34 Biotechnology Law Report 59
Number 2, 2015

DOI: 10.1089/blr.2015.9993

Do Biotech Patent Lawsuits Really "Overwhelmingly Lose?": A Response to *Our Divided Patent System*

By CHRISTOPHER M. HOLMAN

My new study with Allison & Schwartz shows that software and biotech patent lawsuits overwhelmingly lose.[1]

—Mark Lemley

THIS PROVOCATIVE TWEET from Mark Lemley, a professor at Stanford Law School, refers to his recent article entitled *Our Divided Patent System* (the "Study"), which he co-authored with two other law professors from the University of Texas and IIT Chicago-Kent College of Law.[2] Taken at face value, his assertion that "biotech patent lawsuits overwhelmingly lose" holds troubling implications for biotechnology. After all, conventional wisdom has long held that robust patent protection plays a critically important role in incentivizing innovation in biotechnology.[3] If attempts by biotech patent owners to enforce their patents "overwhelmingly" end in failure, one might conclude that biotechnology's reliance on the patent system has been misplaced.

In order to better understand the basis for Lemley's assertion, I reanalyzed the underlying data and found that the situation is not nearly as bleak as his tweet might suggest. My significantly different interpretation of the same lawsuits arises in part from my decision to focus on *favorable litigation outcomes* rather than *final patent adjudications*. Thus, while the Study found that biotech companies have only won with respect to 8% of the patents that have been taken to judgment, I looked at the same set of lawsuits and found that, out of a total of sixteen distinct biotech patent litigations, seven appear to result in favorable outcomes for the patent owner. It is a relatively small data set, but my conclusion that biotech patent litigation resulted in favorable outcomes for patent owners 44% of the time should provide some solace for any biotech patent owners or investors who might have been disturbed by Lemley's tweet.

Not only did biotech patent owners benefit from favorable outcomes in nearly half of the litigations, the magnitude of these favorable outcomes was often substantial. For example, the Roundup Ready litigation between Monsanto and DuPont resulted in a jury award to the patent owner Monsanto of $1 billion,[4] and ultimately a settlement pursuant to which the accused infringer DuPont reportedly agreed to pay at least $1.75 billion to license the use of Monsanto's patented technology.[5] In another litigation, Amgen leveraged a victory at the district court level into a settlement agreement that delayed market entry of

Christopher M. Holman is the Executive Editor of *Biotechnology Law Report* and a Professor at the University of Missouri–Kansas School of Law.

[1]Mark Lemley, TWITTER (Oct. 14, 2014, 3:55 PM), https://twitter.com/marklemley/status/522158711196766209

[2]John R. Allison, Mark A. Lemley and David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. (forthcoming 2015), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2510004 [hereinafter *Study*].

[3]Orton Huang *et al.*, *Biotechnology Patents and Startups*, para. 1 (2003), *available at* http://www.integrityip.com/Patent_Library/Community/Other/BioTechPatentsVentureCapital.pdf ("[P]atents are absolutely essential to the success of traditional biotech startups."); DAN L. BURK AND MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009).

[4]*Monsanto Co. v. E.I. DuPont De Nemours & Co.*, No. 4:09CV00686 ERW, 2012 WL 5830580, at *1 (E.D. Mo. Nov. 16, 2012).

[5]Carey Gillam, *Monsanto, DuPont Strike $1.75 Billion Licensing Deal, End Lawsuits*, REUTERS (Mar. 26, 2013), http://www.reuters.com/article/2013/03/26/us-monsanto-dupont-gmo-idUSBRE92P0IK20130326

biosimilar products that otherwise would have likely competed with its human granulocyte colony stimulating factor products Neupogen and Neulasta.[6]

In this Report, I assess the outcome of each biotech litigation identified in the Study and explain the basis for my determination of favorable or unfavorable outcomes from the perspective of the patent owner.[7] I also explain why I found a smaller number of unique litigations than did the authors of the Study. This reassessment of the biotech lawsuits identified in the Study is useful in a number of respects. First, it shows that there is more than one way to analyze patent litigation, and a focus on pragmatic outcomes can yield a different result than focusing solely on adjudicated wins and losses. It also serves to illustrate how difficult it is to empirically analyze a large data set of lawsuits, and the underlying complexity of litigation that can be masked when one focuses solely on tallying wins and losses.

I. THE STUDY

The Study is an empirical work which "evaluate[d] all substantive decisions rendered by any court in every patent case filed in 2008 and 2009—decisions made between 2009 and 2013."[8] The Study reported "dramatic differences in the outcomes of patent litigation by both technology and industry."[9] For example, it found that owners of patents in the pharmaceutical industry "fare much better in dispositive litigation rulings than do owners of patents in the computer [and] electronics industry, and chemistry patents have much greater success in litigation than their software or biotech counterparts."[10]

The Study identified "one technology and industry that is a startling anomaly: biotechnology."[11] In particular, the Study found that when biotech companies have taken their patents to judgment, they have only won 8% of their adjudications on a per-patent basis.[12] On a per-lawsuit basis, the authors reported a similar trend—"3 patentee definitive victories, 13 accused infringer definitive victories, and 6 lawsuits that settled with at least one patent still alive."[13] The Study defines "definitive victories" to include final rulings by district courts (resolved either at trial or by grant of summary judgment), even if the parties settle their dispute in lieu of appealing the decision to the Court of Appeals of the Federal Circuit ("Federal Circuit").[14]

To their credit, the Study's authors specifically identified all of the lawsuits that form the basis for their conclusion that biotech lawsuits overwhelmingly lose,[15] and suggested that "more detailed

---

[6]Lianne Dane, *Teva, Amgen Reach Settlement Agreement Over Neupogen, Neulasta*, FirstWord Pharma (July 15, 2011), http://www.firstwordpharma.com/node/889353#axzz3Td2nl0Yo

[7]The favorable cases are discussed *infra* at Part II.A, and include *Monsanto Co. v. E.I. DuPont De Nemours & Co.*; *Teva Pharms., U.S.A., Inc. v. Amgen Inc.*; *LadaTech, LLC v. Illumina, Inc.*; *Gen-Probe Inc. v. Becton Dickinson & Co.*; *OptiGen, LLC v. Int'l Genetics, Inc.*; *INOVA Diagnostics, Inc. v. Euro-Diagnostica AB*; and *PSN Illinois, LLC v. Abbott Labs.* The unfavorable cases are discussed *infra* at Part II.B, and include *MedImmune, LLC v. PDL BioPharma, Inc.*, *Central Institute for Experimental Animals v. Jackson Labs.*, *AntiCancer, Inc. v. Fujifilm Medical Sys. U.S.A., Inc.*, *Bayer Healthcare, LLC v. Centocor Ortho Biotech, Inc.*, *Abbott GmbH & Co., KG v. Centocor Ortho Biotech, Inc.*, *Sanofi-Aventis Deutschland GMBH v. Genentech, Inc.*, *Billups-Rothenberg Inc. v. Associated Reg'l and Univ. Pathologists, Inc.*, *Illumina, Inc. v. Affymetrix, Inc.*, *E8Pharms. LLC v. Affymetrix, Inc.*

[8]*Study*, *supra* note 2, at 1.

[9]*Id.*

[10]*Id.*

[11]*Id.* at 65.

[12]*Id.* at 66.

[13]*Id.* at 67.

[14]*Id.* at 61.

[15]*Id.* at 68 n. 115. Here is the entire list of biotech cases reported in the Study, copied verbatim from footnote 115 of the Study: "3:08-cv-00845 INOVA Diagnostics, Inc. v. Euro-Diagnostica AB *et al*; 3:08-cv-04909-SI, Genentech, Inc. *et al* v. Sanofi-Aventis Deutschland GMBH *et al*; 8:08-cv-01349-MRP-SS, Billups-Rothenberg Inc. v. Associated Regional and University Pathologists, Inc. *et al*; 5:08-cv-05568-RMW, The Central Institute for Experimental Animals -v- The Jackson Laboratory; 5:08-cv-05590-JF, Medimmune, LLC v. PDL Biopharma, Inc.; 5:09-cv-00006-GTS-ATB, OptiGen, LLC v. International Genetics, Inc. *et al*; 3:09-cv-00277-bbc, Illumina, Inc. v. Affymetrix, Inc.; 4:09-cv-00686-ERW, Monsanto Company *et al* v. E.I. Dupont De Nemours and Company *et al*; 1:09-cv-04515-RWS, Association For Molecular Pathology *et al* v. United States Patent and Trademark Office *et al*; 3:09-cv-01311-GPC-JMA, AntiCancer, Inc. v. Fujifilm Medical Systems U.S.A., Inc. *et al*; 4:09-cv-11340-FDS, Abbott GmbH & Co., KG *et al* v. Centocor Ortho Biotech, Inc.; 2:09-cv-00242, Ambato Media, LLC v. Clarion Co., Ltd *et al*; 1:09-cv-00627-SLR, LadaTech LLC v. Illumina Inc.; 1:09-cv-05879, PSN Illinois, LLC v. GenScript Corporation; 3:09-cv-02319-BEN-NLS, Gen-Probe Incorporated v. Becton Dickinson and Company; 3:09-cv-04919-SI, Sanofi-Aventis Deutschland GMBH v. Genentech, Inc. *et al*; 3:09-cv-00665-bbc, Illumina, Inc. v. Affymetrix, Inc.; 2:09-cv-05675-SD, Teva Pharmaceuticals USA, Inc. v. Amgen Inc.; 4:09-cv-11362, Bayer Healthcare, LLC, v. Centocor Ortho Biotech Inc.; 4:09-cv-40002, Abbott Laboratories *et al*. v. Bayer Healthcare, LLC; 1:08-cv-11132, E8 Pharmaceuticals LLC *et al* v. Affymetrix, Inc.; 1:09-cv-10112, Teva Pharmaceuticals USA, Inc. *et al* v. Sandoz Inc. *et al.*"

case studies of the 2008 and 2009 biotech cases or empirical study of additional years of litigation would be fruitful."[16] Their identification of the lawsuits permitted me to independently evaluate the underlying data and ultimately arrive at a quite different interpretation. As an aside, I would argue that, at least as a general matter, empirical studies such as this should be given little, if any, weight in the development of patent policy unless the underlying data is made available for confirmation and independent analysis.[17] Without pointing to any article in particular, suffice it to say this is not always the case.

II. REANALYSIS OF THE BIOTECH LITIGATION DATASET

In reanalyzing the biotech patent cases the Study found to overwhelmingly result in losses for the patent owner, I delved deeper into the specific facts and context of those cases in an attempt to discern the outcome from the perspective of the patent owner. Favorable outcomes were invariably the result of a settlement agreement entered into prior to a final resolution of the lawsuit. Analyzed from this perspective, I found seven instances in which a patent owner was successful in enforcing its biotech patents, compared to nine instances in which the patent owner was not successful. Notably, there were favorable outcomes in some of the most important cases, involving highly successful biotechnology products and a direct threat of competition, *e.g.*, Monsanto's Roundup Ready technology and Amgen's biologic drugs Neupogen and Neulasta.[18]

Part of the discrepancy between my conclusion and that of the authors of the Study results from their treatment of district court decisions as "definitive" even if not affirmed on appeal.[19] In contrast, I would only characterize a decision as definitive once all appeals are exhausted. Relative to the cost of litigation through to a district court decision, appeal to the Federal Circuit is not overly expensive, and parties that lose at the district court level routinely appeal to the Federal Circuit, oftentimes with success.

Centocor Ortho Biotech, Inc. v. Abbott Labs provides a noteworthy example of this in the context of biotechnology.[20] At the district court level, a jury awarded the patent owner $1.67 billion in damages, which the Study would have tallied as a definitive victory if the decision were not appealed.[21] In fact, however, the decision was appealed and ultimately reversed by the Federal Circuit, which found the infringed claim invalid under the written description requirement.[22]

Interestingly, none of the biotech cases identified in the Study resulted in what I would call a definitive victory, since in all of the cases in which the patent owner prevailed in the district court, the parties settled prior to review by the Federal Circuit. Rather than characterizing these cases as definitive adjudications for the patent owner, I would characterize them as favorable outcomes based on settlement. In contrast, seven out of the nine unfavorable outcomes were district court decisions against the patent owners which were affirmed by the Federal Circuit.[23] Thus, at least with respect to this relatively small sampling of litigations, the parties tended to settle cases which were decided in favor of the patent owner at the district court level—presumably on terms favorable to the patent owner—but to pursue appeals to the Federal Circuit in cases in which the patent owner lost at the district court level.

A. Favorable outcomes

Of the seven cases I characterized as resulting in favorable outcomes for the patent owner,[24] two stand out as significant examples of biotech patents performing what many would consider to be the core mission of patents, *i.e.*, blocking market entry by a direct competitor. In *Monsanto v. DuPont*, DuPont sought to bring genetically modified soybeans to market which incorporated Monsanto's patented Roundup Ready technology, which would have directly competed with Monsanto's authorized Roundup Ready soybeans.[25] In *Teva v. Amgen*, the accused infringer was a generic drug company attempting to obtain FDA approval to

---

[16] *Id.* at 68.

[17] While the Study does disclose the biotech lawsuit dataset, it does not disclose the rest of the dataset, *i.e.*, non-biotech lawsuits filed in the relevant timeframe of 2008–2009. However, the Study states that the authors "plan to release the dataset to the public after the completion of [their] third and final article on this project." *Study, supra* note 2, at 7 n. 17.

[18] *See supra* text accompanying notes 4–6.

[19] *See supra* at 2–3.

[20] *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 669 F. Supp. 2d 756 (E.D. Tex. 2009).

[21] This lawsuit did not fall within the scope of the Study because it was initially filed in 2007, rather than 2008–2009.

[22] *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011).

[23] *Supra* note 7.

[24] *Id.*

[25] *Monsanto Co. v. E.I. DuPont De Nemours & Co.*, No. 4:09CV00686 ERW, 2012 WL 5830580, at *1 (E.D. Mo. Nov. 16, 2012).

market what was essentially a biosimilar version of Amgen's biologic drug Neupogen.[26] In both cases the patent owner settled on what would appear to be quite favorable terms, thereby avoiding appeal to the Federal Circuit.

Of course, by settling the cases, the accused infringers were able to obtain some benefit that would not have been available if the Federal Circuit affirmed the district court decisions. In lieu of the jury's $1 billion damages verdict, DuPont was able to negotiate a license agreement that allows both companies to move forward in commercializing Monsanto's patented technology, while ensuring that Monsanto is adequately compensated.[27] Teva appears to have negotiated a somewhat early market entry. The terms of that agreement allowed Teva to come to market November 10, 2013, while the Amgen patents at issue did not expire until early December 2013.[28]

In the *Monsanto* and *Amgen* cases, patents appear to be functioning just fine for biotechnology innovators, at least with respect to the patented technologies, *i.e.*, biologic replacement drugs and genetically modified seeds. These are two of the core products of conventional biotechnology. The question remains whether other important categories of biotechnology products will be as well served by the patent system—as discussed below, the biotech litigations identified in the Study suggest reason for concern with respect to two important categories of biotechnology products: therapeutic antibodies and molecular diagnostic testing.

There was a third litigation that also resulted in a victory for the patent owner at the district court level, *LadaTech v. Illumina*.[29] In that case, a jury returned a verdict finding LadaTech's patent not invalid and infringed by Illumina's genome analyzer systems that incorporate Solexa DNA sequencing technology.[30] The parties subsequently agreed to a settlement that stipulated that the patent was infringed and not invalid,[31] thereby avoiding an appeal to the Federal Circuit. Although the terms of the settlement were not released, the fact that the case settled after a finding of Illumina's infringement supports an inference that the settlement was on terms favorable to LadaTech, the patent owner. The parties in this case do not appear to have been competitors, and in fact Illumina characterized Ladatech as a patent holding company.[32]

The other four cases with favorable outcomes for the patent owner involved lawsuits that settled prior to any dispositive resolution by the district court, but on terms that appear to be favorable to the patent owner.

In *Gen-Probe v. Becton Dickinson,* the allegedly infringing products were used to perform automated DNA analysis, primarily for diagnostic purposes. The court granted partial summary judgment of infringement with respect to several patents, but left unresolved the question of validity and enforceability.[33] The parties settled the case and dismissed the action with prejudice. Becton Dickinson reported that the settlement included a license from the patent owner to make, use, and sell certain products that had been accused of infringing, in return for upfront fees and ongoing royalties of an unspecified amount.[34]

OptiGen v. International Genetics was another case involving diagnostics that settled prior to dispositive resolution in the district court.[35] The patents asserted by OptiGen are directed towards methods of testing for specific genetic variations associated with disease in canines.[36] OptiGen is itself in the business of genetically testing dogs, so this is an example of a patent owner using patents to block direct competition in the market. Settlement agreements with competing diagnostic testing services, including International Genetics (InGen) and the University of Texas, appear to have been on terms favorable to the patent owner. For example, it was reported that the InGen defendants agreed under the settlement to "among other things, cease[] any and all sales of testing related to these patents and [] not to resume any such testing in the future."[37]

INOVA Diagnostics v. Euro-Diagnostica AB provides another example of a case in which the district

---

[26]*Teva Pharms., U.S.A., Inc. v. Amgen Inc.,* No. 209CV05675, 2010 WL 2667091 (E.D.Pa. May 4, 2010).
[27]Gillam, *supra* note 5.
[28]Dane, *supra* note 6; Alex Philippidis, *The Lists, Biosimilars: 10 Drugs to Watch*, Genetic Engineering & Biotechnology News (Apr. 29, 2013).
[29]*LadaTech LLC v. Illumina Inc.*, 841 F. Supp. 2d 860 (D. Del. Jan. 24, 2012).
[30]*Id*.
[31]Illumina, Inc., Quarterly Report, at 29 (Form 10-Q) (July 30, 2012), *available at* http://www.sec.gov/Archives/edgar/data/1110803/000111080312000126/ilmn2q1210q.htm
[32]*Id*. LadaTech represents itself as a company jointly owned by Glaxo SmithKline and IP Finance Holdings.
[33]*Gen-Probe Inc. v. Becton Dickinson & Co.*, 899 F. Supp. 2d 971 (S.D. Cal. 2012).
[34]*BD, Gen-Probe Settle Patent Dispute*, GenomeWeb (Dec. 4, 2012), https://www.genomeweb.com/clinical-genomics/bd-gen-probe-settle-patent-dispute
[35]*OptiGen, LLC v. Int'l Genetics, Inc.*, 777 F. Supp. 2d 390 (N.D.N.Y. 2011).
[36]*Joint Statement by OptiGen and InGen*, OptiGen (Dec. 4, 2012), http://www.optigen.com/opt9_ingenstatemnt.html
[37]*Id*.

court's decision apparently led to a favorable outcome for the patent owner in the form of a settlement.[38] The patent at issue is directed towards peptide antigens used to diagnose rheumatoid arthritis (referred to as "anti-CCP technology").[39] Subsequent to claim construction, but prior to any dispositive resolution of the case, the case settled on terms that were apparently favorable to the patent. Although the terms of the settlement were not disclosed, the patent owner's Chief Executive Officer commented: "We are very pleased to have settled this case, reinforcing our strong global IP position and ensuring anti-CCP tests in the market are properly licensed. We look forward to further expansion of the market for this important test for the early diagnosis of rheumatoid arthritis."[40]

Finally, in *PSN Illinois v. GenScript* the litigation did not result in a dispositive decision but did lead to a favorable settlement for the patent owner.[41] PSN Illinois's asserted patent is essentially directed toward a research tool useful for drug discovery and development, involving G-coupled receptors. Drug companies like Abbott (one of the accused infringers) use these receptors in screening studies to identify potential drug candidates.[42] According to an attorney representing the patent owner, the lawsuit has involved "multiple cases covering 19 defendants to date, who have agreed to the validity of the patents-in-suit, concerning type of G-protein coupled receptors useful for drug manufacture, and/or paid royalties to license same."[43]

B. Unfavorable outcomes

According to my reckoning, there were nine biotech litigations identified in the Study which appear to have resulted in an outcome that was not favorable to the patent owner.[44] In four of these litigations, the district court entered dispositive decisions in favor of the accused infringer, and the parties subsequently settled rather than pursuing an appeal to the Federal Circuit. Given the posture of these cases at the time of settlement, I assume that the settlements were not particularly favorable for the patent owner, although it's hard to be sure given that settlement terms were not disclosed. The other five unfavorable outcomes for the patent owner were terminated by Federal Circuit decisions against the patent owner.

MedImmune v. PDL Biopharma involved a patent directed towards methods of engineering humanized monoclonal antibodies for use as human therapeutics.[45] The patent owner, PDL, alleged that the patent was infringed by MedImmune's marketing of the biologic drug Synagis. MedImmune had entered into a licensing arrangement with PDL requiring MedImmune to pay royalties on its sale of Synagis. According to PDL, it received from MedImmune more than $280 million in royalties under the agreement from 1988 to the end of 2009.[46] However, in 2008 MedImmune brought a lawsuit challenging the patents and the agreement, seeking to recoup some or all of the royalties paid.

The *MedImmune* litigation was quite complex, involving many issues beyond patent validity and infringement. In fact, there was only one patent claim at issue in the case, claim 28 from the U.S. Patent 6,180,370.[47] On a motion for partial summary judgment, the district court found the claim invalid based on anticipatory prior art.[48] This decided the case with respect to the only patent claim at issue, but there were still numerous outstanding issues to be resolved. Rather than litigate those issues and appeal the patent ruling, the parties settled, with PDL agreeing to refund $92.5 million of the royalties paid by MedImmune.[49]

In *Central Institute for Experimental Animals v. Jackson Laboratory* the patent owner also suffered dispositive defeat in the district court and then settled the case rather than pursuing appeal to the Federal Circuit.[50] The patent at issue was directed towards a particular strain of immunodeficient mice used in research. After the district court

---

[38] *INOVA Diagnostics, Inc. v. Euro-Diagnostica AB*, No. 08-CV-0845 H(JMA), 2009 WL 2602608 (S.D. Cal. Aug. 24, 2009).

[39] *Id.*; Press Release, Axis-Shield plc, Axis-Shield Reaches Commercial Settlement In Anti-CCP Litigation (Aug. 6, 2010), *available at* http://uk.reuters.com/article/2010/08/06/idUS49577+06-Aug-2010+RNS20100806

[40] *Id.*

[41] *PSN Illinois, LLC v. Abbott Labs.*, No. 09 C 5879, 2011 WL 4442825 (N.D. Ill. Sept. 20, 2011).

[42] *Id.* at *1–2.

[43] *Exemplary List of Cases in Which Mike Mazza Has Had Primary or Significant Involvement*, MICHAEL P. MAZZA LLC: INTELLECTUAL PROPERTY ATTORNEYS (last visited Mar. 7, 2015), http://www.mazzallc.com/cases.html

[44] *See supra* note 7.

[45] *Medimmune, LLC v. PDL Biopharma, Inc.*, No. C 08-5590 JF (HRL), 2011 WL 61191 (N.D. Cal. Jan. 7, 2011).

[46] Press Release, PDL BioPharma Announces Decisions on Summary Judgment in its Litigation with MedImmune (Jan. 10, 2011), *available at* http://investor.pdl.com/releasedetail.cfm?ReleaseID=611854

[47] *See id.*

[48] *MedImmune*, No. C 08-5590 JF HRL, 2011 WL 61191.

[49] Press Release, MedImmune and PDL BioPharma Resolve Patent Disputes (Feb. 16, 2011), *available at* http://investor.pdl.com/releasedetail.cfm?ReleaseID=611859

[50] *Central Inst. for Experimental Animals v. Jackson Lab.*, 726 F. Supp. 2d 1045 (N.D. Cal. 2010).

found no infringement on a motion for summary judgment, the parties settled under terms I assume were favorable to the alleged infringer, given the district court's ruling.[51]

Anticancer v. Fujifilm Medical System is the third litigation that was not appealed to the Federal Circuit but which I classified as an unfavorable outcome for the patent owner.[52] The patented technology relates to methods of modern gene expression using fluorescent imaging of green fluorescent protein (GFP). Anticancer appears to be a patent holding company, and has brought lawsuits against numerous companies, with a notable lack of success.[53]

In a fourth litigation that resulted in an unfavorable outcome for the patent owner, Bayer Healthcare sued Abbott and Centocor, claiming that both of the companies' anti-TNF products, *i.e.*, Humira and Simponi, infringed a Bayer patent.[54] Bayer does not appear to sell a competing product. Although two separate lawsuits were filed, the same patent claims of U.S. Patent 5,654,407 were asserted as being infringed, and the same claim construction was used in both cases.[55] In both cases, the parties stipulated noninfringement based on the district court's relatively narrow interpretation of the claim term "human monoclonal antibody," and in both cases the parties settled rather than pursuing an appeal to the Federal Circuit.[56]

Of the five cases in which the district court's decision was appealed and the Federal Circuit ruled against the patent owner, *Abbott v. Centocor* stands out as a major loss for a biotech patent owner. The patent owner AbbVie (formerly Abbott) sued Centocor, alleging that Centocor's human IL-12 neutralizing antibody (ustekinumab, sold under the trade name Stelara) infringed U.S. Patents 6,914,128 and 7,504,485.[57] AbbVie had developed its own human IL-12 neutralizing antibody, briakinumab, but it has not been approved in the U.S. or Europe, so in that sense the companies are not direct competitors.[58] A jury found all of the asserted claims to be invalid for lack of adequate written description, lack of enablement, and obviousness.[59] On appeal, the Federal Circuit affirmed the jury's decision with respect to the written description requirement.

In *Sanofi-Aventis v. Genentech*, Sanofi alleged that Genentech had infringed its patent when Genentech engineered recombinant mammalian cell lines used in the production of its biologic drugs Rituxan and Avastin.[60] The Sanofi patent claims methods of introducing DNA enhancers into mammalian cells.[61] The district court held on summary judgment that Genentech did not infringe the claims, and this decision was upheld by the Federal Circuit on appeal.[62] In particular, the asserted claims require a step of "inserting" an isolated DNA enhancer into a mammalian cell, and the parties stipulated that "inserting" in this context means "putting or introducing into." Genentech acknowledged that the cell lines used to produce Rituxan and Avastin were derived by inserting foreign DNA into mammalian cells, but the court found that since those acts occurred before the asserted patent issued in 1988, they could not constitute infringement.[63]

In *Billups-Rothenberg v. Associated Regional & University Pathologists*, the patent owner alleged

---

[51]Press Release, National Institutes of Health Intervenes to End Patent Infringement Suit Against the Jackson Laboratory Concerning Mouse Models for Alzheimer's Research (Aug. 16, 2011), *available at* http://www.wolfgreenfield.com/newsstand/406-national-institutes-health-intervenes-end-patent-infringement-suit-against

[52]*AntiCancer, Inc. v. Fujifilm Medical Sys. U.S.A., Inc.*, No. 09-cv-1311-GPC (JMA), 2013 WL 947397 (S.D. Cal. Mar. 12, 2013).

[53]*See, e.g.*, *AntiCancer, Inc. v. Pfizer, Inc.*, 769 F.3d 1323 (Fed. Cir. 2014); *see also*, Christopher Holman, *Judge Calls Anticancer Inc.'s Attempts to Enforce GFP Patents ''Misguided,'' Warns that Future Enforcement Activity Could Warrant an Award of Attorney's Fees*, HOLMAN'S BIOTECH IP BLOG (June 30, 2013), http://holmansbiotechipblog.blogspot.com/search?q=anticancer

[54]*Bayer Healthcare, LLC, v. Centocor Ortho Biotech Inc.*, No. 4:09-cv-11362-FDS (D. Mass. Jan. 28, 2011); *Abbott Labs. v. Bayer Healthcare, LLC*, No. 09-40002, 2010 WL 4340565 (D. Mass. Oct. 25, 2010).

[55]The district court in the *Centocor* case adopted the same construction set forth in the *Abbott* case.

[56]*Bayer Healthcare LLC v. Centocor Ortho Biotech, Inc.*, 458 F. App'x 895 (Fed. Cir. 2011); *Abbott Labs. v. Bayer Healthcare LLC*, 458 F. App'x 895 (Fed. Cir. 2011).

[57]*AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014).

[58]Kevin Grogan, *Abbott Withdraws Briakinumab Applications in USA, Europe*, PHARMATIMES DIGITAL (Jan. 17, 2011), *available at* http://www.pharmatimes.com/article/11-01-17/Abbott_withdraws_briakinumab_applications_in_USA_Europe.aspx#ixzz3TuL0Nptz

[59]*Largest Patent Infringement Damage Award Ever*, FULCRUM INQUIRY (July 2009), http://www.fulcrum.com/JNJ_Abbott.htm

[60]*Sanofi-Aventis Deutschland GmbH v. Genentech, Inc.*, No. C 09-4919 SI, 2010 WL 2525118 (N.D. Cal. June 23, 2010); *Genentech, Inc. v. Sanofi-Aventis Deutschland GmbH*, No. C 08-04909 SI, 2010 WL 1136478 (N.D. Cal. Mar. 20, 2010).

[61]"Enhancers" are essentially DNA sequences that are positioned in a functional relationship with a recombinant gene to increase the expression protein from that gene.

[62]*Sanofi-Aventis Deutschland GmbH v. Genentech, Inc.*, 473 F. App'x 885, 892 (Fed. Cir. 2012).

[63]*Id.*

infringement of patents directed towards the use of diagnostic testing to identify instances of Type I hereditary hemochromatosis.[64] The district court held the claims invalid for anticipation and failure to comply with the written description requirement, and this decision was affirmed on appeal.[65]

In *Illumina v. Affymetrix*, Illumina alleged infringement of patent claims relating to DNA microarray technology.[66] Illumina and Affymetrix compete in the DNA hybridization array market. The district court adopted Affymetrix's relatively narrow construction of the asserted patent claims and found that Affymetrix technology did not infringe.[67] This unfavorable outcome for the patent owner was affirmed by the Federal Circuit.[68]

Finally, in *E8 Pharmaceuticals v. Affymetrix*, the district court found no infringement by Affymetrix and Navigenics with respect to their DNA analysis products.[69] The district court found that the accused products did not incorporate "randomly primed PCR-derived RCG," a limitation recited in the asserted claims, and the Federal Circuit affirmed this decision on appeal.[70]

C. Counting biotech patent lawsuits is not straightforward

The observant reader will have noticed that while the Study identified twenty-two biotech patent lawsuits, when I investigated those same lawsuits, I concluded that there were really only sixteen distinct litigations. The truth is, counting patent lawsuits is a notoriously tricky business. There is no single correct answer, and there are different ways to actually draw the line.

In this section I explain my methodology and the basis for the discrepancy. Since I focused my attention on the relatively small number of biotech lawsuits identified in the Study, I was able to delve into the specifics of the cases in a manner which would have been impractical for Lemley and his co-authors. In my view, a fundamental weakness of large-scale empirical studies of patents and patent litigation is that as a practical matter, it is virtually impossible to accurately account for the complexity of litigation without painstakingly delving into the substance of each matter.

To begin with, two of the lawsuits identified as "biotech" in the Study did not, to my mind, involve biotechnology. The patent at issue in *Ambato Media v. Clarion* appears to relate to global positioning system (GPS) technology, and the defendants were non-biotech companies, such as Garmin and TomTom.[71] The inclusion of this lawsuit was clearly a coding error, something that is probably inevitable in any large empirical study such as this.

I also excluded *Teva v. Sandoz* as not truly a biotech case, although the basis for this decision to exclude is a bit more subtle than in *Ambato*.[72] The asserted patents in *Teva v. Sandoz* are directed towards polypeptides, *i.e.*, proteins, which superficially connotes biotechnology. In fact, however, this patent litigation arises out of the filing of an Abbreviated New Drug Application (ANDA).[73] The patent owner is a pharmaceutical company attempting to block market entry by a generic version of a non-biotech drug by alleging that the generic company will infringe if it uses the patented polypeptides as calibration standards in analyzing the molecular weight of the generic non-biotech drug.[74] The Study explicitly distinguishes between pharmaceutical and biotech patent litigation, and in my view, *Teva v. Sandoz* should have been characterized as pharmaceutical rather than biotech.

In addition, I excluded *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, the infamous gene patent case often referred to simply as "*Myriad*."[75] Although the Supreme Court's decision in *Myriad* was clearly a "loss" for biotechnology companies in general, in my opinion *Myriad* is not a case of a patent owner attempting to enforce its patent. Myriad Genetics clearly had no intention of enforcing its patent against any of the plaintiffs named in the case. Furthermore, the case only addressed a handful of patent claims specifically targeted by the plaintiffs, leaving untouched the vast majority of claims in the various Myriad patents relating to BRCA1 and BRCA2 that were at issue in the case. Significantly, the patent claims

---

[64] *Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc.*, 642 F.3d 1031 (Fed. Cir. 2011).
[65] *Id.*
[66] *Illumina, Inc. v. Affymetrix, Inc.*, No. 09-cv-665-bbc, 2010 WL 2803460 (W.D. Wis. July 14, 2010); *Illumina, Inc. v. Affymetrix, Inc.*, No. 09-cv-277-bbc, 2009 WL 3062786 (W.D. Wis. Sept. 21, 2009).
[67] *Id.*
[68] *Illumina, Inc. v. Affymetrix, Inc.*, 427 F. App'x 898 (Fed. Cir. 2011).
[69] *E8 Pharmaceuticals LLC v. Affymetrix, Inc.*, 680 F.Supp.2d 292 (D. Mass. 2010).
[70] *E8 Pharm., LLC v. Affymetrix, Inc.*, 538 F. App'x 902 (Fed. Cir. 2013).
[71] *Ambato Media, LLC v. Clarion Co.*, No. 2:09CV00242, 2012 WL 6192533 (E.D. Tex. Oct. 15, 2012).
[72] *Teva Pharm. USA, Inc. v. Sandoz Inc.*, Nos. 09 Civ. 10112(KBF) & 10 Civ. 7246(KBF), 2013 WL 3732867 (S.D.N.Y. July 16, 2013).
[73] *Id.*
[74] *Id.*
[75] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

targeted by the plaintiffs were not the most relevant to genetic diagnostic testing, which is Myriad's business, and were not representative of the patent claims Myriad would have asserted if it had chosen to bring a lawsuit. This is clearly illustrated by the number of lawsuits filed by Myriad against competitors alleging infringement of patent claims that were left unaffected by the Supreme Court's decision.[76]

Another cause for a discrepancy in the total count of lawsuits has to do with the fact that in some cases, a single allegation of infringement results in multiple lawsuits. For example, it is common for the patent owner and the alleged infringer to each file separate lawsuits, with the patent owner alleging infringement and the alleged infringer seeking a declaratory judgment of noninfringement and/or patent invalidity. Sometimes a single party files more than one lawsuit asserting the same patent against the same defendant. This can result in multiple lawsuits being docketed that involve the same parties, the same patents, and the same allegations of infringement. These lawsuits are typically soon consolidated. To my mind, this constitutes but a single litigation. In contrast, the Study sometimes—but not always—counts each as a distinct lawsuit, and this double counting contributed to their conclusion that biotech patent owners overwhelmingly lose.

For example, the litigation between Genentech and Sanofi involved near simultaneous filings of infringement lawsuits by patent owners and declaratory judgment actions by accused infringers.[77] The lawsuits are simply mirror images of each other: they involve the same patents and the same allegedly infringing products, and ultimately the lawsuits were consolidated. The Study treated these as two separate lawsuits. However, in other cases where mirror image infringement and declaratory judgment actions were filed, for no apparent reason, the Study treated them as a single lawsuit.[78] For consistency, I deemed it better to treat all such occurrences of mirror image infringement/declaratory judgment lawsuits as single litigations.

The Study also counted two lawsuits filed by Illumina against Affymetrix as distinct lawsuits, while I treat them as a single litigation. Although initially two different patents were asserted in the lawsuits, the allegedly infringing products were the same in both lawsuits, and the court quickly consolidated them into a single litigation, which was ultimately decided as a single matter on appeal to the Federal Circuit.[79] In fact, many of the lawsuits tallied as single lawsuits in the Study involve the assertion of two or more patents, so treating the *Illumina v. Affymetrix* litigation as multiple lawsuits seemed arbitrary and inconsistent to me.

I also counted as a single litigation the two lawsuits in which Bayer Healthcare alleged infringement by Centocor's and Abbott's respective anti-TNF monoclonal antibody therapeutics Simponi and Humira. In both cases, the same patent claims were asserted, and both cases resulted in a stipulation of noninfringement based on a relatively narrow interpretation of the claim term "human monoclonal antibody."[80] Indeed, the Abbott court directly adopted the exact interpretation of the term from the district court hearing the Centocor case.

Although the Study treated Centocor and Abbott Laboratories as two distinct lawsuits, I rejected this approach as inconsistent with the way the Study treated similar instances of multiple lawsuits involving the same patent as a single lawsuit. For example, during the relevant timeframe considered by the Study, *i.e.*, 2008–2009, OptiGen filed distinct lawsuits against InGen and Texas A&M University System, but the Study only counted the lawsuit against InGen.[81] As was the case in *Illumina v. Affymetrix*, the district court consolidated the two cases, even though not only were the accused services different, but so were the accused infringers.[82]

The Study also treated lawsuits filed against multiple accused infringers as single lawsuits. For example, one of the cases which resulted in a favorable outcome for the patent owner, *PSN Illinois v. GenScript*, involved at least nineteen different defendants accused of using the patented technology in different ways.[83] The Study also only counted one lawsuit involving Monsanto, *Monsanto v. DuPont*, even though during the relevant period, Monsanto filed a large number of lawsuits that involved the same agricultural biotechnology patents, all of which resulted in favorable outcomes for the patent owner.[84]

---

[76]Tracy Vence, *Yet Another Lawsuit Over Genetic Tests*, The Scientist (June 17, 2014), http://www.the-scientist.com/?articles.view/articleNo/40260/title/Yet-Another-Lawsuit-over-Genetic-Tests/

[77]*Supra* note 60 and accompanying text.

[78]This occurred, for example, with respect to a litigation between Abbott and Bayer concerning Humira.

[79]*Illumina, Inc. v. Affymetrix, Inc.*, 427 F. App'x 898, 899 (Fed. Cir. 2011).

[80]*Supra* note 54, and accompanying text.

[81]*OptiGen, LLC v. Texas A&M University System*, No. 5:09-cv-00457 (N.D.N.Y.); *OptiGen, LLC v. International Genetics, Inc.*, No. 5:09-cv-00006, (N.D.N.Y.).

[82]*See* Consolidation Order, *available at* http://www.gpo.gov/fdsys/pkg/USCOURTS-nynd-5_09-cv-00457/pdf/USCOURTS-nynd-5_09-cv-00457-0.pdf

[83]*Supra* note 43, and accompanying text.

[84]*See, e.g.*, *Monsanto Co. v. Hargrove*, No. 4:09-CV-1628 (CEJ), 2011 WL 5330674 (E.D. Mo. Nov. 7, 2011).

III. CONCLUSION

A total of only sixteen distinct litigations is probably not a large enough sample to form the basis for any sort of sweeping conclusion regarding the ability of biotech patent owners to effectively enforce their patents. Still, far from overwhelmingly losing, I would say that a significant number of the biotech litigations identified in the Study resulted in favorable outcomes for the patent owner. In cases where the patent owner did not prevail, more often than not, it was not because the patent was invalid, but rather because it simply did not cover the allegedly infringing product or activity. In fact, in some cases, it looks like the non-prevailing patent owner was simply attempting to overreach with its patent.

Two important types of patented technologies, however, clearly did not do well in the biotech patent litigations identified in the Study. One of these is monoclonal antibody therapeutics. All three litigations involving these patents (which the study counted as four lawsuits) resulted in definitive losses for the patent—two out of three based on invalidity, and the other on noninfringement. I think this might very well accurately reflect the current state of affairs. For a variety of reasons, I believe it is difficult to effectively patent antibodies; given the importance of monoclonal antibodies, this could be a problem for biotechnology.

Molecular diagnostics is another important aspect of biotechnology that might not be amenable to effective patent protection under the current state of patent law. Patents directed towards methods of diagnosis and personalized medicine that are based on the discovery of clinically significant biomarkers are particularly at risk since the Supreme Court's decision in *Mayo v. Prometheus*, as I have previously discussed.[85] Two of the biotech litigations identified in the Study, *Billups-Rothenberg* and *OptiGenetics*, involved these sorts of patents, but both cases were resolved prior to *Mayo*, so the Supreme Court's decision was not an issue. Post-*Mayo*, owners of patents on diagnostics and personalized medicine might truly find themselves in the position of "overwhelmingly" losing in attempts to enforce their patents.

• • •

[85]Christopher M. Holman, *Caught Between a Rock and a Hard Place: How Limelight Compounds the Challenges Facing Biotechnology Innovators After Mayo and Myriad*, 33 BIOTECH. L. REP. 135 (2014); Christopher M. Holman, *Mayo, Myriad, and the Future of Innovation in Molecular Diagnostics and Personalized Medicine*, 15 N.C. J. L. & TECH. 639 (2014); Christopher M. Holman, *District Court's Interpretation of Mayo in Arioso Diagnostics Does Not Bode Well for Patent Eligibility of Diagnostics and Personalized Medicine,* 33 BIOTECH. L. REP. 46 (2014).