THE MAJORITY OF A THREE-JUDGE PANEL OF THE FEDERAL CIRCUIT HAS APPROVED THE TWO-WAY TEST OF WINTER v. FUJITA—BUT HELP MAY BE ON THE WAY

By

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I. Introduction

In the most important Federal Circuit interference opinion in many years, the majority of a three-judge panel of the Federal Circuit approved (or, at least, did not reject) the Trial Section's two-way test for interfering subject matter.[3] Eli Lilly & Co., v. Board of Regents of the University of Washington, ____ F.3d ____, 67 USPQ2d 1161 (Fed. Cir. 2003) (opinion of the panel delivered by Circuit Judge Garjarsa and joined by Circuit Judge Michel; dissenting opinion delivered by Circuit Judge Lourie). However, the losing interferent (Eli Lilly) has sought reconsideration in banc, the court has granted an extension of time for the submission of amicus briefs supporting the request for

[3] For any reader not familiar with the Trial Section's two-way test, it basically says that, in a simple two-party situation, the Trial Section will not declare an interference or, if an interference has already been declared, will enter a judgment of no-interference-in-fact (thereby terminating the interference) unless the subject matter defined by at least one claim of each party or prospective party would have been obvious in view of the subject matter defined by at least one claim of the other party or prospective party.

reconsideration in banc,[4] and several amici have supported that request. Accordingly, there is some hope either that the majority on the original panel will reverse itself or that the entire court, sitting in banc, will do that for them.

This article is primarily policy-based, explaining what I think are the socially unproductive consequences of the majority's decision, rather than precedent-based. That is because there is only one really significant precedent (i.e., the BPAI's opinion enunciating the two-way test), and that precedent is not binding on the Federal Circuit.

II. What the Panel Did

The majority treated this case as fundamentally involving the PTO's discretion to interpret its own rule. According to the dissent, "the Board's action constitutes an abuse of discretion because the language of Rule 601(n) plainly describes a one-way test and does not support a two-way test. While *Winter* does hold that a two-way test is appropriate, its conclusion, not binding on us, is unsupported by any reasoning."[5]

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[4] Lest the reader mistakenly suppose that I am a neutral observer on this issue, this is to inform the reader (a) that I am a co-author of two amicus briefs supporting Eli Lilly's request for reconsideration in banc (one filed by Guilford Pharmaceuticals Inc. and one filed by Oblon, Spivak, McClelland, Maeir & Neustadt, P.C.) and (b) that I was co-counsel for Fujita in Winter v. Fujita, 53 USPQ2d 1234 (PTOBPAI 1999) (expanded panel; opinion by SAPJ McKelvey), the case in which the Trial Section originally enunciated the two-way test. (Fujita won on the merits, so my client was not able to or interested in appealing from the Trial Section's enunciation of that rule.)

[5] ____ F.3d at ____, 67 USPQ2d at 1167.

37 CFR 1.601(n) reads as follows:

> Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Also relevant here are 37 CFR 1.633(b), which reads as follows:

> A motion for judgment on the ground that there is no interference-in-fact. A motion under this paragraph is proper only if the interference involves a design application or patent or a plant application or patent or no claim of a party which corresponds to a count is identical to any claim of an opponent which corresponds to that count. See § 1.637(a). When claims of different parties are presented in "means plus function" format, it may be possible for the claims of the different parties not to define the same patentable invention even though the claims contain the same literal wording.

and 37 CFR 1.601(j), which reads as follows:

> An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

During the preliminary motions period, UW filed a 37 CFR 1.633(b) motion for a judgment that there was no interference-in-fact, a panel of the Trial Section consisting of

APJs Schafer, Torczon, and Tierney (opinion by APJ Tierney) granted that motion, and this appeal was from that decision.[6] Interestingly, the Solicitor filed an amicus curiae brief supporting UW's and the Trial Section's interpretation of 37 CFR 1.601(n).

According to the majority's opinion:

> This case presents the question of whether the Director's two-way test[7] for determining whether two parties claim the "same patentable invention" reflects a permissible reading of 37 C.F.R. § 1.601(n), promulgated pursuant to 35 U.S.C. § 135(a), where a species claim to a

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[6] The opinions of both the majority and the dissent in the Federal Circuit are confused about what actually happened below. The majority states that "the Board…dismissed the interference," ____F.3d at ____, 67 USPQ2d at 1162, and that Lilly took a particular action "[a]fter failing to instigate an interference…," ____ F.3d at ____, 67 USPQ2d at 1162. Similarly, the dissent states that "[t]he Board of Patent Appeals and Interferences here declined to declare an interference between Lilly's reissue application and the University of Washington's patent…." ____ F.3d at ____, 67 USPQ2d at 1167. Actually, the panel of the Trial Section entered a judgment (that there was no interference-in-fact), and Eli Lilly had successfully instigated the interference (if the interference had not been "instigated"—"declared" is the usual term for what happened--, there would have been no preliminary motions period).

[7] More accurately, it was the Trial Section's two-way test. However, under In re Alappat, 33 F.3d 1526, 1531-36, 31 USPQ2d 1545, 1547-51 (Fed. Cir. 1994) (in banc), the BPAI, including the Trial Section, is deemed to be a mere mouthpiece for the Director.

presumptive senior party allegedly anticipates a genus claim to a presumptive junior party.[8]

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Section 135 of the United States Code, Title 35, governs patent interference proceedings, which are designed to determine whether two patent applications (or a patent application and an issued patent) are drawn to the "same patentable invention" and, if so, which of the competing parties was first to invent the duplicative subject matter. *See Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100-01 [30 USPQ2d 1626] (Fed. Cir. 1994). The statutory basis for declaring an interference proceeding, 35 U. S.C. § 135(a), reads in pertinent part:

> 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.

35 U.S.C. § 135(a) (2000) (emphases added [by the Court]). The plain meaning of this statute demonstrates that Congress has expressly indicated its preference that the declaration of an interference pursuant to § 135 be discretionary. *Burton v. Adang*, 162 F.3d 1140, 1144 [49 USPQ2d 1128] (Fed. Cir. 1998) ("The plain meaning of this statute is clear from the use of the permissive term 'may' that the [Director] has discretion whether to declare an interference."); *see also In re Alappat*, 33 F.3d 1526, 1531 [31 USPQ2d 1545] (Fed. Cir. 1994) (*en banc*) ("When statutory interpretation is at issue, the plain and unambiguous meaning of a statute prevails in the absence of clearly expressed legislative intent to the contrary.") Section 135(a) states that the Board shall determine questions of priority once an interference proceeding is declared. This authority for the Board to determine questions of priority, however, does not vitiate the Director's discretion to begin or discontinue an interference once declared. *See* 35 U.S.C. § 135(a). Accordingly, the

[8] ____ F.3d at _____, 67 USPQ2d at 1163.

> mandatory language only instructs the Board of its jurisdiction over an active interference. *See id*.[9]

The majority concluded that the Trial Section's interpretation of 37 CFR 1.601(n), while "underinclusive because it concludes there is no interference-in-fact even if an interference proceeding would have led to the conclusion that the species was invented before the genus,"[10] was "textually defensible"[11] and "at least as plausible as competing…[interpretations[12] of 37 CFR 1.601(n)]."[13] According to the majority:

> the one-way test is overinclusive because it concludes there is an interference-in-fact even if an interference proceeding would have led to the conclusion that the genus was invented before, and separately patentable from, the species. Section 1.601(n) reasonably can be interpreted to require an election between either a one-way or a two-way test. The 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. To read the regulation, as Lilly and our colleague in dissent urge, to require the continuance of an interference proceeding where a genus claim to a presumptive junior party is allegedly anticipated by a species claim to a presumptive senior party, is a plausible alternative reading,

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[9] ____ F.3d at ____, 67 USPQ2d at 1163.

[10] ____ F.3d. at ____, 67 USPQ2d at 1165.

[11] ____ F.3d at ____, 67 USPQ2d at 1165.

[12] Actually, I believe that there are only two competing interpretations of 37 CFR 1.601(n)—the two-way test adopted by the Trial Section in Winter and the one-way test espoused by Eli Lilly—and many (probably most) members of the interference bar.

[13] ____ F.3d at ____, 67 USPQ2d at 1165.

> but a reading which in the Director's discretion he has chosen not to accept.[14]

According to the dissent:

> In each case [i.e., in each sentence in 37 CFR 1.601(n)], a one-way test is set forth: whether invention A is the same as or is obvious with respect to invention B, *assuming B is prior art with respect to A*. The rule does not require that B be the same as or obvious with respect to A, or assume that A is prior art with respect to B. Thus, the rule provides a one-way test, not a two-way test, as the Board erroneously held.[15]
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> Applying the one-way test clearly set forth by Rule 601(n), UW's generic claim 1 must be held to be the same patentable invention, not because a genus and a species are the same, but because Rule 601(n) refers to 35 U.S.C. § 102 after its reference to "same invention," and thereby indicates that the phrase "same patentable invention" encompasses the concept of "is anticipated by." Lilly, on the present record, would be the senior party were an interference to be declared.[16] Clearly, the species in Lilly's prior filed claims anticipates UW's later-filed generic claim. If an interference were to be declared, UW might antedate Lilly's claim, in which case UW's generic claim would remain in force. In that case, however, Lilly's species claim would also remain, because the Board already found the species to be a separate patentable invention with respect to the prior genus. The interference will seem to have been conducted in vain, but the issues will have been settled in accordance with the statutory procedure for resolving a possible conflict of priority

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[14] ____ F.3d at ____, 67 USPQ2d at 1165-1166.

[15] ____ F.3d at ____, 67 USPQ2d at 1168.

[16] Of course, an interference had been declared, and Eli Lilly was the senior party in that interference.

> between an application (albeit a reissue application) and a patent. If UW does not antedate Lilly's species, then UW's generic claim will be invalid under 35 U.S.C. 102(g), and the matter will have been settled by the optimal tribunal.[17]

III. The Court's Responsibility to the Public as the PTO's Principal Reviewing Authority

Most of us think that we are over-worked and under-paid. However, it is part of the Federal Circuit's responsibility to the public to keep the PTO's nose to the grindstone.

What the majority's decision does is to approve the board's latest labor-saving stratagem. In the interference context, the Federal Circuit has twice rejected such labor-saving stratagems in recent years—to the general approbation of the interference bar.

The board's first labor-saving stratagem was to hold that an interferent's filing of a 37 CFR 1.633(a) motion attacking the patentability of an opponent's claim designated as corresponding to the or a count over the prior art was a binding admission that the interferent's claim or claims designated as corresponding to that count were unpatentable over the prior art. Guglielmino v. Winkler, 11 USPQ2d 1389 (PTOBPAI 1989). The Federal Circuit overruled that labor-saving stratagem in Winkler v. Guglielmino, 17 USPQ2d 1175 (Fed. Cir. 1990) (per curiam) (non-precedential). The Federal Circuit's opinion was, unfortunately, non-precedential. However, the Court's holding fortunately led to a Commissioner's Notice published at 1118 OG 19 (Sept. 11, 1990) that required the board to abandon that labor-saving stratagem.

The board's second labor-saving stratagem was to hold that, if a count is unpatentable over the prior art, all claims designated as corresponding to that count are

[17] ____ F.3d at _____, 67 USPQ2d at 1168.

unpatentable over that prior art. The Federal Circuit overruled that labor-saving stratagem in In re Van Geuns, 988 F.2d 1181 (Fed. Cir. 1993), which held that the patentability of the claims designated as corresponding to the or a count must be determined on a claim-by-claim basis.

This is the board's third, conceptually similar labor-saving stratagem. Its origin, as previously pointed out, is Winter v. Fujita, 53 USPQ2d 1234 (PTOPBAI 1999) (expanded panel), 53 USPQ2d 1478 (PTOBPAI 2000) (expanded panel)—so it is not a "long-standing…test," as erroneously stated by the majority.[18] Presumably what the majority meant was that 37 CFR 1.601(n) is, relatively speaking, long-standing. However, 37 CFR 1.601(n) does not set forth a two-way test. Rather, the Trial Section created the two-way test out of whole cloth in Winter v. Fujita—and, as the dissent correctly noted, the Trial Section's holding in Winter v. Fujita is "unsupported by any reasoning."[19]

I am not entirely unsympathetic to the Trial Section's efforts to avoid unnecessary or socially unproductive labor. However, the problem with the Trial Section's latest labor-saving stratagem is that the labor that it is attempting to avoid is neither unnecessary nor socially unproductive.

IV. 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.*

[18] ____ F.3d at ____, 67 USPQ2d at 1166

[19] ____ F.3d at ____, 67 USPQ2d at 1167.

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 Trial Section and the majority of the panel of the Federal Circuit 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.[20] 35 USC 102(g)(2). However, 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.

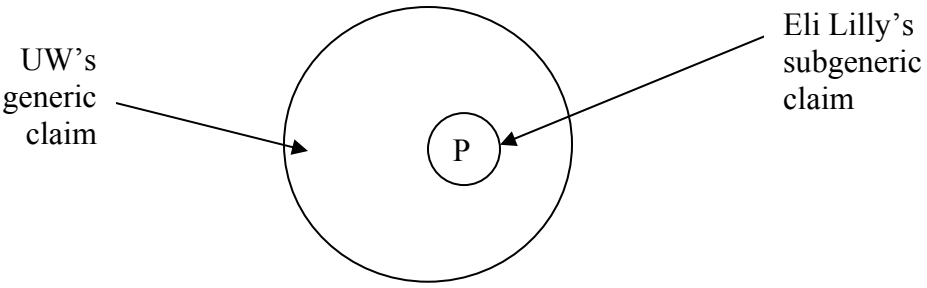
The two-way test creates the situation that, if the invention made by the first inventor is patentably distinct from the invention made by the second inventor (as is apparently true in this case), but the invention made by the second inventor is not patentably distinct from the invention made by the 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, 55 USPQ2d 1609, 1619 (Fed. Cir. 2000) ("a later genus claim is not patentable over an earlier species claim.")

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

In this case, Eli Lilly's species is presumptively prior to UW's genus. The genus cannot be patentably distinct from the species since it is anticipated by the species. Thus, the Trial Section's interpretation of 37 CFR 1.601(n), if not reversed by the court in banc, will result in the issuance of Eli Lilly's reissue application but will leave UW's patent containing at least some presumptively invalid claims "blowing in the wind."[21]

V. The Practical Effect of the Trial Section's Interpretation of 37 CFR 1.601(n)

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.



[21] Query: would the board's decision been different if the interference had involved a reissue application owned by UW and a patent owned by Eli Lilly? The two-way test would have yielded the same result (no interference in fact), but the PTO would have been placed in the position of issuing for the second time a presumptively invalid patent. If the examiner had rejected one or more claims in UW's reissue application over Eli Lilly's patent under 35 USC 102(e), then the PTO would have had to "interpret" 37 CFR 1.131's reference to 37 CFR 1.601(n) consistently with Winter, ignoring the 35 USC 102(g) issue.

What that means is:

(1) Eli Lilly cannot safely commercialize P without paying for a license from UW;

(2) UW or a licensee of UW's cannot safely commercialize P without a license from Eli Lilly; and

(3) Third parties cannot safely commercialize P without paying for a license from both UW and Eli Lilly because both UW and Eli Lilly could sue it for patent infringement—perhaps in different courts![22]

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

Of course, if Eli Lilly really did make its invention before UW made its invention (as Eli Lilly alleges was the case), UW's generic claim is invalid. However, the majority in deciding to affirm the Trial Section gave deference to the Trial Section'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 I cannot go into here in detail because of the space limitation, it costs approximately ten times as much to succeed in infringement

[22] And wouldn't it be interesting if the different courts reached conflicting judgments! Of course, the Federal Circuit might ultimately sort things out—but at what a cost!

litigation as it costs to succeed in an interference.[23]

Second, a company concerned by a situation such as this (and, perhaps, hesitating to start or to continue 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.

VI. A Verbal Example

For readers who did not grow up using Venn diagrams to simplify complex issues, I now offer a verbal example taken from Guilford's amicus brief in support of Eli Lilly's petition for rehearing in banc.[24]

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[23] 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 Judge Lourie in his dissent, the Trial Section would be "the optimal tribunal," ____ F.3d at ____, 67 USPQ2d at 1168, to decide the validity issue which the Trial Section and the majority ducked.

[24] This example is used here with the kind permission of Nancy Linck, a former Solicitor and now Chief Intellectual Property Counsel at Guilford.

Drug Co A discovers Compound A, a potential brain cancer treatment. A patent application is filed to protect it. After Drug Co A's discovery of Compound A, Drug Co B independently invents a genus of compounds ("Genus B") that encompasses compound A and files a patent application containing claims that encompass but do not specifically identify Compound A. Drug Co A spends several years and millions of dollars to determine whether Compound A will be safe, first in animals and then in humans (Phase I clinical trials). It is then further tested to determine whether it will actually work in humans, typically taking another several years and costing many more millions of dollars (Phase II). The results of Phase II indicate that Compound A may not only prolong the life of brain cancer patients but may actually provide a cure.

Then, as Drug Co A begins a costly registration trial (Phase III), Drug Co B's patent issues with claims to Genus B. Drug Co A's application is still pending, even though it was filed six months before the filing date of Drug Co B's patent.

Under the BPAI's relatively new two-way test, there is no interference-in-fact, because, even though Genus B is not patentable over Compound A, Compound A *is* patentable over Genus B. Thus, Drug Co A cannot provoke an interference and is faced with a very difficult decision: Continue to develop Compound A and incur immense costs, often more than $100 million, knowing that Drug Co B's patent may block the commercialization of Compound A, or abandon development of Compound A.

VII. 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 UW'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, 221 USPQ 196, 200 (Fed. Cir. 1984), Eli Lilly's application was on its face an "impediment to granting" UW's patent, but that fact was apparently inadvertently overlooked by the examiner handling UW's application. Such inadvertent errors inevitably occur in the PTO's complex examination system, and in fact they occur with distressing frequency.

In the past, the Commissioner/Director has generally attempted to exercise his[25] 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 district courts to determine which patent is valid in subsequent expensive and socially unproductive litigation.

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, 24 USPQ2d 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

[25] I know that it is now politically correct to use feminine pronouns when the name of the antecedent is not given. However, the historical fact is that all of the Commissioners and Directors have been masculine.

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.

I am hoping that, in response to Eli Lilly's request for reconsideration, the court will tell the Director to apply the same exercise of discretion to determine which competing assignee (i.e., Eli Lilly or UW) 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 UW's claims meet the statutory requirements of 35 USC 102 and 103.

In any realistic sense, both Eli Lilly and UW are claiming the same invention, although UW claims that invention more broadly. That fact has been recognized by the Federal Circuit when the same issues have arisen in a "double patenting" context. *In re Berg,* 140 F.3d 1428, 1431-32, 46 USPQ2d 1226, 1229-30 (Fed. Cir. 1998). In that context, the Federal Circuit has clearly recognized that a one-way test is proper in order to determine whether a genus can properly issue without a terminal disclaimer when a species has already been patented. Why should the two-way test rather than the one-way test apply simply because the genus and species are sought to be separately patented by entities that are not identical or commonly owned?

VIII. Eli Lilly's Impossible Position

As a practical matter, there may be no way, apart from an interference, for Eli Lilly to determine whether UW'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 Federal Circuit's opinion in *Slip-Track Systems, Inc. v. Metal-Lite Inc.*, 159 F.2d 1337, 48 USPQ2d 1055

(Fed. Cir. 1998).[26] If the reexamination examiner should conclude, as did the Trial Section, that two-way distinctness is necessary for the declaration of an interference, UW would be allowed to antedate Eli Lilly's filing date (i.e., its 35 USC 102(e) date) by an "antedating" declaration under 37 CFR 1.131, and Eli Lilly's actual invention date could not be considered by the reexamination examiner.

Some significant formal 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 Eli Lilly that UW's invention date was probably "prior to" Eli Lilly's filing date. However, it is very likely (absent simultaneous conception and constructive reduction to practice) that Eli Lilly's invention date under 35 USC 102(g) is earlier than its filing date!

In sum, Eli Lilly's only remedy might well be to assume the risk of infringement in order to provoke UW into providing enough basis for Eli Lilly to file a declaratory judgment action! Moreover, if Eli Lilly chooses not to assume that risk, the public may be deprived of the benefits of the invention for many years to come.

IX. Conclusion and Plea

The majority's holding is not a "victimless crime." It has appalling real-world consequences. In view of those consequences, it is very important that the Federal

[26] See my discussion of Slip Track in Gholz, A Critique of Recent Opinions of the Federal Circuit in Patent Interferences, 81 JPTOS 241 (1999) at 251-53.

Circuit grant Eli Lilly's petition for a rehearing in banc and, ultimately, keep the Trial Section's nose to the grindstone.

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