

United States Court of Appeals for the Federal Circuit

02-1610
(Interference No. 104,733)

ELI LILLY & CO.,

Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

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Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

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DECIDED: July 3, 2003

Before MICHEL, LOURIE, and GAJARSA, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA. Circuit Judge LOURIE dissents.

GAJARSA, Circuit Judge.

This is an appeal from a patent interference proceeding before the United States Patent and Trademark Office (“PTO”) Board of Patent Appeals and Interferences (“Board”). The Board granted the Board of Regents of the University of Washington’s (“UW’s”) motion declaring that no interference-in-fact existed on the grounds that the invention of the corresponding claims of U.S. Reissue Application No. 09/185,663 (“the ‘663 reissue application”) to Eli Lilly & Co. (“Lilly”) are separately patentable over that of U.S. Patent No. 5,302,529 (“the ‘529 patent”) assigned to UW. Bd. of Regents of the Univ. of Wash. v. Eli Lilly & Co., Patent Interference No. 104,733 (Bd. Pat. App. & Int. June 11, 2002). Because the Director of the PTO’s (“Director’s”) interpretation of 37 C.F.R. § 1.601(n) as establishing a “two-way” test for determining whether two parties are claiming the “same patentable invention” is neither plainly erroneous nor inconsistent with the regulation, and the Board committed no reversible error in applying the two-way test to determine that the ‘529 patent and the corresponding claims of the ‘663 reissue application do not define the same patentable invention, we affirm.

I. BACKGROUND

On November 4, 1998, Lilly filed the ‘663 reissue application to surrender its own U.S. Patent No. 4,775,624 (“the ‘624 patent”) and requested an interference between its reissue application and the ‘529 patent. The Board declared an interference on August 7, 2001 between the ‘663 reissue application and the ‘529 patent. The claimed subject matter relates to a complementary deoxyribonucleic acid (“cDNA”) sequence that codes for human protein C, which plays an important role in the regulation of blood coagulation and generation of fibrinolytic activity *in vivo*. Lilly filed new claims 1-82 and 84-90 of the ‘663 reissue application and requested that only claim 3 of the ‘529 patent be designated as corresponding to the sole count in the interference: “A plasmid or transfer vector of Foster claim 3 [of the ‘529 patent].”

Claim 1 of the ‘529 patent, which is the independent claim from which claim 3 depends, reads:

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.

'529 patent, col. 6, ll. 48-52.

Claim 3 recites:

3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp [base pair] 127 to bp 1383.

Id. at col. 6, ll. 57-59.

UW's '529 patent was a continuation of, and was accorded the benefit of, U.S. Patent No. 4,968,626 (issued Nov. 6, 1990), which was filed on August 15, 1985. Lilly's '663 reissue application was accorded the benefit of the February 8, 1985 filing date of the '624 patent (issued Oct. 4, 1988). Accordingly, in the declaration of interference in which claim 3 of the '529 patent was the interference count, Lilly was made the presumptive senior party.

During the preliminary motions period, UW filed a motion for judgment on the ground that there is no interference-in-fact, explaining that the parties' cDNA molecules have different sequences, i.e., chemical structures. The Board agreed that the evidence established the differences and found that Lilly's claims do not define the same patentable invention as claim 3 of the '529 patent. Thus, the Board granted UW's motion for no interference-in-fact and dismissed the interference.

After failing to instigate an interference with the '529 patent based upon claim 3, Lilly filed a motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as also corresponding to the sole count in the interference. Lilly proposed two alternative constructions of claim 1 of the '529 patent: (1) a narrow construction claiming the specific cDNA sequence recited in Figure 3 of the '529 patent ("species claim construction"), and (2) a broad construction claiming any cDNA sequence that codes for human protein C ("genus claim construction"). Applying a two-way test pursuant to its regulation, 37 C.F.R. § 1.601(n), the Board found that, whether claim 1 of the '529 patent is construed as a genus or as a species, the corresponding claims of the '663 reissue application do not define the "same patentable invention" as claim 1 of the '529 patent, and determined that there is no interference-in-fact between the corresponding claims of the '663 reissue application and claim 1 of the '529 patent. Accordingly, the Board dismissed as moot Lilly's motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as also corresponding to the count. Lilly timely appealed to this court, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. STANDARD OF REVIEW

An agency's interpretation of its own regulations is entitled to substantial deference, and that interpretation will be accepted unless it is plainly erroneous or inconsistent with the regulation. Auer v. Robbins, 519 U.S. 452, 461-62 (1997) (citing Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945)); Am. Express Co. v. United States, 262 F.3d 1376, 1382 (Fed. Cir. 1996).

This court reviews a Board decision pursuant to the permissive rules governing a patent interference proceeding for abuse of discretion. Abrutyn v. Giovanniello, 15 F.3d 1048, 1050-51 (Fed. Cir. 1994) (citing Gerritsen v. Shirai, 979 F.2d 1524, 1527-28 (Fed. Cir. 1992)). An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision. Id. This court reviews the legal conclusion of obviousness without deference. In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Anticipation is a question of fact, and this court upholds the decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. In re Hyatt, 211 F.3d 1367, 1371-72 (Fed. Cir. 2000).

III. DISCUSSION

A. 35 U.S.C. § 135(a)

This case presents the question of whether the Director's two-way test 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 presumptive senior party allegedly anticipates a genus claim to a presumptive junior party. We also consider whether the Board reasonably has applied the two-way test to dismiss as moot a motion to redefine the interfering subject matter by designating a claim as corresponding to a count.

Pursuant to authority granted by 35 U.S.C. § 135, the Director established the current interference rules to implement the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, §§ 201-02. Patent Interference Proceedings, 49 Fed. Reg. 48,416 (Dec. 12, 1984); 37 C.F.R. § 1.601-1.690 (2003). 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 (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). 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. Barton v. Adang, 162 F.3d 1140, 1144 (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 (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 mandatory language only instructs the Board of its jurisdiction over an active interference. See id.

B. 37 C.F.R. § 1.601(n)

Lilly concedes that 35 U.S.C. § 135(a) permits some discretion, and Lilly also does not raise any general challenge to the Director's reliance on the two-way test to determine whether two parties are claiming the "same patentable invention." Lilly, however, argues that the Director's discretion under 35 U.S.C. § 135(a) is bridled by statutory mandate that requires issuance of only one patent to the first inventor. See 35 U.S.C. § 102(g) (2000). Specifically, where a genus claim to a presumptive junior party is allegedly anticipated by a species claim to a presumptive senior party, Lilly argues that the proper test for whether two claims are the same patentable invention is a "one-way" test, i.e., the claimed invention of Party A is the same patentable invention as the claimed invention of Party B when the claimed invention of Party A anticipates or renders obvious the claimed invention of Party B, or the claimed invention of Party B anticipates or renders obvious the claimed invention of Party A.

We conclude that the Board properly rejected Lilly's arguments. Under regulations promulgated by the Director, an interference proceeding is declared when two parties are claiming the "same patentable invention." 37 C.F.R. § 1.601(i). According to the regulations, an "interference-in-fact" exists only if both parties to an interference have at least one claim that defines the "same patentable invention." Id. § 1.601(j). The phrase "same patentable invention" is defined 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."

Id. § 1.601(n). The first sentence of § 1.601(n) states that "same patentable invention" means that the invention of one party anticipates or renders obvious the other party's invention. Section 1.601(n) also defines "separate patentable invention" to mean that the invention of one party is new and nonobvious in view of the other party's invention.

The Director, in an amicus brief, interprets § 1.601(n) as requiring a two-way test to determine whether two parties

claim the “same patentable invention.” The two-way test assures that an interference proceeding will be conducted only when warranted. The Director’s approach rejects a wooden requirement under the overinclusive one-way test of declaring an interference proceeding where a species claim allegedly anticipates a genus claim. If the interference proceeding, however, leads to a conclusion that the genus claim was invented first, it is possible that both the genus and the species are separate patentable inventions. Thus, the Director’s two-way test avoids the proliferation of unnecessary, wasteful interference proceedings concluding that both parties are entitled to patents in situations in which the claimed inventions do not define the same patentable invention, but merely overlap in scope. This is the clear application of discretion that is inherent in the authority granted pursuant to 35 U.S.C. § 135(a) of the statute.

Because the two-way test is an interpretation of the Director’s own regulations, the Director’s interpretation of them is controlling unless “plainly erroneous or inconsistent with the regulation.” Auer, 519 U.S. at 461 (citing Seminole, 325 U.S. at 414); see also United States v. Cleveland Indians Baseball Co., 532 U.S. 200, 220 (2001) (giving “substantial judicial deference” to the Internal Revenue Service’s reasonable longstanding interpretation of its own regulations); Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (noting that the agency’s interpretation must be given “controlling weight unless it is ‘plainly erroneous or inconsistent with the regulation’” (quoting Seminole, 325 U.S. at 414)); Udall v. Tallman, 380 U.S. 1, 16 (1964) (stating that when “an interpretation of an administrative regulation [is required,] a court must necessarily look to the administrative construction of the regulation if the meaning of the words used is in doubt” (citing Seminole, 325 U.S. at 413-14)); see generally Richard J. Pierce, Jr., Administrative Law Treatise § 6.11 (4th ed. 2002). We have formulated the degree of this deference, under our jurisprudence, variously as “substantial,” Am. Express, 262 F.3d at 1382-83, and, in the context of a ruling of the Board, as “considerable respect,” Kubota v. Shibuya, 999 F.2d 517, 520 (Fed. Cir. 1993) (citing Ford Motor Credit Co. v. Milhollin, 444 U.S. 555, 566 (1980)). See also Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377, 1381 (Fed. Cir. 2002); Morganroth v. Quigg, 885 F.2d 843, 848 (Fed. Cir. 1989) (stating that the Director’s “interpretation of [the regulatory provisions governing abandonment and revival of patent applications] is entitled to considerable deference.”). But see Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co., 272 F.3d 1365, 1370 (Fed. Cir. 2001) (subjecting the PTO’s interpretation of its own reissue rule to a de novo standard of review), petition for cert. filed, 71 U.S.L.W. 3191 (U.S. Sep. 11, 2002) (No. 02-429).

The deferential standard of Seminole is easily met here.^[1] The critical phrase “assuming invention B is the prior art with respect to invention A” comfortably bears the meaning the Director assigns. Because it is not conclusively known which of the two inventions is the prior art and the critical phrase does not require that invention B is the invention of the presumptive senior party, the Director may interpret the phrase to mean that both UW and Lilly may be the assumed “prior art” invention B. Thus, the claimed invention of Party B (UW) is assumed to be prior art vis-à-vis Party A (Lilly) and the claimed invention of Party B (Lilly) is assumed to be prior art vis-à-vis Party A (UW). Thus, under the Director’s chosen two-way test, to determine whether two parties are

claiming the “same patentable invention,” the claimed invention of Party B (UW) must anticipate or render obvious the claimed invention of Party A (Lilly) and the claimed invention of Party B (Lilly) must anticipate or render obvious the claimed invention of Party A (UW). In the circumstances of this case, where the agency’s interpretation of its own regulation is at least as plausible as competing ones, there is little, if any, reason not to defer to the agency’s construction.

Besides being textually defensible, the Director’s reading of 37 C.F.R. § 1.601(n) comports with the PTO’s Notice of Final Rule that accompanied the promulgation of the regulation. 49 Fed. Reg. at 48,433. According to the Notice of Final Rule, the PTO addressed the issue of genus and species claims by stating that genus and species claims define “separate patentable inventions” if the species is “separately patentable from the genus.” *Id.* at 48,433 (“[T]he standard of patentability will not be applied ‘on a mutual basis.’ Thus, if a species is patentable over a genus, the species is a ‘separate patentable’ invention from the genus.”).

Furthermore, the two-way test for determining whether two parties claim the “same patentable invention” is reasonable and consistent in light of the precedent concerning genus/species inventions. On the one hand, this court has 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 & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001), *cert. denied*, 122 S. Ct. 913 (2002). On the other hand, earlier disclosure of a genus does not necessarily prevent patenting a species member of the genus. *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001).

A primary issue unleashed by application of the two-way test has been whether, under that test, an “interference-in-fact” should exist whenever there exists a theoretical possibility of an interference, or rather only when the parties’ claims define the “same patentable invention.” This court’s case law suggests that the two-way test is 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. On the other hand, 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, but a reading which in the Director’s discretion he has chosen not to accept.

While Lilly’s objections would perhaps support an alternative one-way test where a species claim to a presumptive senior party allegedly anticipates a genus claim to a presumptive junior party, we cannot conclude that they compel it. The Director’s view that a presumptive senior party with a species claim and a presumptive junior party with a genus claim are not so differently situated with regard to determining a separate patentable invention as to require revision of the Director’s long-standing two-way test simply cannot be said to be unreasonable. Accordingly, we hold that the Director’s interpretation of 37 C.F.R. § 1.601(n) as establishing a two-way test for determining whether two parties are claiming the “same patentable invention” is neither plainly erroneous nor inconsistent with the language of the regulation.

C. Motion to Designate Claim 1 of the '529 Patent as Corresponding to the Count

One issue remains unresolved: Lilly asks this court to vacate the Board’s dismissal of Lilly’s motion under 37 C.F.R. § 1.633(c)(3) to redefine the interfering subject matter by designating claim 1 of the '529 patent as corresponding to the count, because Lilly believes the Board manifestly erred by not definitively construing the claim before applying the two-way test. While in many cases this proposition is correct, for the reasons given below, it is possible under the particular circumstances of this case for the Board to dismiss the motion to designate claim 1 of the '529 patent as corresponding to the count even if the claim is not definitively construed.

“A count defines the interfering subject matter between two or more applications or between one or more applications and one or more patents.” 37 C.F.R. § 1.601(f). Typically, the PTO determines which claims correspond to the count in order to determine the subject matter of the interference. *Id.* (“Any claim of an application or patent that is designated to correspond to a count is a claim involved in the interference . . .”); *id.* § 1.603. In determining whether it is proper to designate an application or patent claim to correspond to a count, the pertinent inquiry is whether that “claim defines the same patentable invention as another claim whose designation as corresponding to the count the moving party does not dispute.” *Id.* § 1.637(c)(3)(ii). In that regard, what constitutes the “same patentable invention” is defined by 37 C.F.R. § 1.601(n), which was formulated to determine the extent of interfering subject matter as between applications (or a patent application and an issued patent) of potentially conflicting parties. *See In re Van Geuns*, 988 F.2d 1181, 1185 (Fed. Cir. 1993). Accordingly, the two-way test promulgated pursuant to 37 C.F.R. § 1.601(n), as discussed above, Part III.B,

supra, is applied to determine whether a claim is properly designated to correspond to the count.

That the Board failed definitively to construe claim 1 of the '529 patent is plain enough. To the extent that any procedural error occurred, however, we conclude that the Board did not commit reversible error in this case because the Board applying the two-way test found that, whether construed broadly or narrowly, claim 1 of the '529 patent does not define the same patentable invention as the corresponding claims 1-82 and 84-90 of the '663 reissue application, whose correspondence to the count Lilly does not dispute. The Director's two-way test is usefully illustrated by reference to this case.

First, with respect to the species claim construction of claim 1 of the '529 patent proposed by Lilly, the Board found no interference-in-fact because the specific cDNA sequence of claim 1 of the '529 patent does not teach or suggest the cDNA sequences claimed in the corresponding claims of the '663 reissue application. Because the cDNA sequences claimed in the corresponding claims of the '663 reissue application are not anticipated by and not obvious over a narrowly construed claim 1 of the '529 patent (assuming the '529 patent is the prior art), the cDNA sequences claimed in the '663 reissue application do not define the same patentable invention. Thus, under the species claim construction as proposed by Lilly, the Board found that Lilly failed to carry its burden to show that claim 1 of the '529 patent should be designated as corresponding to the count.

Similarly, with respect to the genus claim construction of claim 1 of the '529 patent proposed by Lilly, the Board found no interference-in-fact because the evidence presented failed to teach or suggest the selection of the cDNA sequences claimed in the corresponding claims of the '663 reissue application from among the vast number of cDNA sequences potentially encompassed by a broadly construed claim 1 of the '529 patent. Because the cDNA sequences claimed in the corresponding claims of the '663 reissue application are not anticipated by and not obvious over a broadly construed claim 1 of the '529 patent (assuming the '529 patent is the prior art), the cDNA sequences claimed in the '663 reissue application do not define the same patentable invention. Thus, under the genus claim construction as proposed by Lilly, the Board also found that Lilly failed to carry its burden to show that claim 1 of the '529 patent should be designated as corresponding to the count.

The Board therefore tested both of Lilly's proposed claim constructions for interfering subject matter. Because neither construction yielded the same patentable invention as any of the corresponding claims of the '663 reissue application, however, it was unnecessary for the Board to adopt either one of the two claim constructions proffered by Lilly as definitive. Accordingly, we hold that the Board did not commit reversible error when it dismissed as moot Lilly's motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as corresponding to the count, because there was no interference-in-fact based on either of the two claim constructions proposed by Lilly of claim 1 of the '529 patent. Based on this procedure, namely accepting both constructions proposed by Lilly of claim 1 of the '529 patent and finding that upon either claim construction no interference-in-fact need be declared, there was no need by the Board to definitively construe the claim.

IV. CONCLUSION

The issue is not without its difficulties whichever way we turn. Though not the sole permissible one, the Director's interpretation of 37 C.F.R. § 1.601(n) as establishing a two-way test for determining whether two parties claim the same patentable invention is neither plainly erroneous nor inconsistent with the regulation. The discretionary authority granted to the Director in establishing interferences must be given considerable respect and, when it is neither plainly erroneous nor inconsistent with the promulgated regulation, cannot be second-guessed by this court and must be affirmed. We also hold that the Board committed no reversible error in applying the two-way test to determine that the '529 patent and the corresponding claims of the '663 reissue application do not define the same patentable invention. The judgment of the Board is

AFFIRMED.

United States Court of Appeals for the Federal Circuit

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LOURIE, Circuit Judge, dissenting.

I agree that the Director has discretion whether or not to declare an interference. The statute, 35 U.S.C. § 135, expressly provides that “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.” (emphases added). However, that discretion is not unlimited. It is cabined by the requirement that it not be exercised contrary to the statute under which the Director operates the PTO, and, of particular importance here, the Director must exercise his discretion in a manner that complies with the Patent Office rules of practice.

The Board of Patent Appeals and Interferences here declined to declare an interference between Lilly’s reissue application and the University of Washington’s patent on the ground that a two-way test applies for determining whether the claims presented by the parties create an interference-in-fact, and, under that test, the parties do not claim the same invention. In so holding, the Board relied on its own decision in Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999), and its strained interpretation of 37 C.F.R. § 1.601(n) (“Rule 601(n)”) set forth therein. The Board also either failed to consider or chose to ignore the fact that, on the record, Lilly is senior to UW.

I believe 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. UW and the majority opinion argue that the PTO’s comments in promulgating its interference rules should be considered in our interpretation of the rules, but, when they are contrary to their plain meaning, such comments cannot alter the meaning of the rules.

The Board found that there was no interference-in-fact between claims 1-82

and 84-90 of Lilly's U.S. Reissue application 09/185,663, on the one hand, and claims 1 and 3 of UW's issued '529 patent, on the other. Rule 601(j) (i.e., 37 C.F.R. § 1.601(j)) defines the existence of an interference-in-fact in terms of whether or not the parties claim the "same patentable invention," a term that is defined in Rule 601(n). Rule 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."

(second emphasis added).

In each case, 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.

In the case before us, the parties agree that UW's claim 3 is patentably distinct from Lilly's claims 1-82 and 84-90, even though the sequences they claim differ from each other only in two codons out of 419 and yield the same peptide product. Hence, they do not claim the same invention and there is no interference-in-fact with respect to those claims.

As for UW's claim 1, the Board did not construe that claim to determine whether it is generic or directed to a species. Although Lilly has not asked us to construe claim 1 as a generic claim, it asserts that it was error for the Board not to construe the claim at all. Claim construction is a matter of law and construction of claim 1 is necessary to the resolution of this appeal. Claim 1 is directed to a nucleic acid plasmid or vector comprising cDNA coding for a specified 419 amino acid sequence shown in Figure 3 of the patent. Given the degeneracy of the genetic code, the parties agree, or at least do not contest, that the indicated 419 amino acid sequence can be coded for by more than 10^{23} different cDNA sequences. Thus, it is clear that claim 1 covers all of those cDNA sequences, and must therefore be construed as generic.

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. 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 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.

The majority and the Director urge that upholding the Board's decision would avoid unnecessary interferences, which it is said are a burden on the Patent Office. The answer to that assertion is that it is the job of the Office, which has the expertise to evaluate contending claims for patent, to determine which of those claims have priority and should issue as patents. It is clearly more efficient for even an overburdened Patent Office to make determinations in the arcane world of interferences than for the overburdened courts to do so.

In the present case, affirmance may well lead to a prolonged action in a district court unaccustomed to evaluating interference issues involving cDNA sequences, whereas reversal would result in the more experienced Patent Office determining the respective rights of the parties. Such a determination would likely not be overturned by the courts, see In re Gartside, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir. 2000), thereby leaving the first and most important determination of a complex factual matter in the tribunal best able to carry it out.

In summary, the Board abused its discretion by interpreting Rule 601(n) to require a two-way test for determining when separate patentable inventions are involved and by failing to consider the effective filing dates of the respective parties. I would therefore reverse the Board's decision finding no interference-in-fact.

[1] To reach Seminole deference, a court must first address the straightforward Chevron question, if presented, of whether a procedural regulation promulgated by the PTO violates the statute. Merck & Co. v. Kessler, 80 F.3d 1543, 1549 (Fed. Cir. 1996) (stating that 35 U.S.C. § 6(a) authorizes the Director to promulgate procedural but not substantive regulations); see also Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). Because Lilly does not dispute the validity of the regulation, we only address the Seminole question of whether the agency's interpretation is consistent with the regulation.