

Patent Prosecution and Joint Ownership of United States Patents

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Alliances in the biotechnology and pharmaceutical industries have become a necessity for many companies that are faced with the obstacles associated with identifying and developing potential drugs. Thus, many patentable discoveries are resulting from collaborations of researchers employed at different companies. In this article, we discuss the impact of a decision from the Court of Appeals for the Federal Circuit ("the Federal Circuit") on the prosecution of patent applications before the United States Patent and Trademark Office (USPTO) that arise out of such collaborations. In particular, as discussed below, the Federal Circuit has created a legal setting whereby the allocation of ownership rights can be dramatically altered merely by prosecuting claims directed to different inventions in the same patent application, rather than in separate patent applications.

In *Ethicon, Inc. v. U.S. Surgical Corp.*,¹ the patent at issue contained fifty five claims and listed one individual — In-Bae Yoon — as the sole inventor.² Yoon granted Ethicon, Inc. an exclusive license to the patent,³ and together Yoon and Ethicon sued U.S. Surgical Corp. for infringement of two of the fifty-five claims.⁴ During the litigation, the defendant U.S. Surgical teamed up with Young Jae Choi, who maintained that he had erroneously been omitted from inventorship.⁵ Choi granted U.S.

Surgical a retroactive license, and U.S. Surgical moved to correct the inventorship.⁶ U.S. Surgical argued that Choi was a co-inventor of four of the fifty-five claims in the patent.⁷ The district court agreed that Choi was indeed an inventor of two claims,⁸ and later dismissed Ethicon's infringement complaint.⁹ On appeal, the Federal Circuit affirmed the lower court's dismissal of the complaint, on the ground that Choi, as a joint owner of the patent, had not consented to the infringement action against U.S. Surgical.¹⁰

Pursuant to the 1984 amendment to the inventorship statute,¹¹ inventorship is determined on a claim-by-claim basis, and to be an inventor, one must contribute to the conception of the subject matter of at least one claim.¹² It is important to note that Choi was not an inventor of the claims which Ethicon alleged U.S. Surgical had infringed. However, over a sharp dissent,¹³ the Federal Circuit interpreted the joint ownership statute¹⁴ to mean that, unlike inventorship, patent ownership is not determined on a claim-by-claim basis. According to the Federal Circuit, Choi enjoyed joint ownership status of not only the subject matter of the two claims he invented, but also the subject matter of the fifty-three claims directed to subject matter he had *not* invented.

A detailed review of the Federal Circuit's holding in *Ethicon* has been provided elsewhere.¹⁵ To illustrate this decision's impact on prosecution of patent applications, assume the following hypothetical situation. Two inventions — Compound X and a method of using Compound X for reducing inflammation — arise out of a collaboration between Able and Baker, who are employed at Acme and BoomCo, respectively. If Able and Baker are co-inventors of both inventions, the *Ethicon* decision would have little impact on the prosecution of one or more applications claiming these inventions. Regardless of whether Compound X and the method of reducing inflammation are claimed in the same application or in separate applications, Acme and BoomCo would each jointly own any

patent that issued claiming either invention.

The decision of whether to claim both inventions in one patent application or to pursue them in separate applications becomes critical if Compound X was invented solely by Able, and the method of reducing inflammation was co-invented by Able and Baker together.¹⁶ If Acme controls prosecution, Acme should consider obtaining a first patent claiming only Compound X, and pursuing a second patent claiming the method of reducing inflammation. Acme would be no worse off in terms of its own ownership status (Acme would still own both inventions) and, importantly, would prevent BoomCo from jointly owning a patent to Compound X *per se*.

Thus, if Acme followed this strategy, BoomCo's patent rights would extend only to the method of reducing inflammation. This is very important because, absent a license from Acme, BoomCo would have no right to make, use, or sell Compound X in the United States for any purpose,¹⁷ including the method of reducing inflammation, without infringing the first patent.¹⁸ Prosecuting claims to Compound X and the method of reducing inflammation in separate applications would dramatically limit BoomCo's freedom to operate.¹⁹ In addition, Acme would not have to obtain BoomCo's consent to bring suit based on the first patent against an alleged third party infringer.

In contrast, if BoomCo controls prosecution, then BoomCo should make every effort to obtain a single patent that claims both Compound X and the method of reducing inflammation. Under *Ethicon*, if compound and method claims issued in the same patent, BoomCo would own the subject matter of every claim in the patent, regardless of whether Baker invented the subject matter of every claim. Thus, if compound and method claims issued in the same patent, BoomCo would jointly own not only a claim encompassing the method of reducing inflammation, but also a claim directed to

Compound X *per se*. Of course, owning a claim directed to Compound X *per se* is a decidedly superior property right, since it would not be limited to the method of reducing inflammation. Instead, such a claim would dominate all uses of Compound X.²⁰ Moreover, by virtue of being a joint owner of the first patent claiming Compound X *per se*, BoomCo would have freedom to operate without having to account to Acme.²¹

In practice, patent applicants may not always be free to pursue more than one invention in a single application, because the USPTO often issues restriction requirements,²² which require applicants to elect one out of two or more patentably distinct inventions²³ for further prosecution in the application pending before the examiner. To pursue non-elected inventions that have been withdrawn pursuant to the restriction requirement, applicants are required to file separate divisional applications -- one divisional for each distinct invention.

Thus, in the above hypothetical, if an examiner deemed Compound X and the method for treating inflammation to be distinct inventions, there would be little choice but to pursue the two inventions in separate applications.²⁴ In such a scenario, even if BoomCo controls prosecution, USPTO restriction practice would prevent BoomCo from benefitting from the *Ethicon* holding. However, there are a number of strategies relied on by patent practitioners to get more than one distinct invention examined in the same patent application. For example, for a restriction requirement to be proper, not only must the inventions be distinct, examination of the inventions in one application must create an undue burden on the examiner.²⁵ Thus, where an examiner can be convinced that there would be no undue burden, the patent applicant will be free to prosecute both inventions in the same application, if such a course of action were advisable in light of *Ethicon*.²⁶

Also, in *In re Ochiai*²⁷ and *In re Brouwer*²⁸, the Federal Circuit held that an otherwise

conventional process was patentable if it was limited to making or using a novel and nonobvious product. In light of these two holdings, the USPTO Commissioner published guidelines for examining product and process claims.²⁹ Where product and process claims appear in the same application, the guidelines recognize that an applicant may, pursuant to a restriction requirement, be called on to elect either the product or process for further prosecution.³⁰ However, the guidelines expressly indicate that, "in the case of an elected product claim, rejoinder [of the process claim] will be permitted when a product claim is found allowable and the withdrawn process claim depends from and otherwise includes all the limitations of an allowed product claim."³¹ Thus, in the above hypothetical, even if subject to a restriction requirement, BoomCo would be able to take advantage of the *Ethicon* decision and pursue claims to Compound X and the method of reducing inflammation in the same application. This would simply involve initially electing Compound X for further prosecution pursuant to the restriction requirement, and requesting rejoinder of the withdrawn method claims once the claims to Compound X had been found allowable.

Further, under USPTO election of species practice, patent practitioners routinely obtain allowance of claims directed to distinct "species inventions" examined in the same patent application.³² Finally, where the claims are directed to distinct polynucleotide sequences, the Commissioner has decided to partially waive the requirements of 37 C.F.R. 1.141 *et seq.* and permit a reasonable number (up to ten) of such polynucleotide sequences to be examined in a single application.³³ Thus, USPTO restriction practice notwithstanding, in many instances patent practitioners will be able to fully take advantage of the *Ethicon* holding.³⁴

In summary, under *Ethicon*, the assignee of any inventor named on the face of a patent has joint ownership rights to every claim in the patent, regardless of how many claims the inventor actually

invented. Because patent practitioners are often able to control whether claims are issued in the same patent or in separate patents, the Federal Circuit has created a legal setting whereby the allocation of ownership rights to inventions arising out of collaborations can be dramatically altered by whomever is controlling prosecution. Thus, when forming research collaboration agreements, collaborating institutions should think carefully before relinquishing the right to control patent prosecution to the collaborating partner. At the very least, the right to review all prosecution decisions made by the collaborating partner should be retained.

1. 937 F. Supp. 1015 (D. Conn. 1996), *aff'd*, 135 F.3d 1456 (Fed. Cir. 1998), *cert. denied*, 199 S. Ct. 278 (1998).

2. *See* 937 F. Supp. at 1018.

3. *See Id.*

4. *See* 937 F. Supp. at 1019.

5. *See Id.*

6. *See Id.*

7. *See Id.*

8. *See* 937 F. Supp. at 1036.

9. *See Ethicon, Inc. v. United States Surgical Corp.*, 954 F. Supp. 51, 54 (D. Conn. 1997), *aff'd*, 135 F.3d 1456 (Fed. Cir. 1998); *cert. denied*, 119 S.Ct. 278 (1998).

10. *See* 135 F.3d at 1468.

11. The Patent Law Amendments Act of 1984 (Pub. L. No. 98-622, § 104(a), 98 Stat. 3383, 3384-85 (1984)) amended the first paragraph of 35 U.S.C. § 116 to read in part:

When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though . . . (3) each did not make a contribution to the subject matter of every claim of the patent.

The third criterion in the first paragraph of amended 35 U.S.C. § 116 abrogated the "all-claims" rule that had been adopted by some courts requiring that each named inventor have contributed to each claim of the patent. See W. Fritz Fasse, *The Muddy Metaphysics of Joint Inventorship: Cleaning Up After the 1984 Amendments to 35 U.S.C. § 116*, 5 HARV.J.L. & TECH.153,182 (1992).

12. See *Burroughs Wellcome Co. v. Barr Labs. Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).

13. In her dissent in *Ethicon*, Judge Newman argued that Choi's joint inventorship of only two claims should not have entitled him to joint ownership of all fifty-five claims. According to Judge Newman, "[b]y amending § 116 in order to remove an antiquated pitfall whereby patents were being unjustly invalidated [because not every named inventor conceived of each claim in a patent], the legislators surely did not intend to create another inequity. Apparently no one foresaw that judges might routinely transfer pre-1984 ownership concepts into the changed inventorship law." See 135 F.3d at 1471.

14. The incidents of joint ownership are codified in 35 U.S.C. § 262 as follows:

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import that patented invention into the United States without the consent of and without accounting to the other owners.

15. See Dale L. Carlson & James R. Barney, *The Division of Rights Among Joint Inventors: Public Policy Concerns After Ethicon v. U.S. Surgical*, 39 IDEA - THE JOURNAL OF LAW AND TECHNOLOGY 251 (1999); Dale L. Carlson & James R. Barney, *Who Owns What's In Your Patent?*, INTELLECTUAL PROPERTY TODAY, June 1998, at 8.

16. In representing clients in the biotech and pharmaceutical industries, it has been our experience that subsequently conceived uses for a compound often involve input from one or more collaborators employed at a different company.

17. BoomCo might qualify for one of the exemptions from patent infringement that are recognized under U.S. patent law. For example, 35 U.S.C. § 271(e)(1) exempts from patent infringement activity that reasonably relates to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs or veterinary biological products. Further, *de minimis* activity, if practiced for an experimental purpose and not for profit, is arguably not infringing. See 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03[1] (1999).

18. Even if BoomCo were a joint owner of the second patent (to the method of treating inflammation), BoomCo would still not be able to practice the method of reducing inflammation without infringing the first patent (to Compound X) that is solely owned by Acme. A patent does not grant a patentee the affirmative right to practice an invention. Instead, the patent grant is the right to *exclude* others from making, using and selling the claimed subject matter. See 35 U.S.C. § 154(a)(1) (1996); see also *Kewanee Oil. Co. v. Bicron Corp.*, 416 U.S. 470, 477-78 (1973) ("the patent is granted . . . giving

what has been described as the ‘right of exclusion’”). Thus, if the inventions were claimed in separate patents, whereas Acme would have the right to exclude others (including BoomCo) from making, using, or selling Compound X, BoomCo would have only the right to exclude others (except Acme) from practicing the method of reducing inflammation.

19. Of course, our recommended prosecution strategies might change if there was an existing licensing agreement between Acme and BoomCo, or if inventorship of the two inventions was different than that described in this hypothetical.

20. *See* 35 U.S.C. 271(a) (1994).

21. *See* 35 U.S.C. § 262; *see also* 5 LIPSCOMB'S WALKER ON PATENTS § 19:39, at 464-65 (2d ed. 1986).

The tenant in common may make, use and sell specimens of the patented invention to any extent, and may license others to do so, and neither the tenant nor the tenant's licensees can be enjoined from a continuance in so doing. Nor can any recovery of profits or damages be had against such licensee at the suit of any co-tenant of any such licensor. And no recovery of profits or damages can be had against one co-tenant who, without the consent of the others, has made, used, or sold specimens of the patented thing.

Id. (footnotes omitted). *See generally* Robert P. Merges & Lawrence A. Locke, *Co-Ownership of Patents: A Comparative and Economic View*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 586 (1990).

22. *See* 35 U.S.C. § 121 (1975) and 37 C.F.R. 1.141 (1987) *et seq.*

23. Arguably, for restriction to be proper, not only must the inventions be "distinct", they must also be "independent." *See* 35 U.S.C. § 121 ("If two or more independent *and* distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.") (emphasis added). Similarly, the implementing regulation also reads "independent *and* distinct." *See also* 37 C.F.R. 1.141. However, this express wording in the statute and the rule notwithstanding, in accordance with longstanding USPTO practice, restriction is proper where an examiner can demonstrate *either* independence *or* distinctness. *See* MANUAL OF PATENT EXAMINING PROCEDURE § 802.01 ("The law has long been established that dependent inventions (frequently termed related inventions) . . . may be properly divided if they are, in fact, "distinct" inventions, even though dependent.").

24. Under 37 C.F.R. § 1.144 (1997), applicants can petition to the USPTO Commissioner for review of a restriction requirement that has been made final by an examiner. Further, applicants can seek review of an adverse decision from the Commissioner by writ of mandamus and the Administrative Procedure Act. *See* 4 DONALD S. CHISUM, CHISUM ON PATENTS §§ 11.06[3][a], 12.04[4] (1999). Of course, due to the great cost (in terms of both time and money) associated with pursuing a judicial remedy, it has traditionally made more sense to simply file a divisional application(s). However, in the

wake of *Ethicon*, there may be instances where the cost of pursuing a judicial remedy will be justified.

25. *See* MANUAL OF PATENT EXAMINING PROCEDURE § 803 (1998).

26. As a caveat, convincing an examiner that it would not require an undue burden to examine two or more distinct inventions in a single application can be difficult.

27. 71 F.3d 1565 (Fed. Cir. 1995).

28. 77 F.3d 422 (Fed. Cir. 1996).

29. *See* Guidelines on Treatment of Product and Process Claims, 1184 O.G. 86 (March 26, 1996).

30. *See Id.*

31. *See Id.*

32. Under 37 C.F.R. § 1.146 (1997), if a generic claim embraces more than one patentably distinct species, the examiner may require the applicant to elect a species to which the claim will be restricted if no claim to the genus is found to be allowable. The examiner will then examine the elected species. If the species is patentable, the examiner will examine the other species, until either the full scope of the generic claim has been examined and found to be patentable, or until prior art is found over which a species is *prima facie* unpatentable.

33. *See* 1192 O.G. 68 (November 19, 1996); *see also* MANUAL OF PATENT EXAMINING PROCEDURE § 803.04.

34. Yet another way to have more than one distinct invention examined in the same patent application is to enter the U.S. national phase from an international application filed under the Patent Cooperation Treaty ("PCT"). If there is a common "technical relationship" that links the claims together, under the PCT "unity of invention" standard, all of the claims should be examined together in a single application, even if restriction would have been proper had the application been filed under 35 U.S.C. 111(a). *See* MANUAL OF PATENT EXAMINING PROCEDURE §§ 1850 and 1893.03(d).