PSN Illinois, LLC v. GenScript Corporation Doc. 164

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PSN ILLINOIS, LLC, Plaintiff, v. ABBOTT LABORATORIES AND ABBOTT BIORESEARCH CENTER, INC., Defendants.	09cv5879 Case No. 09 C 5879 The Honorable William J. Hibbler

MEMORANDUM OPINION AND ORDER

PSN Illinois, LLC alleges that Abbott Laboratories, Inc (Abbott) and Abbott Bioresearch Center, Inc. (ABC) have infringed upon several of its patents. Defendants move for summary judgment, arguing that their activities are protected by the Safe Harbor provision of 35 U.S.C. § 271(e)(1), that PSN's settlement and license agreements with third parties has exhausted their rights in the patents, and that PSN failed to comply with the notice requirements of 35 U.S.C. § 287(a).

I. Factual Background

A. The Patents

PSN owns the patents to the molecular cloning and expression of human and rat G-protein coupled receptors in the S1P family of receptors. G-protein coupled receptors are protein molecules that occur naturally in the body and are expressed on the cell surface. (Defendant's 56.1(a) Statement (Def. St.) ¶ 6). Different receptors bind to different signaling molecules (ligands) and are involved in a variety of bodily processes. (Def. St. ¶ 6). The S1P family of receptors, S1P1-5, are

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involved in the regulation of vasculature and immune systems. (Def. St. ¶ 7). Specifically, PSN owns three patents related to the S1P2 receptor. (Major Decl. Exs. JJ-LL).

B. Defendants' Research

Beginning in 2005, Abbott began to research potential drug candidates that might interact with one or more of the S1P receptors to achieve therapeutic objectives. (Def. St. ¶¶ 8,10). Abbott or ABC used S1P2 receptors to screen thousands of potential drug candidates for activity at the S1P2 receptor, including potential adverse effects. (Def. St. ¶ 11; Pl. 56.1(b)(3)(C) Statement (Pl. St.) ¶ 11).

In order to conduct its research, ABC first purchased S1P2 receptor primers (human, rat, and mouse) from Applied BioSystems, Inc. in 2005, which it used through 2010. (Def. St. ¶ 10). It used these S1P2 receptor primers to measure the relative expression of the S1P2 receptor as compared to other S1P receptors in order to determine whether activity at the S1P2 receptor was responsible for certain cell behavior. (Def. St. ¶ 11). In 2005, ABC also purchased a human S1P2 receptor primer from Invitrogen. (Def. St. ¶ 12). The S1P2 receptor primer purchased from Invitrogen did not contain the full receptor nucleotide sequence. (Def. St. ¶ 12). ABC then cloned the primer it purchased from Invitrogen and used the in-house cloned receptor from 2005 to 2009 in tests to determine whether a drug candidate exhibits undesirable activity. (Def. St. ¶ 13-14). Abbott also used the primer from Invitrogen to design and validate a Fluorescent Imaging Plate Reader (FLIPR) assay to screen for compounds that have effects on the activity of certain receptors, particularly to identify S1P2 receptor antagonists. (Def. St. ¶ 15).

The in-house cloned S1P2 receptor originating from Invitrogen did not work to Abbott's satisfaction, so it purchased a cell line that expressed S1P2 from DiscoveRx Corp in November 2007.

(Def. St. ¶ 16, 18). Abbott used the cell line from DiscoveRx to conduct high-throughput screening to identify S1P2 antagonists. (Def. St. ¶ 19). ABC used the cell line purchased from DiscoveRx to do follow-up research on the high-throughput screening in an effort to identify an asthma drug candidate. (Def. St. ¶ 20). Abbott and ABC ceased using the cell line they purchased from DiscoveRx by February 2009. (Def. St. ¶¶ 19-20).

In addition, ABC purchased a S1P2 receptor antagonist from EMD Bioscience, Inc. in 2007. (Def. St. ¶¶ 22-23). ABC used the receptor antagonist in receptor binding experiments to look for potential side effects due to binding at S1P receptors and to test a hypothesis about the functionality of the S1P2 receptor. (Def. St. ¶¶ 24-25).

Finally, in 2009, Abbott purchased a rat S1P2 DNA fragment that included a version of a rat S1P2 receptor from GenScript Corp. (Def. St. ¶ 31). Abbott used the S1P2 DNA fragment to over-express the rat S1P2 receptor to conduct experiments aimed at understanding binding selectivity at different S1P receptors to avoid potential side effects caused by binding at S1P receptors. (Def. St. ¶ 32). It used the technology purchased from GenScript from January 2009 through mid-2009.

In addition to purchasing primers and expressed S1P2 receptors, ABC also cloned a rat S1P2 receptor in 2007 and expressed a rat S1P2 receptor in 2008. (Def. St. ¶¶ 27-28). Defendants do not identify the source from which they obtained the S1P2 sequence used to create the cloned S1P2 receptors or to introduce that sequence into a cell. (Def. St. ¶¶ 27-28).

Defendant's research revealed, among other things, three potential drug candidates (ABT-924, ABT-413, ABT-459). (Def. St. ¶ 36-37). None of the compounds that Abbott has identified contain the S1P2 receptor nucleotide sequence or protein. (Def. St. ¶ 36). Abbott has not sold or

offered for sale any of the potential drug candidates. (Def. St. ¶ 36). However, Abbott has submitted information regarding ABT-924 and ABT-413 to the FDA. (Def. St. 40).

C. PSN Licenses

On February 14, 2008 PSN first licensed its patents to one of several corporations. PSN licensed two of the patents to Genetex to manufacture and sell products generated from S1P2 technologies. (Def. St. ¶ 48). In turn, Genetex agreed to pay PSN a royalty from the revenues generated from such sales. (Def. St. ¶ 48). Over the next two years, PSN settled claims against DiscoveRx, EMD Chemicals, Inc., GenScript Corporation, and Life Technologies Corporation. (Def. St. ¶¶ 49-53). Each of these settlements waived claims PSN held for past infringement and granted licenses to the companies to commercialize the S1P2 technology. (Def. St. ¶¶ 49-53). Each company paid PSN consideration for its past infringement and agreed to the payment of royalties for future sales. (Def. St. ¶¶ 49-53). The Court later discusses further details of these agreements.

II. Standard of Review

Courts must grant a motion for summary judgment when "there is no genuine issue as to any matter fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). To defeat a motion for summary judgment, the nonmoving party must establish that there is a genuine dispute over material facts. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A "material" fact is any fact that may affect the final adjudication of the case under existing law and if it creates an inference that would a reasonable jury to find in favor of the nonmoving party. *Id.*

The court, however, must evaluate all admissible evidence in a light most favorable to the nonmoving party. *Payne v. Pauley*, 337 F.3d 767, 770 (7th Cir.2003). Nevertheless, to survive summary judgment, the party must present more than speculation and conjecture. *Id.* In other words, the nonmoving party cannot rely on the pleadings and "must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 248.

III. Analysis

A. Safe Harbor Exemption

Under the Federal Food, Drug, and Cosmetic Act (FDCA), drugmakers and manufacturers of medical devices must submit products for regulatory review at various points in the development process prior to market entry. 21 U.S.C. § 355 & 360e; *Merck KGA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005). The FDCA's regulatory scheme creates two distortions in the lives of patented drugs and medical devices. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 672, 669-670, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990); *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1260-61 (Fed. Cir. 2008). First, patent holders are deprived of the benefit of the patents in the early years of the term as the product awaits regulatory approval. *Eli Lilly*, 496 U.S. at 669-670. Second, those who plan to compete with a patentee at the expiration of a patent's term face delays while they await similar regulatory approval, which artificially extends the life of the patent. *Id.* at 670.

To minimize the effect of these distortions, Congress enacted the Hatch-Waxman Act. *Proveris Scientific Corp.*, 536 F.3d at 1260; *Classen Immunotherapies, Inc. v. Biogen Idec*, — F.3d —, 2011 WL 3835409, at *13 (Fed. Cir. Aug. 31, 2011). The portion of the Act that dealt with the second distortion, now codified at 35 U.S.C. § 271(e)(1), provides that "[i]t shall not be an act of

infringement to make, use, offer to sell, or sell within the United States, or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." The parties dispute whether the safe harbor exemption protects Abbott's use of the S1P2 technology in its research.

In 1990, the Supreme Court addressed the scope of the safe-harbor exemption. *Eli Lilly*, 496 U.S. 661. In *Eli Lilly*, the Supreme Court addressed whether § 271(e)(1) applied to medical devices in addition to drugs or pharmaceutical products. *Eli Lilly*, 496 U.S. at 663-664. The principal dispute in *Eli Lilly* centered on the interpretation of the phrase "under a Federal law which regulates the manufacture, use, or sale of drugs," particularly whether that phrase referred only to individual provisions of federal law that regulates drugs or the entirety of any act that regulates drugs. *Eli Lilly*, 496 U.S. at 665-66. In answering the question, the Court observed that § 271(e)(1) was not a model of elegant statutory draftsmanship, conceding that the statute was ambiguous. *Eli Lilly*, 496 U.S. at 679. Even though the Court conceded that the natural meaning of the statute implied that the phrase referred only to individual provisions of federal law, it questioned the logic of such a conclusion. *Id.* at 668. Ultimately, the Court concluded that the legislative intent behind § 271(e)(1) was to make it coextensive with § 156(f), which concerned the first distortion caused by the FDCA and did apply to medical devices. *Id.* at 673-74, 79. Thus, the Supreme Court made clear that the safe harbor exemption applies not only to drugs but also to any medical device that would require approval under the FDCA.

The Supreme Court again took up the clarity of § 271(e)(1) in 2005. *Merck*, 545 U.S. 193. In *Merck*, the Court addressed whether the safe-harbor exemption protected uses of patented

inventions in pre-clinical research the results of which were not ultimately submitted to the FDA. *Id.* at 195. In *Merck*, the responded held a patent related to a tripeptide sequence known as the "RGD peptide." *Id.* at 197. The RGD peptide promoted cell adhesion by attaching to receptors on the outer surface of certain cells. *Id.* The petitioner discovered that certain RGD peptides might act as angiogenesis inhibitors and evaluated their suitability as potential drug candidates. *Id.* at 198-199. In other words, the petitioner used the patented invention itself as a component in a potential therapeutic application. *Id.* at 197-99. In the end, the petitioner's research took it in another direction and it did not file an investigational new drug application (IND) or a new drug application (NDA) with the FDA based on its use of the patented RGD peptides. *Id.* The petitioner nonetheless sought the protection of the safe harbor exemption.

In addressing the petitioner's claims, the Court observed the breadth of the § 271(e)(1) exemption. *Merck*, 545 U.S. at 202 (commenting that § 271(e)(1)'s exemption "extends to all uses of patented inventions reasonably related to the development and submission of *any* information under the FDCA") (emphasis in original)). The Court rejected the contention that § 271(e)(1) would provide safe harbor for infringing activities only if the infringing party ultimately filed an IND or NDA with the FDA, noting that the scientific process requires trial and error. *Id.* at 206-07. It thus concluded that the use of patented compounds in preclinical studies is protected under § 271(e)(1) so long as there is a reasonable basis to conclude that the experiments will produce the type of information that are relevant to an IND or NDA even if the alleged infringer never submits such information to the FDA. *Id.* at 208.

Neither *Eli Lilly* nor *Merck*, however, dealt directly with § 271(e)(1)'s applicability to research tools.[1] In fact, in *Merck* the Supreme Court explicitly stated that it did not express a view about whether or to what extent § 271(e)(1) exempts from infringement the use of research tools. *Merck*, 545 U.S. at 205 n. 7 (noting that respondents had not contended that the RGD peptides were used as research tools). In *Proveris*, however, the Federal Circuit took up the question. The plaintiff in *Proveris* held a patent in a device for characterizing aerosol sprays used in drug delivery devices. *Proveris*, 536 F.3d at 1258. The defendant manufactured a device that infringed on several claims of the patented device and offered to sell it to pharmaceutical companies to use exclusively to gather information relevant to regulatory approval. *Id.* at 1259-60.

In *Proveris*, the defendant manufactured and sold a patented device, an optical spray analyzer (OSA), that other companies used in their drug development research. *Id.* at 1259-60. The OSA itself did not require regulatory approval, but the drugs and aerosol sprays being researched by the defendant's customers did. *Id.* In applying the reasoning of *Eli Lilly* to the facts before it, the court reasoned that because the patented device "is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration, [the defendant] is not a party who . . . could be said to have been adversely affected by the second distortion [of the FDCA.]" *Id.* at 1265 Similarly, it reasoned that because the patented device is not one which is subject to regulatory approval, the plaintiff is not a party who would be adversely affected by the first distortion of the FDCA. *Id.* Consequently, it concluded that the OSA was not a "patented invention" within the

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[1] Research tools are "'tools that scientists use in the laboratory including cell lines, monoclonal antibodies, reagents, animal models, groth factors, combinatorial chemistry and DNA libraries, clones cloning tools . . ., methods, laboratory equipment, and machines.'" *Integra LifeSciences I, Ltd. v. Merck KGAA*, 496 F.3d 1334, 1347 n.3 (Fed. Cir. 2007) (quoting The National Institutes of Health, 64 Fed. Reg. 72,090, 72092 n.1 (Dec. 23, 1999)).

meaning of § 271(e)(1). Instead, only "patented inventions" for which regulatory approval is required fall within the scope of the safe harbor exemption. *Id.* at 1265-66. In short, *Proveris* excluded research tools from the purview of the safe harbor exemption.

In reaching its conclusion that § 271(e)(1) does not extends its protection to the use of research tools, the Federal Circuit relied on the history and purpose of the Hatch-Waxman Act. The court noted that the "basic idea behind [§ 271(e)(1)] was to allow competitors to begin the regulatory approval process while the patent was still in force, followed by market entry immediately upon patent expiration." *Id.* at 1260-61; *see also Classen Immunotherapies*, 2011 WL 3835409, at **13-14; *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992). The court has since reiterated this legislative purpose. *Classen Immunotherapies*, 2011 WL 3835409, at **12-13 (observing that the legislative history of Section 271(e)(1) identifies the statute's purpose as preparation for premarketing approval of generic drugs) (citing H.R. Rep. No. 98-857, pt.1, at 45 (1984)). In fact, the legislative history of the Hatch Waxman Act suggests that the "only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." H.R. Rep. No 98-857, pt. 2, at 8 (1984). Every decision examining the safe harbor exemption has "appreciated that [it] is directed to premarketing approval of generic counterparts before patent expiration." *Classen Immunotherapies*, 2011 WL 3835409, at *13-14 (noting that "there is no dispute as to the statutory purpose, and no contrary precedent."); *see also Eli Lilly*, 496 U.S. at 671; *Proveris Scientific Corp.*, 536 F.3d at 1261; *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

Despite the Federal Circuit's clear holding, Defendants argue that § 271(e)(1) provides safe harbor for the use of research tools that would otherwise constitute an act of infringement. In support, Defendants first offer quotations from *Merck* with all context stripped away. Defendants quote *Merck* and emphasize its use of the word "any," *see Merck*, 545 U.S. at 202, to argue that the use of a patented invention reasonably related to the development and submission of information to the FDA falls within the safe harbor exemption. (Def. Br. at 6). In so arguing, Defendants contend that the legislative purpose behind the Act is something other than what is stated by the Supreme Court, the Federal Circuit, and the statute's legislative history.

Quite simply, *Merck* stands for the principal that even where the alleged infringer fails to submit information to the FDA it still can receive the protection of the safe harbor exemption. *Merck*, 545 U.S. at 208. Most certainly, *Merck* does not stand for the broad principal that Defendants urge— that *any* use of a patented invention to gather information to submit to the FDA is protected. Indeed, the Supreme Court in *Merck* made explicitly clear that it was not addressing the question of whether the use of research tools is protected within the safe harbor exemption. *Id.* at 205 n. 7. Defendants' argument or implication to the contrary is without merit.

Defendants next attempt to distinguish *Proveris*. They argue that the accused infringer in *Proveris* did not itself engage in developing or submitting information to the FDA, but rather sold the patented device to third parties who engaged in developing or submitting information to the FDA. Defendants thus contend that the Federal Circuit's holding in *Proveris* is limited to those who actively commercialize the infringing product. This distinction makes little sense. Making, using, and selling patented inventions are all acts of infringement. Defendants offer no reasoned

explanation why the safe harbor exemption would apply more broadly to an alleged infringer who infringes only by use and more narrowly to an alleged infringer who infringes by manufacture and sale.

The reasoning set forth in *Proveris* makes clear that Defendants' distinction is irrelevant. In *Proveris*, the Federal Circuit relied heavily on the history and purposes behind the safe harbor exemption. *Proveris*, 536 F.3d at 1265. Central to the court's reasoning is its position that the safe harbor exemption is designed to allow competitors to enter the market with a product that competes with a patented invention at precisely the time the patented invention loses its protected status. *Id.* Here, Defendants were not infringing on the S1P2 receptors in order to obtain FDA approval to introduce a generic receptor to compete in the marketplace when the patent on those receptors expired. They were using a patented invention to develop their own patentable product. *Proveris* is on point and makes clear that 271(e)(1) offers no protection to such activity. Rather, under *Proveris*, because the S1P2 receptors do not require regulatory approval, they are not a "patented invention" within the meaning of § 271(e)(1).

B. Patent Exhaustion

Defendants next contend that in settling infringement claims against various third parties, PSN authorized those parties to sell S1P2 receptor products and so has exhausted its rights in the patents. The doctrine of patent exhaustion prevents a patentee from further controlling the sale or use of a patented article after the patentee has authorized that article's unconditional sale by another. *Quanta Computer Inc. v. LG Elec., Inc.*, 553 U.S. 617, 636, 128 S.Ct. 2109, 170 L.Ed.2d 996 (2008). The rationale underlying the doctrine rests upon the theory that an unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of that item thereafter because the

patentee has bargained for and received the full value of the goods. *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (citing *B. Braun Med., Inc. v. Abbott Lab.*, 124 F.3d 1419 (Fed. Cir. 1997) & *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992)). Where a patentee makes or grants a conditional sale or license, it is more reasonable to infer the negotiated price reflects only the value of the rights conferred by the patentee. *Id.* (citing *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 181, 58 S.Ct. 849, 82 L.Ed. 1273 (1938)).

The exhaustion doctrine is triggered only by a sale authorized by the patent holder. *Quanta Computer, Inc.*, 553 U.S. at 635-36. However, authorized sales are not limited to traditional commercial transactions. *See, e.g., Transcore v. Elec. Transaction Consultants*, 563 F.3d 1271 (Fed. Cir. 2009); *Jacobs v. Nintendo of Am., Inc.*, 370 F.3d 1097 (Fed. Cir. 2004). In *Transcore*, a patentee settled infringement claims against a competitor. *Transcore*, 563 F.3d at 1273. The settlement agreement released the competitor from any claims for future infringement. *Id.* After the claims had been settled, the competitor sold allegedly infringing devices to another party. *Id.* The patentee then sued the downstream customer. *Id.* The patentee argued that the settlement agreement, containing a covenant not to sue, did not authorize the competitor to sell the patented device and therefore patent exhaustion did not apply. *Id.* at 1274. The Federal Circuit disagreed, noting that the settlement agreement released the competitor from future infringement claims and contained no restriction or limitation, such as limiting the release to making or using the patented device but restricting the competitor's right to sell or offer for sale the patented device. *Id.* at 1276. Thus the relevant question for the Court here is whether the settlement agreements and associated licenses authorized DiscoveRx, EMD, Applied Bio Systems, Invitrogen, and GenScript to have sold S1P2

products. *Id.* at 1276. Because the focal point of the Court's inquiry is the language of the settlement agreements, the Court examines each in turn.[2]

1. DiscoveRx

Abbott purchased a cell line that expressed an S1P2 receptor from DiscoveRx in November 2007. It used the cell line purchased from DiscoveRx to conduct high throughput screening until approximately November 2008. In addition, it used the cell line purchased from DiscoveRx to perform follow-up characterization work through February 2009.

In April 2008, PSN settled claims against DiscoveRx and entered into a settlement and license agreement. The PSN-DiscoveRx settlement agreement purports to do two things: (1) make peace between PSN and DiscoveRx for "any prior use" of the S1P2 technology; and (2) extend a license to DiscoveRx for to make and sell S1P2 technology. (Major Decl. Ex. OO). Specifically, the agreement states that "as full compensation to PSN for any prior use of S1P2 Technology" DiscoveRx would pay PSN a fixed sum and in exchange PSN would "fully, finally and forever release [DiscoveRx] from any future claims of infringement of PSN's patents." (Major Decl. Ex. OO at ¶¶ 1,9). The PSN-DiscoveRx agreement thus appears to grant DiscoveRx an unconditional release for its prior use of PSN patents. However, the agreement contains one restriction upon DiscoveRx's customers' use of S1P2 technology, acknowledging that "customers of DiscoveRx are licensed to use S1P2 . . . cell lines obtained from DiscoveRx for internal research, drug discovery and drug development purposes, but only to the extent permitted by the safe harbor exemption of 35 U.S.C. § 271(e)(1)." (Major Decl. Ex. OO at ¶ 7(b)).

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[2] PSN concedes that JTE-013, which Abbott purchased from EMD, does not contain the S1P2 receptor and therefore does not infringe. Accordingly, the Court does not address whether PSN's settlement with EMD exhausted its interest in the patents.

Although the PSN-DiscoveRx agreement limits the use to which DiscoveRx customers may employ the patents, Defendants contend that this limitation, found in Subparagraph 7(b), is forward looking only — that it applies only to S1P2 technologies sold after the agreement and that the agreement provides an unconditional release for prior use of the patents. PSN argues on the other hand that Subparagraph 7(b) limits DiscoveRx customers' use of the patented technologies regardless of when the customer obtained the technology. Neither party offers any reasoned explanation for its interpretation of the PSN-DiscoveRx agreement, but rather simply asserts that its position is correct. To resolve the argument, the Court fist looks to the plain language of the PSN-DiscoveRx agreement.

Where a contract is unambiguous, its interpretation is matter of law and a court must enforce it as it is written. *Lewitton v. ITA Software, Inc.*, 585 F.3d 377, 379 (7th Cir. 2009); *Curia v. Nelson*, 587 F.3d 824, 829 (7th Cir. 2009).[3] A contract is ambiguous if it is reasonably susceptible to more than one meaning. *Temme v. Bemis Co.*, 622 F.3d 730, 734-35 (7th Cir. 2010); *Curia*, 587 F.3d at 829. In construing a contract, a court should look to the contract as a whole, viewing each part in relation to the others. *Temme*, 622 F.3d at 734-35; *Curia*, 587 F.3d at 829. In addition, a court should adopt a construction that gives meaning and effect to every clause, phrase and word. *Temme*, 622 F.3d at 734-35; *Curia*, 587 F.3d at 829.

When considering the PSN-DiscoveRx agreement in its entirety, the only reasonable interpretation of the agreement between PSN-DiscoveRx is that Subparagraph 7(b) limits only future

[3] The settlement agreement between PSN and DiscoveRx was made in Illinois, resolved a lawsuit that was filed in Illinois, and directed DiscoveRx to make payments to PSN in Illinois. Just as neither party offers any explanation for its interpretation of the PSN-DiscoveRx agreement, neither party sets forth any argument regarding whether the Court should interpret the agreement using Illinois law or federal common law. The applicable principles of contract law, however, are the same whether the Court applies Illinois law or federal common law.

authorized sales of the patented technologies. At the outset of the agreement, it distinguishes the consideration to be paid for prior infringement from that to be paid for the license to be granted. The first sentence of Paragraph 1 states that DiscoveRx provides full consideration to PSN for any prior use. The final sentence of Paragraph 1 states that "[i]n addition, . . . DiscoveRx shall pay a patent royalty to PSN for the future manufacture, us, sale and/or offer for sale of S1P2 Technology." (Major Decl. Ex. 00 at ¶ 1). The structure of Paragraph 1 clearly reflects an intent to separate prior use and future licensed use. In addition, Paragraphs 4 and 5, which identify the parties' intent for DiscoveRx to further commercialize the S1P2 technology and define the royalty structure under which it will do so, similarly reflect the parties' intention to separate prior use from future licensed use. (Major Decl. Ex. OO at ¶¶ 4,5).

The structure of Paragraph 7, when viewed in its entirety, also reflects this intent. The first subparagraph of Paragraph 7 states that "PSN grants a nonexclusive license to DiscoveRx under the S1P2 Technology to make, have made, use, offer for sale and sell [the patented technologies.]" (Major Decl. Ex. OO at ¶ 7(a)). Subparagraph 7(a) explicitly employs the past tense to include previous manufacture of the patented technologies. It does not, however, employ the past tense to include previous sales of the patented technologies. Thus Subparagraph 7(a) looks forward and not backward. Subparagraph 7(b) cannot be stripped from the context in which it appears and must be read in connection with Subparagraph 7(a). Paragraph 7, concerning the license granted to DiscoveRx, unambiguously applies to future sales and not past sales

Paragraphs 1 and 9 unconditionally grant a release for any prior infringing activity by DiscoveRx. Those paragraphs do not limit the release to DiscoveRx's manufacture or use of the S1P2 technology and so must necessarily release it from any sale of the S1P2 technology. The only

limitation in the PSN-DiscoveRx agreement, contained in Subparagraph 7(b) applies only to future sales of the technology. Given the holding of *Transcore*, the Court thus concludes that the PSN-DiscoveRx agreement authorized the 2007 sale of S1P2 materials from DiscoveRx to Defendants. *See Transcore*, 563 F.3d at 1276 (holding that a settlement agreement that released competitor from all future infringement claims authorized party to sell patented items and exhausted the patents with respect to downstream purchasers). The Court therefore holds that PSN's patent rights in the S1P2 technology that Defendants purchased from DiscoveRx have been exhausted.

This result is consistent with the purposes behind the patent exhaustion doctrine. When PSN negotiated the settlement with DiscoveRx it could have learned through discovery to whom DiscoveRx had sold the S1P2 technologies. PSN then could bargain for and receive the full value of the goods when it negotiated the settlement with DiscoveRx. *See Princo Corp. v. Int'l Trad Comm'n*, 616 F.3 dat 1328 (discussing the rationale underlying the exhaustion doctrine). In fact, PSN did negotiate the consideration DiscoveRx's past infringement, which included the sale of the S1P2 technology to Defendants, and specified the consideration to be paid for past infringement in the settlement agreement. Thus, it is reasonable to assume that PSN received full compensation for that infringement and not reasonable to allow PSN to seek a double recovery by later going after DiscoveRx's customers.

The Court therefore GRANTS Defendants' Motion for Summary Judgment with respect to any use of the patents it received from DiscoveRx.

2. Applied BioSystems and Invitrogen

ABC purchased S1P2 receptor primers from Applied BioSystems in 2005, which it used through early 2010 in its research to help identify whether activity at the S1P2 receptor was

responsible for various cell behaviors. It also purchased an S1P2 receptor primer from Invitrogen in 2005, which it used through 2009 in counter-screen assays to test identify undesirable activity among potential drug candidates. In November 2008, Applied BioSystems and Invitrogen merged to form Life Technologies Corporation (LTC).

In April 2010, PSN settled its claims against LTC and entered into a settlement and license agreement. (Major Decl. Ex. SS). Under the agreement, PSN released LTC "and each of its parents, subsidiaries, affiliates, and all of its officers, directors, principals, shareholders, representatives, agents, successors, predecessors, assigns, and other representatives," and waived "any and all claims and liability for all losses, costs, claims, liabilities, expenses, demands or obligations . . . related to the PSN Patents and/or the litigation arising before the effective date, including without limitation any claims for infringement of the PSN patents." (Major Decl. Ex. SS at ¶ 8). In addition to the release of prior claims, the agreement also granted LTC a license to continue to make, buy, use and sell the PSN patents. (Major Decl. Ex. SS at ¶ 3). It limited this license for "internal use only," and as an example "[LTC] shall not have the right to utilize the PSN patents for any clinical or therapeutic use, and cannot convey such a right to others." (Major Decl. Ex. SS at ¶ 3).

The language of Paragraph 8 is unconditional, granting LTC from any and all claims of infringement prior to the effective date of the agreement, April 29, 2010. Paragraph 8 releases LTC from any prior claims "including without limitation any claims for infringement." The release contains no restrictions or limitations upon sales, and thus authorizes "all acts that would otherwise be infringing." *See Transcore* , 563 F.3d at 1276.

PSN first argues that the license agreement with LTC does not apply to Defendants because they purchased the S1P2 technologies from Applied BioSystems and Invitrogen and not LTC. This

argument is frivolous. Paragraph 8 of the agreement states explicitly that the release is granted to all of LTC's predecessors. It is undisputed that Applied BioSystems and Invitrogen merged to form LTC and, thus, they fall within the scope of the release.

PSN next argues that the license is conditional and does not protect Defendants. In support, PSN points to the limiting language of Paragraph 3 of the agreement. As it did with its interpretation of the agreement with DiscoveRx, PSN interprets Paragraph 3 as an isolated and independent paragraph. In doing so, PSN distorts the plain language of Paragraph 3. Paragraph 3 states that the licensee (LTC) does not have the right to utilize the PSN patents "for any clinical or therapeutic use, and cannot convey such a right to others." (Major Decl. Ex. SS at ¶ 3). PSN reads only the phrase "cannot convey such a right to others," interpreting it to mean that LTC cannot convey *any* rights to other parties. But of course, this makes no sense, because Paragraph 3 also grants LTC the right to sell the patents, which would be rendered meaningless if LTC could convey no rights in the patents to its customers. PSN neglects to consider that the phrase it focuses upon is modified. The right that cannot be conveyed is the right to use the patents "foy any clinical or therapeutic use." A clinical or therapeutic use would be one in which the patents are used to treat actual patients and not one in which the patents are used in experimentation or theory. See Webster's Third New Int'l Dictionary 423, 2372 (3d ed. 1986) (defining clinical as depending on observation of the living patient and therapeutic as relating to the treatment of disease). PSN offers no evidence that Defendants used the patents in a clinical or therapeutic manner.

Because the PSN-LTC agreement also releases LTC's predecessors from any and all claims of prior infringement, Applied BioSystems' and Invitrogen's sale of the S1P2 primers to Defendants in 2005 constitutes an "authorized sale," which triggers the patent exhaustion doctrine. The Court

therefore GRANTS Defendants' Motion for Summary Judgment with respect to any use prior to April 29, 2010 of the patents in issue it obtained from Applied BioSystems and Invitrogen.

3. GenScript

Abbott purchased a rat S1P2 DNA fragment from GenScript in 2009 and used the fragment to over-express the S1P2 receptor in various experiments related to its drug research. Later in 2009, PSN settled its infringement claims against GenScript and entered into a license agreement. Among other things, that agreement releases Genscript "fully, finally and forever . . . from any future claims of infringement of PSN's patents." (Major Decl. Ex. RR at ¶ 8). Like the PSN-LTC settlement, this release is unconditional and therefore authorizes GenScript's sale of the S1P2 technologies to the Defendants.

PSN makes little to no argument that the license agreement it entered into with GenScript does not exhaust its patent.[4] In short, PSN points to another paragraph of the agreement to suggest that it limited the use to which GenScript's customers could put the patents. Paragraph 6 of the Agreement licenses GenScript customers to use the patents for "internal research, drug discovery, and drug development purposes." (Major Decl. Ex. RR at ¶ 6). It also restricts GenScript customers from reselling S1P2 products, deriving any S1P2 sequences or amino acids from any purchased products, or selling any drugs using the S1P2 technology. (Major Decl. Ex. RR at ¶ 6). PSN argues that Paragraph 6 limits Defendants' licensed use of the patents. It does; but PSN has not shown that Defendants have exceeded the limits placed upon it. PSN admits that Defendants have not sold any drugs and further admits that even the drugs that Defendants have tested do not contain S1P2

[4] In fact, PSN states that "it appears that Abbott made little use of the GenScript materials,"which is curious given that the statement trivializes its own infringement claims.

technology. PSN points to no evidence that Defendants resold the S1P2 technology or that it derived any S1P2 sequence from the products that it purchased from GenScript. Thus, Paragraph 6 simply does not apply.

The Court therefore GRANTS Defendants' Motion for Summary Judgment with respect to any use of the patents it obtained from GenScript.

4. Cloned or Expressed Technology

Defendants limit their argument regarding patent exhaustion to their use of the items they purchased (Def. Br. at 8). In its summary judgment materials, however, Defendants admit that ABC both cloned and expressed S1P2 receptors. First, Defendants state that ABC cloned human S1P2 receptors purchased from Invitrogen in 2005 and then used the in-house cloned receptors through 2009. (Def. St. ¶¶ 13-14). Defendants also state that ABC cloned a rat S1P2 receptor in 2007 and expressed a rat S1P2 receptor in 2007 or early 2008. (Def. St. ¶ 27-28). Defendants do not, however, identify the source of the cloned or expressed technologies.

The patent exhaustion doctrine provides that the initial authorized sale of a patented item terminates all patent rights to *that item*," not to the patent generally. *Quanta Computer*, 553 U.S. at 625. Defendants thus could use the S1P2 technologies they purchased without fear of infringement and could resell those technologies. But the manufacture of an additional S1P2 technologies is an independent act of infringement not exhausted by an initial authorized purchase. Thus, the Court holds that to the extent that Defendants cloned or expressed S1P2 receptors the exhaustion doctrine does not protect those acts of infringement.

C. Failure to Mark

The patent marking statute requires patentees to provide constructive notice of the patent by marking it or actual notice of alleged infringement to an accused infringer prior to recovering damages. 35 U.S.C. § 287(a). Although a non-manufacturing patent owner without licenses need not comply with the marking statute, *see* Donald S. Chisum, *Chisum on Patents*, § 20.03[7][c][I] (2005), once PSN began to license the sale of its patents its licensees were required to mark the items for it.

The parties do not genuinely dispute the applicability of § 287(a). Defendants do not contend that any use of the patents prior to PSN's issuance of a license on February 14, 2008, are excused. Nor do Defendants contend that PSN's filing of the lawsuit on September 22, 2009 provided it with actual notice of alleged infringement. Rather, the parties dispute only whether PSN can recover damages for Defendants' alleged infringement between February 14, 2008 and September 22, 2009. PSN's argument that it need not have complied with the marking statute during that period is based entirely on its arguments that its settlement and license agreements with DiscoveRx, LTC, and GenScript did not create authorized sales. The Court rejected that argument and so rejects its argument regarding its failure to mark (or have its licensees mark).

Accordingly, the Court holds that, subject to the limitations in Part III.B of this subsection, PSN may recover damages for infringing activities prior to February 14, 2008 and after September 22, 2009.

IT IS SO ORDERED.

9/20/11
Dated

Wm. J. Hibbler
Hon. William J. Hibbler
U.S. District Court