

Appeal No. 02-1610
(Interference No. 104,733)

**IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

ELI LILLY & CO.,

Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

APPEAL FROM THE
BOARD OF PATENT APPEALS AND INTERFERENCES
**AMICUS BRIEF OF OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C. IN SUPPORT OF ELI
LILLY'S PETITION FOR REHEARING IN BANC**

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I. Concise Statement of the Identity of the Amicus Curiae, Its Interest in the Case, and the Source of Its Authority to File

Oblon, Spivak, McClelland, Maier & Neustadt, P.C. (“OSMMN”) obtains more patents annually than any other law firm—more than 3500 in 2002. In addition, OSMMN believes that its interference section handles more interferences than any other law firm.

While OSMMN has no interest in the specific invention at issue in this interference or in either party, it has a strong interest in seeing that the interference laws are correctly interpreted to serve the purposes for which they were intended and in seeing that the Patent & Trademark Office fulfills its responsibilities to the system’s users and the public. The majority’s decision in this case frustrates those goals.

OSMMN submits that its amicus brief is FRAP 29(b)(2) “desirable” because it focuses more on the broad policy issues underlying this dispute and less on the specifics of this interference than do the briefs of the parties.

II. Argument

A. The Statute Trumps the Director’s Interpretation of His Rule

It is a basic concept of administrative law that no agency may interpret a rule to contravene a statute. *Federal Election Comm’n v. Democratic Senatorial Campaign Committee*, 454 U.S. 27, 70 L. Ed. 2d 23,

102 S. Ct. 38 (1981), and *Chevron, USA v. Natural Resources Defense Council*, 467 U.S. 387, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984). However, the interpretation placed on 37 CFR 1.601(n) by both the Board of Patent Appeals and Interferences (“BPAI”) and by the majority in this case contravenes specific statutory provisions. Congress through the patent statute has clearly stated that a patent shall be issued to the first to invent and not to a later inventor.¹ 35 USC 102(g)(2). The authority to conduct interferences between two interfering applications or a pending application and a patent is provided by 35 USC 135(a), which requires the BPAI to determine questions of priority of an invention once an interference has been declared. Here the interpretation of 37 CFR 1.601(n) provided by the BPAI and by this Court will inevitably frequently result in a second inventor’s obtaining a patent.

The two-way test creates the situation that, if the invention made by the first inventor is patentably distinct from the invention made by the second inventor (as is apparently true in this case), but the invention made by the second inventor is not patentably distinct from the invention made by

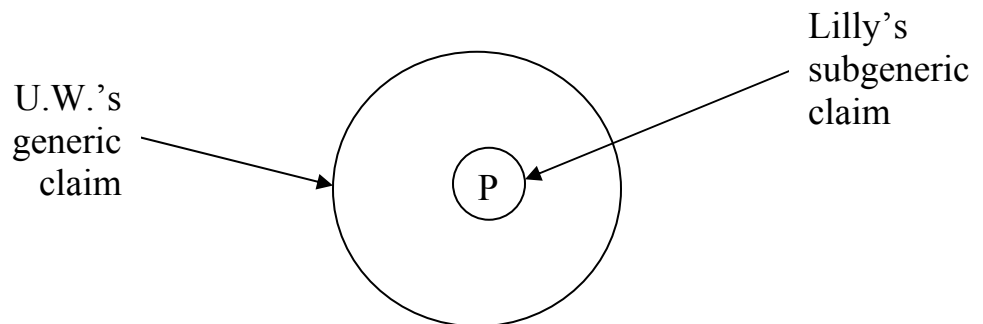
¹ Except when the first inventor has abandoned, suppressed or concealed the invention—which is not an issue in this case.

the first inventor, both can obtain patents. This anomaly will occur most often in cases where the first inventor has claimed a species or a sub-genus and the second inventor has claimed the genus and a species or a different sub-genus. In that case, the two species may be patentably distinct, and the claims to the two species may not interfere. However, the same is not true as between the first inventor's species and the second inventor's genus. In that case, the first inventor's species may in fact be patentably distinct from the second inventor's genus, but the second inventor's genus is not patentably distinct from the first inventor's species, since it is black letter law that a species anticipates a genus. *See Eli Lilly & Co. v. Barr Industries, Inc.*, 222 F.3d 973, 987 (Fed. Cir. 2000) (“a later genus claim is not patentable over an earlier species claim.”) Thus, a genus is not patentably distinct from the species.

In this case, Lilly's species is presumptively prior to the University of Washington's genus. The genus cannot be patentably distinct from the species since it is anticipated by the species. Thus, the BPAI's interpretation of 37 CFR 1.601(n) will result in the issuance of a patent to a party that is presumptively the second inventor—in contravention of the statute.

B. The Practical Effect of the Director's Interpretation of His Rule

OSMMN is not entirely unsympathetic to the BPAI's efforts to control interference practice in the USPTO. However, the BPAI cannot exercise such control in a manner inconsistent with the statutory scheme created by Congress. A simple Venn diagram will illustrate why the current practice vitiates the statutory scheme of issuing patents to only the first inventor and is contrary to the policy behind issuing patents to the first inventor.



What that means is:

- (1) Lilly cannot safely commercialize P without paying for a license from U.W.;
- (2) U.W. or a licensee of U.W.'s cannot safely commercialize P without a license from Lilly; and

(3) Third parties cannot safely commercialize P without paying for a license from both U.W. and Lilly.

Thus, there is a real probability that P will not be available to the public until one of the Lilly and U.W. patents expires or is held to be invalid.

Of course, if Lilly really did make its invention before U.W. made its invention (as Lilly alleges was the case), U.W.'s generic claim is invalid. Both the majority and the dissent recognized that. However, the majority in deciding to affirm the BPAI gave deference to the agency's interpretation of its rules even though the interpretation was contrary to the statutory scheme of issuing patents to the first inventor.

The problem with the majority's reasoning, from the perspective of the users of the patent system, is twofold.

First, for a variety of reasons that OSMMN cannot go into here in detail because of the space limitation, it costs approximately ten times as much to succeed in infringement litigation as it costs to succeed in an interference.²

² In brief, interferences are an order of magnitude less expensive than district court infringement litigations because (a) they are tried to specialized judges who do not need to be educated concerning basic patent law and (b) juries are not involved. Accordingly, as noted by the dissent, the BPAI would be

Second, a company concerned by a situation such as this (and, perhaps, hesitating to start a multi-million dollar project because of that concern) cannot even bring a declaratory judgment action to deal with that concern unless it has been placed in justifiable apprehension of being sued for patent infringement—a situation it will not be in unless it commits the resources to bring the product to market. In sharp contrast, all that such a company needs to provoke an interference is an application containing an interfering claim to which it is entitled but for the existence of the prospective interference.

C. The Director’s Previous Exercises of His Discretion

Generally, the Commissioner/Director has exercised his discretion in the past in a manner calculated to “cure” errors committed in the examination process mandated by 35 USC 131.

The simple fact is that the U.W.’s patent was not issued in accordance with law as required by 35 USC 131. In the words of *Case v. CPC International, Inc.*, 730 F.2d 745, 750 (Fed. Cir. 1984), Lilly’s application was on its face an “impediment to granting” U.W.’s patent, but that fact was

“the optimal tribunal,” slip opinion page 4, to decide the validity issue which the board and the majority ducked.

apparently inadvertently overlooked by the examiner handling U.W.'s application. Such inadvertent errors inevitably occur in the PTO's complex examination system.

In the past, the Commissioner/Director has generally attempted to exercise his discretion to "cure" such errors. Interferences are conventionally declared when the examination process uncovers a patent claiming the same patentable invention and having an effective filing date later than the application's effective filing date. However, in the future the Director could, under the majority's reasoning, simply issue the senior application and allow the Federal courts to determine which patent is valid.

In the past, the Commissioner/Director has declared interferences even in those instances where (prior to the American Inventors Protection Act of 1999), arguably, both patents could be valid (i.e., where the "senior" patent is senior, but only by virtue of a 35 USC 119 priority date. *In re Deckler*, 977 F.2d 1448 (Fed. Cir. 1992). Although recent amendments to 35 USC 102(e) have closed the so-called "Hilmer" loophole with regard to that statute, the problem still remains with regard to 35 USC 102(g). That is because inventions made abroad can defeat earlier filed applications or patents only by use of 35 USC 135—i.e., only in an interference.

The Director should be told to apply the same exercise of discretion to determine which competing assignee (i.e., Lilly or U.W.) is entitled to a patent, or whether both are so entitled. It is important to the health of the patent system that a simple mechanism exist for determining whether U.W.'s claims meet the statutory requirements of 35 USC 102 and 103.

In any realistic sense, both Lilly and U.W. are claiming the same invention, although U.W. claims that invention more broadly. That fact has been well recognized by this Court when the same issues have arisen in a “double patenting” context. *In re Berg*, 140 F.3d 1428, 1431-32 (Fed. Cir. 1998). In that context, this Court has clearly recognized that a one way test is proper in order to determine whether a genus can properly issue when a species has already been patented. Why should a different rule apply simply because the genus and species are sought to be separately patented by entities that are not identical or commonly owned?

D. Lilly's Impossible Position

As a practical matter, there may be no way, apart from an interference, for Lilly to determine whether U.W.'s claim 1 is valid. In theory, a “cure” for the error presented on this appeal might lie in the reexamination process. However, the impracticality of that process for such a “cure” was illustrated by the opinion in *Slip-Track Systems, Inc. v. Metal-*

Lite Inc., 159 F.2d 1337 (Fed. Cir. 1998). If the reexamination examiner should conclude, as did the board, that two-way distinctness is necessary for the declaration of an interference, U.W. would be allowed to antedate Lilly's filing date (i.e., its 35 USC 102(e) date) by an "antedating" declaration under 37 CFR 1.131, and Lilly's actual invention date could not be considered by the reexamination examiner.

Some significant differences between an interference proceeding and ex parte antedation of a reference are set forth in *Anderson v. Norman*, 185 USPQ 371 (Comm'r 1968). In addition to those formal differences, the allegations and proofs in a declaration under 37 CFR 1.131 are often quite sparse—and virtually never corroborated. At the very best, such a declaration might inform Lilly that U.W.'s invention date was probably "prior to" Lilly's filing date. However, it is very likely (absent simultaneous conception and constructive reduction to practice) that Lilly's invention date under 35 USC 102(g) is earlier than its filing date!

In sum, Lilly's only remedy might well be to assume the risk of infringement in order to provoke U.W. into providing enough basis for Lilly to file a declaratory judgment action!

III. Conclusion and Plea

The majority's holding is not a "victimless crime." It has appalling real-world consequences. In view of those consequences, OSMMN implores this Court to grant Eli Lilly's petition for a rehearing in banc.

Respectfully submitted,

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**AMICUS BRIEF OF OBLON, SPIVAK, McCLELLAND, MAIER, &
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REHEARING IN BANC**

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