

BRIEF OF *AMICUS CURIAE*, THE DIRECTOR OF
THE UNITED STATES PATENT AND TRADEMARK OFFICE,
SUPPORTING APPELLEE AND OPPOSING REHEARING

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

ELI LILLY & CO.,
Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,
Appellee.

On Combined Petition for Panel Rehearing
and Petition for Rehearing *En Banc*.

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**STATEMENT OF IDENTITY OF THE *AMICUS CURIAE*,
SOURCE OF AUTHORITY TO FILE, AND INTEREST IN THE CASE**

The Director (Director) of the United States Patent and Trademark Office (PTO) files this brief pursuant to Fed. R. App. P. 29(a), opposing rehearing.

The Director's interest in this case is whether the PTO's interpretation of its regulation and the statute for declaring patent interferences is within its discretion under 35 U.S.C. § 135(a). *See* 37 C.F.R. § 1.601.

ISSUE

Did the panel majority err in holding that the Director may reasonably interpret PTO regulations to require a two-way test to declare an interference?

RESPONSE TO EN BANC PETITION

This case does not come close to meeting the rigorous standards for en banc rehearing. Under the Federal Rules of Appellate Procedure and this Court's Local Rules, en banc review is appropriate only if "necessary to secure or maintain uniformity of the court's decisions" or "the proceeding involves a question of exceptional importance." Fed. R. App. P. 35(a). Petitioner Eli Lilly & Co. (Lilly) attempts to show that the panel's decision conflicts with cases from this Court and from the Supreme Court which hold that "all agency action must be consistent with the enabling statute of the agency." Pet. 1, 5-11, citing, *e.g.*, *United States v. Larionoff*, 431 U.S. 864 (1997), and *Areolineas Argentinas v. United States*, 77 F.3d 1564 (Fed. Cir. 1996). Specifically, Lilly argues that 35 U.S.C. § 102(g) requires use of a "one-way" test for declaration of interference proceedings and thus bars the Director from using the "two-way" test approved by the panel. Pet. at 8. But § 102(g) applies "during the course of an interference" and has nothing to do with whether an interference is declared. Instead, as both the majority and dissent agreed, 35 U.S.C. § 135(a) makes abundantly clear that the Director has

discretion to determine the type of test used for interference proceedings. *Eli Lilly & Co. v. Board of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1267 (Fed. Cir. 2003) (plain language expressly assigns discretion); 334 F.3d at 1272 (dissent agreeing that the Director has discretion whether or not to declare interference). There is no conflict between the Director’s use of 35 U.S.C. § 135(a) to administer a two-way test and 35 U.S.C. § 102(g). In short, the Director’s two-way test is consistent with the patent laws. Thus, there is no conflict whatsoever between the panel’s decision endorsing the Director’s test and the cases cited by Lilly. The petition for en banc review should be denied.

RESPONSE TO PANEL REHEARING

Lilly’s panel rehearing petition is a transparent attempt to re-litigate this case. Under the Federal Rules of Appellate Procedure and this Court’s Local Rules, panel rehearing is appropriate only if the “court has overlooked or misapprehended” a point of fact or law. Fed. R. App. P. 40(a). As we next show, the panel’s decision is entirely correct.

The question in this case is whether the Director is within his discretion under 35 U.S.C. § 135(a) in declaring interferences only when each party’s claims actually do interfere with the other party’s claims, and not whenever there is a mere “theoretical possibility” of an interference. As the panel majority explained,

what is at stake is the Director's authority under § 135(a) to decide how similar an application claim and an issued patent claim have to be to declare an interference, and to pull the issued patent back into costly and lengthy proceedings. The panel majority holds that the PTO may decide to declare an interference when the application claim (A) and the issued patent claim (P) are indeed the same inventions, *i.e.*, A anticipates or renders obvious P, and P anticipates or renders obvious A—a two way test. When each invention would render the other unpatentable, the two are the same and an interference will be declared, authorizing the Board to determine priority between A and P. At the end of the interference, one and only one (the first to invent) can have the contested claim.¹

Under Lilly's approach—the one way test—all that is necessary to begin an interference is that either A anticipates or renders obvious P, or P anticipates or renders obvious A. However this approach, as the majority aptly recognized, establishes only “a theoretical possibility of an interference,” because it is very possible that in the end, A and P do not interfere. *Lilly*, 334 F.3d at 1270. That is, after priority is determined, if the “junior” party inventor of a genus is awarded priority over the “senior” species, both parties are entitled to patents. As the panel

¹ It is also possible that the Board will find neither parties' claims patentable. However, for purposes of this discussion we assume the claims are allowable. Note that interferences may also arise between pending patent applications.

held, the statute does not mandate that the Director declare an interference to explore theoretical possibilities.

A. Section 135(a) Governs Interference Proceedings, Not Section 102(g), And § 135(a) Gives The Director Significant Discretion For Declaring An Interference.

Section 135(a) states:

Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability. (Emphasis added).

1. Section 135(a) Gives The Director Significant Discretion To Declare And Conduct Interferences.

As the majority and dissent both recognized, § 135(a) authorizes the Director to declare and conduct interferences. As both recognized, § 135(a) gives the Director significant discretion to do so. This is evidenced by not one, but two different phrases in the statute, *i.e.*, “in the opinion of the Director” and “an interference may be declared.”

Lilly’s and amici’s primary argument is that 35 U.S.C. § 102(g) mandates the use of a one-way test for the declaration of an interference. This argument was properly rejected by the panel majority for several reasons. 334 F.3d at 1268-70. First, this would eliminate any discretion the Director has for declaring an

interference. Second, § 102(g) does not mandate exploring a theoretical possibility that an interference can be shown.

Implementing § 135(a), the Director has promulgated rules governing the declaration and conduct of interferences. *See* 37 C.F.R. Subpart E - Interferences. The key regulation at issue here, 37 C.F.R. § 1.601(n) (Rule 601(n)), defines “same patentable invention.” That phrase is used in Rule 601(j) to define claims that can give rise to an “interference-in-fact.” It is likewise used to define those claims that may not be the subject of an affidavit of prior invention under 37 C.F.R. § 1.131 (Rule 131). As such, Rule 601(n) helps define whether the Office will address issues of the date of invention in the course of *ex parte* examination or will instead (whether at an applicant’s request or over its objection) divert examination into an interference proceeding. Thus, contrary to Lilly’s allegation, Pet. at 7, the rule at issue is a procedural one. In any event, as applied to defining the circumstances in which the Director will declare an interference, Rules 601(j) and (n) and the Office’s interpretation of the rules implement the discretion specifically delegated to the Director under 35 U.S.C. § 135(a).

As the panel decision recognizes, under the interpretation that the Office has given to its rules, the Office exercises the discretion to declare or maintain an interference only when it is clear that, regardless of the priority decision that it

reaches, claims of two parties define the same invention. By doing so, it avoids the risk of prolonging examination of patent applications of applicants that do not seek an interference when a priority contest may be unnecessary to allow the grant of patents, and avoids the risk of subjecting issued patents to unnecessary contests before the Office after issuance. Such an approach may, as in the current case, lead to the issuance of two presumably valid patents, one of which can only be practiced upon the grant of a license under the other, but there is nothing unusual in this circumstance. The Office's practice does not deprive parties of rights to interferences, since the statute specifically provides for district courts to hear interferences. 35 U.S.C. § 291. No party or amicus has suggested that the Office's longstanding practice has led to a major interference practice in district court. As the panel majority recognized, the appellant faces a high hurdle to establish that the PTO has exceeded the discretion granted under § 135(a).

2. Section 102(g) Does Not Mandate A One-way Test For Declaring An Interference.

UW's Claim 1, whether generic or not, does not claim the "same patentable invention" as Lilly's species claim. The panel properly rejected Lilly's objections that a species claim of a presumptive senior party allegedly anticipates a genus claim of a presumptive junior party. 334 F.3d at 1268. The panel's conclusion

that this circumstance does not compel an interference is consistent with precedent, and accords with the discretion granted under the plain language of § 135(a).

Lilly and amici argue for rehearing that the Director, contrary to the permissive language of § 135(a), is compelled to apply a one-way test because otherwise, they allege, UW would evade examination under § 102(g). Section 102(g) provides, in part:

A person shall be entitled to a patent unless—
(g)(1) during the course of an interference conducted under section 135 or 291, another inventor establishes, to the extent permitted in section 104, that before such person’s invention thereof the invention was made by such other inventor and not abandoned, suppressed or concealed, or
(2) before such person’s invention thereof, the invention was made in this country by another inventor

(Emphasis added). On its face, subsection (g)(1) provides a substantive test to be applied “during the course of an interference,” whether before the PTO or in district court. On its face, subsection (g)(1) does not set out a standard for declaring an interference. Rather the declaration of an interference is committed to the Director’s discretion by § 135(a), which makes no reference to § 102(g).

Nothing on the face of § 135(a) suggests that the Director must declare an interference any time a question under § 102(g) might be at issue if an interference were declared. Indeed, to the contrary, in adding subsection (1) to § 102(g) in 1999, Congress did not amend § 135(a), thus preserving the Director’s discretion.

As will be seen, the two-way approach to the exercise of that discretion was already well-established, so Congress cannot be understood to have intended to alter that standard by the amendment of § 102(g). Moreover, the fact that § 102(g)(1) applies to interferences before the PTO under § 135(a) and in district court under § 291 substantiates that the amendment was intended to be neutral with respect to decisions to declare interferences in the PTO. The panel's reasoning—that the PTO is not required by § 135(a) to declare an interference because an issue of priority might arise—equally applies to the proposal to require the PTO to declare an interference if an issue under § 102(g)(1) might arise.

To the extent Lilly would rely on subsection (g)(2), that subsection does not mandate declaring an interference to investigate the theoretical possibility that a rejection could be made. Indeed, the underlying history of this case shows the question was resolved *ex parte*: a rejection was made and overcome. That is, UW's parent application claims were rejected as anticipated by Lilly's patent disclosure. UW overcame the rejection by filing a declaration under 37 C.F.R. § 1.131 (Rule 131).

Even the dissent did not adopt Lilly's reasoning that § 102(g) mandates a one-way test. 334 F.3d at 1272. The dissent disagreed with the majority interpretation of Rule 601(n). 334 F.3d at 1273. The dissent never suggested the

PTO was statutorily prohibited from promulgating a rule requiring the two-way test.²

B. A Genus Is Not The “same patentable invention” As A Species And Thus An Interference Is Not Required.

Lilly’s allegation that the PTO “issued two patents for the same invention” is without support in either law or logic. To the contrary, issuing two or more patents involving a genus and a species is permissible because a genus and a species are not the same invention. *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1572 (Fed. Cir. 1992); *see also*, *Hester v. Allgeier*, 687 F.2d 464, 467 (CCPA 1982); *accord*, *In re Sasse*, 629 F.2d 675, 680 (CCPA 1980).

When an inventor obtains a patent for a generic invention, other inventors may obtain patents for patentably distinct species within the genus. Thus, multiple patents issue without claiming the “same patentable invention.” The case law establishes that there is no interference-in-fact when there is patentable distinctness between the claims of the parties. *E.g.*, *Case v. CPC Int’l, Inc.*, 730 F.2d 745 (Fed. Cir. 1984); *Nitz v. Ehrenreich*, 537 F.2d 539 (CCPA 1976); *Aelony v. Arni*, 547

² The PTO is considering a proposal to clarify and revise interference rules.

F.2d 566 (CCPA 1977). Lilly’s proposed test fails to recognize patentable distinctness, because it tests only for one-way anticipation or obviousness.³

C. The Two-way Test For “same patentable invention” Is Consistent With The Application Of Rule 601(n) As Incorporated Into Rule 131 After A CCPA Suggestion.

Lilly’s one-way test would also produce undesirable consequences outside of interferences. Rule 131 provides that a patent applicant can “swear behind” the date of a reference disclosure, if the applicant can declare that the applicant made the invention before the date of disclosure by the reference. However, Rule 131 provides that “[p]rior invention may not be established under this section if . . . [t]he rejection is based upon a U.S. patent . . . which claims the same patentable invention as defined in § 1.601(n).” (Emphasis added).

Rule 131 originally permitted “swearing behind” for an application that “does not claim the rejected invention.” The CCPA “conclude[d] that the phrase ‘does not claim the rejected invention’ should be construed favorably to an applicant, if possible, so that unless applicant is clearly *claiming the same*

³ Genentech's suggestion that PTO should apply the two-way test only sometimes, such as when a species inventor is the senior party, makes little sense. As the majority recognized a senior and junior party are not that differently situated. 334 F.3d at 1270. That is, the designations “junior” and “senior” may change during the course of an interference, and at the final priority determination, the positions may be reversed. Genentech's suggestion has no basis in the statute or the regulations.

invention as the U.S. patent reference, he will not lose his rights under Rule 131.” *In re Eickmeyer*, 602 F.2d 974, 979 (CCPA 1979) (italics in original). The PTO amended Rule 131 by replacing the phrase “the rejected invention” with the phrase “the same patentable invention as defined in § 601(n).” 53 Fed. Reg. 23728 (June 23, 1988).

The two-way application of Rule 601(n) for permitting “swearing behind,” as incorporated in Rule 131, thus permits applicants the flexibility in prosecution that the *Eickmeyer* court suggested. Lilly’s one-way test for Rule 601(n), in contrast, would treat applicants unfavorably and limit Rule 131 availability.

D. The Two-way Test Is Not New.

The panel majority properly recognized the two-way test implements a “long-standing” policy. 334 F.3d at 1270. Lilly argues that the practice of using a two-way test is not long standing, and that the Board departed from precedent when it said a “two-way” test is used. Pet. at 13, citing *Winter v. Fujita*, 53 USPQ2d 1234 (Bd. Pat. App. Interf. 1999). However, Lilly provides no analysis of prior precedent showing that a two-way test is a departure from any precedent. Moreover, neither Lilly nor amici have shown that the panel overlooked any precedential decision on the interference-in-fact question.

The Board's two-way procedure, consistent with the overall regulatory scheme, confirms that each party has a claim that is anticipated or rendered obvious by a claim of the other party. 37 C.F.R. § 1.601(j). Thus, the Board's two-way procedure achieves the results that precedent requires; Lilly's suggested one-way test does not. *See, e.g., Case; Nitz; Aelony*. Moreover, under the Board's two-way test each party proves its earliest date for the "same" invention. Under Lilly's one-way test for genus and species, the parties will likely be proving invention dates for their respective different inventions, (i.e., one will be proving the invention date for its genus, the other for its species). And it is very possible that in the end the two different dates for the two different inventions may not result in rejection of either one.

Lilly's citation of three Board decisions, in an attempt to show inconsistent agency practice, is unpersuasive. Pet. at 12. None of the cited opinions states that a one-way test was used to declare the interference; all are consistent with the outcome of a two-way test. In *Daniels v. Daum*, 214 USPQ 911 (Bd. Pat. Int. 1982), both parties had multiple claims to identical compounds, in addition to generic claims. In *Antos v. Juguin*, 220 USPQ 722 (Bd. Pat. Int. 1981), one party copied the other's claims. In *Sakano v. Rutemiller*, 158 USPQ 47 (Bd. Pat. Int. 1968), the parties claimed aluminum alloys defined by % alloying metals and

Rutemiller copied Sakano's claims with narrow ranges. *Case* and *Nitz* are precedential CCPA decisions involving overlapping range claims that did and did not, respectively, interfere in fact. The Board's two-way procedure would correctly replicate each precedent—Lilly's one-way test would fail to replicate the precedents.

The general rule of no interference between a species and a genus is old. *See, e.g.*, Archie R. McCrady, PATENT OFFICE PRACTICE (1928) at 243-44 (excerpt and references attached):

Sec. 300. Parties Claiming Genus and Species. An interference should not be declared between one party who is claiming only a species, and a second party who shows a different species and is also claiming the genus. *Hammond v. Hart*, 83 O.G. 743; 1898 C.D. 52. . .

It was pointed out in *Drawbaugh v. Blake*, 23 O.G. 1221; 1883 C.D. 17, that if one party is claiming a species specifically, and another applicant is claiming a different species together with the genus, the man who is claiming only his own species knows that the genus is not his invention, and until he asserts title to that genus, there is no reason for declaring an interference between the two applications. . . .

AND at 21. The phrase “two-way” the Board used in 1999 may have been new, but “two-way” restates an old rule in continuous use for over a century.

E. Interferences Are Not General Cancellation Or Alternate Reexamination Proceedings.

The Petitioner and amici briefs argue at length that the primary reason the PTO adopted the two-way test is to reduce its workload and decrease the resources

spent conducting interferences. That is only one consideration. As the majority aptly put it, the PTO believes interferences should be conducted when there is truly interfering subject matter, not when there might be: “[t]he Director has reasonably opted for a two-way test to avoid subjecting broad patents for basic inventions to interferences, some of which would have been unnecessary.” 334 F.3d at 1270.

It is no secret that a portion of the interference bar wants to use interference proceedings as the substitute for a general cancellation proceeding. Particularly in the procedural posture in which Lilly has sought to provoke an interference, Lilly's one-way test is a none-too-thinly disguised effort to create such a mechanism. Under a one-way test, whenever a genus and a later improvement patent issue, one or the other could easily provoke an interference by filing a reissue application. Such actions would turn both reissue and interference proceedings to uses that they were not intended to serve.⁴ Cancellation of a patent claim via interference is available only if both parties each have a claim to the “same patentable invention.” Rule 601(j). Lilly’s attempt to create a new way to reexamine issued patents via interferences should be rejected because the requirements of Rules 601(j) and (n) are not met.

⁴ Genentech’s allegation that the PTO should have rejected UW’s claim as anticipated by Lilly’s patent overlooks the fact that the PTO did reject UW’s claims over Lilly’s patent and UW overcame the rejection. *See* Lilly’s opening brief at 27. Lilly’s desire to reexamine UW’s patent is not sufficient basis for declaring an interference.

In its “21st Century Strategic Plan,” the PTO included a proposal for a patent cancellation proceeding.⁵ However, Congress has not yet considered this proposal. It is not appropriate for the PTO, as Lilly and amici effectively urge, to use the discretion it was given under § 135(a) to create a general cancellation proceeding in advance of Congressional action.

CONCLUSION

Lilly and amici fail to cite any precedent contrary to the panel decision or show that a two-way test for declaring interferences is anything other than a concisely stated procedure for reaching a result completely consistent with precedent. The petition for panel rehearing and for rehearing *en banc* should be denied.

Respectfully submitted,

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⁵ See “Summary of Proposed Post-Grant Review Procedures,” available at <http://www.PTO.gov/web/offices/com/strat21/action/sr2.htm>.

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of September 2003, I served the foregoing BRIEF OF *AMICUS CURIAE*, THE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, SUPPORTING APPELLEE AND OPPOSING REHEARING upon counsel by causing two copies to be delivered by Federal Express to:

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