United States Court of Appeals for the Federal Circuit

CLASSEN IMMUNOTHERAPIES, INC., A MARYLAND CORPORATION,
Plaintiff-Appellant

JOHN BARTHELOW CLASSEN,
Counterclaim Defendant

v.

ELAN PHARMACEUTICALS, INC., A DELAWARE CORPORATION,
Defendant/Counterclaimant-Appellee

2014-1671

Appeal from the United States District Court for the District of Maryland in No. 1:04-cv-03521-WDQ, Judge William D. Quarles, Jr.

Decided: May 13, 2015

JOSEPH J. ZITO, DNL ZITO, Washington, DC, argued for plaintiff-appellant.

JAMES B. MONROE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for defendant/counterclaimant-appellee. Also represented by PAUL WILLIAM BROWNING.

Before PROST, *Chief Judge,* LOURIE, *Circuit Judge*, and GILSTRAP, *District Judge.*[*]

LOURIE, *Circuit Judge.*

Classen Immunotherapies, Inc. ("Classen") appeals from the decision of the United States District Court for the District of Maryland granting summary judgment that Elan Pharmaceuticals, Inc. ("Elan") did not infringe U.S. Patent 6,584,472 ("the '472 patent") based on the safe harbor provision of 35 U.S.C. § 271(e)(1). *See Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 466 F. Supp. 2d 621 (D. Md. 2006) (granting summary judgment); *Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 981 F. Supp. 2d 415 (D. Md. 2013) (denying reconsideration). We conclude that the district court correctly decided that § 271(e)(1) exempts Elan's activities reasonably relating to developing clinical data on its approved drug Skelaxin® ("Skelaxin") and submitting that information to the Food and Drug Administration ("FDA") in a citizen petition and a supplemental new drug application ("sNDA").

Classen also asserts that certain activities that occurred after the FDA submissions infringed the '472 patent and that those activities are not exempt under the safe harbor of § 271(e)(1). Because the district court did not determine whether those activities constituted infringement or whether they were exempt from liability under the safe harbor, we *vacate* the judgment of noninfringement and *remand*.

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[*] Honorable Rodney Gilstrap, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

BACKGROUND

Elan has marketed and sold metaxalone, a muscle relaxant, under the brand-name Skelaxin, and was the owner of an approved new drug application ("NDA"). In early 2001, years after the initial approval of Skelaxin, Elan learned that another company conducted *in vivo* bioequivalence fasting studies and *in vitro* dissolution tests on metaxalone and that, based on the results of those studies, the FDA proposed to change the designation of metaxalone tablets from "non bioproblem" to "bioproblem." J.A. 1531–32.

In July 2001, Elan initiated its own clinical study on Skelaxin administered with and without food in humans and observed a significant effect of food on the drug's bioavailability. In October 2001, Elan submitted a citizen petition to the FDA, requesting that the FDA require both fed and fasting bioavailability data from an applicant of an abbreviated new drug application ("ANDA") for a generic version of Skelaxin. Concurrently, Elan also submitted an sNDA, *viz.*, a labeling supplement to the Skelaxin NDA, to revise its product label. *See* 21 C.F.R. § 314.70. Elan included its clinical study report with those FDA submissions and explained to the FDA that the results of its clinical study showed that "the bioavailability [of Skelaxin] was significantly increased when Skelaxin was administered with food in that both the rate . . . and extent of absorption . . . were increased." J.A. 1532. The FDA subsequently granted Elan's citizen petition and approved its sNDA.

In December 2001 and March 2002, Elan filed two patent applications in the United States Patent and Trademark Office ("PTO") based on its clinical bioavailability data. The second application is a continuation of the first and shares the same specification. Those applications issued as U.S. Patents 6,407,128 and 6,683,102 ("the Elan patents"). However, all claims of the Elan patents were

later invalidated in light of prior art. *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1283 (Fed. Cir. 2010).

Classen owns the '472 patent, which is directed to a method for accessing and analyzing data on a commercially available drug to identify a new use of that drug, and then commercializing that new use. Classen sued Elan in 2004, alleging that Elan infringed the '472 patent when it studied the effect of food on the bioavailability of Skelaxin, used the clinical data to identify a new use of the drug, and commercialized the new use. *Classen*, 466 F. Supp. 2d at 624. Elan moved for summary judgment of noninfringement. The district court granted the motion in 2006, finding Elan protected by the safe harbor provision of § 271(e)(1) because Elan submitted its clinical data to the FDA with its citizen petition and sNDA, and thus its activities were "reasonably related to the submission of information" under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* at 625.

The lawsuit was then stayed pending an *ex parte* reexamination of the '472 patent, during which the PTO cancelled 107 of the 137 originally issued claims. Of the remaining claims, only claims 36, 42, 48–50, 59, 73–76, 84, 131, and 135 were asserted against Elan. Prior to issuing the reexamination certificate, the PTO Examiner stated, as reasons for patentability, that the "prior art of record fails to teach or fairly suggest the limitation of 'a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.'" J.A. 1484.

Claim 36 is representative of the asserted method claims and depends from cancelled claim 33; both are reproduced below:

> 33. [(cancelled during reexamination)] A method for creating and using data associated with a

> commercially available product, wherein the method comprises the steps of:
>
> *accessing* at least one data source, comprising together or separately, adverse event data associated with exposure to or use of the product and commercial data regarding marketing, sales, profitability or related information pertaining to the product;
>
> *analyzing* the accessed data to *identify* (i) at least *one new adverse event* associated with exposure to or use of the product, (ii) at least *one new use* for the product responsive to identification of the at least one new adverse event, and (iii) the potential commercial value of the at least one new use for the product; and
>
> *commercializing* the newly identified product information based upon the analyzed data.
>
> 36. The method of claim 33, wherein the *commercializing* step comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product, or documenting same, such that *a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.*

'472 patent col. 26 ll. 38–53, 60–67 (emphases added). The asserted kit claims depend from the method claims. Claim 59 is representative and reads as follows:

> 59. A proprietary kit comprising (i) product and (ii) *documentation notifying a user* of the product of at least *one new adverse event* relating to the product, wherein determination of the new ad-

> verse event is based upon the data provided by the method of claim 36.

'472 patent reexamination certificate col. 2 ll. 5–9 (emphases added).

After the reexamination certificate issued in 2010, Classen filed a motion in the district court seeking to lift the stay and to vacate the 2006 summary judgment. Classen argued that our decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) warranted reconsideration of the summary judgment because we held in *Biogen* that certain post-approval routine submissions to the FDA are outside the safe harbor of § 271(e)(1). In response, the district court lifted the stay but denied reconsideration of its 2006 decision. The court concluded that Elan was protected by the safe harbor under both *Biogen* and our subsequent decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012). The court reasoned that unlike *Biogen*, where the post-approval submissions were routine, Elan's submissions to the FDA were "not routine" because they were necessary to update the Skelaxin product label and to change the FDA-approval process for generic versions of Skelaxin. *Classen*, 981 F. Supp. 2d at 421–22.

On the parties' joint motion, the district court entered final judgment of noninfringement under Rule 54(b) of the Federal Rules of Civil Procedure. Elan's invalidity counterclaim is still pending at the district court. Classen appealed from the judgment of noninfringement, and we have jurisdiction under 28 U.S.C. § 1295(a)(1).[1]

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[1] Because issues of validity are not before us in this appeal, we express no opinion as to whether the asserted claims cover patent ineligible subject matter in light of

DISCUSSION

We review the grant of summary judgment under the law of the regional circuit in which the district court sits, here, the Fourth Circuit. *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1381 (Fed. Cir. 2001). Applying the law of the Fourth Circuit, we review the district court's grant of summary judgment *de novo*. *Gallagher v. Reliance Standard Life Ins. Co.*, 305 F.3d 264, 268 (4th Cir. 2002). Summary judgment is appropriate when, drawing all justifiable inferences in the nonmovant's favor, "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Section 271(a) of the patent statute provides that "[e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). In 1984, as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Congress created an exemption from the general rule of infringement for certain uses of a patented invention in the federal regulatory process. Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1)). The safe harbor provision of § 271(e)(1) provides in relevant part that:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . *solely for uses reasonably related to the*

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the Supreme Court's decision in *Alice Corp. v. CLS Bank International*, 573 U.S. __, 134 S. Ct. 2347 (2014).

> *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) (emphasis added).

In the district court, Classen alleged that Elan infringed the '472 patent by conducting a clinical study on the bioavailability of Skelaxin and submitting the results to the FDA to revise the Skelaxin product label, among other accused activities. *Classen*, 466 F. Supp. 2d at 624; *see also Classen Immunotherapies, Inc. v. King Pharm., Inc.*, No. 04-3521, ECF No. 123-8 (D. Md. Dec. 23, 2005). On appeal, Classen no longer asserts that Elan's clinical study and FDA submissions are infringing, Appellant's Br. 7, 20–27, 29, 40, 43, 45, 46–47, 50, but it nevertheless argues that the district court erred in finding those activities exempt under the safe harbor because, according to Classen, those activities are merely routine post-approval reporting to the FDA, *id.* at 4 & n.2, 29.

Under § 271(e)(1), the exemption from infringement "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (emphasis in original). The statute does not exclude "certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." *Id.* Nor does the statute limit the safe harbor only to those activities necessary for seeking approval of a generic version of a brand-name drug product. *Id.* at 206.

Although in the post-approval context it may be less straightforward to determine whether an accused infringer's use of a patented invention was "*solely* for uses reasonably related to the development and submission of information" under the FDCA, 35 U.S.C. § 271(e)(1) (emphasis added), the statutory language does not cate-

gorically exclude post-approval activities from the ambit of the safe harbor, *Momenta*, 686 F.3d at 1359. Indeed, under the FDCA, drug manufacturers may voluntarily, or sometimes may be required to, conduct post-approval studies on their products for purposes of developing and submitting information to the FDA. *See* 21 U.S.C. § 355(e), (o); *id.* § 356(c)(2)(A); 21 C.F.R. § 314.70.

In some circumstances, drug manufacturers voluntarily conduct post-approval scientific studies and clinical trials to support "supplemental" new drug applications, seeking the FDA's approval to revise the label of their products. *See* 21 C.F.R. § 314.70. Just like NDA or ANDA applicants, sNDA applicants must submit relevant data to the FDA to support their applications. *Id.* § 314.70(b)(3). Thus, after the initial approval of a drug, its manufacturer may perform additional research to further characterize the drug and submit that information to the FDA for a labeling change. Such post-approval studies serve similar purposes as pre-approval studies in ensuring the safety and efficacy of approved drugs. As an integral part of the regulatory approval process, those activities are "reasonably related to the development and submission of information" under the FDCA, 35 U.S.C. § 271(e)(1), and are therefore exempt from infringement liability.

Here, Elan's clinical study and its FDA submissions clearly fall within the scope of the safe harbor. After learning that the FDA proposed to change the designation of metaxalone tablets, Elan initiated its own clinical trial to characterize the effect of food on the absorption of Skelaxin and observed a significant increase in bioavailability when Skelaxin was administered with food. Elan submitted that information to the FDA to revise the Skelaxin product label and to propose changes to the approval requirements for generic versions of Skelaxin. Those activities were anything but "routine" post-approval reporting, *Biogen*, 659 F.3d at 1070; rather, they

were "necessary" to the approval of both the brand-name and generic versions of Skelaxin, *Momenta*, 686 F.3d at 1358. The district court therefore did not err in holding that Elan's clinical activities and FDA submissions are exempt from infringement under the safe harbor provision.

Classen also argues that after Elan generated and submitted the clinical data to the FDA, its subsequent actions of reanalyzing the clinical data to identify patentable information and filing patent applications are commercial activities outside the scope of the safe harbor. Classen also argues that Elan infringed the kit claims by making and selling Skelaxin with the revised label that contained the information derived from the clinical study. Classen contends that the safe harbor does not protect those post-submission commercial uses of information derived from the clinical study.

Elan responds that it generated the clinical data on Skelaxin mainly for submission to the FDA and that it did not reanalyze the data when filing the patent applications. Elan contends that subsequent uses of clinical data generated for the FDA in other contexts do not result in the removal of the safe harbor protection. Elan also responds that because each of the kit claims depends from a method claim that Elan did not infringe, Elan's making and selling of Skelaxin with the revised label is likewise not infringing.

As indicated, we have concluded that Elan's clinical study and its FDA submissions are exempt under the safe harbor provision. We have also held that the subsequent disclosure or use of *information* obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that exemption of the clinical study, provided that the subsequent disclosure or use is itself not an *act of infringement* of the asserted claims.

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

In *Telectronics*, the patentee conceded that the dissemination of *information* derived from an exempt clinical study, including the activities of "presenting clinical trial data at a cardiology conference, reporting clinical trial progress to investors, analysts and journalists, and describing clinical trial results in a private fund-raising memorandum," did not, in and of itself, constitute an act of infringement in that case. *Id.* We held that the patent statute does not identify the mere dissemination of data as a potentially infringing activity and that, when enacting § 271(e)(1), Congress did not intend to prevent competitors "from using, in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes." *Id.* at 1524–25.

Here, unlike in *Telectronics*, Classen alleges that Elan's post-submission *activities* using the clinical data for non-regulatory purposes *infringed* the claims of Classen's '472 patent. Specifically, Classen asserts that Elan's filing of patent applications based on the clinical data infringed the method claims and that Elan's sale of Skelaxin with the revised label containing information derived from the clinical trial infringed the kit claims. As indicated, when granting summary judgment of noninfringement, the district court did not determine whether those post-submission activities constituted infringement of the '472 patent or whether they were exempt under the safe harbor. Rather than deciding those issues in the first instance on appeal, we vacate the judgment of noninfringement and remand the case to the district court for further proceedings on the parties' pending claims and counterclaims, including issues of validity, enforceability, and infringement of the asserted patent.

To assist the district court in its analysis of infringement, if the court reaches that issue on remand, we make

the following observations of the record. Filing a patent application is generally not an infringement of a patent. It is not the making, using, offering to sell, selling, or importing of an invention. It is the act of approaching an agency of the government in order to obtain a limited privilege and to fulfill a public goal of making knowledge of an invention available to the public. It is not commercializing an invention, which requires introducing an invention into commerce, or making preparations to do so. Moreover, infringing a multi-step method claim requires carrying out all the steps of the claim. As filing a patent application is not commercializing an invention, a method claim requiring commercialization, as claim 36 does, is likely not infringed by Elan's actions here.

In addition, placing the *information* submitted to the FDA on the product label after sNDA approval generally cannot be an infringement. Information obtained from exempt activities does not cease to be exempt once the sNDA is approved. It is a requirement of law that a drug product contains the labeling approved by the FDA. This is not to say that a pharmaceutical patent claiming a method of treatment, a method of preparation, or a composition of matter cannot be infringed by the subsequent *actions* of making, using, offering to sell, selling, or importing of a drug covered by that patent based on information derived from exempt activities. But that is not the case here.

Having stated the above, we leave it to the district court to deal with any infringement or other issues as it deems appropriate.

CONCLUSION

We have considered Classen's remaining arguments but find them unpersuasive. For the foregoing reasons, we vacate the district court's judgment of noninfringement and remand.

VACATED AND REMANDED

COSTS

Costs to Elan.