

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

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In The  
United States Court of Appeals  
For the Federal Circuit

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ELI LILLY AND COMPANY  
*Plaintiff-Cross Appellant,*

v.

BARR LABORATORIES, INC., and APOTEX, INC. AND BERNARD SHERMAN,  
and GENEVA PHARMACEUTICALS, INC.

*Defendants-Appellants*

and

INTERPHARM, INC.,

*Defendant*

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**BRIEF *AMICUS CURIAE* OF THE BIOTECHNOLOGY INDUSTRY  
ORGANIZATION IN SUPPORT OF PLAINTIFF-CROSS APPELLANT'S  
PETITION FOR REHEARING OR REHEARING *EN BANC***

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CERTIFICATE OF INTEREST

Counsel for *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 any 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 appear for the *amicus* now or are expected to appear in this court are:

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## **BRIEF *AMICUS CURIAE***

Pursuant to Federal Rule of Appellate Procedure 29(b), the Biotechnology Industry Organization (“BIO”) respectfully submits this brief *amicus curiae* in support of Plaintiff-Cross Appellant’s Petition for Rehearing Or Rehearing *En Banc*, under cover of the accompanying motion for leave to file required by Federal Circuit Rule 35(g).

### **INTERESTS OF *AMICUS CURIAE***

BIO is a trade association consisting of over 900 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. Accordingly, BIO and its members have a substantial interest in ensuring that the law of obviousness-type double patenting is applied consistently and fairly. BIO believes that the Panel’s decision in *Eli Lilly & Co. v. Barr Laboratories*, 222 F.3d 973, 55 USPQ2d 1609 (Fed. Cir. 2000) is inconsistent with a well-established body of law governing obviousness-type double patenting. Furthermore, BIO believes that *Eli Lilly* creates uncertainty in the law that will discourage innovation by its members.

## SUMMARY OF ARGUMENT

The Panel’s decision in *Eli Lilly* conflicts with the well-established precedents of the Federal Circuit and its predecessor courts which govern determinations of obviousness-type double patenting. Rehearing or rehearing *en banc* is necessary to ensure uniformity in the law of the Circuit.

## ARGUMENT

### **I. The Precedent of This Court Bars Species Claims Under the Doctrine of Obviousness-Type Double Patenting *Only* if the Species Is Obvious in Light of the Earlier Genus Claim.**

The law governing determinations of obviousness-type double patenting has been well-settled for more than three decades. The most cogent statement of the test to be employed in such determinations was set forth by the U.S. Court of Customs and Patent Appeals (“CCPA”) in *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). The CCPA in *Vogel* held that obviousness-type double patenting<sup>1</sup> exists if “any claim in the application [or later patent] define[s] merely an obvious variation of an invention disclosed and claimed in the [earlier] patent.” *Id.* This analysis has been consistently followed by the Federal Circuit.

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<sup>1</sup> The other type of double patenting is statutory double patenting under 35 U.S.C. § 101, which is not at issue here. The Panel in *Eli Lilly* explicitly stated that it was conducting an obviousness-type double patenting analysis. 222 F.3d at 985, 55 USPQ2d at 1617. In any event, statutory double patenting would not be found here, as the test is “whether one of the claims could be literally infringed without literally infringing the other.” *Vogel*, 422 F.2d at 441, 164 USPQ at 622.

*See, e.g., Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326, 52 USPQ2d 1590, 1593 (Fed. Cir. 1999); *In re Berg*, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998); *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272, 1278, 23 USPQ2d 1839, 1843 (Fed. Cir. 1992); *In re Braat*, 937 F.2d 589, 592, 19 USPQ2d 1289,1292 (Fed. Cir. 1991); *Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 686, 16 USPQ2d 1436, 1439 (Fed. Cir. 1990); *In re Kaplan*, 789 F.2d 1574, 1579, 229 USPQ 678, 682 (Fed. Cir. 1986); *In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985).

Under this precedent, this Court has held, without deviation, that domination of a subsequent species claim by an earlier genus claim is not dispositive of the question of obviousness-type double patenting.<sup>2</sup> Instead, it has held that such determinations must turn on whether or not the later species claim is *obvious* in view of the earlier genus claim. Specifically, in *Kaplan*, this Court held that “[d]omination is an irrelevant fact” in judging non-obviousness. 789 F.2d at 1578, 229 USPQ at 682. Both this Court in *Kaplan* and the CCPA in *In re Sarett* quote the identical passage from Stringham’s *Double Patenting* in support of the

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<sup>2</sup> By definition, an earlier claim to a genus will “dominate” a later claim to a species. *See Kaplan*, 789 F.2d at 1577, 229 USPQ at 681.

conclusion that domination cannot, standing alone, give rise to a finding of double patenting:

One of the simplest, clearest, soundest and most essential principles of patent law, is that a later invention may be validly patented, altho [sic] dominated by an earlier patent, whether to the same or to a different inventor. No one will seriously deny the correctness of this statement, in principle.

*Kaplan*, 789 F.2d at 1578, 229 USPQ at 682; *In re Sarett*, 327 F.2d 1005, 1014, 140 USPQ 474, 482-483 (CCPA 1964) (quoting Emerson Stringham, *Double Patenting* 207 (1933)). Few principles of patent law have ever been articulated so clearly.

Moreover, this Court and its predecessors have used the test for non-obviousness set forth in *Graham v. John Deere*, 383 U.S. 1, 17-19 (1966), in applying the obviousness element of the obviousness-type double patenting inquiry.<sup>3</sup> Under this test, a later claimed species is to be barred only if there has been positive assessment that the claim is *obvious* over the earlier claimed genus – assessment that does not depend on whether the later claimed species is *dominated* by the earlier claimed genus. In this respect, this Court can rely on the large body of precedent that addresses the question of whether a species claim may be

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<sup>3</sup> See *Longi*, 759 F.2d at 892, n. 4, 225 USPQ at 648, n. 4 (obviousness-type double patenting “is ‘analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. § 103,’ except that the patent principally underlying the double patenting rejection is not considered prior art.”).

independently patented over an earlier, dominating generic claim. For example, in *In re Ornitz*, the CCPA stated that “[i]t is basic patent law that claims of a patent may dominate those of an application yet that is not necessarily determinative of whether the invention defined in the application is obvious in view of the teachings set forth in the prior art patent.” 376 F.2d 330, 335, 153 USPQ 453, 458 (CCPA 1967). This principle is repeated in *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) and *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). These cases reinforce the clear statements of this Court and its predecessor that domination is not dispositive of the obviousness-type double patenting determination.

## **II. The Longstanding Practice of the Patent and Trademark Office Reflects This Precedent of the Federal Circuit and Its Predecessors.**

The practice of the Patent and Trademark Office (“PTO”), as reflected in the *Manual of Patent Examining Procedure* (7th ed., 1st rev., 2000) (“*MPEP*”), follows the precedent of this Court and its predecessors derived from the *Vogel* decision. In its discussion of the “Requirements of a Double Patenting Rejection,” the PTO, through the *MPEP*, cautions examiners that “domination and double patenting should not be confused. They are two separate issues. . . . Domination by itself . . . cannot support a double patenting rejection.” *MPEP* § 804(II) (citing *Kaplan*, 789 F.2d at 1577-78, 229 USPQ at 681, and *Sarett*, 327 F.2d at 1014-15, 140 USPQ at 482). Moreover, the PTO advises examiners that, for the purposes of

a non-obviousness determination, “[t]he patentability of a claim to a specific compound or subgenus embraced by a prior art genus should be analyzed no differently than any other claim.” *MPEP* § 2144.08(II).

Examination policies promulgated by the PTO and reflected in the *MPEP* are designed to follow the precedent of this Court. In this respect, the clear guidance provided by the PTO in the *MPEP* on the assessment of obviousness-type double patenting reinforces the well-accepted nature of the precedent governing obviousness-type double patenting.

### **III. The Double Patenting Test Applied by the Panel Conflicts with Well-Established Precedent Governing the Determination of Obviousness-Type Double Patenting.**

The Panel in *Eli Lilly* (the “Panel”) articulated a standard for obviousness-type double patenting determinations that conflicts with well-established precedent of this Court and its predecessors. 222 F.3d at 985-988, 55 USPQ2d at 1617-1619. The Panel’s error resulted from its reliance on domination as the *dispositive* inquiry in situations where the same entity is the holder of the earlier claim to a genus and the later claim to a species within that genus. This reliance was misguided.

The Panel incorrectly began its analysis by overlaying the claim of the later patent against the claim of the earlier patent “to determine whether the later claim encompasses subject matter previously cited.” 222 F.3d at 985, 55 USPQ2d at

1617. Thus, instead of seeking to ascertain the *differences* between the later and earlier claimed inventions, the Panel focused its inquiry on the question of dominance of the later claim by the earlier claim. The Panel then erred by formulating a theory that obviousness-type double patenting existed as a consequence of two findings: namely, that the later claim is dominated by the earlier claim, and that the two claims are commonly owned. 222 F.3d at 986, 55 USPQ2d at 1618. Both elements of this theory are fundamentally flawed. First, the former finding is tautological – all species claims are by definition “dominated” by earlier genus claims. *See Kaplan*, 789 F.2d at 1577, 229 USPQ at 681 (defining domination as a situation where “the broader claim ‘embraces’ or ‘encompasses’ the subject matter defined by the narrower claim.”). Second, the latter finding, common ownership, is not a factor in the tri-partite test for non-obviousness set forth in *Graham v. John Deere*. *See also O’Reilly v. Morse*, 56 U.S. 62, 122 (1853) (holding that the validity of a patent cannot “be impeached upon the ground that it is an improvement upon a former invention, for which the patentee had himself already obtained a patent.”). Thus, nothing in the test applied by the Panel even resembles the obviousness-type double patenting precedent of this Court or its predecessors, as described in Part I.

The practical consequence of the Panel’s test would be to render all species claims following an earlier genus claim *per se* “obvious” if the claims are

*commonly owned*. This approach cannot be reconciled with the principle, summarized above, that domination standing alone is insufficient to support a conclusion of obviousness-type double patenting.

In support of its erroneous statement of the obviousness-type double patenting test, the Panel mistakenly cited *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d at 1326, 52 USPQ2d at 1539 (Fed. Cir. 1999), and *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d at 1279, 23 USPQ2d at 1844 (Fed. Cir. 1992). *See Eli Lilly*, 222 F.3d at 985, 55 USPQ2d at 1617. In fact, *Georgia-Pacific* and *General Foods* both cite *Vogel* and rely on the well-established definition of obviousness-type double patenting described therein. *Georgia-Pacific*, 195 F.3d at 1326, 52 USPQ2d at 1593; *General Foods*, 972 F.2d at 1279, 23 USPQ2d at 1843. Neither of these cases, nor any others, support the Panel's novel approach to obviousness-type double patenting.

The Panel further erred by considering whether the patent owner would be able to enforce a species claim after the dominating genus claim had expired. 222 F.3d at 987-88, 55 USPQ2d at 1618-19. Certainly, one motivation for prohibiting double-patenting is to prevent an “*unjustified* extension of the term” of exclusive rights. *Berg*, 140 F.3d at 1431-32, 46 USPQ2d at 1229. However, the question of whether an extension of exclusive rights is justified turns on whether the later species invention is a non-obvious, and, therefore, *patentably distinct invention*.

Finally, the Panel impermissibly relies on *Sarett* to support its domination-centric test for obviousness-type double patenting. The Panel quotes *Sarett* for the notion that “[w]e are not here concerned with what one . . . would be aware from reading the claims but with what inventions the claims define.” 222 F.3d at 986, 55 USPQ2d at 1618 (citing *Sarett*, 327 F.2d at 1013, 140 USPQ at 481 (CCPA 1964)). Rather than supporting the Panel’s erroneous test for obviousness-type double patenting, however, this quote from *Sarett* simply restates the subsidiary principle that, in conducting a double patenting analysis, the focus is on the *claims* of the first patent rather than on its disclosure. In fact, the late Judge Rich, the author of *Sarett*, used this exact quote almost thirty years later in *General Foods* to demonstrate that “precedents prohibit [the] use of disclosure of [the] patent cited to support double patenting.” 972 F.2d at 1281, 23 USPQ2d at 1846.

#### **IV. Sound Policy Arguments Support the Present Petition for Rehearing Or Rehearing *En Banc*.**

The Panel’s approach to obviousness-type double patenting would sow confusion in the law of the Federal Circuit and establish a disturbing and counter-productive public policy. Because obviousness-type double patenting is a judicially created doctrine,<sup>4</sup> it is proper for the Court to consider the policy implications of the Panel’s approach.

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<sup>4</sup> See, e.g., *Longi*, 759 F.2d at 892, 225 USPQ at 648 (describing obviousness-type double patenting as “a judicially created doctrine grounded in public policy.”).

Patent protection is designed to stimulate not only innovation but also disclosure of inventions through the filing of patent applications and the granting of patents. The Panel's holding would discourage inventors from seeking patent protection for *otherwise patentable inventions* if the inventor had previously patented an earlier form of the invention. The Panel's approach is particularly troubling for two reasons. First, it fails to recognize that a patent owner who develops an expertise and commercial presence within a particular technological sector will be more likely to produce improvements to the initial invention than others. Second, it would discourage the inventor of a genus from attempting to obtain generic claims, as these inventors would be subsequently barred from obtaining later patents on a new and non-obvious species falling within that genus. There is no defensible public policy for prohibiting these inventors from receiving patents for their new, useful and *non-obvious* inventions, particularly in view of the fact that third parties would be able to use the initial patent disclosure to develop and patent *the very same species*.

## **V. Conclusion**

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

Respectfully submitted,

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October \_\_, 2000

*CERTIFICATE OF SERVICE*

I, Jeffrey P. Kushan, counsel for *amicus curiae*, hereby certify that on this \_\_\_ day of October, 2000, I caused two (2) correct copies of the foregoing BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PLAINTIFF-CROSS APPELLANT'S PETITION FOR REHEARING OR REHEARING *EN BANC* 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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