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IN THIS ISSUE:

REACH-THROUGH ROYALTIES
Miranda M. Biven
Matthew R. Cohen 1

DNA ARRAY SUITS CONCLUDE
Kenneth H. Bridges 2

CEASE & DESIST LETTERS
Mario F. Greco 4

TIMING OF PATENT CLAIM INTERPRETATION
Rachel E. Pernic 5

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Welcome to Kirkland's *Biotech Update*

The field of biotechnology has matured tremendously over the past decade, and its recent successes even command the attention of the general public. The law too has developed as it struggles to keep pace with and adapt to the issues raised by the new technology. Although the law interfaces with biotechnology on many fronts, the attorneys here in the Kirkland & Ellis Intellectual Property Department are especially interested in the ways the law is "evolving" to create, protect and/or limit rights in these new technologies.

As a way to share information and commentary on intellectual property law as it develops in this exciting field, it is my pleasure to introduce the first issue of *Biotech Update*, a Kirkland & Ellis publication. Each issue will include articles addressing subjects of general interest ranging from licensing to patent infringement litigation, but in most instances the focus will be upon biotechnology, pharmaceuticals and the life sciences. There are obvious limitations to this type of format. We cannot, for example, provide legal advice in this context, and Kirkland & Ellis itself must disclaim any views or comments of individual authors as not necessarily being the views of the firm or of any of our clients.

We hope that you will find *Biotech Update* both informative and interesting. To that end, we invite your comments and suggestions as to how *Biotech Update* can best fulfill your interests and needs.

Mark A. Pals

Reach-Through Royalties in Research Tool Licenses: *Bayer AG v Housey Pharmaceuticals*

Miranda M. Biven and Matthew R. Cohen

Biotech companies that specialize in the development of research tools face a quandary: how do they maximize the value and financial return in licensing patent and other rights to these tools? These "research tools" do not directly produce an end product that can be marketed and sold. Instead, they are used, for example, to screen or identify compounds that may ultimately be commercialized after further development. A biotech company that decides to license others to use a patented research tool – rather than retain the rights for its own exclusive use – might charge royalty payments based on the use of the tool. Because it can be difficult to capture the true value of a research tool through use-based royalties, however, some biotech companies have structured their licenses so that they share in the upside if the use of their research tool leads to the successful commercialization of an end product by their licensee – a so-called "reach-through royalty."

Reach-through royalties have attracted significant attention and generated widespread speculation as to their viability under the patent misuse doctrine and the antitrust laws. There is currently, however, precious little jurisprudence on these issues. A recent decision by the U.S. District Court for the District of Delaware suggests that such licensing programs may, in the future, be subject to extensive, fact-specific scrutiny in the courts. In *Bayer AG v. Housey Pharmaceuticals, Inc.*, 169 F. Supp. 2d 328 (2001), the court denied a motion by Housey Pharmaceuticals, Inc. to dismiss Bayer's claim that Housey had licensed its patents on terms that amounted to patent misuse. The court concluded that Bayer's allegations, if true, could make out a claim for patent misuse.

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Bayer filed its complaint seeking a declaration that Housey committed patent misuse through its licensing program and that the four patents at issue were therefore unenforceable. Housey's patents related to research methods for drug discovery, and included claims to a screening method used to

identify candidate therapeutic compounds. According to Bayer, Housey's licenses included a reach-through royalty that required a licensee to make payments based on the sales of any therapeutic compound identified using Housey's patented method, even though the claims of the licensed patents did not cover such compounds. In addition, Bayer alleged that Housey improperly required its licensees to make royalty payments for the term of any patents covering a licensee's commercialized therapeutic compound, rather than the term of Housey's own patents. According to Bayer, these licenses extended the requirement for royalty payments on therapeutic compounds identified using Housey's patented screening method beyond the expiration of Housey's patents.

The court held that Bayer's complaint contained allegations which, if true, could be the basis of a finding of patent misuse. It is important to keep in mind that the court in Bayer was required to accept Bayer's allegations as true for purposes of deciding the motion to dismiss. Thus, the court did not assess whether Housey actually employed the alleged licensing program or whether Bayer could prove that Housey's licensing program and royalty structure amounted to patent misuse.

Nonetheless, this case is one of the first forays by the courts into the substantive legal issues, including antitrust and patent misuse issues, associated with today's increasingly common reach-through royalty structures. It remains to be seen how Housey's royalty structure, as well as other similar royalty structures, hold up in the face of scrutiny by the courts. This decision suggests that courts are willing to examine, and perhaps strike-down, a licensing arrangement in which a licensor seeks to share in the profitability of a commercialized therapeutic compound identified using the licensor's patented research tools. Depending on the specific details of such a licensing program, it could be construed to be an anti-competitive practice that extends a patent owner's rights beyond the reasonable scope of its patent claims. This would risk a finding that not only the patent license, but the patent itself, is unenforceable.

It remains to be seen how the courts will address a practice where the royalty structure may be a logical way of determining the value of a license in a situation where commercialization of the end product may occur many years after use of the research tool. It is clear, however, that careful attention should be paid to any licensing situation involving the possibility of an allegation of post-expiration royalties.[1]

Significant DNA Array Suits Conclude

Kenneth H. Bridges

After a flurry of litigation over the last five years, the exploding new technology of DNA arrays has entered a period of relative calm in the courts. Since 1997, Affymetrix, Hyseq, Incyte, and Oxford Gene Technology (OGT) have battled one another over rights to one of the most significant new analytical devices for biotechnology research. With the recent settlements of *Hyseq v. Affymetrix* in October 2001 and *Affymetrix v. Incyte* in December 2001, combined with the end of *OGT v. Affymetrix* in April 2001, the most significant DNA array lawsuits are now over. The implications for the industry, however, are not yet clear. Nor is it clear whether the current lack of major litigation represents the future or only a temporary pause in the fight over rights to DNA array technology.

OGT v. Affymetrix

Oxford Gene Technology (OGT), founded by Dr. Edwin Southern who also developed the "Southern blot," was the last of the four companies to become involved in litigation, but its case was resolved first, and was the only one to go to trial. In June 1999, OGT sued Affymetrix in the District of Delaware for infringement of U.S. Patent No. 5,700,637 related to methods for making and using DNA arrays. In November 2000, OGT won a jury verdict of infringement against Affymetrix.

Just prior to that trial, a parallel dispute between the two companies was resolved in the Courts of England. Affymetrix had attempted to gain a license to OGT's patent from Beckman-Coulter, Inc., already a licensee of OGT. After a trial court in England ruled that Affymetrix did not gain a license through its dealings with Beckman-Coulter, Affymetrix succeeded in partially overturning that decision on appeal, obtaining Beckman's license, effective from June 1999 forward. OGT and Affymetrix, now licensed but found infringing for its prior array activities, settled their outstanding disputes in March 2001, allowing Affymetrix to practice OGT's '637 patent under license.

Hyseq v. Affymetrix

Hyseq and Affymetrix wrote the longest chapter in DNA array litigation, which came to an end by way of a global resolution between the companies on October 25, 2001. Hyseq and Affymetrix began their litigation in March 1997 and the war eventually escalated to include four lawsuits and interference proceedings before the PTO.

Hyseq acted first, suing Affymetrix in the Northern District of California on March 3, 1997 on three patents directed at the basic method of using hybridization information to sequence targets (sequencing by hybridization or "SBH"). The court's initial claim construction order severely limited Hyseq's claims in ways that would likely have been helpful to non-infringement arguments by Affymetrix. Upon Hyseq's request for reconsideration, however, the court issued a revised claim construction that for the most part reversed the earlier order and revived Hyseq's claims. The case then lay dormant with nearly no docket activity until the global settlement was reached in October 2001.

In parallel to this first suit, Hyseq and Affymetrix fought one

ENDNOTES FOR EACH ARTICLE APPEAR ON THE BACK PAGE

another in three other suits, also in the Northern District of California. Hyseq sued Affymetrix twice more on newly issued patents in December 1997 and October 1999. In the meantime, Affymetrix had launched an attack on Hyseq in N.D. Cal. and on rival Incyte in Delaware, alleging infringement of three Affymetrix patents in each suit (two of three patents were in common in the suits). Incyte won a motion to transfer the Delaware case to California, which was then consolidated with the Hyseq suit. The October 2001 settlement halted all four active pieces of litigation for Hyseq (the consolidated suit continued against Incyte).

Some monetary terms of the settlement remain secret, but the basic deal is as follows. Affymetrix will own a 10% stake in a new subsidiary of Hyseq called "Callida." Callida in turn will own a subsidiary called "N-mer," which will act as a collaboration between Hyseq and Affymetrix to focus on DNA arrays for *de novo* sequencing. Affymetrix is to be the exclusive supplier of arrays to N-mer as well as exclusive sales agent of all N-mer products. Affymetrix also has an option exercisable at any point over the next five years to buy a majority stake in N-mer.

With the recent settlements . . . the most significant DNA array lawsuits are now over.

As for the companies themselves and their patents, Hyseq obtained a license to certain Affymetrix array patents, but for internal use only. Hyseq signed a "BiotechAccess" supply agreement with Affymetrix, suggesting that Hyseq itself may be moving out of the business of making arrays, turning this over to Affymetrix either directly or through the N-mer subsidiary. Affymetrix agreed to grant to Callida, the Hyseq subsidiary, licenses to certain non-array patents and to the Affymetrix patents involved in interferences with Hyseq. Finally, Affymetrix received a non-exclusive license to Hyseq's patents relating to arrays for all fields except "universal probe arrays," apparently referring to those arrays containing every possible sequence of DNA of a certain length. Given that Affymetrix has never sold or offered such an array (and that it may apparently now do so if it wishes through the N-mer joint venture), it appears that Affymetrix is now fully licensed to all Hyseq patents that were in dispute.

Affymetrix v. Incyte

As mentioned already, Incyte was pulled into litigation over arrays when Affymetrix sued it in 1998 in Delaware. After winning its motion to transfer, Incyte took advantage of the procedures and slower pace of litigation in the Northern District of California to score several victories against the asserted Affymetrix patents. In January 2001, Judge Fogel construed the claims of the patents. Two of the three patents claim DNA arrays themselves, while the third, U.S. Patent No. 5,800,992, relates to the "differential expression" of genes from multiple types of cells. The court construed the two array patents to require that each subunit (region, cell, etc.) of the array is an area activated "through the exposure of the localized area to an energy source . . ." Before any decision as to whether Incyte avoided infringement because it made arrays by "spotting" – *i.e.,* depositing active chemical reagents onto the array surface without using light or other radiation – the court granted Incyte's motion for summary judgment of noninfringement of the array patents based on the length of the DNA strands immobilized on Incyte's arrays. In parallel, Incyte won summary judgment of invalidity of all five claims of the third Affymetrix patent, the '992 patent relating to differential expression (claims 1-3 invalid for indefiniteness; claims 4-5 invalid for lack of written description).

In the meantime, Incyte started a counter-offensive lawsuit in 2001, asserting two "RNA amplification" patents against Affymetrix. Affymetrix responded by asserting two additional array patents in the second suit.

On December 21, Affymetrix and Incyte settled nearly all their outstanding disputes, excluding only an appeal to the district court by Incyte of a Board of Patent Appeals and Interferences decision relating to patent applications licensed by Incyte from Stanford University. The terms of the settlement are confidential, but it is known that Affymetrix paid $4.5 million in past damages for Incyte's RNA amplification patents. From the press releases and SEC filings, it would also appear that Affymetrix and Incyte will each end up with some type of cross-license under the patents at issue. Apparently some of the licenses are limited to internal use only, but the terms of the licenses on a patent-by-patent basis have not been disclosed.

Finally, as it was not reported that the judgments regarding the Affymetrix patents have been carved-out of the settlement, it does not appear they will be challenged on appeal. If true, the '992 patent would remain invalid as the summary judgments should have preclusive effect against Affymetrix. As for the claim construction rulings, whether other district courts apply them in any future litigations or not, the rulings will likely be the basis for future claim construction arguments and decisions under these patents (and perhaps other Affymetrix patents as well).

Conclusion

After nearly five years of litigation involving key patents to DNA arrays, the most significant suits now appear to be over. Affymetrix appears to have emerged with licenses to some patents of OGT, Hyseq and Incyte and apparently the ability to continue to mass-produce and supply arrays. Meanwhile, the extent of rights gained by OGT, Hyseq or Incyte have not been disclosed, nor is it clear which of them intend to manufacture and supply arrays in the future. Many rights have now been sorted out between the old players in the DNA array industry and for now there is relative calm. It remains to be seen, however, whether this will last or whether there will be future suits involving DNA array technology among these players and/or more recent entrants to the industry.

Note: Kirkland & Ellis represented Oxford Gene Technology in its infringement suit against Affymetrix. All information contained in this summary is derived from public sources, including press releases from the websites of the parties (www.affymetrix.com, www.hyseq.com, www.incyte.com, and www.ogt.co.uk); SEC statements including 8-K reporting statements of the respective settlements; and various public docket entries from the settled cases (*OGT v. Affymetrix*, 99-348 (D. Del); *Hyseq v. Affymetrix*, 97-20188, 99-21163, 00-20050 (N.D. Cal.); *Affymetrix v. Incyte*, 99-21164; 99-21165; 01-20065 (N.D. Cal.)).

Cease and Desist Letters: Walking the Line between Notice and Threat of Infringement

Mario F. Greco

You just received a call from one of your clients. Its biggest competitor is "knocking off" one of their best-selling products. This is the product your client has spent millions to research, develop and protect with patents. You plan to send a sternly worded letter threatening to sue if they don't immediately stop selling their infringing product. The letter you send must be specific enough to notify the competitor of its infringement to ensure that damages have started to accrue (just in case your advice to mark the product with the patent number wasn't followed)[1], but you don't want to trigger a declaratory judgment action. That should be easy enough...

But is it?

The Federal Circuit recently provided some additional guidance for the drafting of patent infringement notice letters in *Gart v. Logitech*, 59 U.S.P.Q.2d 1290 (Fed. Cir. 2001). Samuel Gart was issued a patent in 1989 on an ergonomically shaped mouse for use with a computer. Gart licensed his patent to Mousetrak, Inc., which began selling its mouse under the license.

Gart then learned of a possible infringement by Logitech, Inc., and began a letter writing campaign through his patent attorney:

Round 1: On April 5, 1995, Gart sent a letter to Logitech attaching a copy of Gart's patent, claiming ownership of the patent, noting that Logitech was selling a Trackman Vista mouse, and suggesting to Logitech that it may "wish to have [its] patent counsel examine the enclosed patent (particularly claims 7 and 8) to determine whether a non-exclusive license is needed under the patent." Logitech responded a few weeks later that it would take some time to evaluate Gart's patent.

Round 2: On September 4, 1996, Gart sent a second letter to Logitech, again attaching a copy of Gart's patent and indicating that Logitech "may find the patent particularly interesting" relative to its Trackman Vista and Trackman Marble products. Logitech responded three weeks later stating that Gart's patent "does not cover any of Logitech's trackball products."

Round 3: On January 30, 1997, Gart replied to Logitech's letter stating that Gart was investigating whether Logitech's Trackman Vista and Trackman Marble trackball products infringed his patent. Logitech again denied infringement three months later.

On July 23, 1998, Gart filed a complaint against Logitech for patent infringement alleging that Logitech's Mouseman, Trackman Vista, Trackman Marble and Trackman Marble FX (among other products) infringed claim 7 of Gart's patent. Nearly a year later, Logitech filed a motion for summary judgment seeking to limit its damages pursuant to 35 U.S.C. § 287(a), claiming that Gart did not give notice of Logitech's alleged infringement for the Trackman products until January 30, 1997 and for the Mouseman products until the complaint was filed. The district court granted Logitech's motion, and Gart appealed.

. . . it is irrelevant whether the alleged infringer subjectively believes that the patentee's letter is a charge of infringement.

The Federal Circuit partially reversed, holding that "no reasonable jury could find that Logitech was not 'notified of infringement pursuant to section 287(a)' as to its Trackman Vista product as of April 5, 1995 [the date of the first notice letter], and as to its Trackman Marble and Marble FX products as of September 4, 1996 [the date of the second notice letter]."[2] Gart had not, however, identified the Mouseman products in any of his letters, and the court agreed that he did not give valid notice until he filed his complaint on July 23, 1998.

The Federal Circuit ruled that the statutory requirement of actual notice is met as long as the communication from the patentee provides sufficient specificity regarding its belief that the recipient may be an infringer. The patentee needs to identify the patent, specifically identify the infringing activity, and make a proposal on how to abate the infringement (for example, a proposal to discuss licensing). The patentee does not have to make an unqualified charge of infringement that would support a declaratory judgment action. And it is irrelevant whether the alleged infringer subjectively believes that the patentee's letter is a charge of infringement.[3]

Although not specifically at issue in *Gart*, the case law shows that this is a fact intensive area with no foolproof way (other than marking) to give an infringer notice without exposing your company to the risk that your competitor will file and maintain a declaratory judgment action. While there is always a risk that a "notice" letter will trigger and, depending on the facts, support a declaratory judgment action, a company may decide to risk a declaratory judgment action in order to ensure that damages have started to accrue.

Of course, once a letter is sent, do not assume that no news is good news. You must diligently follow up with the competitor's counsel in order to protect your client's right to bring a timely suit for patent infringement if it becomes necessary.

Patent Claims Are Construed As They Would Have Been Understood At The Time Of Filing, Not As Understood Today

Rachel L. Pernic

It is black letter patent law that the claims of a patent define the "metes and bounds" of an invention. The precise contours of those "metes and bounds" are typically subject to intense litigation in an infringement action and must ultimately be further defined by the court, which construes patent claims as they would be understood by one of ordinary skill in the art. But understood as of ***when***? In fast-developing fields such as biotechnology, patent claim terms may change meaning in the time from the filing of a patent application to the filing of an enforcement action. Where this occurs, time can play a crucial role in the proper construction of patent claims.

. . . ignoring the aspect of time in construing claims is not an option – claim terms must be given the meanings they had as of the filing of the patent application, not as of the filing of litigation.

Until recently, the time frame in which claims were construed was largely a non-factor in the published case law. Two recent Federal Circuit decisions have signaled that ignoring the aspect of time in construing claims is not an option – claim terms must be given the meanings they had as of the filing of the patent application, not as of the filing of litigation.

First came *Schering Corp. v. Amgen Inc.*[1] in August 2000. Faced with a claim term that had broadened in meaning from the filing of the patent application to the filing of the litigation, the Federal Circuit held that the claims were limited to the meaning they had when the application was filed.

The *Schering* patent claimed the DNA sequences that code for a "polypeptide of the IFN-α type."[2] In modern parlance, the term "IFN-α" denotes a whole class of interferons produced by leukocytes. The Federal Circuit, however, held that Schering's patent covered only *one* interferon within the IFN-α class: the "IFN-α-1" subtype.

The court's holding resulted from the fact that, at the time prior to the filing of the patent application, scientists had conclusive evidence of only two types of interferons, one of which was an interferon produced by leukocytes that was known simply as "IFN-α."[3] The court explained that "***at that time***...the scientific community and [the inventor] understood that this interferon was the sole interferon polypeptide produced by leukocytes."[4] Furthermore, "***at the time of the [patent] application,*** neither [the inventor] nor others skilled in the art knew of the existence of, let alone the identity of, the specific polypeptides now identified as subtypes of IFN-α...."[5] Thus, those subtypes could not be within the scope of the claims.

Because the specific identity of the polypeptide coded for by the DNA isolated by the inventor was unknown, the claims were limited to cover only the polypeptide coded for by the inserts deposited by the inventor. When sequenced, the inserts were discovered to code for "IFN-α-1." Thus, that was the only interferon subtype the patents covered.[6] The claim term "IFN-α" could not be interpreted to cover forms of interferon that were not understood by one of ordinary skill in the art to fall within the meaning of that term as of the filing date of the patent application.

Any notion that the decision of *Schering* may have been an anomaly was largely dispelled by the Federal Circuit's recent decision in *Kopykake Enterprises, Inc. v. Lucks Co.*[7] There the court once again limited the scope of a claim by interpreting a disputed term as of the patent's filing date.

Kopykake involved a method of printing edible pictures on foods such as cakes. The relevant claim read: "screen printing said at least one edible pictorial image onto said edible base shape."[8] The sole issue on appeal was whether "screen printing" was properly interpreted to cover the ink-jet printing methods used by the defendant. The patent specification defined "screen printing" as including "any other conventional printing process and any other conventional means and methods" for applying pictorial images to foodstuffs.[9] The term "screen printing" could not be construed to cover ink-jet printing images onto foodstuffs because there was no showing that ink-jet printing was a conventional method of printing images on foodstuffs as of the filing date of the patent application. Whether ink-jet printing had become "a conventional printing process" for making images on foodstuffs was irrelevant for claim construction purposes. The claim had to be construed from the viewpoint of what ***was***, not what ***is***.

Any notion that the decision of *Schering* may have been an anomaly was largely dispelled by the Federal Circuit's recent decision in *Kopykake* . . .

The requirement that claim terms be construed as of the time of filing may narrow claims, as seen in *Schering* and *Kopykake*, but it may in other circumstances broaden the scope of claims. Where a term has become more specific over time, the proper claim construction as of the filing date of the application could result in a broader scope than would be apparent from the later day meaning of the term.

Any rule concerning the timing of claim interpretation is of special significance to a rapidly-developing field like biotechnology. Disputes over biotechnology patent claims frequently center on technical terms that may be recently coined and have meanings and uses that evolve as the field matures. The impact of time in construing patent claims – particularly those in the field of biotechnology – can be a useful tool in litigation for the well-informed, but a dangerous trap for the unwary.

Notes

REACH-THROUGH ROYALTIES (from pages 1-2)

1 *See also, Administrators of the Tulane Educational Fund v. Debio Holding S.A.*, 60 U.S.P.Q.2d 1901 (E.D.La. 2001) (rule against post-expiration royalties applied to non-US patents).

CEASE & DESIST LETTERS (from page 4)

1 *See* 35 U.S.C. § 287(a).

2 59 U.S.P.Q.2d 1290, 1299 (Fed. Cir. 2001).

3 59 U.S.P.Q.2d at 1298-99. *Gart* is the latest in a line of cases that has brought some clarity to the law of notice. *See, e.g., SRI Int'l, Inc. v. Advanced Technology Laboratories, Inc.*, 127 F.3d 1462 (Fed. Cir. 1997) (informing the alleged infringer of the identity of the patent and the infringing activity, accompanied by a proposal to abate the infringement, whether by license or otherwise, complies with the actual notice requirement of the marking statute); *see also, Amsted Industries, Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178 (Fed. Cir. 1994) (a communication including a specific charge of infringement by a specific accused product is sufficient to give actual notice.) As in *Gart*, the Federal Circuit in *Amsted* did not require an unqualified charge of infringement or threat of litigation for effective notice.

TIMING OF PATENT CLAIM INTERPRETATION (from page 5)

1 222 F.3d 1347 (Fed. Cir. 2000).

2 *Id.* at 1350, 1351, 1353 (quoting Patent No. 4,530,901).

3 The patent application term originally read "leukocyte interferon" instead of "IFN-α." The inventor amended the claims to read "IFN-α" because the scientific community officially changed the terminology after the patent was applied for, but before it issued.

4 *Schering,* 222 F.3d at 1353 (emphasis added).

5 *Id.* (emphasis added).

6 After the district court closed its claim construction proceeding, Schering proffered evidence that one of the original deposits codes for IFN-α-14, another interferon subtype. The district court denied Schering's motion to reopen the record and reinterpret the claims to account for those test results. The Federal Circuit found that the district court did not abuse its discretion in denying the motion. *See Schering*, 222 F.3d at 1354-55.

7 264 F.3d 1377 (Fed. Cir. 2001).

8 *Id.* at 1380 (quoting Patent No. 5,017,394). Although less than grammatically perfect the quotation is verbatim.

9 *Id.* (quoting Patent No. 5,017,394).

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