Nos. 01-1357, -1376, 02-1221, -1256

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

KNORR-BREMSE SYSTEME FUER NUTZFAHRZEUGE GMBH,
PLAINTIFF-CROSS APPELLANT,

V.

DANA CORPORATION,
DEFENDANT-APPELLANT,
AND
HALDEX BRAKE PRODUCTS CORPORATION,
AND HALDEX BRAKE PRODUCTS AB,
DEFENDANTS-APPELLANTS

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA IN 00-CV-803,
JUDGE T.S. ELLIS, III

BRIEF OF *AMICUS CURIAE*
BIOTECHNOLOGY INDUSTRY ORGANIZATION
IN SUPPORT OF NEITHER PARTY

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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 law firms and the partners or associates that appeared for the *amicus* now or are expected to appear in this Court are:

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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 it will impact the amount of research and development resources and the process required to defend against willfulness allegations.

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.

Each of the parties consented to the filing of this brief.

II. ARGUMENT

Question 1: When the attorney-client privilege and/or work-product privilege is invoked by a defendant in an infringement suit, is it appropriate . . . to draw an adverse inference with respect to willful infringement?

A. An adverse inference from asserting the attorney-client privilege should cease to exist because it unduly burdens innovators by creating a need to obtain legal opinions solely to defend against a willfulness finding and possible treble damages, and discourages obtaining objective legal advice required for everyday decision-making.

The attorney-client privilege exists to protect the right to effective counsel. It is severely undermined whenever failing to waive the privilege exposes the client to potentially draconian consequences. The opportunity for treble damages under the patent statute is one such draconian consequence. For this reason alone BIO urges this Court to overrule precedent allowing for a so-called "adverse inference" when an accused infringer asserts its privilege to protect opinions rendered by its legal counsel in a defense to willful infringement and a treble damages claim. *See: Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1572-73 (Fed. Cir. 1988).

Under existing Federal Circuit precedent, clients regularly create and later produce at trial "exculpatory opinions" of patent counsel as a defense to willfulness allegations and treble damages claims. These exculpatory

opinions are not run-of-the-mill legal advice. Their aim is not guiding an alleged infringer's future conduct, intelligently informing of potential risks of infringement, or aiding the formation of some reasoned business judgments. Instead, they are opinions whose entire reason for being is to defend against a willfulness finding and possible treble damages.

Unsurprisingly, biotechnology companies are particularly burdened by the "exculpatory opinion" business. Innovation in the biotechnology field is tightly tied to intellectual property rights and risks whose assessments requires full, frank, and objective legal advice for everyday decision-making. The optimal advice given to a possible infringer will entail sample roadmaps that the patent owner could use to establish infringement, counter-strategies the patent owner might adopt to bolster patent validity, and the patent owner's potential line of response to possible attacks on enforceability. Such a full and informing opinion – however honest and helpful to guiding a possibly infringing client – would at best be counterproductive at trial when a willfulness allegation is made. Even if the infringer faithfully adhered to its duty of due care, a frank opinion of counsel would assuredly be used by the patent owner to suggest otherwise.

Biotechnology companies are especially burdened by the need to generate "exculpatory opinions," specifically crafted with an eye to

presentation as a willfulness defense at trial. The need arises from the convolution of research and patenting practices that work together in the development of biotechnology drugs.

Typical biotechnology drug development periods exceed a decade and only one in every 10,000 potential drugs that enters pre-clinical testing will receive U.S. Food and Drug Administration approval as a novel medicine. Biotechnology companies do much research and undertake much product development that may implicate dozens to hundreds of patents every year. When a molecule proceeds along the final steps to approval for marketing, a typical biotechnology company will own some or many of the potentially relevant patents, but competitors and others may hold many others.

A biotechnology company commonly evaluates hundreds of patents over the course of a year to which its research activities are relevant. Unsurprisingly, dozens of issues of potential patent infringement can arise. For example, a single molecule may trigger the opportunity to examine a spectrum of relevant patents ranging from basic patents on fundamental technologies to patents on nucleotide sequences, peptides, vectors and plasmids, cell lines, screening and treatment methods, formulations, and manufacturing processes. A company may face the risk of being sued for

infringing any one of these patents – and prudence under current law may demand securing exculpatory opinions for each.

BIO believes ending this counterproductive practice will foster greater innovation in the biotechnology industry – and accelerate progress in the useful arts.

Question 2: When the defendant has not obtained legal advice, is it appropriate to draw an adverse inference with respect to willful infringement?

B. Biotechnology patent law is too unpredictable and evolving for the current "duty of due care" to be reasonably applied.

BIO believes it is inappropriate to draw an adverse inference for not obtaining legal advice regarding possible patent infringement. This Court should overrule precedent perceived to establish a duty to obtain legal advice before initiating possible infringing activity. *See: Underwater Devices, Inc. v. Morrison-Knudsen Co., Inc.*, 717 F.2d 1380, 1389-90 (Fed. Cir. 1983). The duty of due care – even though grounded on a plausible policy rationale – operates as a litigation albatross. Biotechnology patent law provides the epitome of the problematic nature of the duty when put to practice. The biotechnology patent law is emerging, it is dynamic, it has aspects that different judges on this Court have expressed fundamentally different views

in the opinions that they have written, and much of it is based on incredibly complicated science.

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 hindsight 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 has become difficult to know what lengths to go to secure enough advice so that in hindsight it will assuredly look to have been competent.

Courts – including the Federal Circuit – have not offered any decisive guidance over the 15 years since the "duty of due care" was first pronounced as nationwide patent law. Indeed, courts have questioned the competency of

oral opinions; opinions from "in-house" and foreign counsel; those not analyzing the prosecution history or covering every infringement and validity theory; etc. *See:* D. Chisum, Patents, Section 20.03 [4][b][v][d] (2000).

The result is that a prototypical "exculpatory opinion" can carry quite a price tag. "Simple" opinions can start at $10,000, but complicated ones have been known to creep beyond $100,000!

However, even at these princely sums – utterly vast for most biotechnology companies – there are no guarantees that the duty of due care has been discharged successfully once, at trial, a hindsight analysis exposes some lacuna in the law or misunderstanding of a complex bucket of facts.

Although it would be unfortunate, should this court determine to maintain the judge-created "duty of due care," greater flexibility in discharging the duty should reflect a jurisprudential priority. Instead of the emphasis that existing precedent places on securing a full, formal, competent legal opinion that is decisively exculpatory, less formal manifestations of appropriate care ought to suffice. Thus, the existing law on adverse inference should change. It focuses on the imperative of producing the exculpatory opinion itself rather than a primary focus on the most direct testimonial evidence on state of mind.

The ultimate resolution of the balance between waiver and adverse inference would be for this court to overrule the judge-made duty of due care ensconced in its precedent. Taking this decisive step would moot the existence of an exculpatory opinion rendered at the time the alleged infringement began and return the giving of legal advice to its core function – helping best guide a potential infringer's future conduct.

Question 4. Should the existence of a substantial defense to infringement be sufficient to defeat liability for willful infringement even if no legal advice has been secured?

C. A substantial defense should be sufficient to defeat liability for willful infringement.

BIO supports an assessment of willfulness that – wherever possible – turns on objective factors and is determined by the court as the declarant of the law. Thus, alleged willfulness should be defeated as a matter of law where the merits of an accused infringer's defense presented at trial demonstrate some substantial basis on which the patent might have been deemed invalid, unenforceable, or not infringed.

Thus, at a minimum, the existence of a substantial defense should eliminate any possibility of concluding the infringement was willful.

Taking this step need not preclude the patent owner from obtaining multiplied damages in every case. Just as the patent statute now permits

damages to be trebled, if liability were contested in a manner without merit, a court could assess increased damages and even award attorneys fees.

Thus, a "substantial defense" as a complete defense to an allegation of willfulness provides the patentee with no disrespect or undue prejudice.

As set above, strong policy considerations support a balance in which accused infringers are afforded some relief from the risks attendant to failure to procure an exculpatory opinion. Where a patent on its face were subject to substantial doubt as to its validity, that substantial doubt would be enough for a prudent business – in its exercise of due care – to avoid the $100,000 exercise in securing the exculpatory opinion.

The Court need not make any radical adjustment to its precedent to render such a holding. This Court has held that increasing damages for willfulness is generally inappropriate when the infringer mounts a good faith and substantial challenge to the existence of infringement, *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 20 (Fed. Cir. 1984); the closeness of the issues is a relevant factor in assessing willfulness, *Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1057 (Fed. Cir. 1994); and recently upheld a ruling of no willfulness where an infringer did not produce an opinion but presented a reasonable defense it believed it

was licensed. *State Contracting and Engineering Corp. v. Condotte American, Inc.*, U.S. App. Lexis 20422 (Fed. Cir. 2003) (slip op., at 16).

Thus, in many ways, an explicit *en banc* holding by the Court would represent a clarifying change to a law already tilted against willfulness holdings where the infringement holding was not without substantial doubt.

BIO believes taking this next precedential step, to allow a substantial defense to defeat liability for willful infringement, will also serve the public by providing an appropriate incentive to challenge patents believed in good faith to be invalid and facilitate licensing on more reasonable terms. For example, an accused or prospective licensee who can rely on a substantial defense, without the current risks and burdens associated with defending against willful infringement allegations, will be more likely to challenge weak patents. Successful challenges will result in encouraging earlier competition by preventing an unwarranted monopoly. In addition, a patentee who recognizes that a substantial defense is likely, and the windfall associated with enhanced damages is unlikely, will be more likely to accept more reasonable license or settlement terms.

The Court might consider taking one additional step – remove "state of mind" of an adjudicated infringer as relevant to any issue of liability or damages. It is already the law that a wholly "innocent" infringer, unaware

the patent even exists, can be held to account for the full and complete damages suffered by the patentee – lost profits, price erosion damages, prejudgment interest, and lost sales of convoyed goods.

Just as an innocent state of mind can be no defense to infringement, a culpable mental state should expose the infringer to the full and complete damages available to the patent, but no more. This Court could determine that patent infringement is determined wholly based upon objective factors. Neither "willfulness" nor "innocence" impacts the finding of infringement – or the resulting damages. Under this regime, advice of counsel would be irrelevant to any legal issue before a court.

Where an accused infringer contested the patent – and presented no credible defense at trial – the court would have the discretion set out in the statute to enhance damages and award attorneys' fees.

Patentees would never be left less than whole. Accused infringers would never be subject to the *in terrorem* effect of a claim of "willfulness" that might chill the will to challenge a dubious infringement allegation. The attorney-client privilege would be unimpaired – advice of patent counsel would be sought and received solely to frankly advise the client as to future conduct, not to inoculate the client from a holding of culpable intent.

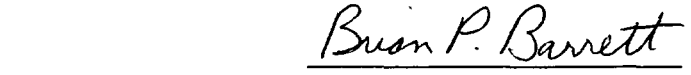
In one key respect patent rights are unlike tangible property rights, such as real property. A chain-link fence, with barred wire arrayed across the top and with posted "No Trespassing" signs along the perimeter defines precisely the metes and bounds of a parcel of real property. When the perimeter of protected rights is well defined and their validity self-evident, a duty of due care to avoid willful trespass – with multiplied damages for their disregard – may indeed legitimately vindicate private property interests.

Patents – especially biotechnology patents – are not surrounded by "bright line" perimeters and certain validity. Applying a "duty of due care" to such inherently uncertain, unpredictable, shifting patent property perimeters is particularly problematic. This Court should unweave the portion of the patent law fabric mandating "due care," having determined that unleashing the resources that today are unproductively employed in exculpatory opinion drafting, in discovery of the accused infringer's state of mind, and in litigating the issue of intent might be better employed elsewhere. For biotechnology companies the benefit would be scarce resources would go to directly promoting the progress of the useful arts.

III. CONCLUSION

This Court should revise the law to eliminate adverse inferences and establish an objective assessment of the legal basis upon which a court would exercise the statutory authority for awarding multiplied damages.

Respectfully submitted,



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I hereby certify that on this ___ day of October 2003, two (2) copies of the foregoing BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF NEITHER PARTY were caused to be served via overnight courier, to:

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I also hereby certify that on this ____ day of October, 2003, one (1) signed original and thirty (30) bound copies of the foregoing BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION were filed, via hand delivery, in the Office of the Clerk, United States Court of Appeals for the Federal Circuit.

_____

CERTIFICATE OF COMPLIANCE

Amicus curiae Biotechnology Industry Organization submits its brief under Rules 32(a)(5)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. As required by Rule 32(a)(7)(C), I hereby certify that *amicus curiae* Biotechnology Industry Organization's brief complies with the type-volume limitation therein provided and with the Court's order limiting the length of *amicus* briefs to 2500 words. I further certify that the foregoing BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION contains 2,469 words. In preparing this certificate, I have relied on the word count of the word processing system used to prepare this brief, including headings, footnotes, and quotations.

By: Brian P Barrett
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Dated: 10-29-03