

Comment Responsive to
Notice of Proposed Rule Making 68 FR 66689, dated November 26, 2003,
concerning Proposed Rule §41.203(a)

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I. This comment addresses proposed Rule § 41.203(a), which revises the definitions currently provided in 37 CFR §§ 601(j) and 601(n) concerning interfering subject matter. The proposed rule reads:

(a) Interfering subject matter. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and *vice versa*.

The proposed rule codifies the conclusions of *Winter v. Fujita*, 53 USPQ2d 1234 (BPAI 1999), and *Eli Lilly v. Bd. of Regents of U. of Washington*, 334 F.3d 1264, 67 USPQ2d 1161, 1163 (Fed. Cir. 2003) regarding interferences under 35 U.S.C. § 135 and of *Medichem v. Rolabo*, 353 F.3d 928, 69 USPQ2d 1283 (Fed. Cir. Dec. 23, 2003) concerning civil actions between interfering patents under 35 U.S.C. § 291. Specifically, these decisions announced that an interference or an action for interfering patents in Federal District Court could be pursued only if the so-called two-way test were satisfied. The two way-test is codified by the words “*vice versa*” in the proposed rule.

II. This comment respectfully submits that the rules of law announced in the *Eli Lilly* and *Medichem* decisions places the United States in violation of the Uruguay Round GATT Treaty. Codification of that result would continue the violation. Therefore, the proposed rule should be revised to provide avoid such violations.

This comment begins by reviewing the circumstances where the distinction between the one-way and the two-way tests becomes critical. Consider parties A and B each of whom has conceived and reduced to practice a compound before the priority date of the other. Both parties would be entitled to claims to the compound upon submission of 37 CFR § 131 Declarations. If both parties claim the specific compound, an interference would be declared and the first inventor would be determined. However, consider the result when the second inventor, B, claims not the species but a genus containing the species, while the first inventor claims the species. Provided the species is patentable in view of the genus, a circumstance that is common in the pharmaceutical arts, an interference would not now be declared. B’s receiving an award of priority as to the genus would not affect A’s entitlement to the species claim. The two-way test is not met and no interference can be declared. The award of priority to A would, of course, deprive B of entitlement to the generic claim, but that fact only satisfies one prong of the two-way test.

The issue can be usefully viewed as a procedural matter affecting the allocation of judicial and Patent Office resources. The sole substantive issue is the validity of each party's claim. Whether that validity is determined in an infringement action or separately in an interfering patent suit does not affect the patentee's substantive rights. Thus, in the above example if A invented its species in the United States prior to B's invention of the genus, then B's generic claim would fall whether or not A is himself sought a patent much less claimed the species, so long as the invention was not abandoned, suppressed or concealed. 35 U.S.C. § 102(g)(2). The questions whether the Patent Office or a Federal District Court is the proper forum, and if the District Court, whether priority should be settled prior to any party's alleged or threatened infringement of some claim, involve only considerations of judicial and administrative economy, not substantive rights.

III. However, a substantive issue arises when one party's invention was made outside of the United States. Evidence of an inventor's acts outside the United States are admissible to show a date of invention in a priority contest to which the inventor is a party under §135 or § 291. 35 U.S.C. 102(g)(1). Evidence of inventive acts outside of the United States cannot be used to show invalidity. 35 U.S.C. § 102(g)(2)

IV. Consider the same hypothetical case as above where one of the inventors is foreign. Again each inventor reduced a species to practice before priority date of the other and after January 1, 1996, the earliest date that acts in WTO countries can be used to show priority. If both inventors claim the species an interference is proper and the second inventor could not obtain a generic claim dominating the species claim of the other. If the domestic party concludes that its priority case will fail, however, it may disclaim or cancel any species claim and, provided the domestic party can otherwise validly claim a genus broader than the foreign party could claim, the domestic party could obtain and enforce a claim to that genus despite the prior invention of the other party. Under these circumstances only the one-way test would be met. There would be no interference and the foreign party's actual reduction to practice would not be prior art against the generic claim. The foreign party could, of course also obtain a generic claim by the same strategy. However, the foreign party's generic claim could not be enforced against the domestic party because of the domestic party's § 102(g)(2) defense.

Accordingly, as between a domestic inventor and a foreign inventor, the domestic inventor may be able to obtain and enforce a generic patent claim, even if the domestic inventor were not the first inventor of a species within the genus, while the foreign inventor could not enforce such a generic claim *mutatis mutandis*.

V. The Uruguay Round Treaty of the General Agreement on Trade and Tariffs contains Annex 1C, entitled "Agreement on Trade-Related Aspects of Intellectual Property Rights." (the Annex)

Article 3.1 of the Annex commits the United States as a Member as follows

Each Member shall accord the nationals of other Members treatment no less favorable than it accords its own nationals with regard to the protection³ of intellectual property, subject to the exceptions already provided in [not here relevant.]

The term protection is defined as follows in footnote 3.

For the purposes of Articles 3 and 4, “protection” shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights addressed in this agreement.

Article 27 of the Annex requires

[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, . . .

V. The foregoing example illustrates, the treatment accorded the nationals of other members is less favorable than that accorded to United States nationals with regard to the acquisition and enforcement of patent rights.

Accordingly, when proposed Rule §41.203, which will governs the availability of § 135 interferences, and, under *Medichem*, also § 291 interfering patent actions, is combined with the limitations on the use of foreign acts to prove a date of invention under § 102(g)(2) results in a violation of the Article 3.1 of the Annex.

The foregoing example also illustrates discrimination in the availability and enjoyment based on the place of invention. Under the present United States law and under proposed Rule § 41.203 a first inventor inside of the United States cannot be subject to a dominating generic claim, while a first foreign inventor may. There is discrimination in the enjoyment of patent rights based on place of invention. Therefore, proposed Rule § 41.203 results in violation of Article 27 of the Annex.

VI. This commentator submits that the responsibility for the corrective action to prevent violations of the Uruguay Round Treaty lies initially with the Director. *Lilly* expressly relies on the Director’s discretion to determine the proper test to determine when an interference under §135 may be declared. *Medichem* inasmuch as it relies on the interference rules to determine the scope of the interfering patent statute, § 291, implicitly relies upon the Directors discretion.

The Director’s discretion is limited by the treaty obligations of the government of the United States. Accordingly, the commentator respectfully submits that the Director’s discretion permit an interference by a one-way test if a party can show that application of the two-test results in discrimination as to place of invention and or results in a United States national having opportunity to obtain and enjoy patent rights not available to the nationals of other members.

A revised § 41.203 is suggested

(a) Interfering subject matter. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and, **unless the priority case of at least one party to the**

interference would foreseeably rely on acts outside of the United States, *vice versa*.

By permitting foreign inventors to enter an interference or interfering patent suit in Federal Court under the one-way test, the revised Rule § 41.203, would restore substantive equality between foreign and domestic inventors.