BRIEF OF AMICUS CURIAE, THE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

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.

Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

> JAMES A. TOUPIN General Counsel

JOHN M. WHEALAN Solicitor

Of Counsel

SCOTT R. McINTOSH MARK S. DAVIES

Attorneys

Department of Justice

STEPHEN WALSH

HENRY G. SAWTELLE

Associate Solicitors P.O. Box 15667

Arlington, Virginia 22215

703-305-9035

Attorneys for the Director of the

United States Patent and

Trademark Office

February 4, 2003

TABLE OF CONTENTS

	rag	е
INTERES	T OF THE DIRECTOR	1
STATEME	ENT OF THE ISSUE	2
STATEME	ENT OF THE FACTS	2
SUMMAR	RY OF THE ARGUMENT	4
ARGUME	NT	5
A.	Standards of Review.	5
В.	The Purpose Of An Interference Proceeding Is To Assure That Only One Patent Issues For One Invention	6
	1. The Board's Two-Way Test Identifies The "same patentable invention" Where A One-Way Test Fails	7
	2. The Board's Two-Way Test Effectively Distinguishes Between "same patentable invention" And "separate patentable invention."	0
C.	The Board Correctly Determined That In This Case There Is No "interference-in-fact" Between A UW Genus And A Lilly Species. 12	2
	1. If Generic, UW Claim 1 Does Not Define The "same patentable invention" As Lilly Claim 2	4
	2. If The Disclosure Of A Genus Does Not Anticipate Or Render Obvious The Invention Of A Species, The Two Are Not The "same patentable invention."	5

	D.		The "same patentable invention."	20
	E.	Interf	There Is No "interference-in-fact," Discontinuing An Gerence Properly Avoids An <i>Ultra Vires</i> Cancellation eeding.	22
		1.	Concern About Claim Domination Is Not A Basis For An Interference.	23
		2.	The Claim Construction That Lilly Wants Would Be Dictum That Would Not Bind Later Tribunals	
CON	CLUS	ION .		26

TABLE OF AUTHORITIES

Cases	Page
Advance Transformer Co. v. Levinson, 837 F.2d 1081, 5 USPQ2d 1600 (Fed. Cir. 1988)	10, 20
Aelony v. Arni, 547 F.2d 566, 192 USPQ 486 (CCPA 1977)	. 6, 22
Albert v. Kevex Corp., 729 F.2d 757, 221 USPQ 202 (Fed. Cir. 1984)	20
Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 18 USPQ2d 1677 (Fed. Cir. 1991)	23
Auer v. Robbins, 519 U.S. 452 (1997)	8
Baird, In re, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994)	18
Barton v. Adang, 162 F.3d 1140, 49 USPQ2d 1128 (Fed. Cir. 1998)	. 5, 24
Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377, 64 USPQ2d 1045 (Fed. Cir. 2002)	5
Bell, In re, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993)	18
Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945)	5
Bristol-Myers Squibb Co. v. Ben Venue Labs. Inc., 246 F.3d 1368, 58 USPQ2d 1508 (Fed. Cir. 2001)	17, 18
Cochrane v. Deener, 94 U.S. 780 (1876)	20, 21
Cooper v. Goldfarb, 240 F.3d 1378, 57 USPQ2d 1990 (Fed. Cir. 2001)	12
Credle v. Bond, 25 F.3d 1566, 30 USPQ2d 1911 (Fed. Cir. 1994)	5
Deuel, In re, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995)	13

Eastman Kodak Co. v. Bell & Howell Document Mgmt. Prods. Co., 994 F.2d 1569, 26 USPQ2d 1912 (Fed. Cir. 1993) 8
Eli Lilly and Co. v. Barr Laboratories Inc., 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001)
Ewing v. The Fowler Car Co., 244 U.S. 1 (1917)
Goodman, In re, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993) 17
Hitzeman v. Rutter, 243 F.3d 1345, 58 USPQ2d 1161 (Fed. Cir. 2001) 5
Kaplan, In re, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986)
<i>Kubota v. Shibuya</i> , 999 F.2d 517, 27 USPQ2d 1418 (Fed. Cir. 1993) 5
<i>McGrew, In re</i> , 120 F.3d 1236, 43 USPQ2d 1633 (Fed. Cir. 1997)
Miller v. Eagle, 151 U.S. 186 (1894)
Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 24 USPQ2d 1321 (Fed. Cir. 1992)
Nitz v. Ehrenreich, 537 F.2d 539, 190 USPQ 413 (CCPA 1976) 6
Petering, In re, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)
Schaumann, In re, 572 F.2d 312, 197 USPQ 5 (CCPA 1978)
Slayter, In re, 276 F.2d 408, 125 USPQ 345 (CCPA 1960) 17-19, 21
Syntex v. USPTO, 882 F.2d 1570, 11 USPQ2d 1866 (Fed. Cir. 1989)
Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Interf. 1999) 7, 10

Statutes

35 U.S.C. § 102(g)	6
35 U.S.C. § 135	22
35 U.S.C. § 135(a)	6, 22, 23
35 U.S.C. § 135(b)	23
35 U.S.C. § 2(b)(2)(A)	2
35 U.S.C. § 291	
Regulations	
37 C.F.R. Subpart E–Interferences, §§ 1.601-690	2
37 C.F.R. § 1.131	23
37 C.F.R. § 1.601	22
37 C.F.R. § 1.601(f)	12, 16
37 C.F.R. § 1.601(i)	6
37 C.F.R. § 1.601(j)	
37 C.F.R. § 1.601(n)	4, 7, 9-11, 15, 16, 26
Other Authorities	
49 Fed. Reg. 48416	15-16
Fed. R. App. P. 29(a)	1
Manual of Patent Examining Procedure § 715.05	19

BRIEF OF *AMICUS CURIAE*, THE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

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.

Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

INTEREST OF THE DIRECTOR

The Director (Director) of the United States Patent and Trademark Office (USPTO), is an officer of the United States and is filing as *amicus curiae* under the authority of Fed. R. App. P. 29(a). The Director supports affirmance.

The threshold standard for determining when every interference should be declared and/or conducted, as well as the USPTO rules governing this standard, are at the heart of this appeal. In particular, the case concerns the rule for deciding whether two inventions are the "same patentable invention," a phrase defined in

37 CFR § 1.601(n). Pursuant to 35 U.S.C. § 2(b)(2)(A), and predecessor statutes, the Director established the regulations in 37 CFR Subpart E–Interferences, §§ 1.601-690. The issue of the proper test for starting or for terminating an interference proceeding is an issue of institutional concern to the USPTO. The Director has a continuing interest in the interpretation of the rules governing interferences and wishes to assist the Court by presenting the USPTO interpretation of the pertinent rules.

STATEMENT OF THE ISSUE

Giving appropriate deference to the Board's interpretation of its own rules, was it plainly erroneous for the Board to find that a party's broad genus claim is not the "same patentable invention" under 37 C.F.R. § 1.601(n) as another party's narrower species claim?

STATEMENT OF THE FACTS

Appellant Eli Lilly & Co. (Lilly) requested an interference between its patent application and an issued patent assigned to the Board of Regents of the University of Washington (UW). A9-10, see F[acts]11-14. Lilly asserted that its Claim 2 and UW's Claim 3 recited identical cDNA (chemical) structures. *Id.* The USPTO Board of Patent Appeals and Interferences (Board) accepted Lilly's

representations and declared the interference, using UW Claim 3 as the interference "count." A12.

During the motions period at the beginning of the interference proceeding, UW filed a motion for "no interference-in-fact," explaining that the parties' cDNA molecules have different sequences, i.e., chemical structures. A13. The Board agreed the evidence established the differences and that the molecules are neither the same nor obvious over each other. A31. Thus, the Board granted UW's motion. A34.

Lilly filed a motion to designate UW's Claim 1 as corresponding to the count. A13. Applying a two-way test, the Board determined that Lilly's claims are <u>not</u> the "same patentable invention" as UW Claim 1, and consequently, there is no "interference-in-fact" between any of the UW claims and the Lilly claims.

A32-34. Under these circumstances, the Board held Lilly's motion to designate the additional UW claim as moot. A38. That is, even if UW's Claim 1 were added, there would be no interfering subject matter.

The Board terminated the interference when it determined that no reading of the parties' claims established that they defined the "same patentable invention." A34. In the absence of any "interference-in-fact," UW's existing patent claims created no impediment to the issuance of Lilly's application claims. *Id.* The

central issue in this appeal is whether the Board's two-way test for "same patentable invention" is a permissible interpretation of 37 C.F.R. § 1.601(n).

SUMMARY OF THE ARGUMENT

The main issue in this case, and the extent of the USPTO's interest as amicus curiae, is the proper interpretation of the USPTO regulations relating to "interference-in-fact" and "same patentable invention." The Board applied the USPTO's long-standing and consistent interpretation that parties' claims must anticipate each other or render each other obvious in order to find an "interference-in-fact" – the so-called two-way test for "same patentable invention." This interpretation is reasonable both textually and as a matter of policy, and is entitled to deference.

Because UW's claim 1, if generic, does not anticipate nor render obvious any of Lilly's species claims, the parties have not claimed the "same patentable invention." Thus, the Board properly discontinued this interference.

The USPTO is under no obligation to adopt Lilly's flawed "one-way" test.

That test is inadequate for confirming that two parties claim the "same patentable invention." When the claimed inventions are not the same, but merely overlap in scope, the one-way test leads to a proliferation of unnecessary, wasteful proceedings concluding that both parties are entitled to patents.

ARGUMENT

A. Standards of Review.

The interpretation of an interference Count is a question of law that this Court reviews *de novo*. *Credle v. Bond*, 25 F.3d 1566, 1571, 30 USPQ2d 1911, 1915 (Fed. Cir. 1994). This Court affirms the Board's factual determinations if they are supported by substantial evidence and reviews the Board's legal conclusions *de novo*. *Hitzeman v. Rutter*, 243 F.3d 1345, 1353-54, 58 USPQ2d 1161, 1166-67 (Fed. Cir. 2001).

This Court reviews the Board's statutory constructions *de novo*. *Barton v*. *Adang*, 162 F.3d 1140, 1144, 49 USPQ2d 1128, 1132 (Fed. Cir. 1998). The USPTO's construction of its own regulations is entitled to deference unless plainly erroneous or inconsistent with the regulation. *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1381, 64 USPQ2d 1045, 1048-49 (Fed. Cir. 2002); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *Kubota v. Shibuya*, 999 F.2d 517, 521, 27 USPQ2d 1418, 1421 (Fed. Cir. 1993). A Board decision pursuant to the interference rules is reviewed for abuse of discretion. *Barton*, 162 F.3d at 1145, 49 USPQ2d at 1133.

B. The Purpose Of An Interference Proceeding Is To Assure That Only One Patent Issues For One Invention.

Only the first person to achieve an invention may be awarded a patent for the invention. 35 U.S.C. § 102(g). Interference proceedings are instituted to assure that only one patent issues for a single patentable invention, and to assure that the first inventor receives the patent. 35 U.S.C. § 135(a). In short, the law contemplates that "where different inventive entities are concerned—that only one patent should issue for inventions which are either identical to or not patentably distinct from each other." *Aelony v. Arni*, 547 F.2d 566, 570, 192 USPQ 486, 490 (CCPA 1977).

An interference proceeding may be initiated to settle questions of priority between two or more parties whose claims interfere. 37 C.F.R. 1.601(i); *Nitz v. Ehrenreich*, 537 F.2d 539, 543, 190 USPQ 413, 416 (CCPA 1976) ("[T]he existence or nonexistence of interfering subject matter goes to the very foundation on which an interference rests."). The decision as to whether claims interfere has long been assigned to the Director. *Ewing v. The Fowler Car Co.*, 244 U.S. 1, 10 (1917) ("in the opinion of the Commissioner" in § 4904 (Comp. Stat. 1913) construed to mean "not to be questioned except at the instance of the Commissioner by an exercise of judgment upon the circumstances"). Thus, the

Director established regulations for declaring and conducting interferences.

Interferences are declared only when there is an "interference-in-fact," that is, the parties claim the "same patentable invention." 37 C.F.R. § 1.601(j) and (n) define the terms:

- (j) 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.
- (n) 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 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."

1. The Board's Two-Way Test Identifies The "same patentable invention" Where A One-Way Test Fails.

To decide whether parties claim the "same patentable invention" under 37 C.F.R. § 1.601(n), each parties' claims are used, in turn, as prior art to the other. *Winter v. Fujita*, 53 USPQ2d 1234, 1243 (Bd. Pat. App. & Interf. 1999). If the claims are not patentably distinct from each other, they interfere. Testing the claims in turn against <u>each other</u> assures that interferences are conducted when the parties' claims define the "same patentable invention." *Id.* As Congress has given the Director broad discretion to declare interferences, the USPTO determination

that a two-way test is appropriate to implement Rule 601(n) is entitled to deference. Fowler Car, 244 U.S. at 10; Auer v. Robbins, 519 U.S. 452, 457 (1997) ("Because Congress has not 'directly spoken to the precise question at issue,' we must sustain the Secretary's approach so long as it is 'based on a permissible construction of the statute.""); Eastman Kodak Co. v. Bell & Howell Document Mgmt. Prods. Co., 994 F.2d 1569, 1572, 26 USPQ2d 1912, 1916 (Fed. Cir. 1993) (applying Chevron deference for review of USPTO Trademark Trial and Appeal Board's interpretation of Lanham Act).

Some shorthand notation has developed that may assist in this analysis.

Assume we have two claims: A and B. To determine if A and B claim the "same patentable invention," two conditions must be satisfied: (i) A is anticipated by or obvious over B, and (ii) B is anticipated by or obvious over A. This has come to be referred to as the "two-way" test. If one of the two conditions is not satisfied, they are not claims to the "same patentable invention," there is no "interference-infact," and an interference proceeding is not needed. This is the test the Board properly used, and since it found one condition was not met, it ended the interference.¹

¹ The Board did not explicitly refer to the test as a "two-way" test, but rather analyzed the parties' claims to determine whether they were "separate patentable inventions." *See* A34. However, it is clear from the Board's decision that the

Lilly contends that the proper test for whether two claims are to the "same patentable invention" is a one-way test, i.e., only <u>one</u> of the two conditions need be met. *E.g.*, Lilly Br. at 37-39. Since one was met under one claim construction assumption, Lilly contends the interference should continue.

Thus, another way to state the primary issue presented in this case is: which is the proper test for determining when two claims are to the "same patentable invention:" a two-way test as the Board used, or a one-way test as Lilly argues? The answer to this question will affect many interferences. Under Lilly's proposed one-way test, a significant number of additional interferences will occur, many of which will have been unnecessary. If only a one-way test is used, it is simple to see that many additional interferences would be declared, regardless of whether the applicant or patentee objects. Using the species/genus hypothetical, since a species would anticipate the genus, an interference would be declared. However, if the proceeding leads to a conclusion that the genus was invented first, it is quite likely that both the genus and the species are patentable. Thus, after a lengthy proceeding, it will be determined that the status quo can continue.

Rule 601(n) standard was applied two ways, and it is clear that Lilly contends that this two-way application was erroneous. Br. at 39.

2. The Board's Two-Way Test Effectively Distinguishes Between "same patentable invention" And "separate patentable invention."

Under Rule 601(j), an "interference-in-fact" exists only if both parties to an interference have at least one claim that defines the "same patentable invention." Rule 601(n) states that "same patentable invention" means that the invention of one party anticipates or renders obvious the other party's invention. Rule 601(n) also defines "separate patentable invention" to mean that the invention of one party is new and non-obvious in view of the other party's invention.

The Board implements Rule 601(n) with a two-way test. That is, each party must be shown to claim the "same patentable invention" with respect to the other. Each party's claim is tested in turn against the other's. This two-way test correctly identifies "interference-in-fact" because it correctly identifies when each party claims the "same patentable invention." The Board's Trial Section has previously explained that the two-way test results in interferences only where the "same patentable invention" is claimed by different parties. *Winter*, 53 USPQ2d at 1243. This is appropriate and similar to tests used in district courts for interference suits brought by patent holders under 35 U.S.C. § 291 "Interfering Patents." *E.g.*, *Advance Transformer Co. v. Levinson*, 837 F.2d 1081, 1084, 5 USPQ2d 1600, 1602 (Fed. Cir. 1988) ("The threshold issue under section 291 is whether the

patents contain claims to the same subject matter. . . . the district court did not err in <u>determining whether the claims 'cross-read'</u>") (emphasis added).

Under the two-way test, an interference is only declared when both parties claims are to the "same patentable invention." Not only does a proper interpretation of the rules dictate this outcome, but policy considerations and common sense do as well. Under the two-way test in an application vs. patent context, the USPTO will only hold an application from issue if it finds that the substantially the same claim has already issued. This makes sense since the USPTO reasons that both the claim about to issue, and the issued claim to the same invention, cannot ever coexist. The USPTO thus declares an interference to determine which inventor was first (entitled to priority), and thus entitled to the claim. Only one of the parties—either the applicant or the patentee—can prevail and be entitled to the claim. The interference is needed to determine which one was first.

A one-way test fails to assure that an interference will be conducted only when warranted. Under some circumstances it is possible for party A to have a "separate patentable invention" with respect to party B according to Rule 601(n) second sentence, but party B's invention is anticipated by party A according to Rule 601(n) first sentence. In this circumstance, a one-way test would lead to

interference proceedings even though the inventor of the "separate patentable invention" will always be entitled to its claims. That is, there is no impediment to the claims to the "separate patentable invention" because those claims are not interfered with by the claims of the other party. If the invention awarded priority does not anticipate nor render obvious the other invention, then both parties are entitled to their claims. Thus, an interference declared under the one-way test may end with a priority decision that means there never was any "interference-in-fact" to begin with.

Proceedings begun on the basis of the one-way test may or may not involve interfering claims because the one-way test fails to assure that each party claims the "same patentable invention." That is, the one-way test cannot assure that the two party's claims interfere with each other. The Board's two-way test is the more reasonable test because it does not result in futile proceedings.

C. The Board Correctly Determined That In This Case There Is No "interference-in-fact" Between A UW Genus And A Lilly Species.

An interference count defines the interfering subject matter. 37 C.F.R. § 1.601(f); *Cooper v. Goldfarb*, 240 F.3d 1378, 1382, 57 USPQ2d 1990, 1992 (Fed. Cir. 2001) ("The precise scope of the interfering subject matter is defined by

the interference 'count.' 37 C.F.R. § 1.601(f)."). In this case, the count was UW's dependent Claim 3 which reads:

3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp 127 to bp 1383. A6-7.

Neither party disputes the Board's finding that the parties' specific cDNA molecules are not the same, because they have different sequences.² Neither party disputes the Board's conclusion that the parties' specific cDNA molecules do not render each other obvious. Thus, both parties agree the Board properly found no "interference-in-fact" between UW Claim 3 and Lilly Claim 2.

However, Lilly argues that UW's Claim 1, if construed as a genus because it does not recite a specific cDNA molecular sequence, is the "same patentable invention" as Lilly's own Claim 2, which does recite a unique cDNA molecular sequence. Br. at 29. Lilly says this is true because Lilly species Claim 2 would anticipate UW genus Claim 1 (the one-way test is satisfied). *Id.* Lilly makes no argument that UW Claim 1 could anticipate or render obvious Lilly Claim 2, effectively conceding that the second part of the two-way test is not met.

² A protein, such as human protein C, is made of a string of amino acids. *See* A29. Amino acids are coded in cDNA sequences by DNA base-pair triplets called "codons." Some amino acids can be represented by more than one codon. Thus, there may be multiple cDNA sequences that code for the same protein. *See In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995). It is uncontested that the parties' two species are apparently genetic variants. A12.

1. If Generic, UW Claim 1 Does Not Define The "same patentable invention" As Lilly Claim 2.

UW Claim 1	Lilly Claim 2	
1. A bacterial plasmid or bacteriophage transfer vector comprising cDNA coding for the amino acid sequence of FIG. 3, starting with alanine, number 1, and ending with proline, number 419, said cDNA sequence coding for human protein C. A59.	2. A plasmid comprising the DNA of claim 1 [A constructed DNA compound that comprises double-stranded deoxyribonucleic acid that encodes a polypeptide with human protein C activity, wherein the coding strand is: [lengthy sequence not reproduced here]]. A1057-59.	

The Board considered Lilly's two proposed constructions for UW Claim 1: (1) that the plasmid comprises the cDNA molecule with the sequence recited in UW Figure 3, and (2) that the plasmid comprises any cDNA molecule that codes for human protein C. A33. It is undisputed that the first construction is not the "same patentable invention" as Lilly Claim 2, and that there is no "interference-infact" under the first, or "species," construction.

Under the second construction, UW Claim 1 would be generic, that is, it would include plasmids that comprise any of the cDNA's that encode protein C. Lilly's arguments about genus and species attempt to show that a generic UW Claim 1 and its own species Claim 2 would be the "same patentable invention." Br. at 24-25. In other words, a genus and each species member of the genus are the "same patentable invention."

A chemical compound that is a single species in a broad genus including other compounds is not the same invention as the broad genus. For example, the species table salt (NaCl) is not the same invention as the genus "all salts." The law recognizes that a genus and its member species are not identical to each other: "although [patentee's] specific claims are subsumed in [the prior art] generalized disclosure . . ., this is not literal identity." *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1572, 24 USPQ2d 1321, 1332 (Fed. Cir. 1992) (emphasis added).

2. If The Disclosure Of A Genus Does Not Anticipate Or Render Obvious The Invention Of A Species, The Two Are Not The "same patentable invention."

When the current interference regulations were adopted, the USPTO took care to assure that the rules would be applied consistently with the law and established precedent. The current interference rules were adopted to implement the Patent Law Amendments Act of 1984, PL 98-622, sections 201-202. 49 FR 48416 (Dec. 12, 1984). In the notice of final rule, the USPTO responded to public comments on Rule 601(n). In particular, one comment, 49 FR at 48432-33,

offered a concern that the new rule would not allow for an interference with separate "counts" to genus and species.³

The USPTO responded that the commentator was not correct and that an interference with two counts, one to a genus and one to a species, would be proper if the species is patentable over the genus:

[I]f a species is patentable over a genus, the species is a "separate patentable invention" from the genus. Compare *In re Taub*, 348 F.2d 556, 146 USPQ 384 (CCPA 1965) (fluorine species might be patentable over genus of Markush group of hydrogen and halogen). A first count to a genus and a second count to a species which is patentable over the genus may properly appear in an interference. See, e.g., Example 4 [49 FR at 48420].

49 FR at 48433, 3rd column. And:

Commentator's Example B suggests-incorrectly-that if an interference is declared with a count to a species that no motion under § 1.633(c)(1) to add a count to a genus can ever be granted. If the species ("invention A" referred to in § 1.601(n)) is not anticipated by or obvious in view of the genus ("invention B" referred to in § 1.601(n)), a motion to add a separate count to the genus may be proper.

49 FR at 48434, 3rd column.

As the Board explained, the two-way test for identifying "same patentable invention" is consistent with precedent concerning genus/species inventions and

³ The Rule 601(n) "same patentable invention" test is relevant to the question of whether two counts may properly be included in an interference, because each count "shall define a separate patentable invention." 37 CFR § 1.601(f).

with the USPTO's original Federal Register Notice. A25-6. The earlier disclosure of one chemical compound in a genus of compounds prevents patenting the later discovered genus. The rule applied is: "an earlier species disclosure in the prior art defeats any generic claim." *In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960). This court has similarly explained: "case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." *Eli Lilly and Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 971, 58 USPQ2d 1865, 1880 (Fed. Cir. 2001), *cert. denied*, 122 S.Ct. 913 (2002) (emphasis added).

However, the opposite situation is not as simple. That is, the earlier disclosure of a genus of compounds does not necessarily prevent patenting a species member of the genus. Instead, the prior art is examined to determine how specifically the prior art generic disclosure describes its species members. *E.g.*, *Bristol-Myers Squibb Co. v. Ben Venue Labs. Inc.*, 246 F.3d 1368, 1380, 58 USPQ2d 1508, 1517 (Fed. Cir. 2001) (remanding to district court for determination of whether prior art suggestion to premedicate would have suggested premedicating with certain compounds). Thus, a species can be patentably distinct from the genus to which it belongs.

Cases involving this situation thus fall into two categories. First, "the disclosure of a small genus may anticipate the species of that genus even if the species are not themselves recited." *Id.*, *citing In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962). *See also*, *In re Schaumann*, 572 F.2d 312, 316-17, 197 USPQ 5, 9 (CCPA 1978) (description of a limited number of compounds anticipated the claimed compound).

In the second category, the prior art generic disclosure gives little guidance to a particular species in the genus, and the species is patentable. *E.g.*, *In re Baird*, 16 F.3d 380, 383, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (prior art teaching of vast number of possible diphenol compounds did not teach or suggest selection of Baird's claimed bisphenol A); *In re Bell*, 991 F.2d 781, 787, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) ("[G]iven the nearly infinite number of possibilities suggested by the prior art, and the failure of those possibilities to suggest which is the human sequence, the claimed sequences would not have been obvious").

In this case, the Board determined that if UW's Claim 1 is generic, it fails to describe or to suggest the species invention in any of Lilly's claims, and Lilly is entitled to its claims. Lilly shows no error in the Board's application of the test, but merely argues that the *Slayter* rule (species anticipates genus) controls. Br. at 29-30. If the genus and species render each other unpatentable, the *Bristol-Myers*

Squibb inquiry would also lead to a conclusion of unpatentability of the species over in view of the genus. However, in this case it does not, as the Board correctly explained. A29-30. Accordingly, the two claims do not define identical subject matter and are not the "same patentable invention." The weakness of the Lilly's one-way test is apparent: it is inadequate for distinguishing between "same" and "separate" patentable inventions. The Board's two-way test resolves this question whereas Lilly's one-way test fails.

The *Slayter* and *Petering* lines of cases are not in conflict because they address different situations: (1) in the *Slayter* line, a prior art species always anticipates the genus that would subsume it, and (2) in the *Petering* line, a prior art genus may or may not anticipate a member species. Hypothetically, a genus and one of its member species could be the "same patentable invention" if they anticipate each other or render each other obvious. But mere one-way anticipation or obviousness is insufficient to establish that claims are for the "same patentable invention."

Likewise, Lilly's claim that a species is "identical" to a genus, Br. at 27 (discussion of MPEP [MANUAL OF PATENT EXAMINING PROCEDURE] § 715.05), should be rejected as merely wrong. If it were true that any species member of a genus is identical to the genus, then UW's Claim 3 species is identical to UW's

genus. If the two species were identical to the genus, it would follow that the two species are identical to each other, a plainly erroneous conclusion that neither party accepts. *Cf., Advance Transformer*, 837 F.2d at 1083, 5 USPQ2d at 1602 ("interfering patents are not patents that are or may be infringed by the same device; interfering patents are patents that claim the same subject matter"), *citing Albert v. Kevex Corp.*, 729 F.2d 757, 758 n.1, 221 USPQ 202, 204 n.1 (Fed. Cir. 1984) ("Two or more patents interfere . . . when they claim the same subject matter").

D. Claims Related As Dominating Genus To Species Are Not The "same patentable invention."

The Board correctly held that a broad, dominating claim is not drawn to the same invention as the narrow claim it dominates by inclusion. A27. *E.g.*, *Cochrane v. Deener*, 94 U.S. 780, 787 (1876) ("One invention may include within it many others, and each and all may be valid at the same time"); *In re Kaplan*, 789 F.2d 1574, 1577, 229 USPQ 678, 681 (Fed. Cir. 1986) ("By domination we refer, in accordance with established patent law terminology, to that phenomenon, which grows out of the fact that patents have claims, whereunder one patent has a broad or 'generic' claim which 'reads on' an invention defined by a narrower or more specific claim in another patent, the former 'dominating' the latter because

the more narrowly claimed invention cannot be practiced without infringing the broader claim.").

Lilly argued that if UW Claim 1 is construed as generic, it would have a "dominating genus to species" relation with Lilly's Claim 2, requiring a conclusion that UW Claim 1 and Lilly Claim 2 are the "same patentable invention". A27. The Board correctly found this argument unpersuasive. As valid patents may dominate other valid patents, a dominating relation is not evidence of the "same patentable invention." *Cochrane*, 94 U.S. at 787; *see also*, *Miller v. Eagle*, 151 U.S. 186, 198 (1894) ("where the second patent covers matter described in the prior patent, essentially distinct and separable from the invention covered thereby and claims made thereunder, its validity may be sustained"). Thus, even if UW's Claim 1 dominates Lilly's claims, that is no impediment to Lilly's claims and no grounds for an interference.

It has been settled since the 19th century that inventors may properly be awarded patents for improvements on basic (dominating) inventions, and that a species may be patentable over a genus. Lilly requests that this settled practice be up-ended by a wooden one-way application of the *Slayter* rule (species anticipates genus) and a selective reading of Rule 601(n) that ignores the significance of the rule's second sentence. The rule is reasonably read as a whole as when both of its

tests are performed on the parties' claims: i.e., two claims are tested against each other for "same patentable invention" and for "separate patentable invention." The two-way test avoids subjecting broad patents for basic inventions to innumerable interferences as narrower improvements are claimed. If the one-way test were used, inventions that overlap but are different in scope (such as a species and a genus) would be deemed the same even though they are different. The Board properly followed precedent holding that overlap is not the dispositive criterion. A18, citing *Aelony*, 547 at 570, 192 USPQ at 490.

E. When There Is No "interference-in-fact," Discontinuing An Interference Properly Avoids An *Ultra Vires* Cancellation Proceeding.

The USPTO may cancel claims in an issued patent pursuant to 35 U.S.C. § 135(a) if an "interference-in-fact" is established under 37 C.F.R. § 1.601 and the proceedings establish the patentee is not entitled to the claims. In the absence of an "interference-in-fact," the USPTO's authority does <u>not</u> extend to provide an alternative avenue for third parties to attempt patent correction or cancellation under § 135. The statute does not provide for alternative theories as a basis for an interference.

1. Concern About Claim Domination Is Not A Basis For An Interference.

Although Lilly complains that UW may have obtained a dominating, generic claim by an improper use of 37 C.F.R. § 1.131, Br. at 27, Lilly's complaint should not be heard because it provides no basis for declaring an interference. The ability of a patent applicant like Lilly to drag an issued patent into an interference is limited by the requirements of § 135(a) and (b). Lilly failed to show it is entitled to challenge UW's claims in an interference since the claims are not to the "same patentable invention." Generally, patent prosecution is an ex parte proceeding and applicants who fail to establish "interference-in-fact" have no more standing than nonapplicant third parties to police another's patent prosecution. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 925, 18 USPQ2d 1677, 1685 (Fed. Cir. 1991) ("we find nothing in the law which gives rise to a right in nonapplicants to object to the way in which patent applications of others are prosecuted").

Lilly argues that as senior party it "presumptively invented the subject matter claimed in UW Claim 1, if that claim is construed as a genus claim, before UW did." Br. at 20. However, Lilly does not claim the genus, but rather, only a

species within that genus. Therefore, this argument does not establish a presumptive "interference-in-fact."

As Lilly has failed to establish that it claims the "same patentable invention" that UW claims, it is not entitled to use an interference proceeding to disparage or attack UW's claims, dominating or not. The Board properly terminated the interference after it was satisfied that Lilly claims a "separate patentable invention." *Barton*, 162 F.3d at 1144, 49 USPQ2d at 1132 (the Director has discretion to discontinue an interference).

The Board correctly noted that Lilly may pursue alternative remedies. Bd. at 38. If UW asserts its allegedly dominating Claim 1 against Lilly in the future, Lilly may answer with attacks on the UW claim. *See also, Fowler Car*, 244 U.S. at 10 (when an interference is not declared, "there is no defeat of ultimate rights; there may be a postponement of their assertion remitted to a suit in equity under § 4918"); *Cf., Syntex v. USPTO*, 882 F.2d 1570, 1576, 11 USPQ2d 1866, 1871 (Fed. Cir. 1989) (frustrated reexam requester not entitled to more than the reexam statute provided; "Syntex's remedy, if any, must await confrontation with the patent owner").

2. The Claim Construction That Lilly Wants Would Be Dictum That Would Not Bind Later Tribunals.

The Board found that whether UW Claim 1 is narrow or broad, there is no "interference-in-fact" with Lilly's claims. The Board tested both of Lilly's proposed claim constructions for interfering subject matter. A32-4. But since neither construction yielded the "same patentable invention" as any of Lilly's claims, it was unnecessary to choose one of the two constructions as "definitive." The Board did not abuse its discretion in declining to make the unnecessary choice.

The question before the Board was whether UW Claim 1 interferes with any of Lilly's claims. The Board answered that neither of the potential constructions for UW Claim 1 interferes with Lilly's claims. Thus, there was no need for the Board to endorse one construction over the other. Under these circumstances, if the Board had made an unnecessary choice, the choice would have been dictum. *In re McGrew*, 120 F.3d 1236, 1238, 43 USPQ2d 1633, 1635 (Fed. Cir. 1997) ("dictum consists, inter alia, of statements in judicial opinions upon a point or points not necessary to the decision of the case"). A later decision maker would be free to disregard the unnecessary construction. *Id*.

CONCLUSION

The Board plainly did not err in determining under Rule 601(n) that UW Claim 1 was not the "same patentable invention" as Lilly's species Claim 2.

Therefore, because there was no "interference-in-fact" under Rule 601(j), the Board properly discontinued the interference.

Respectfully submitted,

February 4, 2003 JAMES A. TOUPIN

General Counsel

JOHN M. WHEALAN

Solicitor

Of Counsel SCOTT R. McINTOSH

MARK S. DAVIES *Attorneys*

Department of Justice

STEPHEN WALSH HENRY G. SAWTELLE

Associate Solicitors

P.O. Box 15667

Arlington, Virginia 22215

703-305-9035

Attorneys for the Director of the

United States Patent and Trademark Office

Interference Rules Discussed In This Brief

37 C.F.R. § 1.601:

(f) A *count* defines the interfering subject matter between two or more applications or between one or more applications and one or more patents. When there is more than one count, each count shall define a separate patentable invention. Any claim of an application or patent that is designated to correspond to a count is a claim involved in the interference within the meaning of 35 U.S.C. 135(a). . . .

- (i) An *interference* is a proceeding instituted in the Patent and Trademark Office before the Board to determine any question of patentability and priority of invention between two or more parties claiming the same patentable invention. . . .
- (j) 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.

(n) 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 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."

(Italics in original).

RULE 32(a)(7)(C) CERTIFICATE OF COMPLIANCE

I certify pursuant to Fed. R. App. Proc. 32(a)(7) that the foregoing brief complies with the type-volume limitation. The total number of words in the foregoing brief, excluding the table of contents and table of authorities, is 5577 as calculated by the word processing program used to prepare the brief.

Stephen Walsh Associate Solicitor

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of January 2003, I served the foregoing BRIEF OF *AMICUS CURIAE*, THE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE upon counsel by causing two copies to be delivered by express mail to:

Plaintiff's Counsel

Charles E. Lipsey Kenneth J. Meyers Deborah Katz Finnegan, Henderson, Farabow, Garrett & Dunner, LLP 1300 I St., NW Suite 700 Washington DC 20005 (202) 408-4000

Defendant's Counsel Henry N. Wixon Hale and Dorr, LLP 1455 Pennsylvania Ave., NW Washington DC 20004 (202) 942-8459 Of Counsel Brian P. Barrett Steven P. Caltrider Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46282 (317) 276-7243

Stephen Walsh Associate Solicitor