American Intellectual Property Law Association
Biotechnology Committee

Biotechnology in the Courts Subcommittee Report

Summaries of Recent Decisions of Interest to the Biotechnology Community

Prepared for the AIPLA Biotechnology Committee
June 26, 2013

Edited By:

Melanie Szweras
Subcommittee Chair
Bereskin & Parr LLP
E-mail: mszweras@bereskinparr.com

Nicholas Landau
Subcommittee Vice Chair
Bradley Arant Boult Cummings LLP
E-mail: nlandau@babc.com

C O N T R I B U T O R S

Bruce Vrana
Lynn C. Tyler
Michael R. Brunelle

The AIPLA Biotechnology in the Courts Subcommittee Report is a forum for members of the subcommittee to present summaries and commentary on recent judicial decisions of interest to the biotechnology community. Any view of a contributor expressed in a summary should be understood to reflect only the present consideration and views of the contributor, and should not be attributed to the AIPLA or any of its committees, the contributor's firm, employer, or past or present clients, to other contributors, or to the editor. To request an electronic copy of the Report, or if you are interested in summarizing a case for a future edition, please contact Melanie Szweras at mszweras@bereskinparr.com.

CONTRIBUTORS:

Bruce Vrana received a BS from Cornell University in 1977. From 1978 through 1989, he worked in research at the Microbiology and Immunology Department at Duke University. He received a law degree from Norman Adrian Wiggins School of Law in 1993 and subsequently worked at an IP Law Firm until 1999, when he joined Novartis, now Syngenta, as a Sr. Patent Attorney. He has served as adjunct professor of Intellectual Property at Norman Adrian Wiggins School of Law and is a member of the American Intellectual Property Association, where he served as Chair of the Trade Secret Committee and is currently co-chair of the AIPLA Plant Biotechnology subcommittee. Bruce advises Syngenta Seed's Open Innovation enterprises on IP and Legal issues since initiation in 2008. The bulk of his responsibilities are management of IP issues relating to Enabling Technologies. His main focus is patent preparation and prosecution, FTO, due diligence, portfolio management and value capture for critical methodologies that, alone or in combination with associated technologies, provide the means to generate leaps in performance. Relevant methodologies include gene silencing, targeted insertion, precision transformation, gene regulation and modulation, and gene stacking.

Lynn C. Tyler is a partner and registered patent lawyer in the Intellectual Property Department of Barnes & Thornburg LLP in Indianapolis. He concentrates his practice in litigation of intellectual property matters, representing clients at all stages of the process.

Mr. Tyler is listed in *Best Lawyers in America*® and *Indiana Super Lawyers*®. He is the author of several published articles on issues of intellectual property or federal procedure in a variety of peer-reviewed publications. In 2010, one of his articles won the prestigious Burton Award for Legal Achievement. The first of his two articles on inequitable conduct has been cited by two Federal Circuit Judges in published opinions.

Mr. Tyler graduated *summa cum laude* in 1981 from the University of Notre Dame and in 1984 received his J.D. *magna cum laude* from the University of Michigan Law School. In 2007, he received a M.S. in Biology from Purdue University (Indianapolis campus).

Mr. Tyler's civic activities include being a co-founder, past president, and volunteer for the Neighborhood Christian Legal Clinic. For his work on behalf of the Clinic, he received the Indianapolis Bar Association's Pro Bono Award in 2002 and was a co-recipient of the firm's inaugural Joseph A. Maley Pro Bono Award in 2009.

Michael R. Brunelle is an associate in the Indianapolis, Indiana office of Barnes & Thornburg LLP, and a member of the firm's Intellectual Property Department. He concentrates his practice on intellectual property litigation.

Mr. Brunelle received his B.S. in chemical engineering from Purdue University in 2004. He received his J.D. magna cum laude in 2008 from Indiana University School of Law – Bloomington. During law school, Mr. Brunelle served as a managing editor of the

Indiana Law Journal, as executive problem editor of the Sherman Minton Moot Court Board, and was selected for membership in the Order of the Coif.

Prior to attending law school, Mr. Brunelle worked as a process engineer at Tate & Lyle North America, a specialty starch producer in Lafayette, Indiana.

Mr. Brunelle is a member of the Indiana State Bar Association, and is admitted to practice in the state of Indiana as well as the U.S. District Courts for the Northern and Southern Districts of Indiana, the Western District of Michigan, and the U.S. Court of Appeals for the Federal Circuit.

TABLE OF CONTENTS

Case Summaries

I. *Organic Seed Growers and Trade Ass'n v. Monsanto Company*, Case No. 2012-1298 (Fed. Cir., June 10, 2013)

Reported by Bruce Vrana

Summary

A group of organic farmers, seed sellers, and agricultural organizations sought declaratory judgments of non-infringement and invalidity of twenty-three patents owned by Monsanto. The U.S. District Court for the Southern District NY dismissed the case for lack of jurisdiction. The U.S. Court of Appeals for the Federal Circuit affirmed, based on statements made by Monsanto during litigation that it has no intention of suing any of the plaintiffs if they unintentionally grow infringing crops due to accidental cross-pollination, which the court held would estop Monsanto from filing any such suits.

Invention

Monsanto's patents-in-suit cover all its genetically modified (GM) crops, in particular, its glyphosate resistant crops. Monsanto sells seed to farmers under a limited license, allowing them to "plant, harvest and sell a single generation of genetically modified seed."

Posture

Appellants grow conventional and non-GM seed, and include organic farmers. Appellants do not purchase GM crops from Monsanto and are not authorized under any limited license to grow, sell, or otherwise use its patented seed. They contend that their crops are at risk of contamination with the transgene in the Monsanto crop, thereby exposing Appellants to an infringement action by Monsanto. Appellants contend that it is well known in the industry that Monsanto has sued a large number of growers in the past, and that this knowledge compelled the appellants to "take costly precautions to avoid contamination" to avoid being sued by Monsanto. One Appellant stated that due to such fear of being sued, he refrained from growing certain crops. Consequently, Appellants filed a declaratory judgment action, stating that these facts show a "substantial risk" that they could be sued by Monsanto for infringing the patents.

The Appellants had asked Monsanto to sign a covenant not to sue, which Monsanto refused to do. However, Monsanto pointed Appellants to its website, which stated: "It has never been, nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seeds or traits are present in farmer's fields as a result of inadvertent means." Monsanto's counsel of record also sent a letter basically stating the same: "Monsanto here claims that it has not previously sued 'inadvertent infringers,' and that the Appellants are therefore not similarly situated to those that have been sued" by it

in the past. Importantly, Monsanto relied on these facts in arguing to the court that there was in fact no "substantial risk" to any of the Appellants that they would be sued by Monsanto, and so the Appellants lack standing.

Decision

The question before the court was whether the Appellants can establish a "substantial risk that the harm will occur, which may prompt them to reasonably incur costs to mitigate or avoid that harm," and whether Monsanto's assurances on its website and direct communications with Appellants, that it would not sue farmers for "trace amounts of its patented seeds present in farmer's fields as a result of inadvertent means," would legally dispel the potential controversy. The court based its decision on the general standard that "Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in a position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do."

The panel of the Federal Circuit (Dyk, Bryson, and Moore) assumed that a farmer is an infringer if the farmer's crop or seed inadvertently contains Monsanto's transgene by virtue of being previously cross-pollinated with wind-borne pollen from a nearby field in which a crop containing Monsanto's patented transgene(s) is growing. A number of cases were cited holding that *de-minimis* infringement is still infringement. The panel referred to a study cited by Appellants indicating that contamination has already occurred in a large majority of conventionally-bred seed samples. Thus, the court opined that Appellants' fear that they might be infringing Monsanto's patent was not unreasonable.

The court ruled that "Because Monsanto has made binding assurances that it will not 'take legal action against growers whose crops might inadvertently contain trace amounts of Monsanto biotech genes (because, for example, some transgenic seed or pollen blew onto the growers land)'... and appellants have not alleged any circumstances placing them beyond the scope of those assurances," there was no justiciable case or controversy.

The court stated that "[t]aken together, Monsanto's representations unequivocally disclaim any intent to sue Appellant grower, seed sellers, or organizations for inadvertently using or selling 'trace amounts' of genetically modified seeds." The court further opined that "while Monsanto's representations are not a covenant not to sue, they have a similar effect. If we rely on Monsanto's representations to defeat the appellants' declaratory judgment claims (as we do), those representations are binding as a matter of judicial estoppel."

Commentary

Of interest in this case is that Monsanto's disclaimer is of limited scope. It "applies only to growers or sellers of 'trace' amounts of [contaminated] seed." Thus, a farmer that never buys the Monsanto seed, yet accumulates GM seed greater than trace amounts, remains at risk.

In view of this ruling, a patent holder should be careful when making statements similar to ones made by Monsanto on its website or by other communication, as the scope of such statements will be examined by the Court and might result in estoppel commensurate with such scope. Similarly, a party should be able to rely on clear statements made by a patent holder not to sue for certain activities allegedly covered by a patent.

II. *Dey, L.P. v. Sunovion Pharmaceuticals, Inc.*, Case No. 2012-1428 (Fed. Cir. May 20, 2013)

Reported by: Lynn C. Tyler and Michael R. Brunelle

Summary

When Dey sued Sunovion for infringement of certain patents related to treatments for chronic obstructive pulmonary disease ("COPD"), Sunovion successfully argued on summary judgment that Dey's patents were invalid because a Sunovion clinical trial in which Sunovion tested its own products constituted a prior public use of Dey's inventions under 35 U.S.C. § 102(b) (pre-AIA). The Federal Circuit reversed and remanded, finding that important issues of fact remained in dispute, principally whether sufficient precautions were taken to exclude members of the public from obtaining information about the potentially invalidating prior art.

Decision

Factual background

Dey's patents issued in 2008 and 2009 and claimed priority to an application filed on July 10, 2003. Sunovion produced its commercial product, Brovana, in 2007, but its development began well before that time. Sunovion filed an Investigational New Drug application with the FDA in 1998, seeking FDA approval to conduct clinical trials on human subjects. In February 2002, Sunovion proceeded with human trials. During a Phase III trial, Sunovion administered (in a double-blind and randomized study) various dosages of its formulation, including a formulation designated "Batch 3501A." The parties stipulated that Batch 3501A was identical to the formulation that Sunovion eventually marketed as Brovana.

Over 100 of the trial subjects received Batch 3501A and at least some of those individuals received that formulation prior to July 10, 2002—i.e., more than one year before Dey filed the application that led to the family of patents at issue. The participants in the study were given information about the study, but were not provided with the specific formulation of Batch 3501A. The participants signed a consent form stating that the medication "must be taken only by the person for whom it was intended" and that they would keep usage logs and return unused medications. The consent form noted that the participants may want to discuss the study with their regular doctors and it did not otherwise prohibit the participants from talking to others about the study.

Court's analysis

The Federal Circuit reviewed whether Sunovion's use of Dey's invention constituted an invaliding prior use—i.e., "whether the purported use: (1) was accessible to the public; or (2) was commercially exploited." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1380 (Fed. Cir. 2005). The Court noted that the fact that the alleged

prior public use was carried out by or at the direction of a third party (and not the inventor-patentee as is usually the case) did not alter the analysis. "[E]ven in the case of third-party uses, being 'accessible to the public' still requires public availability; secret or confidential third-party uses do not invalidate later-filed patents." *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371 (Fed. Cir. 1998).

Here, the Federal Circuit found that fact issues remained as to whether sufficient precautions were taken to exclude members of the public from obtaining information about Batch 3501A. The Court did not agree with the trial court that the Sunovion studies were indisputably "open and free." The Court noted that the subjects had agreed that only they would take the medications and that they would keep accurate usage logs and return all unused medications. In addition, trial administrators could only dispense the medications to the test subjects and they were held accountable for secure storage and records of medication use. In light of these conditions, the Court did not agree that the allegedly anticipating prior art was clearly used "without restriction."

The Court also disagreed with the trial court's conclusion that the confidentiality obligations imposed during the study were so loose that summary judgment was justified. The Court noted that the participants were not told of the identity of the particular drug or formulation they were receiving. The investigators, who were the most knowledgeable persons involved in the study, were required to sign a pledge of confidentiality. Thus, the Court found that "the 'public use' inquiry [was] replete with factual considerations, such as the (disputed) extent to which the study participants were informed of and able to disclose the pertinent details of the claimed prior art."

In addition to reviewing the factual record concerning the public use of Sunovion's human drug trial, the Court took the opportunity to correct the trial court regarding several other aspects of its summary judgment decision. For example, the district court had found it significant that the patent holder, Dey, did not control Sunovion's clinical studies and that study participants did not owe any obligation of confidentiality to Dey. The Federal Circuit stated that it "measure[s] the adequacy of the confidentiality guarantees by looking to the party in control of the allegedly invalidating prior use. In third-party cases, that is the third party."

The district court had also "seized on language" from *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002), for the proposition that "the core issue is not public knowledge of the invention, but the public *use* of it." The Federal Circuit responded that the language from *New Railhead* was derived from "experimental use" case law and that it made sense in that context—i.e., during experimentation—the public might have knowledge of an invention (because they see it), but may not be using the invention within the meaning of the statute (because the inventor is experimenting). The district court had also noted that "public use need not be enabling in the sense of disclosing each later-claimed feature to the interested public." *Egbert v. Lippmann*, 104 U.S. 333 (1881). The Federal Circuit responded that although Sunovion was correct that the Court does not ask for an "enablement-type inquiry" under 102(b), a court must still

decide whether the "claimed features of the patents [were placed] in the public's possession."

Finally, the district court had attempted to distinguish prior use case law by holding that this case was not one in which the third party, Sunovion, was using the invention confidentially or hiding a trade secret because Sunovion was "operating within the patent and regulatory system," not outside of it. The Federal Circuit found this inquiry irrelevant. "The issue for purposes of this appeal is not whether Sunovion pursued the proper administrative channels in order to patent and develop *its* invention . . . the issue is whether Sunovion kept its use of *Dey's* inventions confidential."

Commentary

This case is generally good news for those who pursue patents on inventions that must undergo clinical trials in order to obtain regulatory approval. In cases such as this, where two parties are developing the same solution and racing each other to the PTO and FDA, both parties have the same incentive to keep their clinical trials confidential. To the extent they do so properly, neither one should be able to use its clinical trials as prior art against the other (or have them used as prior art against itself). It is only because Sunovion was arguably "loose" with its procedures that it was able to create a factual issue that its clinical trials may be prior art against Dey's invention.

The case is also useful in that it clarifies both the context of the statement quoted above from *New Railhead* and the reach of the statement quoted above from *Egbert*. With respect to the *New Railhead* issue, as the PatentlyO blog observed, "One major consequence of this opinion is that it makes the argument against clinical trials being public uses much easier and simpler. Rather than attempt to deal with the complexity of arguing that a clinical trial falls into the experimental use exception to public use (a challenging task, given Federal Circuit precedent over the last decade), *Dey* provides an excellent grounding for the argument that many clinical trials are not public uses at all."[1]

Indeed, the Court considered directing the entry of summary judgment for Dey on the issue of public use, but declined in a lengthy, concluding footnote. The reasons included the fact that Dey had neither sought summary judgment on the issue in the district court nor asked the Federal Circuit to direct entry of judgment for it on the issue. In dissent, Judge Newman argued the Court should have directed entry of judgment for Dey on this issue. From the facts, it appears that the "looseness" in Sunovion's procedures was limited to the patients in the clinical trial. The investigators were subject to confidentiality agreements. Yet, the Court also said that patients customarily are not required to sign confidentiality agreements and that in the past courts nonetheless have not found clinical trials amounted to a public disclosure of the invention. Thus, it appears the Court could have resolved the issue as a matter of law in Dey's favor and remanded for trial only on other issues, but for the procedural reasons given in the concluding footnote. In the middle of page 11 of the slip opinion, there is also a suggestion that there

[1] Jason Rantanen, *Dey v. Sunovion* (June 3, 2013), http://www.patentlyo.com/patent/2013/06/dey-v-sunovion.html.

may have been a factual dispute over the extent to which Sunovion's drug was disclosed to the patients. The Court may have simply been describing precedent in this passage, however, so it is not clear that there was such a dispute or that it contributed to the Court's decision not to direct the entry of judgment for Dey. While perhaps not a model of clarity, overall this opinion is a good one for patentees.