1276, –1278) 2 (emphasis added). The information generated as each batch of drug substance is tested is routinely (i.e., habitually, regularly, and repeatedly) recorded and retained as required by regulation. *See* 21 C.F.R. §§ 211.165, .180, .186, .188, .194 (2015).

The routine record retention requirements associated with testing and other aspects of the commercial production process contrast with non-routine submissions that may occur both pre- and post-approval, such as the submission of investigational new drug applications ("INDs"), new drug applications ("NDAs"), supplemental NDAs, or other post-approval research results. *See, e.g.,* 21 U.S.C. § 356b ("Reports of postmarketing studies"); *id.* § 355c(b)(1) (post-approval pediatric data submissions); *id.* § 355(e) (withdrawal of drug approval based upon "new information"); *id.* § 355(*o*)(4) (labeling changes based upon new safety information); *id.* § 355–1 ("Risk evaluation and mitigation strategies"). The routine quality control testing of each batch of generic enoxaparin as part of the post-approval, commercial production process is therefore not "reasonably related to the development and submission of information" to the FDA, and it was clearly erroneous to conclude otherwise.

Amphastar cites *AbTox* in support of its argument that "as long as Amphastar's safety testing is for a use reasonably related to the development and submission of information to the FDA," whether the use is part of commercial production makes no difference. Appellees' Br. (–1276, –1278) 42 (citing *AbTox,* 122 F.3d at 1030). However, *AbTox* stated "[a]s long as [an] activity is reasonably related *to obtaining FDA* ***621** *approval,*" § 271(e)(1) "does not look to the underlying purposes or attendant consequences of the activity." 122 F.3d at 1030 (emphasis added). Here, Amphastar makes no claim that its accused, post-approval use of the patented method is related to obtaining FDA approval. Although *Momenta I* held that "post-approval studies" can fall within the § 271(e)(1) safe harbor, 686 F.3d at 1359, whether such uses are

"reasonably related" to a § 271(e)(1) "submission" requires more critical analysis in the post-approval context.

The conclusion in *Momenta I* that Amphastar's commercial use of Momenta's patented method falls within the safe harbor of § 271(e)(1) would result in manifest injustice. Amphastar points to no case, until *Momenta I,* extending immunity under § 271(e)(1) to encompass activities related to ongoing commercial manufacture and sale. *See, e.g., Merck,* 545 U.S. at 208, 125 S.Ct. 2372 (*Preclinical research* falls within the § 271(e)(1) safe harbor "as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an IND or NDA." (internal quotation marks and citation omitted)); *Eli Lilly,* 496 U.S. at 663–64, 110 S.Ct. 2683 (Section 271(e)(1) exempts activities "necessary to *obtain marketing approval* for a medical device." (emphasis added)); *Classen,* 659 F.3d at 1070 ("[Section] 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." (emphasis added)); *AbTox,* 122 F.3d at 1027 (Section 271(e)(1) applies where "[defendants] conducted limited tests consistent with the collection of data necessary for *filing an application* with the [FDA] ... for approval of its Class II medical device." (emphasis added)); *see also* H.R.Rep. No. 98–857, pt. 2, at 30 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2714 (Under § 271(e)(1) "the generic manufacturer is not permitted to market the patented drug product 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.*" (emphasis added) (capitalization omitted)). [6]

IV. Momenta's Motion to Amend

Momenta served amended infringement contentions that accused two additional Amphastar testing procedures and sought to provide additional documentary support for the new infringement contentions. Thereafter, Momenta moved for leave from the district court to file the amendments. J.A. (–1276, –1278) 11. The district court denied leave, noting Momenta had "failed to seek leave prior to serving [the amendments] as required by the [district court's] scheduling order," and that the amendments would in any event be "futile." J.A. (–1276, –1278) 11–12. The district court's decision to deny leave was based in part on its conclusion that its "summary judgment holding that the [§] 271(e)(1) safe harbor provision applies to ***622** the 15–25% procedures also applies to" one of the two additional accused testing procedures. J.A. (–1276, –1278) 12.

[14] Decisions whether to allow an amendment to pleadings after the scheduling order deadline are reviewed under the law of the regional circuit. *Aventis Pharma S.A. v. Hospira, Inc.,* 675 F.3d 1324, 1333 (Fed.Cir.2012). In the First Circuit, a district court's decision whether to allow an amendment to pleadings after the scheduling order deadline is reviewed for abuse of discretion. *O'Connell v. Hyatt Hotels of P.R.,* 357 F.3d 152, 154–55 (1st Cir.2004). Given our vacation of summary judgment on the reach of § 271(e)(1), the district court may choose to reconsider on remand its denial of leave in light of our holding.

CONCLUSION

For these reasons, the decision of the district court granting summary judgment to Teva is **AFFIRMED** and the decision of the district court granting summary judgment to Amphastar is

AFFIRMED–IN–PART, VACATED–IN–PART, AND REMANDED

COSTS

Each party in the Amphastar litigation shall bear its own costs.

DYK, Circuit Judge, concurring in part and dissenting in part. While I join the majority opinion insofar as it holds that the 35 U.S.C. § 271(e)(1) safe harbor does not immunize Amphastar's accused use of the '886 patent in its manufacturing process, I respectfully dissent from the majority's holding that Teva does not infringe the '886 patent under 35 U.S.C. § 271(g). [1] The majority reasons that a patent related to quality control testing cannot be infringed under § 271(g), which states, "[w]hoever without authority imports into the United States *or* offers to sell, sells, or uses within the United States a product which is *made by* a process patented in the United States shall be liable as an infringer." 35 U.S.C. § 271(g) (2012) (emphasis added). Quality control, according to the majority, is not used to "make" a product. This seems to me too limited a construction of § 271(g).

I

The central question here is whether quality control is part of the process of "manufacturing" a product. The majority holds that it is not, relying primarily on *Bayer AG v. Housey Pharmaceuticals, Inc.,* 340 F.3d 1367 (Fed.Cir.2003). There ***623** we held that § 271(g) "contemplates that 'made' means 'manufactured.' " *Id.* at 1372. We also held that "in order for a product to have been 'made by a process patented in the United States' it must have been a physical article." *Id.* at 1377. Finally, *Bayer* held that "the process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured." *Id.* at 1378. Thus in *Bayer* we held that a method for screening substances to identify promising products was not a method used in the manufacture of a product. *Id.* at 1369, 1378. "A drug product, the characteristics of which were studied using the claimed research processes ... is not a product 'made by' those claimed processes." *Id.* at 1378. [2]

The patent here, however, is not utilized to identify the product to be made, but rather is used in the manufacturing process. The quality control process of the '886 patent is an intermediate step to determine which batches of putative enoxaparin must be discarded, and which batches may be incorporated in the final drug product. It is distinctly part of the manufacturing process of the product.

The dictionary definitions of "make" and "manufacture" relied on by the majority at most suggest that quality control, standing alone, is not making or manufacturing. But they hardly suggest that quality control is not part of making or manufacturing. Nor can there be any suggestion that the processes described in § 271(g) are limited to those that cover the entire manufacturing process. The majority opinion cites no authority that quality control is not a part of manufacturing, other than our non-precedential decision in *Phillip M. Adams & Associates, LLC v. Dell Computer Corp.,* 519 Fed.Appx. 998 (Fed.Cir.2013). In fact, quality control is, as a general matter, considered to be a part of the drug manufacturing process. That is the view of the Food and Drug Administration ("FDA"). The FDA, in its Good Manufacturing Practice regulations, 21 C.F.R. §§ 210.1–210.3, defines "[m]anufacture" as "includ[ing] packaging and labeling operations, testing, and *quality control* of drug products." 21 C.F.R. § 210.3(12) (2011) (emphasis added).

Similarly, statutes and regulations in other areas have recognized that quality control is inherent in the manufacturing process. For example, in the manufacture of chemicals, the Toxic Substances Control Act provides that the Administrator of the Environmental Protection Agency may "require ... [a] manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of [a] chemical substance or mixture." 15 U.S.C. § 2605(b). So, too, in the manufacture of medical devices. A medical device manufacturer, in order to obtain approval of a device under the Investigational Device Exemption, must submit an application with, *inter alia,* a "description of the methods, facilities, and controls used for the manufacture ... of the device ... so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality ***624** control used in the manufacture of the device." 21 C.F.R. § 812.20 (2015). In other words, quality control is "used in the manufacture of the device." *Id.; see also United States v. Castillo,* 928 F.2d 1106, 1108 (11th Cir.1991) ("A device that is used for 'quality control' in the manufacture of any item can be considered a device used in the manufacture of the product.").

II

However, we need not reach the question here of whether quality control is always part of a manufacturing process. Our precedent suggests that we should resolve the question of whether a product was "made by" a process on a case-by-case basis. *See Bio–Tech. Gen. Corp. v. Genentech, Inc.,* 80 F.3d 1553, 1561 (Fed.Cir.1996). Under the facts of this case, the quality control testing of the '886 patent is clearly an integral part of the manufacturing process of enoxaparin. In order to understand why, it is helpful to understand how the final enoxaparin drug product is made.

Heparin is a naturally occurring anticoagulant consisting of a mixture of long chains of sugar molecules. Heparin may be cleaved, using different methods, into shorter sugar chains ("oligosaccharides") to create different low molecular weight heparins ("LMWHs"), each of which is a different heterogeneous collection of oligosaccharides. The different heterogeneous collections of oligosaccharides give each LMWH a different therapeutic effect.

Enoxaparin is one type of LMWH, and was first sold under the brand name Lovenox. As with any LMWH, the sugar chains

in enoxaparin may differ slightly from batch to batch, but they have structural similarities determined to be unique to that LMWH. One such signature structural feature is a 1, 6–anhydro ring structure that is present at approximately 20% of the reducing ends of sugar chains in the collection. The molecular diversity of enoxaparin creates special problems for the manufacturing of a generic version of the drug, which must be bioequivalent to and contain the same active ingredients as the branded drug. Thus, as we previously described,

> 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. These criteria included, *inter alia,* [e]quivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species.... Detecting the presence of a 1, 6 anhydro ring structure is particularly important for proving equivalence....

Momenta Pharm., Inc. v. Amphastar Pharm., Inc. (Momenta I), 686 F.3d 1348, 1350–51 (Fed.Cir.2012) (citations and quotation marks omitted). As required by the FDA, only batches in which 15–25% of the sugar chains contain a 1, 6–anhydro ring structure at the reducing end may be released and combined for further processing to become the finished drug product.

Momenta's '886 patent claims a method of analyzing and selecting batches of intermediate enoxaparin drug substance, based on the appropriate quantity of sugar chains containing the 1, 6–anhydro ring structure. The patent contemplates the usage of its methods during the manufacturing process, teaching, for example, a method that "provides a way to both streamline manufacturing and reduce costs while ensuring a more consistent, higher quality product," U.S. Patent No. 7,757,886 col. 34 ll. 43–52. The specification also notes that the methods of the claimed invention allow for the creation of "LMWH preparations with low batch-batch variability ***625** and a desired structural signature," *id.* at col. 60 l.66–col. 61 l.3. It compares the claimed method of conducting a structural characterization of LMWHs with the prior art "current manufacturing practices for ... LMWHs [which] use functional assays ... and gross physical characterization to provide quality control," *id.* at col. 48 ll. 1–7.

As the majority characterizes it, " 'ma[king]' does not extend to testing to determine whether an already synthesized drug product possesses existing qualities or properties." Maj. Op. at 615–16. While I do not agree with the majority's cabining of the term "making," even under the majority's test, the quality control process is an integral part of the manufacturing of the enoxaparin drug product. The enoxaparin drug substance that is tested using the method of the '886 patent is far from being a finished product. The FDA defines a "drug product" as the "finished dosage form, for example, tablet, capsule, solution, etc." 21 C.F.R. § 210.3(4) (2015). Even after the identity of the drug substance is confirmed utilizing the quality control steps of the '886 patent, further processing steps remain: "weighing, combining the enoxaparin in one batch with other batches of enoxaparin that have been similarly processed and selected by use of the claimed method, compounding the resulting mixture with specially-purified water, sterilizing this compound, placing it into syringes, and labeling and packaging the finished product." J.A. 12440. Only after these additional processing steps are completed is the drug product ready for commercial sale. *See* 21 C.F.R. § 210.3(4). Thus, the quality control testing method of the '886 patent is a necessary intermediate step in the manufacture of enoxaparin.

In this respect this case is similar to *Bio–Technology,* where we considered whether a manufacturer's importation of human growth hormone ("hGH") could infringe two Genentech patents under § 271(g). 80 F.3d at 1558. The first patent was a method of producing hGH in bacterial hosts by inserting a semi-synthetic gene (e.g., a "plasmid"), encoding for hGH and one additional amino acid, into bacterial cells that could then express the hGH product. *Id.* at 1556–57. The second patent's claims were directed to the method for constructing a plasmid, in other words, a method for creating information that the bacterial cells could use to generate the product. *Id.* at 1557. Notably, there was no doubt that the "plasmid product of the claimed process and hGH are entirely different materials." *Id.* at 1561. Nonetheless, we noted that the manufacturer "use[d] the claimed process of making a [plasmid] as an essential part of an overall process for producing hGH," and held that "it cannot be said as a matter of law that the production of hGH is too remote from the claimed process of making a replicable cloning vehicle." *Id.*

In *Bio–Technology,* the practice of the plasmid patent was an essential intermediate component of the overall process for producing hGH. Similarly, here, the quality control step of the '886 patent is an essential intermediate step in the overall production of enoxaparin. In this case, the majority states that "[n]o assertion is made ... that the enoxaparin samples on which tests are performed are themselves incorporated into the finished product or imported into the United States." Maj. Op. at 616–17. But this was also true in *Bio–Technology,* and provides no ground for distinction.

III

Finally, limiting "made" in § 271(g) to "the creation or transformation of a product, such as by synthesizing, combining components, or giving raw materials new ***626** properties," Maj. Op. at 615–16, would lead to anomalous results. Patents on purification methods or the quality control method at issue here, which may be integral to the regulatory or commercial viability of a product, but which do not create or transform a product, combine components, or confer new properties, could be freely infringed simply by outsourcing those processes abroad. Congress could not have intended to create this loophole when it sought to protect process patent owners from foreign competitors using U.S. manufacturing processes abroad. *See generally Eli Lilly & Co. v. Am. Cyanamid Co.,* 82 F.3d 1568, 1571–72 (Fed.Cir.1996).

I respectfully dissent.

All Citations

809 F.3d 610, 116 U.S.P.Q.2d 1961

Footnotes

1 Section 271(e)(1) was not amended by the Leahy–Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011).

2 We invited the United States to present its views as amicus curiae on the statutory interpretation issues raised in these cases. In response, the government argued that the routine use of a patented testing process in the commercial manufacture of a drug is not "reasonably related to the development and submission of information to [the] FDA" and thus not shielded from liability by § 271(e)(1). Brief for the United States as Amicus Curiae 8 (internal quotation marks omitted).

3 Momenta argues "Amphastar's sales activity separately infringes under Section 271(g), which makes it an act of infringement to 'offer [ ] to sell' or 'sell[ ] ... within the United States a product which is made by a process patented in the United States.' " Appellants' Br. (14–1276, 14–1278) 53 (quoting 35 U.S.C. § 271(g)). Amphastar replies that its manufacturing occurs within the United States, and therefore "[§] 271(g) does not apply for the independent reason that Amphastar does not manufacture enoxaparin abroad." Appellees' Br. (14–1276, 14–1278) 50. Because we hold the accused products are not "made by" the patented process within the meaning of § 271(g), we do not reach the question of whether that subsection applies if the patented process is practiced domestically rather than abroad.

4 The dissent asserts this was also true in *Bio–Technology General Corp. v. Genentech, Inc.,* which involved a patent "directed to a method for constructing a replicable cloning vehicle (*e.g.,* a plasmid)" that could be introduced into a microbial organism to enable it to produce human growth hormone. 80 F.3d 1553, 1557 (Fed.Cir.1996). The analogy fails. Unlike *Bio–Technology General,* where the patented process created a tangible product used directly in the manufacture of a final polypeptide product (e.g., human growth hormone), the patented process in the present matter creates only information; it does not create enoxaparin samples that are used in subsequent steps of the manufacturing process. In any event, *Bio–Technology General* differs from the present matter because the legislative history of § 271(g) explicitly states that a polypeptide is "made by" a patented process, within the meaning of § 271(g), where the patented process is used to produce a DNA molecule that is incorporated into a plasmid and that plasmid is inserted into a host organism to produce the polypeptide. *See id.* at 1561 (quoting at length S.Rep. No. 100–83, at 51 (1987)); *see also id.* ("The legislative history precisely anticipated this fact situation...."). The dissent cites no legislative history supporting the extension of § 271(g) to quality control methods.

5 The dissent expresses concern that our holding could exclude purification processes from the scope of § 271(g). Dissent at 625–26. Although the application of § 271(g) to a particular purification process may be fact-dependent, as a general matter purification processes transform impure substances into more pure ones. Purification therefore contrasts with the quality control process at issue in the present case, which provides information regarding a substance that has already been made but does not transform it.

6 *See also Telectronics Pacing Sys., Inc. v. Ventritex, Inc.,* 982 F.2d 1520, 1523 (Fed.Cir.1992) (The display of accused devices to non-physicians at medical conferences, where no sales were solicited, is "merely incidental" to the undisputed

purpose of the display—"obtain[ing] clinical investigators for [pre-approval] trials"—and does not preclude application of the § 271(e)(1) exemption); *Chartrex Int'l PLC v. M.D. Pers. Prods. Corp.,* 5 F.3d 1505, at *2 (Fed.Cir.1993) (unpublished table decision) (Devices "made for FDA approval" do not forfeit their § 271(e)(1) exemption "when used in other noninfringing manners."); *Intermedics, Inc. v. Ventritex Co.,* 991 F.2d 808, at *2 (Fed.Cir.1993) (unpublished table decision) ("All of [the defendant's] activities providing clinical units of the [accused device] to its researcher in Germany were solely reasonably related to generating data for FDA approval.").

1 The majority also determined that Amphastar does not infringe under § 271(g). This has little practical consequence since the majority holds that the § 271(e)(1) safe harbor does not shield Amphastar from liability under § 271(a).

However, the parties dispute whether § 271(g) can apply to products made in the United States. While the primary purpose of § 271(g) was to impose infringement liability for products shipped to the United States but made abroad by a United States patented process, the plain language of § 271(g) admits of no such geographic limitation. And the legislative history is clear that § 271(g) includes situations where the process is practiced in the United States. As the Senate Judiciary Committee report stated, "the process patent bill was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product was made ... in this country or in a foreign country." S.Rep. No. 100–83, at 46 (1987).

The cases on which Amphastar relies as suggesting that the statute is limited to practicing a process abroad hold no more than that § 271(g) applies to that circumstance. *See, e.g., Ajinomoto Co. v. Archer–Daniels–Midland Co.,* 228 F.3d 1338, 1347 (Fed.Cir.2000). They do not suggest that the sale of a product made by the practice of a process in the United States would not be an infringement under § 271(g).

2 *Sharafabadi v. University of Idaho,* No. C09–1043JLR, 2009 WL 4432367 (W.D.Wash. Nov. 27, 2009), relied on by the majority, is similar to *Bayer* and is equally beside the point. Maj. Op. at 616. In*Sharafabadi,* the district court found that the patent holder "alleg[ed] only that the Universities used the [patent] as a research tool to test the characteristics of various yellow mustard seeds" in the course of developing a new IdaGold mustard seed and "[did] not allege that [any defendant] used the [patent] to directly manufacture or produce the IdaGold seeds." *Sharafabadi,* 2009 WL 4432367, at *5 (citing *Bayer,* 340 F.3d at 1378).