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Nos. 02-1052, -1065

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INTEGRA LIFESCIENCES I, LTD. and THE BURNHAM INSTITUTE,

Plaintiffs-Cross Appellants,

and

TELIOS PHARMACEUTICALS, INC.

v.

MERCK KGaA,

Defendant-Appellant,

and

THE SCRIPPS RESEARCH INSTITUTE and DR. DAVID A. CHERESH,

Defendants.

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

OCT 17 2005

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U.S. COURT OF APPEALS
FEDERAL CIRCUIT

Appeal from the United States District Court for the Southern District of California
in case no. 96-CV-1307, Senior Judge James M. Fitzgerald

BRIEF FOR *AMICUS CURIAE* BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA – PATENT, TRADEMARK & COPYRIGHT SECTION IN SUPPORT OF NEITHER PARTY

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October 17, 2005

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INTEGRA LIFESCIENCES V MERCK

02-1052, -1065

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Bar Association of the District of Columbia – Patent, Trademark & Copyright Section certifies the following:

1. The full name of every party or amicus represented by me is:

Bar Association of the District of Columbia – Patent, Trademark & Copyright Section

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Bar Association of the District of Columbia – Patent, Trademark & Copyright Section

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

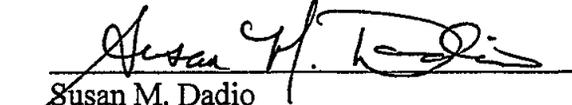
None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

THE ECCLESTON LAW FIRM
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BUCHANAN INGERSOLL PC
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Susan M. Dadio

Dated: October 14, 2004


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US COURT OF APPEALS
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OTHER

Brief for *Amicus Curiae* Bar Association of the District of
Columbia – Patent, Trademark & Copyright Section in Support
of Neither Party, *Merck KGaA v. Integra LifeSciences I, Ltd.*,
No. 03-1237, 2005 WL 435891 (Feb. 22, 2005)2

STATEMENT PURSUANT TO FED. R. APP. P. 29(C)(3)

The Bar Association of the District of Columbia – Patent, Trademark & Copyright Section ("BADC") is one of the senior intellectual property bar associations in the United States. The BADC is uniquely situated in the nation's capital, having a broad cross-section of members from government, industry, and private practice, with members often representing both the interests of patentees and those seeking to avoid patents. The interest of the BADC is entirely pro bono to advance and create a uniform body of predictable case law to guide the patent community.

The Court has *sua sponte* allowed *amicus curiae* briefs. The BADC has no stake in the parties to this litigation or in the result in this case. Nor have the parties to the case contributed in any way to the preparation of this *amicus curiae* brief.

ARGUMENT

By an Order dated August 17, 2005, this Court has recalled the mandate in this case, reinstated the appeal, and required new briefs to be filed in view of the decision by the Supreme Court of the United States in *Merck KGaA v. Integra LifeSciences I, Ltd.*, 125 S. Ct. 2372 (2005).

The BADC urges this Court to refrain from providing a detailed interpretation of the upstream boundary of the safe harbor provision of 35 U.S.C. § 271(e)(1) and, particularly, from any consideration of the common law experimental use exemption that was expressly waived by appellant in the previous consideration of this case before this Court.¹ The Court should therefore simply remand the case to the district court for reconsideration consistent with the Supreme Court's holding.

This is now a fact specific case tied to an arcane jury instruction that, on remand, will almost certainly *never* again be repeated. Accordingly, there would be no precedential value in any holding that may result. Anything the court may say about the safe harbor provision and the common law experimental use exemption would be *dicta* that is better left for another day.

¹ For a discussion of the common law experimental use exemption, see Brief for *Amicus Curiae* Bar Association of the District of Columbia – Patent, Trademark & Copyright Section in Support of Neither Party, *Merck KGaA v. Integra LifeSciences I, Ltd.*, No. 03-1237, 2005 WL 435891, *5-*17 (Feb. 22, 2005).

The Supreme Court noted:

The relevant jury instruction provided only that there must be a "decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question." [The jury instruction] did not say that, to fall within § 271(e)(1)'s exemption from infringement, the patented compound used in experimentation must be the subject of an eventual application to the FDA.

Merck KGaA v. Integra LifeSciences I, Ltd., 125 S. Ct. 2372, 2384 n.8 (2005). The Supreme Court, consistent with its earlier holding in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), construed the safe harbor provision of § 271(e)(1) liberally and expressly rejected the notion that the safe harbor provision only includes experiments that produced information included in an IND or NDA. *Merck KGaA*, 125 S. Ct. at 2383. The Court noted as well that the safe harbor provision could apply to preclinical trials. *Id.*

Above all, the waiver of the common law experimental use defense, at the oral hearing by the patentee before this Court, should preclude its consideration here on remand and makes this case a highly factually-dependent issue of no further precedential value.

As correctly noted by the Supreme Court, "[b]efore the [Federal Circuit], petitioner[-accused infringer Merck] challenged the sufficiency of the evidence supporting the jury's finding that it failed to show that 'all of the accused activities are covered by [§ 271(e)(1)].'" *Id.* at 2384. It is unfathomable that there would

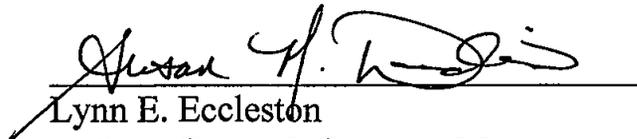
again be as fact specific of a case as this where the identical issue would be present, viz., whether *both* (a) experimentation is exempt from infringement without reliance on the common law experimental use exemption, and (b) the test for whether the safe harbor provision applies would be under a jury instruction that there is a "decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question." *Id.* at 2384 n.8.

The need for a remand to the district court is also signaled in the determination by the Supreme Court that "the evidence presented at trial has yet to be reviewed under the standards set forth in the jury instruction, *which we believe to be consistent with*, if less detailed than, the construction of § 271(e)(1) that we adopt today." *Id.* at 2384 (emphasis added). Just as the Supreme Court "decline[d] to undertake a review of the sufficiency of the evidence under a proper construction of § 271(e)(1) for the first time," the Court, here, should remand this case to the district court to let that body determine the consonance of the jury

instruction with the Supreme Court ruling on the scope of § 271(e)(1) and make a first instance determination before any further review by this court.

Respectfully submitted,

Dated: October 17, 2005


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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 17th day of October, 2005, two (2) copies of the foregoing BRIEF FOR *AMICUS CURIAE* BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA – PATENT, TRADEMARK & COPYRIGHT SECTION IN SUPPORT OF NEITHER PARTY were served via overnight courier, postage prepaid, to the following:

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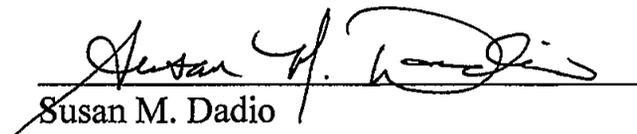
A handwritten signature in black ink, appearing to read "Robert Charles Clark", written in a cursive style.

CERTIFICATE OF COMPLIANCE
UNDER FED. R. APP. P. 32(a)(7)(C)

Below signed counsel for *amicus curiae* Bar Association of the District of Columbia – Patent, Trademark & Copyright Section, certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B). Based on the word count shown by the word-processing program used to prepare this brief, this brief contains 939 words.

Respectfully submitted,

Dated: October 17, 2005


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