Miscellaneous Docket No. 06-830

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE SEAGATE TECHNOLOGY, LLC,
Petitioner.

On Petition for a Writ of Mandamus
to the United States District Court
for the Southern District of New York
in Case No. 00-cv-5141
(Hon. George B. Daniels)

Brief of *Amicus Curiae*, Biotechnology Industry Organization, in Support of Petitioner

Of Counsel:
Scott A.M. Chambers, Ph.D.
Patton Boggs LLP
8484 Westpark Drive, 9th Floor
McLean, Virginia 22102
(703) 744-8085

(Counsel of Record)
(Address)

Attorneys for Biotechnology Industry Organization

CERTIFICATE OF INTEREST

Counsel for the amicus curiae Biotechnology Industry Organization certifies the following:

1. The full name of the amicus that we represent is:

BIOTECHNOLOGY INDUSTRY ORGANIZATION

2. The name of the real party in interest that we represent is:

BIOTECHNOLOGY INDUSTRY ORGANIZATION

3. All parent corporations and publicly held companies that own 10 percent or more of the stock of the amicus curiae that we represent are:

None

4. The names of all firms and partners or associates that appeared for the amicus curiae now or are expected to appear in this Court are:

Scott A.M. Chambers, Ph.D.
Patton Boggs LLP
8484 Westpark Drive, 9th Floor
McLean, Virginia 22102

Hans Sauer, Ph.D.
Biotechnology Industry Organization
1225 Eye Street, N.W., Suite 400
Washington, DC 20005

Date: March 21, 2007

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Scott A.M. Chambers, Ph.D.

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I. INTEREST OF AMICUS

The Biotechnology Industry Organization (BIO) is a trade association consisting of over 1000 companies, academic institutions, and biotechnology centers. BIO members are involved in the research and development of healthcare, agricultural and environmental products. The biotechnology industry has more than 370 biotech drugs currently in clinical trials being studied to treat more than 200 diseases. The vast majority of members are small start-up companies yet to bring a product to the market. Members have great interest in this case because the outcome will impact the amount of research and development resources available to them as well as the process and cost required to defend against willfulness allegations. Greater certainty of the scope of the attorney–client privilege is essential to biotech companies in informing corporate decision makers of potential infringement risks, in allowing for adequate trial preparation and choice of counsel, and to reduce expenses associated with litigating the scope of the waiver.

BIO has no stake in the parties to this litigation or the result in the case, nor have the parties contributed to preparing this brief.

BIO is filing a Motion for Leave to File Amicus Brief concurrently herewith.

II. ARGUMENT

Question 1: Should a party's assertion of the advice of counsel defense to willful infringement extend waiver of the attorney-client privilege to communications with that party's trial counsel? *See In re EchoStar Commc'n Corp.*, 448 F.3d 1294 (Fed. Cir. 2006).

A. A party's assertion of the advice-of-counsel defense to willful infringement should not waive the attorney-client privilege to communications with that party's trial counsel

If reliance on an advice-of-counsel defense leads to a likely waiver of attorney-client privilege for communications with trial counsel, accused infringers would face the choice between (1) an advice-of-counsel defense to willfulness or (2) preservation of privilege for its communications with trial counsel. Loss of attorney-client privilege for communications with trial counsel essentially results in loss of effective assistance of trial counsel. For smaller biotechnology businesses, this is an impossible choice, given the dire consequences of being found to have willfully infringed. Given that "almost every patent infringement complaint includes an allegation of willfulness"[1] and that an advice-of-counsel defense is critical to defeating a claim of willfulness, waiver occasioned by assertion of an advice-of-counsel defense is arguably not truly voluntary and must

[1] David O. Taylor, *Wasting Resources: Reinventing the Scope of Waiver Resulting from the Advice-of-Counsel Defense to a Charge of Willful Patent Infringement*, 12 TEX. INTELL. PROP. L. J. 319, 323 (Winter 2004). *See also* Kimberly A. Moore, *Empirical Statistics on Willful Patent Infringement*, 14 FED. CIR. B.J. 227, 232 (2004-2005) (90% of cases allege willfulness).

be limited to pre-litigation communications with the corporate decision maker on the subject of the opinion relied upon.

Communications with trial counsel involve trial strategies, the probabilities of success, and settlement. Trial counsel advice to an accused infringer will entail analysis of approaches that the patentee might use to pursue alternate theories of infringement, to bolster patent validity, and potential lines of response to possible attacks on enforceability. The advice would also entail possible claim construction arguments, counter arguments, and potential design–around considerations. Even a remote possibility such advice would fall into the hands of the patent holder would preclude creation of such a full and informing communication—no matter how honest and helpful to guiding an accused client. Moreover, the cost in time, money, and distraction to scour through all of the communications with an eye to redaction and the risk that the waiver might expand in scope due to an inadvertent disclosure or an ambiguous document is too great to be justified by the marginal relevance of disclosure to the patent holder. Although naturally involving issues of infringement, validity, and enforceability, trial counsel's work is focused on litigation strategy. Corporate decision makers use such information to decide how best to proceed in the litigation, not to run their businesses. As such, communications from trial counsel are distinct from and at best secondary to the

information relevant to the state of mind of the corporate decision maker prior to litigation.

In contrast, opinion counsel communications are relevant to real-life business decisions that sometimes precede infringement litigation. The vast majority of U.S. biotechnology companies are in early stage product development, far from profitability or having a marketed product. Such companies almost always operate with limited resources, depending on partnering and external financing to develop their products. Investment analysts place strong emphasis on ensuring that the early-stage biotechnology business is not precluded from commercial operation if a product is ever developed. To potential investors, ensuring freedom-to-operate is at least as important as having patent protection for a future product.[2]

Over the course of a year, a biotechnology company commonly evaluates hundreds of patents that are relevant to its research and development (R&D) activities. Issues relating to possible freedom-to-operate obstacles or potential patent infringement arise with some frequency. For example, research on a single molecule may trigger examination of a spectrum of patents ranging from basic

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[2] *See* Marcia H. Anderegg , Joshua M. Thayer & Kathleen M. Williams, *Trendspotting: a shift in intellectual property focus*, NATURE PUBL'G GROUP, available at http://www.nature.com/bioent/building/ip/042006/full/bioent907.html (March 19, 2007).

patents on fundamental technologies to patents on nucleotide sequences, peptides, vectors and plasmids, cell lines, screening and treatment methods, and manufacturing processes. An unanswered freedom-to-operate question raised by research may both scare away investors and raise concerns about being sued for infringement.

Two critical business needs - attracting investment today and gauging the risk of litigation in the future - drive biotech companies to seek candid and practical advice of counsel in evaluating their freedom to develop and commercialize their future products. Such freedom-to-operate analyses often lead to detailed validity and infringement opinions for particular patents, obtained at significant cost in time and money by hiring opinion counsel and diverting internal manpower from other important functions.

Corporate decision makers expect such opinions to provide information needed for immediate business decisions, such as whether to seek a license, to make changes to their activities, or to confidently declare to potential partners or investors their belief they have freedom-to-operate. It is the subject matter of such opinions – not communications from trial counsel - that is most relevant to the state of mind of the corporate decision maker during the events that give rise to infringement litigation. Once litigation starts, communications with trial counsel ascribe to different metric.

Loss of effective counsel is much more disturbing in the context of litigation than in other contexts because enormous amounts of money, and even the existence of a corporate entity, are often at stake. If privilege waiver from reliance on an advice-of-counsel defense is extended to trial counsel, the broad access to privileged communications between the accused infringer and its trial counsel would give a patentee unfair advantage in litigation and in any settlement negotiations. The possibility of such a waiver and potential access to otherwise privileged communications nearly mandates "the filing of claims of willful infringement without regard to their merit" as a litigation tactic. *See Sharper Image Corp. v. Honeywell Int'l, Inc.*, 222 F.R.D. 621, 643 (N.D. Cal. 2004).

Moreover, even if the waiver were not usually extended, the danger it might inappropriately chills communications between trial counsel and client, thereby impairing trial counsel's ability to give the client candid advice regarding the merits of the case. This Court has overruled case law that resulted in "inappropriate burdens on the attorney-client relationship" and "distort[ion of] the attorney-client relationship, in derogation of the foundations of that relationship." *Knorr-Bremse v. Dana Corp*., 383 F.3d. 1337, 1343-44 (Fed. Cir. 2004).

Unfairness, coupled with the fact that trial counsel and accused infringer communications are normally not directed to whether the client can safely engage in potentially-infringing activity, justifies a general rule that assertion of the

advice-of-counsel defense should not extend waiver of the attorney-client privilege to communications with trial counsel after a complaint is filed.

Approaches taken by district courts to allow *limited* waiver of attorney-client privilege are unworkable, expensive, unduly burdensome, and do not adequately lessen the unfair burden that extension of waiver to trial counsel imposes on the accused infringer. For example, in the instant case, the district court noted that "trial counsel will surely address with the client trial strategy concerning validity, infringement, and enforcement in ways that do not implicate the advice-of-counsel defense" and stated that "to the extent that Seagate wishes to withhold or redact documents that would reveal trial strategy or planning, it shall submit those documents for my in camera review." *Convolve, Inc. v. Compaq Computer Corp.*, 224 F.R.D. 98, 105 (S.D.N.Y. 2004). A number of district courts have taken a "middle ground" approach, waiving attorney-client privilege as to communications between trial counsel and client where the communication disparages or casts doubt upon a relied-upon opinion. *See, e.g.*, *Intex Rec. Corp. v. Team Worldwide Corp.*, 439 F. Supp. 2d 46, 49 (D.D.C. 2006).

Such approaches would likely require frequent and extensive *in camera* review of documents where privilege is disputed, as well as appeals of rulings upon rulings regarding such documents. Such review would impose enormous burdens on both trial courts and this Court, undermining judicial economy.

Moreover, it is fundamentally unfair for any party to be forced to allow the courts that will be passing judgment on the merits of that party's case to review documents disclosing its trial strategy.

Attempts to separate trial strategy from advice possibly affecting reasonableness of reliance on opinions would be unworkable and would allow disclosure of attorney client communications to such a degree that the detrimental effects of waiver on the attorney-client relationship would not be alleviated. For example, one district court adopted "a middle approach that seeks to preserve in some fashion trial strategy while requiring disclosure of communications that are central and material to Defendants' decision to engage in allegedly infringing activity." *Genentech, Inc. v. Insmed Inc.*, 442 F. Supp. 2d 838, 847 (N.D. Cal. 2006). Yet that court explicitly would allow discovery of "a communication about the likelihood of success on infringement in light of the venue and probably jury pool [because it] is of central materiality to the ultimate question of infringement . . .. " *Id.* The relevance the vagaries of venue and jury pool to the reasonableness of an accused infringer's reliance on an opinion of non-infringement is marginal. Such detail vastly increases cost and complexity in a system already overtaxed.

While the Court's question refers to "trial counsel" the dangers of a broad waiver apply to both trial counsel and in-house counsel. Both during day-to-day

business operations and in litigation, corporate decision makers receive written and verbal communications from outside attorneys through their own in-house counsel. An in-house attorney who receives an opinion from opinion counsel and communicates it to the decision maker must also be able to participate in communicating with trial counsel during litigation – anything else would be inefficient and counterproductive. This is especially true given that most biotechnology companies have only small legal departments and cannot allocate litigation-related work to separate attorneys. Unless in-house counsel is also the corporate decision-maker, in-house counsel's state of mind and knowledge is not sufficiently relevant to the analysis to justify disclosure. If litigation related information could be obtained by simply deposing in-house counsel, maintaining privilege for trial counsel communication would be irrelevant. Excluding communications with in-house counsel from the scope of the waiver does not contravene the purpose of the waiver. *See Autobytel, Inc. v. Dealix Corp.*, 455 F. Supp. 2d 569, 576 (E.D. Tex. 2006).

Question 2: What is the effect of any such waiver on work-product immunity?

B. Immunity waiver for advice of counsel defense should not extend to communications with trial counsel.

In *EchoStar*, this Court ruled that work product "which is never communicated to the client, is not discoverable. Under Rule 26(b)(3), this so-

called 'opinion' work product deserves the highest protection from disclosure." *In re EchoStar Commc'n Corp.*, 448 F.3d 1294, 1303 (Fed. Cir.), *cert. denied*, 127 S. Ct. 846 (U.S. 2006). The same rule should apply to work product of trial counsel.

As explained above, waiver should not apply to trial counsel after the commencement of litigation. As with waiver of attorney-client privilege, "[t]he overarching goal of waiver [of work product immunity] in such a case [where an accused infringer has asserted an advice-of-counsel defense to a claim of willful infringement] is to prevent a party from using the advice he received as both a sword, by waiving privilege to favorable advice, and a shield, by asserting privilege to unfavorable advice." *EchoStar*, 448 F.3d at 1303.

Courts "recognize work-product immunity because it promotes a fair and efficient adversarial system by protecting 'the attorney's thought processes and legal recommendations' from the prying eyes of his or her opponent." *EchoStar*, 448 F.3d at 1301 (quoting *Genentech, Inc. v. United States ITC*, 122 F.3d 1409, 1415 (Fed. Cir. 1997)). Absent work product immunity, counsel may be reluctant to record their thoughts and opinions for fear that opposing counsel will discover their work and use it to gain an unfair advantage. *See, e.g., id.*; *Hickman v. Taylor*, 329 U.S. 495, 511 (1947). Similarly to the effects of waiver of attorney-client privilege, trial counsel representing accused infringers who may assert an advice-

of-counsel defense to willfulness will be reluctant to communicate their work product to their clients or to memorialize any communications with clients. Such reluctance would reduce the effectiveness of representation. Accordingly, as with waiver of attorney-client privilege, if a party's reliance on an advice-of-counsel defense against a claim of willful infringement results in a waiver of work product immunity for trial counsel, every accused infringer would be forced to choose between (1) an advice-of-counsel defense to willfulness or (2) effective assistance of trial counsel. This Hobson's choice is inappropriate to a fair legal system.

For the same reasons enumerated with regard to attorney-client privilege, the need to preserve work product immunity is more compelling for trial counsel than for counsel not representing a client in litigation, and preservation of immunity for work product of trial counsel generally does not implicate sword and shield concerns. A balancing of relative prejudices to the parties weighs in favor of preservation of work product immunity for trial counsel, absent a compelling reason to extend waiver to it. Additionally, as with attorney-client privilege, a distortion in balance of power between patentee and accused infringer and added incentive for patentees to claim willfulness -- regardless of the merit of the claim -- will result from extension of waiver to work product of trial counsel.

Question 3: Given the impact of the statutory duty of care standard announced in *Underwater Devices. Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983), on the issue of waiver of attorney-client privilege, should this court reconsider the decision in *Underwater Devices* and the duty of care standard itself?

C. BIO believes the duty of care standard as presently articulated is no longer in the best interest of the patent system

A typical patent landscape for a biotechnology product is complex and constantly evolving. A biotechnology company must gauge the risk of being sued for infringing numerous patents throughout the typically ten years or more of product development – and prudence under the duty of due care essentially demands securing opinions for dozens of patents. For fear of enhanced damages, such opinions often take a formal, exculpatory posture[3] that frustrates the corporate decision maker's need for immediate, real-word business advice. A typical opinion can cost $20,000, but complicated ones may cost more than $100,000 – money that biotechnology businesses would much rather invest in their products than in their lawyers. Even at these princely sums there are no guarantees that the duty of due care has been discharged successfully. Biotechnology patent law is emerging, it is dynamic, and much of it is based on incredibly complicated science.

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[3] *See Knorr-Bremse*, 383 F.3d. at 1349 ("While the duty of care is only one factor in the determination of enhanced damages, no one can seriously doubt that, both in the minds of the jurors (in determining willfulness) and in the decision of the district court (concerning enhancement), the duty of care is by far the preeminent factor in the vast majority of cases.").

To further fuel this complexity, the "exculpatory opinions" obtained from patent counsel are always evaluated in hindsight. Given the long development times for products in most fields of biotechnology, the state of the law during the events and decisions that gave rise to the litigation is often ancient history compared to the current state of the patent law and the state of the science when a court assesses its competence. At the time a litigation commences, a nearly absurd reconstruction of the alleged "willfulness" crime scene takes place – What was the *state of mind* of the accused infringer at the then-remote time the alleged infringement began?

Without any question, divining a willfulness judgment from the reconstruction of this mental moment is difficult. With complex, evolving, uncertain and disputed doctrines of patent law as the predicate for gauging the state of mind, it is difficult to know what lengths are needed so that in hindsight it will assuredly look to have been reasonable and competent.

Indeed, courts have questioned the competency of oral opinions, opinions from "in-house" and foreign counsel, those not sufficiently analyzing the prosecution history or covering every infringement and validity theory.[4]

[4] *See generally* Donald S. Chisum, 7-20 CHISUM ON PATENTS § 20.03[4][b][v][d] (2000).

Furthermore, it can fairly be asked whether the existing duty of care standard would pass Constitutional muster. It is undisputed that treble damages are punitive. *See, e.g.*, *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1574 (Fed. Cir. 1996). In other contexts, the Supreme Court has held that punitive damages should be assessed only against those guilty of reprehensible conduct. *See, e.g.*, *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996). Why should there be a different standard under patent law, where punishment for failing to pass the duty of care test -- which is measured against a reasonableness standard -- can result from mere negligence. *See Sharper Image*, 222 F.R.D. at 643 (indicating the duty of care standard seems more like a negligence standard).

While BIO emphatically believes in the importance of discouraging infringing activity, the duty of care as articulated in *Underwater Devices* is unduly burdensome and no longer necessary. Punitive damages should only be imposed for truly reprehensible conduct, such as, for example, deliberate copying, concealing infringing activity or continuing to infringe after a final determination of infringement. BIO believes such a change in precedent would positively impact research and development in the biotechnology industry.

Respectfully submitted,

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Counsel for Amicus Curiae

CERTIFICATE OF COMPLIANCE

Amicus Curiae Biotechnology Industry Organization ("BIO") submits its brief under Rules 32(a)(6)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. Thus, I hereby certify that *Amicus Curiae* BIO's brief complies with the type-volume limitation therein provided, and I further certify that the foregoing Brief for *Amicus Curiae BIO* was prepared with Microsoft Word 2003 using a proportional spaced typeface using 14-point Times New Roman, and contains 3,126 words, as determined by Microsoft Word 2003, including footnotes, excluding the table of contents, table of authorities and certificates of counsel.

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Scott A.M. Chambers

CERTIFICATE OF SERVICE

I hereby certify that on this day I caused two (2) copies of this Brief of *Amicus Curiae*, Biotechnology Industry Organization in Support of Petitioner to be served upon counsel of record for the parties as listed below by sending the copies via U.S. Mail, first class on March 21, 2007 to:

Attorneys for Petitioner Seagate Technology LLC

Terrence P. McMahon
Stephen J. Akerley
Lucy H. Koh
Mary B. Boyle
McDermott Will & Emery LLP
3150 Porter Drive
Palo Alto, California 94304-1212
(650) 813-5000

Raphael V. Lupo
Paul Devinsky
Brian E. Ferguson
McDermott Will & Emery LLP
600 13th Street, N.W., 12th Floor
Washington, D.C. 20005-3096
(202) 756-8000

Attorneys for Respondents Convolve, Inc. and Massachusetts Institute of Technology

Albert L. Jacobs, Jr.
Daniel A. Ladow
Adam B. Landa
Richard E. Kurtz
Greenberg Traurig LLP
200 Park Avenue, 34th Floor
New York, NY 10166
(212) 801-2104

Debra Brown Steinberg
Tom M. Fini
Kevin J. McNamee
Cadwalader, Wickersham & Taft LLP
One World Financial Center
New York, NY 10281
(212) 504-6000

_____

Scott A.M. Chambers, Ph.D.
Counsel for Amicus Curiae