Nos. 99-1262, 99-1263, 99-1264, 99-1303

IN THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ELI LILLY AND COMPANY
Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,
APOTEX, INC. AND BERNARD SHERMAN,
and GENEVA PHARMACEUTICALS, INC.
Defendants-Appellants
and
INTERPHARM, INC.,
Defendant

Petition for Rehearing or Rehearing *En Banc*

BRIEF *AMICI CURIAE* OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE NATIONAL ASSOCIATION OF MANUFACTURERS , AND THE FEDERAL CIRCUIT BAR ASSOCIATION IN SUPPORT OF PLAINTIFF-CROSS APPELLANT'S PETITION FOR REHEARING OR REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

Counsel for *Amici Curiae* Biotechnology Industry Organization, Pharmaceutical Research & Manufacturers of America, and National Association of Manufacturers certifies the following:

1. The full name of the *amici* that we represent are:

(A) BIOTECHNOLOGY INDUSTRY ORGANIZATION
(B) PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
(C) NATIONAL ASSOCIATION OF MANUFACTURERS
(D) FEDERAL CIRCUIT BAR ASSOCIATION

2. The name(s) of the real parties in interest that we represent are:

(A) BIOTECHNOLOGY INDUSTRY ORGANIZATION
(B) PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
(C) NATIONAL ASSOCIATION OF MANUFACTURERS
(D) FEDERAL CIRCUIT BAR ASSOCIATION

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

None

4. The names of all law firms and the partners or associates that appear for the *amicus* now or are expected to appear in this court are:

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

RULES

BRIEF *AMICI CURIAE*

Pursuant to Fed. R. App. P. 29(b), the Biotechnology Industry Organization ("BIO"), Pharmaceutical Research and Manufacturers of America ("PhRMA"), the National Association of Manufacturers ("NAM"), and the Federal Circuit Bar Association ("FCBA") respectfully submit this Brief *Amici Curiae* in Support of Plaintiff-Cross Appellant's Petition for Rehearing or Rehearing *En Banc*.[1] Accompanying this brief is a motion for *en banc* reconsideration of the Court's Order denying BIO's motion for leave to file.

BIO is a trade association consisting of over 950 companies, academic institutions, and biotechnology centers. BIO members file thousands of patent applications each year that concern inventions ranging from fundamental scientific breakthroughs to important commercial refinements of existing technology.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, and serves as the industry's principal policy advocate. Relying heavily on patent protection, PhRMA members account for more than 75% of brand name drug sales in the United States.

The NAM is the nation's largest multi-industry trade association. It

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[1] Plaintiff-Cross Appellant Eli Lilly and Co. is a member of BIO, PhRMA, and the NAM, and Defendant-Appellant Barr Laboratories is a member of the NAM. No

represents 14,000 member companies (including 10,000 small and mid-sized manufacturers) and 350 member associations serving manufacturers and employees in every industrial sector and all 50 states.

The FCBA is a national bar organization of approximately 2,400 attorneys. One of its purposes is to render assistance to this Court in appropriate instances, both in procedural and substantive practice areas, whenever it believes a contribution can be made. The FCBA believes this is such an instance.

ARGUMENT

I. The Two-Way Unpatentability Test for Nonstatutory Double Patenting Comes Into Play When a Later-Filed "Improvement" Patent Issues Before an Earlier-Filed "Basic" Patent.

Nonstatutory double patenting[2] is a judicially created doctrine based on the principle that "claims to inventions closely related to the invention claimed in a patent and not patentably distinguishable therefrom must be included in the same patent." *In re Zickendraht*, 319 F.2d 225, 232, 138 USPQ 22, 28 (CCPA 1963) (Rich, J., concurring). Where the claims are in different patents or applications,

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party has participated in the discussions of any *amicus* as to whether to file or join this Brief, nor has any party contributed financially to the preparation of this Brief.

[2] Because the term "obviousness-type" double patenting has occasioned considerable confusion where no "obviousness" analysis is applicable, this Brief avoids it in favor of reference to "nonstatutory" double patenting. "Obviousness" is not involved where the cited claim "anticipates" the claim in question. *See*, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998).

the Patent and Trademark Office ("PTO") may require a terminal disclaimer in the later-issuing patent to prevent the "unjustified timewise extension" of patent exclusivity. *In re van Ornum*, 686 F.2d 937, 943-44, 214 USPQ 761, 762-63 (Fed. Cir. 1982). A terminal disclaimer is ordinarily required where the claims of a later application are not separately patentable over (*i.e.*, are anticipated by or obvious in view of) the claims of a prior issued patent. *See generally In re Berg*, 140 F.3d 1428, 1431-32, 46 USPQ2d 1226, 1229-30 (Fed. Cir. 1998).

Patent applicants often claim their inventions broadly at an early stage and then more narrowly as the inventions are refined, particularly as their commercial potential becomes clear. "Basic" and "improvement" patents both promote innovation, and patents on each provide critical protection that enable their developers to successfully bring a product to market.

The law governing double patenting, properly applied, ensures that separate patents having distinct terms will be granted only when justified. In particular, one must show that the claims are patentably distinct, demonstrated by analogy to the standards for patentability over the prior art.[3] *In re Vogel*, 422 F.2d 438, 164

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[3] Thus, for example, where an improvement invention, *e.g.*, a chemical species, is claimed after the grant of a patent on a related basic invention, *e.g.*, a chemical genus including the species, the law of obviousness under 35 U.S.C. § 103 dictates that a *claim* to the species must be patentably distinct from a *claim* to the genus for the same reasons that the species would be patentable over a prior art disclosure of the genus. *See, e.g.*, *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994).

USPQ 617 (CCPA 1970). To decide whether nonstatutory double patenting exists, one must first determine whether a one-way or two-way unpatentability test is appropriate. The two-way test – which requires a showing that the claims of *each* patent are unpatentable over the claims of the other – protects the inventor whose applications, through no fault of his own, are examined and issued by the PTO in reverse order relative to their filing dates, so that the inventor's improvement will not defeat the patentability of his own basic invention. *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226.

A focal issue presented here is whether, on the facts of this case, the panel correctly determined the applicability of the two-way test. The panel held claim 7 of U.S. Patent No. 4,626,549 ("'549"), owned by Eli Lilly and Co. ("Lilly"), invalid on grounds of nonstatutory double patenting in view of a claim in the earlier-issued U.S. Patent No. 4,590,213 ("'213"), also owned by Lilly. *Eli Lilly & Co. v. Barr Labs., Inc.*, 2001 WL 578859 (Fed. Cir. May 30, 2001). Looking to the prosecution history of the '549 patent, originally filed some nine years *before* the '213 patent, the panel determined that Lilly was not entitled to a two-way test.[4]

Amici curiae have no interest in which party prevails in this case. Indeed,

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[4] An analysis of whether a one-way or a two-way test should apply was a critical element missing from first panel opinion in this proceeding. *See* 222 F.3d 973, 55 USPQ.2d 1609 (Fed. Cir. 2000), *vacated*, 2001 WL 578859 at *1 (Fed. Cir. 2001).

amici acknowledge that the Court may, on reconsideration, properly determine that Lilly is not entitled to a two-way test. The aspect of the present decision that concerns *amici*, and which *amici* believe merits consideration by the Court *en banc*, is the methodology employed by the panel to determine whether the two-way unpatentability test should be available.

II. The Two-Way Test Is Applied Infrequently, But It Is Critically Important When It Is Invoked.

Amici agree with the precedent of this Circuit holding that the two-way test "is a narrow exception to the general rule of the one-way test" and accordingly applies only in rare circumstances. *In re Berg*, 140 F.3d at 1432, 46 USPQ2d at 1229. Where it is justified, however, the two-way test ensures that patent protection will be available for both early-stage inventions and later refinements. Access to this test is crucial when the prosecution of patent applications is delayed in the PTO for reasons beyond the applicant's control, *e.g.*, while an appeal is awaiting decision or for interference proceedings.

Unjustly denying applicants the refuge of the two-way test will have profound consequences. The new standard announced in the panel decision will render the two-way test inaccessible in all but the most unusual situations. In the view of *amici*, this result would be unfortunate and undesirable as public policy. For example, the "back end" of the patent term offers the greatest economic return

on commercially successful inventions, notably for those in the pharmaceutical industry. The premature termination of patent rights by terminal disclaimer will significantly diminish the value of patents on such inventions and will limit their capacity to stimulate subsequent research and the refinement of basic inventions.

Even for inventions that are not commercial blockbusters, an overbroad rule that improperly imposes a one-way unpatentability test and thus requires a terminal disclaimer will be harmful. The effect of such a disclaimer is not only to curtail patent term, but also to require the continuing common ownership of the cited and disclaimed patents. *See In re van Ornum*, 686 F.2d at 944-945, 214 USPQ at 767-68; 37 C.F.R. § 1.321(c)(3). Where there is more than one patentably distinct improvement invention – *e.g.*, different chemical compounds having dissimilar and unexpected pharmacological properties – terminal disclaimers involving the same basic patent preclude the independent transferability of the improvement patents, thereby lowering the value of each patent and impeding the commercialization of new products. The net result is to discourage the use of the patent system in favor of trade secret protection, particularly for early-stage inventions.

III. This Court Has Refined the Standards for Invoking the Two-Way Test in Several Cases, All of Which Consider the Complete Prosecution History of the Claims in Question.

The trend in this Court's decisions in the last decade has been toward more restricted application of the two-way unpatentability test. *In re Braat*, 937 F.2d

589, 19 USPQ2d 1289 (Fed. Cir. 1991), formalized an approach for the treatment of claims in basic patents *vis-à-vis* claims in commonly owned, later-filed but earlier-issued improvement patents.[5] Reasoning that "an applicant . . . who files applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control," the Court found that "it is not [the assignee's] fault that the combination claims in the ["improvement"] patent issued first" *Id.*, 937 F.2d at 593-94, 19 USPQ2d at 1293. On the facts of that case, the Court held that a two-way unpatentability test should be applied.[6]

In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), applied a one-way unpatentability test to generic claims in a continuing application and patented species claims issued on the parent, finding that "PTO actions did not dictate the rate of prosecution" of the later application. *Id*., 11 F.3d at 1053, 19 USPQ2d at 2016. Similarly, in *In re Emert*, 124 F.3d 1458, 44 USPQ2d 1149 (Fed. Cir. 1997), the appellant was denied a two-way test in view of the finding

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[5] The *Braat* court characterized the claims there as combination and subcombination, but the distinction is of no moment for the present analysis. *Braat*, 937 F.2d at 593, 19 USPQ2d at 1292.

[6] *Braat* involved (as does this case) applications filed by different inventive entities before the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3384, took effect. Because applicants could not file a joint application unless

that he had "orchestrated the rate of prosecution for the two applications." Having delayed a substantive response to the PTO for two years by taking extensions of time and filing continuation applications, the appellant was held "responsible for the delays in prosecution." *Id.*, 124 F.3d at 1461, 44 USPQ2d at 1152.

In *In re Berg*, the appellant sought to test the independent patentability of claims to a genus and an included species by simultaneously filing separate, unrelated, but substantially identical applications. *See* C. Gholz, "What's Left of *In re Braat* after *In re Berg*?," 80 *J. Pat. & Trademark Off. Soc'y* 845 (1998). Finding the "control of prosecution rates" standard inapposite, the Court applied a one-way test "because Berg could have filed the claims of its separate applications in a single application, and it simply chose to file two applications despite nearly identical disclosures." *Berg*, 140 F.3d at 1433, 46 USPQ2d at 1231.[7]

The common characteristic of these decisions is that each involved consideration by the Court of the prosecution history *as a whole* of each relevant application specifically to ascertain whether the absence of a terminal disclaimer would result in an "unjustified timewise extension of the right to exclude granted

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each was an inventor of every claim, the appealed claims could not have been presented in an application related to the patent containing the cited claims.

[7] This rationale would also support imposition of a one-way test where claims in a continuation or continuation-in-part of the application that gave rise to the prior

by a patent," *Braat*, 937 F.2d at 594, 19 USPQ2d at 1293. This is the language of equity. Taking due regard of the public interest, this Court has to date followed an essentially equitable approach to determine the availability of the two-way test in its nonstatutory double patenting analysis. In every case, the Court has examined all of the relevant facts, and it has based its conclusions of law upon them.

IV. The New Panel Opinion Announces a *Per Se* Rule That Departs From Precedent by Omitting Consideration of All of the Relevant Evidence.

The reissued panel opinion in this case represents a departure from the approach of *Braat*, *Goodman*, *Emert*, and *Berg*. In a footnote, the panel cites evidence which, considered in isolation, can be read to indicate that Lilly at least contributed to the delay in issuing the '549 patent. It holds that this evidence is sufficient to preclude the two-way test, citing *In re Berg* for the proposition that "[t]he two-way test is only appropriate in unusual circumstances where, *inter alia*, the [PTO] is '*solely* responsible for the delay in causing the second-filed application to issue prior to the first'" 2001 WL 578859 at *11, n.7 (emphasis added by *Lilly* court). In context, however, the excerpted passage from *Berg* refers to the "control of prosecution rates" test, citing *In re Borah*, 354 F.2d 1009, 148 USPQ 213 (CCPA 1966), and it states that "[t]he two-way test *may* be appropriate,

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patent are entitled to the same effective filing date as the patented claims. *See also In re Goodman*, 11 F.3d at 1049, 29 USPQ2d at 2013.

however, in the unusual circumstance that the PTO is solely responsible for the delay . . . ." *Berg*, *id.* (emphasis added). At a minimum, *Berg* endorses a more detailed and context-sensitive inquiry than the panel opinion undertakes.

There are many proper reasons why a patent applicant might seek an extension of time or file a continuing application, such as to gather evidence for a declaration or to await clarification of an evolving PTO policy. Only in the context of the prosecution history *as a whole* will it be clear whether the applicant's actions constitute a deliberate pattern of delay or are isolated events explainable on other grounds. By announcing that *any* but the most expeditious efforts on the part of the patent applicant will be construed against him, the panel adopts a *per se* rule that will automatically deny most, if not all patentees access to the two-way test.

It is settled law that the two-way test is the exception and the one-way test, the rule. Even so, there are serious consequences to a new *per se* rule that will, at least as to some patent applicants, unjustly require the filing of terminal disclaimers in related but distinct applications. The law and the patent system will benefit from an *en banc* decision, informed by full briefing, that follows clearly articulated methodology that is consistent with this Court's precedent.

CONCLUSION

For the foregoing reasons, *amici curiae* respectfully request that this Court grant Plaintiff-Cross Appellant's Petition for Rehearing or Rehearing *En Banc*.

Respectfully submitted,

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June 20, 2001

CERTIFICATE OF SERVICE

I, Jeffrey P. Kushan, counsel for *amici curiae*, hereby certify that on this ___ day of June, 2001, I caused two correct copies of the foregoing brief *amici curiae* to be dispatched (pursuant to Fed. R. App. P. 25(c)) via a third-party commercial carrier for delivery within 3 calendar days, postage prepaid, for service upon each of the following counsel of record:

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