



Testimony of Eric K. Steffe
Before the U.S. House Judiciary Committee
Subcommittee on Courts, the Internet and Intellectual Property
Regarding a Bill Proposed by Mr. Smith
Amending 35 U.S.C. §§ 102(f) and 103(c) (CREATE)

June 10, 2003

Summary of Testimony of Eric K. Steffe
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My name is Eric Steffe. I have been practicing biotech patent law for over twelve years. I am pleased to have been asked to testify regarding the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003."

I support this bill because it decreases the barrier to research collaborations between separate institutions. CREATE does this in two ways. First, CREATE picks up where the 1984 amendment to 35 U.S.C. § 103(c) left off. That amendment encouraged the free exchange of ideas between researchers within a single institution by removing §§ 102(f) and (g) as prior art sections for §103. However, it left this barrier in place for collaborations between separate institutions. CREATE completely removes § 102(f) as a prior art section for an obviousness determination under § 103, thereby encouraging communication between inventors. Thus, CREATE recognizes the reality of scientific research today, wherein collaborations between separate institutions are commonplace.

Second, CREATE provides flexibility to such institutions by allowing them to delay the decision to create common ownership until a patent application is filed for the invention from the collaboration. This gives collaborators time after the invention is made to decide whether common ownership is needed to avoid the use of an earlier invention as § 102(e) or (g) prior art for § 103.

In fact, I would go further than the proposed bill by not removing mention of § 102(f) from § 103(c), and by amending § 102(f) to read "[a] person shall be entitled to a patent unless . . . he did not himself invent the subject matter sought to be patented, except that subject matter communicated from a co-inventor shall not be considered prior art under this subsection." My proposal would address, among other things, the potential for pirates to file a patent application for an obvious modification of an invention misappropriated from another party. I believe my proposal more surgically addresses the drawbacks of the current § 103(c) and mitigates unintended consequences.

I. Introduction

Thank you Chairman Smith, Ranking member Berman and distinguished members of the Subcommittee on Courts, the Internet, and Intellectual Property of the United States House of Representatives for giving me the opportunity to testify regarding the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003."

I am a partner at Sterne, Kessler, Goldstein & Fox, P.L.L.C., a law firm in Washington D.C. specializing in intellectual property.¹ I have been practicing biotech patent law for over twelve years and have lectured and published extensively on intellectual property issues arising out of industry collaborations, research tools and exemptions from patent infringement. With colleagues, I first published in 1999 regarding the issue CREATE addresses.² I commend the Committee for taking up the important issue addressed by this Bill.

II. Background

35 U.S.C. §103(a) states in part that "[a] patent may not be obtained [even though the claimed invention may be novel] . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art"³ Thus, a claimed invention must not only be novel, but also be nonobvious to be patentable. Importantly, a combination of prior art references or prior art "events" can be used to formulate an obviousness rejection under § 103.

¹ This testimony reflects the present thoughts of its author, Eric K. Steffe, Esq., and should not be attributed to Sterne, Kessler, Goldstein & Fox P.L.L.C. or any of its former, current, or future clients.

² "Biotech Collaborations and Maximizing Patent Protection: Two Hypotheticals," 27 AIPLA Quarterly Journal 149 (1999). A copy of this article is attached.

³ 35 U.S.C. § 103(a)

The content of the prior art on which a finding of obviousness may be based is defined by subsections of 35 U.S.C. § 102.⁴ Presently, 35 U.S.C. § 103(c) exempts subject matter defined by §§ 102(e), (f) and/or (g) from being used as prior art under § 103(a) when certain conditions are met.

A. *Interplay Between 35 U.S.C. §§ 102(f) and 103*

Whether 35 U.S.C. § 102(f) is a prior art section for the purposes of 35 U.S.C. § 103, thereby making § 102(f) art available for obviousness determinations, has been the subject of much controversy. Under §102(f) a person is not entitled to a patent if "he did not himself invent the subject matter sought to be patented."⁵ Section 102(f) applies not only to public knowledge, but also to private communications, even those made under a secrecy agreement. This has traditionally been considered a derivation provision, the purpose of which is to prevent someone from obtaining a patent on that which was invented by someone else. According to case law, two elements are required for establishing derivation under § 102(f). First, "the named inventor in the patent [must have] acquired knowledge of the claimed invention from another."⁶ Second, there must have been a prior conception of the invention, and the conception must have been communicated.⁷

If § 102(f) is a prior art section for an obviousness analysis, then communications of less than the complete invention can be relied on to reject or invalidate a claim to the invention, under certain circumstances. In other words, viewing § 102(f) as a prior art section means that the contents of a communication can be combined with "traditional" prior art disclosures (journal articles, patents, prior uses, etc.) to render a later claimed invention obvious under § 103.

The case law is in a state of disarray concerning whether a derivation under § 102(f) can be combined with other prior art as the basis for a conclusion that the claimed invention is obvious

⁴ See *In re Yale*, 347 F.2d 995, 1000, 146 USPQ 400, 403 (CCPA 1965); see also *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987)("Before answering Graham's 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102 . . .").

⁵ 35 U.S.C. § 102(f).

⁶ *New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 970 F.2d 878, 883, 23 U.S.P.Q.2d 1622, 1626 (Fed. Cir. 1992).

⁷ See *McSherry v. Giannuzzi*, 227 U.S.P.Q. 868, 872 (Bd. Pat. App. & Int. 1985), *aff'd*, 790 F.2d 95 (Fed. Cir. 1986); see also *Price v. Symsek*, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d 1031, 1033 (Fed. Cir. 1993).

under § 103, and therefore unpatentable. For example, the Federal Circuit and the CCPA have made conflicting statements about this issue in dictum in *New England Braiding*⁸ and *In re Bass*⁹ and in a dissenting opinion in *Lamb-Weston, Inc. v. McCain Foods, Ltd.*¹⁰

Further confusion was created by *Gambro Lundia AB v. Baxter Healthcare Corp.*¹¹ In *Gambro*, referring to the dictum in *New England Braiding*, the lower court concluded that to invalidate *Gambro's* patent under § 102(f), "Baxter did not need to prove communication of the entire conception, but rather only so much of the invention 'as would have made it obvious to one of ordinary skill in the art.'"¹² However, the Federal Circuit held that, its dictum in *New England Braiding* notwithstanding, the lower court's holding was clearly erroneous and "applied the wrong legal standard" because it "introduces incorrectly an obviousness analysis into the test for derivation."¹³

The panel in *Gambro*, which was decided in April of 1997, included Chief Judge Archer and Circuit Judges Rader and Lourie. Later, in August of 1997, a different panel of the Federal Circuit, Circuit Judges Michel, Lourie, and Rader, reached the opposite conclusion in *OddzOn Products, Inc. v. Just Toys, Inc.*¹⁴

⁸ 970 F.2d at 883, 23 U.S.P.Q.2d at 1626 ("To invalidate a patent for derivation of invention, a party must demonstrate that the named inventor in the patent acquired knowledge of the claimed invention from another, or at least so much of the claimed invention as would have made it obvious to one of ordinary skill in the art.")

⁹ 474 F.2d 1276, 1290, 177 U.S.P.Q. 178, 189 (C.C.P.A. 1973) (§102(f) has "no relation to § 103 and no relevancy to what is "prior art" under § 103".).

¹⁰ 78 F.3d 540, 548-49, 37 U.S.P.Q.2d 1856, 1863 (Fed. Cir. 1996)("Derived knowledge can indeed be invalidating [under § 102(f)], but this is not properly described as "prior art", which is defined as actual or presumed public knowledge.")(dissenting opinion).

¹¹ 110 F.3d 1573, 42 U.S.P.Q.2d 1378 (Fed. Cir. 1997).

¹² *Id.* at 1577, 42 U.S.P.Q.2d at 1382.

¹³ *See id.*

¹⁴ 122 F.3d 1396, 43 U.S.P.Q.2d 1641 (Fed. Cir. 1997).

Citing 35 U.S.C. §103(c)¹⁵, the OddzOn panel stated that

[w]hile the statute [§ 103(c)] does not expressly state in so many words that § 102 (f) creates a type of prior art for purposes of §103, nonetheless that conclusion is inescapable; the language that states that § 102(f) subject matter is not prior art under limited circumstances clearly implies that it is prior art otherwise. That is what Congress wrote into law in 1984 and that is the way we must read the statute. ¹⁶

The Federal Circuit in *OddzOn* did not cite *Gambro*, which was decided four months earlier, even though *Gambro* enunciated a different legal standard for derivation. According to the Federal Circuit in *Newell Co., Inc. v. Kenney Manufacturing Co.*,¹⁷ where there is a conflict in statements of Federal Circuit law, the earlier statement prevails unless or until it has been overruled *en banc*.¹⁸ Thus, if the issue of whether § 102(f) is a prior art section is again before the Federal Circuit, it would appear that a subsequent panel (if it followed *Newell*) would presumably be forced to hold in the negative and follow the enablement standard as enunciated by the panel in *Gambro*. In my view, absent legislation, an *en banc* decision will be necessary to fully resolve this issue.

¹⁵ A the time OddzOn was written, § 103(c) provided:

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.

Pub. L. No. 98-622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103(c) (1984)).

¹⁶ 122 F.3d at 1403, 43 U.S.P.Q.2d at 1646.

¹⁷ 864 F.2d 757, 9 U.S.P.Q.2d 1417 (Fed. Cir. 1988).

¹⁸ *See id.* at 765, 9 U.S.P.Q.2d at 1423 (stating that subsequent panel opinions may elaborate and refine and thus advance the evolution of judge made law, but they cannot change the law as established in prior rulings)(citing *U.M.C. Elec. Co. v. U.S.*, 816 F.2d 647, 652 n.6, 2 U.S.P.Q.2d 1465, 1468 n.7 (Fed. Cir. 1987)).

B. Interplay Between 35 U.S.C. §§ 102(e), (g) and 103

In contrast to § 102(f), it is well settled that subject matter defined by §§ 102(e) or 102(g) is available as prior art in an obviousness analysis, subject to the limitations in § 103(c).

Under § 102(e), the disclosure of a U.S. patent application is prior art to subject matter invented by others after its U.S. filing date. However, such an application only becomes eligible for use as prior art upon publication of the application under 35 U.S.C. §122(b), or upon maturation into a patent.¹⁹

Under § 102(g), a person is not entitled to a patent if "before [the patent applicant's] invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it."²⁰

C. The § 103(c) Exemption

In 1984, Congress amended § 103 to disqualify events that fall exclusively within §§ 102(f) or (g) from use as prior art under § 103, if specific conditions are met. This amendment provided in pertinent part:

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.²¹

This amendment was reportedly in direct response to the decision in *In re Bass*,²² which arguably created a disincentive to file patents early and discouraged communication between co-

¹⁹ 35 U.S.C. § 102(e)(1) and (2).

²⁰ 35 U.S.C. § 102(g)(2).

²¹ Pub. L. No. 98-622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103).

²² In *Bass* the CCPA affirmed a rejection of claims in a pending application as obvious over an earlier invention by a different, although overlapping, set of inventors, that qualified as prior art under § 102(g). 474 F.2d at 1291, 177 U.S.P.Q. at 189.

workers.²³ In support of the amendment, commentators argued that "[s]uch encouragement of ignorance defeats a fundamental principle of corporate research - the free exchange of ideas between corporate employees. Moreover, it runs counter to both the policy and the spirit of the patent laws because it discourages both invention and the prompt disclosure of new inventions."²⁴ Thus, recognizing the value of team research within corporations, businesses, and universities, Congress amended §103 to eliminate these obstacles to team research.

In 1999, Congress again amended § 103 by passing the American Inventor's Protection Act ("AIPA"). This amendment enlarged the section 103(c) exemption to include section 102(e). Section 103(c) now provides that

subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.²⁵

Thus, the 1984 and 1999 amendments to § 103 disqualify "subject matter developed by another person" if it meets the following criteria:

- 1) it falls only within the definitions of sections 102(e), (f) and/or (g); and

²³ See *Section by Section Analysis: Patent Law Amendments of 1984*, 98th Cong., 130 CONG. REC. H 10525 (1984), reprinted in, 1984 U.S.C.C.A.N. 5827, 5833.

²⁴ *Patent Law Improvements Act: Hearing on S. 1535 and S. 1841 Before the Subcommittee on Patents, Copyrights, and Trademarks of the Senate Committee on the Judiciary*, 98th Cong., 157 (1984)(prepared statement of John E. Maurer).

²⁵ 35 U.S.C. § 103(c).

2) the subject matter of the prior art and of the claimed invention were:

- a) commonly owned,²⁶
- b) "at the time the [second] invention was made."

III. Some of the Issues Unaddressed by Current § 103(c)

The benefits of having the earliest possible filing date for a patent application encourages filing the application as soon as possible after an initial discovery is made. However, due to the basic nature of biotech and pharmaceutical research, an initial discovery is often less commercially important than later discovered improvements. If the inventors of the later discovered improvements are not all under obligation to assign to the same entity, for example, if they are not employed by the same company, the situation is especially complex.

For example, assume that individuals α and β , employed at Company A, discover that a novel antigen, Antigen A, provides a low level of immunity in mice against a pathogen. Company A files a patent application naming α and β as co-inventors and claims Antigen A and its use as a vaccine against the pathogen. α and β then approach γ , who is employed by Company B, and who specializes in adjuvants. Based on her expertise, γ selects a number of adjuvants for testing. One adjuvant, Adjuvant X, is shown to reproducibly boost the immune response to Antigen A to the extent that nearly all immunized mice are protected from pathogenic challenge. Company A files a second application a year after the filing date of the first application claiming Antigen A/Adjuvant X and its use as a vaccine. Company A plans to market the improvement Antigen A/Adjuvant X as a vaccine for humans. The initial discovery claimed in the first application (the Antigen A compound) would be assigned to Company A. However, since γ is employed at Company B, the improvement (the Antigen A/Adjuvant X composition) would be assigned to both Company A and

²⁶ When the PTO implemented § 103(c) by amending 37 C.F.R. § 1.104, it explained that common ownership by the same "person" or "organization" "would include circumstances where the ownership resided in more than one person and/or organization as long as the applications are owned jointly by the same owners. 50 Fed. Reg. 9368, 9373 (1985)(codified at 37 C.F.R. § pt. 1). In other words, for the § 103(c) exception to apply, there must be an identical "ownership entity" between the subject matter which would otherwise qualify as prior art under §§ 102(f) or (g) and the subsequent invention claimed in the later filed patent application.

Company B.²⁷ Thus, not only would there be a potential obviousness rejection under §102(e)/§ 103 against a claim to the improvement in the second application if the first application were to be published or to issue as a patent, there would also potentially be an obviousness rejection under § 102(g)/§ 103 based on the prior reduction to practice of Antigen A by a and β. Further, if communications between co-inventors during the development of an invention can constitute prior art, there would potentially also be an obviousness rejection under § 102(f)/§ 103 based on a and β's communication of Antigen A to γ. This would arise because the second inventive entity, a, β and γ, could be said to have derived the initial discovery, Antigen A, from the first inventive entity, a and β, rendering the improvement obvious if combined with other prior art subject matter.

Thus, these patentability issues must be considered in advance of collaborations between separate institutions. In the hypothetical, to fall within the exemption of § 103(c), Company A and Company B should have considered an agreement whereby Company B assigned or promises to assign its rights to all inventions arising out of the collaboration to Company A, or vice versa. This would have invoked § 103(c) of the statute by causing, at the time the improvement was made, the improvement and the initial discovery to be "owned by the same person or subject to an obligation of assignment to the same person."²⁸

However, from a business standpoint, agreeing to assign all inventions arising out of the collaboration to Company A may be unacceptable to Company B. This is because each joint owner is an owner of an undivided one-half interest in the patent²⁹ and is said to be at the mercy of the other joint owners.^{30,31}

²⁷ In the eyes of the PTO, Company is a different "ownership entity" than the joint entity of Company A-Company B. Final Rules for Miscellaneous Patent Provisions, 50 Fed. Reg. 9368, 9373 (1985)(codified at 37 C.F.R. § pt. 1).

²⁸ 35 U.S.C. § 103(c).

²⁹ Drake v. Hall, 220 F. 905, 906 (7th Cir. 1915).

³⁰ See 5 E. LIPSCOMB'S WALKER ON PATENTS § 19:39 at 464-65 ("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.") (footnotes omitted). See generally Robert P. Merges and Lawrence A. Locke, *Co-Ownership of Patents: A Comparative and Economic View*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 586 (June

Additionally, all co-owners must join in a patent infringement suit. Further, a "primary interest" of a co-owner is "the interest . . . in being able to license third parties under his or her patent without harassing suits by other co-owners."⁶² Thus, clear advantages flow from being a joint owner of a patent, which may make Company B reluctant to enter into an agreement assigning its rights to inventions arising out of the collaboration to Company A.³³

Moreover, under the Bayh-Dole Act, an institution that receives research funds from the government is severely restricted in its ability to assign rights for an invention developed using those funds. The Bayh-Dole Act established a presumption that contractors (i.e., a university or other non-profit institution that has entered into a funding agreement with a federal agency) will acquire title to patents directed to inventions arising out of federally funded research. If it is a nonprofit institution, the contractor cannot assign its rights in the invention in the United States to a third party without the approval of the federal agency. Thus, if one or both collaborating institutions is subject to this Act, that institution must first obtain approval from the federal agency before assigning any rights in the initial invention or the improvement invention. This may be

1990).

³¹ 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 the patented invention into the United States without the consent of and without accounting to the other owners

35 U.S.C. § 262.

³² *Willingham v. Lawton*, 555 F.2d 1340, 1344, 194 U.S.P.Q. 249, 252 (6th Cir. 1977).

³³ Alternatively, Companies A and B could have agreed to assign Company A's initial discovery and all inventions arising out of the collaborative research to a joint venture, incorporated by Companies A and B for the purpose of the collaboration. (This was previously suggested in an article by Virginia C. Bennett and Sorojini J. Biswas in *Protecting the patentability of your collaborative research*, 15 NATURE BIOTECHNOLOGY 472, 473 (1997).) Another option would be for Company A to agree, prior to the start of the collaboration, to assign to Company B an undivided, one-half interest in any patent application directed to Company A's initial discovery, with the assignment conditioned upon the development of patentable improvements from the collaboration. However, the barrier to such agreements is quite high. For example, Company A may not be willing to share its rights in Antigen A with Company B for only the possibility of the development of valuable improvements from the collaboration.

difficult to obtain where it is not yet known whether the collaboration will lead to a significant invention.

Consequently, none of the ownership alternatives above completely abrogates the § 102(e),(f) or (g)/§ 103 prior art problem that plagues collaborations between entities, and discourages free communication between inventors. Because of the great unpredictability and the difficulty in the valuation of potential discoveries from the collaboration, it would be quite valuable to be able to delay the decision of whether to assign until after the improvement invention is produced by the collaboration.

IV. The Proposed Amendment to § 103(c)

The proposed bill, the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003" would amend 35 U.S.C. §§ 102(f) and 103(c). The proposed amendment to § 102(f) would insert after "patented" the language "except that subject matter under this subsection shall not be considered prior art or as evidence of obviousness under section 103 of this title." In addition, the proposed amendment to §103(c) would replace the current language with the following:

Subject matter developed by another person, which qualifies as prior art only under one or both of subsections (e) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time of the earliest filing date for which a benefit is sought under this title, owned by the same person or subject to an obligation of assignment to the same person.

I support this bill, CREATE, because it decreases the barrier to research collaborations between different institutions by narrowing the circumstances in which an initial discovery may qualify as prior art to later developed improvements. CREATE does this in two ways.

First, CREATE picks up where the 1984 amendment to 35 U.S.C. § 103(c) left off. The 1984 amendment encouraged the free exchange of ideas between researchers within a single institution by removing §§ 102(f) and (g) as prior art sections for an obviousness analysis under §103. However, it left this barrier in place for collaborations between separate institutions,

because communication between inventors at different institutions still qualifies as prior art, unless an agreement is made, prior to the development of improvement inventions, to commonly assign ownership. CREATE removes § 102(f) as a prior art section for an obviousness determination under § 103. If enacted, this amendment would encourage communication between inventors, even where they are at separate institutions. Thus, CREATE recognizes the reality of scientific research today wherein collaborations between separate institutions are commonplace.

Second, CREATE amends § 103(c) to provide greater flexibility for collaborating institutions. Currently 103(c) requires that common ownership be in place "at the time the [improvement] invention was made" to avoid § 102(e) or (g) prior art being used for an obvious analysis under § 103. In contrast, the proposed amendment to § 103(c) provides flexibility to collaborating institutions by allowing them to delay the decision to create common ownership until a patent application is filed for the improvement. This gives collaborators time after the improvement invention is made to decide whether common ownership is needed to avoid the use of an earlier invention as § 102(e) or (g) prior art for § 103.

This amendment may be particularly important to nonprofit institutions, such as universities, that are covered by the Bayh-Dole Act. Such institutions need permission from the federal agency that funds their research to assign their patent rights. By allowing such institutions to delay the decision of whether it will be necessary to assign rights until after an improvement invention is made (but before an application for this invention is filed), CREATE may make it easier for the institution to obtain this permission.

In fact, I would go even further than the proposed amendments and would not remove mention of § 102(f) from § 103(c), but would amend § 102(f) to read "[a] person shall be entitled to a patent unless . . . he did not himself invent the subject matter sought to be patented, except that subject matter communicated from a co-inventor shall not be considered prior art under this subsection."

My proposal would address the following issues. First, there may be a concern that the proposed bill inadvertently protects a party who misappropriates the invention of another party, makes minor modifications, and files a patent application, because unpatentability for obviousness based on 102(f) prior would no longer be available. However, an inventor could attempt to protect

herself from this kind of predatory behavior by going to the expense of filing a patent application before communicating her idea to another, thus creating § 102(g) prior art against a patent application filed by the unscrupulous copier.

The second issue is illustrated by the following example: inventor A invents compound X. He then collaborates with inventor B, who works at a different company, and together they invent a "genus" of compounds that includes compound X. That is, together they invent a generic chemical formula that includes compound X as well as other compounds. Under the proposed bill, the generic chemical formula theoretically could be found unpatentable under § 102(f), even though compound X was not disclosed to the public before the invention of the generic formula, because the generic chemical formula lacks novelty over compound X. While, hopefully a court would consider the entire collaboration as an act of invention, and would refuse to find the generic formula unpatentable over the earlier communication of compound X for public policy reasons, CREATE arguably leaves this an open question.

In sum, I believe my proposal more surgically addresses the drawbacks of the current § 103(c) and mitigates unintended consequences.



Biotech Collaborations and Maximizing Patent Protection:

Two Hypotheticals*

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I. Introduction

The benefit of having an earlier filing date than the competition usually warrants filing a patent application soon after an initial discovery is made. However, due to the basic nature of Biotech research, an initial discovery is often less important commercially than later discovered improvements. When developing strategies to maximize patent protection, the interplay of patent issues for inventions resulting from the initial discovery and for inventions resulting from the improvement must be considered.

For example, if the first patent application, directed to the initial discovery, and the second patent application, directed to the improvement, do not name identical inventors, the first application may become available as prior art against the second application under certain circumstances. If not all inventors are employed by the same company the situation becomes more complex. If the initial discovery and the improvement are not commonly assigned, it is possible that the initial discovery may qualify as prior art against the improvement even if the initial discovery is never published and is never the subject of a patent application.

These considerations are discussed below together with recommendations for increasing the likelihood of obtaining patent protection for both the initial discovery and the improvement. The first hypothetical involves the situation where the original research team collaborates with additional researchers at the same company. In the second hypothetical, the collaboration involves researchers at different institutions.

II. Collaborations within a Company

Assume that individuals α and β , employed at Company, discover that a novel antigen, Antigen A, provides a low level of immunity in mice against a pathogen. Company files a patent application naming α and β as co-inventors and claims Antigen A and its use as a vaccine against the pathogen. α and β then approach γ , also employed by Company, who specializes in adjuvants. Based on her expertise, γ selects a number of adjuvants for testing. After 10 months of testing, one adjuvant, Adjuvant X, is shown to reproducibly boost the immune response to Antigen A to the extent that nearly all immunized mice are protected from pathogenic challenge. Company files a second application a year after the filing date of the first application claiming Antigen A/Adjuvant

X and its use as a vaccine. Company plans to market the improvement Antigen A/Adjuvant X as a vaccine for humans.¹

A first issue that must be considered is the inventorship of the second patent application. If the selection of Adjuvant X would have been obvious to one of ordinary skill in the art at the time the improvement was made, perhaps it could be argued that γ is not an inventor of the second patent application since γ contributed nothing novel and nonobvious to the invention. However, both Federal Circuit precedent and practical considerations suggest that inventorship determinations cannot be based solely on this type of an analysis. First, in *Burroughs Welcome Co. v. Barr Laboratories Inc.*² the Federal Circuit considered whether a United States Patent and Trademark Office (PTO) determination that certain claims were obvious over other prior art claims was relevant to a determination of whether the inventors of the two sets of claims were the same.³ In this case, the obvious claims were directed to a method of increasing the number of T lymphocytes with AZT. The prior art claims were directed to a method of treating AIDS with AZT. In holding that the obviousness determination was not controlling, the court concluded, "[f]or conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors had in their minds the required definite and permanent idea."⁴ Second, nonobviousness of an invention can be established long after a patent issues upon consideration of the so-called "secondary factors" of patentability. Thus, if inventorship were

¹ If it is assumed that Antigen A is novel and nonobvious at the time the first application is filed, then open-ended claims could possibly be obtained in the first application encompassing Antigen A alone and Antigen A together with any other compound. Thus, while the first application would possibly dominate the Antigen A/Adjuvant X composition generically, it would not have support to specifically claim the Antigen A/Adjuvant X composition unless Adjuvant X was described in the as-filed specification. *See, e.g.,* University of California v. Eli Lilly and Co., 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997), *In re Vaeck*, 947 F.2d 488, 495-96, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). Hence, the second application is necessary to prosecute claims specifically directed to the commercial embodiment.

² 40 F.3d 1223, 32 U.S.P.Q.2d 1915 (Fed. Cir. 1994), *cert. denied*, 516 U.S. 1070-1071, 516 S. Ct. 771 (1996).

³ *See id.* at 1231-32, 32 U.S.P.Q.2d at 1923.

⁴ *Id.* at 1232, 32 U.S.P.Q.2d at 1923.

determined based on an obviousness analysis, inventorship would theoretically never be settled during the life of a patent.⁵

For the purpose of this hypothetical, we will assume that neither α nor β conceived of Adjuvant X. Therefore, regardless of whether the incorporation of Adjuvant X would have been obvious in light of the initial discovery, the holding in *Burroughs Welcome* suggests that γ should be named as an inventor of the second patent application.

When it issues as a patent, the disclosure of the first application becomes prior art under 35 U.S.C. § 102(e)⁶ as of the date it was filed at the PTO. Since the invention claimed in the second application was invented "by another,"⁷ the improvement may be held to be obvious over the disclosure of the first application by the PTO or a court even though there is common ownership.⁸ Thus, before permitting the first application to issue, Company's patent attorney should weigh the probable strength of an obviousness rejection based on the first application against a claim

⁵ This is not to say that an obviousness analysis has no role to play in making inventorship determinations. Inventorship is determined by identifying those individuals who contributed to a legally adequate conception. In determining whether a conception, containing all elements of a claimed invention, is sufficiently definite, the settled test is whether "the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Id.* at 1228, 32 U.S.P.Q.2d at 1919. This determination may include certain elements of an obviousness analysis. *See infra* note 45. However, it appears that reference to ordinary skill cannot substitute for a missing element of the claimed invention that was not part of the conception.

⁶ Under section 102(e), "[a] person shall be entitled to a patent unless . . . the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent . . ." 35 U.S.C. §102(e).

⁷ The inventors of Antigen A (i.e., α and β) would be a different inventive entity than the inventors of Antigen A/Adjuvant X (i.e., α , β and γ), even though α and β overlap both groups. *See In re Land*, 368 F.2d 866, 881, 151 U.S.P.Q. 621, 634 (C.C.P.A. 1966); *see also, Section by Section Analysis: Patent Law Amendments of 1984*, 98th Cong., 130 CONG. REC. H 10525 (1984), *reprinted in*, 1984 U.S.C.C.A.N. 5827, 5834; *cf. In re Kaplan*, 789 F.2d 1574, 1575, 229 U.S.P.Q. 678, 679 (Fed. Cir. 1986) ("It is a given . . . that a sole inventor and joint inventors including the sole inventor are separate 'legal entities,' a legal proposition from which certain legal consequences flow 'such as who must apply for patent.'")(citation omitted).

⁸ Prior art under 35 U.S.C. §102(e) can be used by the PTO to reject claims as being obvious under 35 U.S.C. §103. Obviousness rejections can combine the disclosures of more than one prior art document. Thus, the text of the first application, which discloses Antigen A, and one or more other references, which disclose Antigen X, could be relied on to reject the improvement as being *prima facie* obvious if the examiner could demonstrate that one of ordinary skill would have been motivated to combine the references to arrive at the claimed invention. To overcome it on the merits, such a *prima facie* rejection could be "attacked" with an argument that there would have been no motivation to combine the references or "rebutted" with extrinsic evidence, such as evidence of unexpected results.

specifically directed to the improvement. If there is a reasonable likelihood that such an obviousness rejection would be difficult to overcome, Company should consider incorporating the text of both applications into a continuation-in-part (CIP) application⁹ that claims both the initial discovery and the improvement and names α , β and γ as co-inventors. After the CIP has been filed claiming priority under 35 U.S.C. §120¹⁰ to the first and second applications, the first and second applications should be abandoned. Hence, the initial discovery and the improvement would be prosecuted out of the CIP and the potential §102(e) prior art problem never materializes because no patent "by another" could issue due to the abandonment of the first application.

As a caveat, in the above hypothetical, assume that the first application was filed one year prior to the filing date of the second application. These filing dates would not necessarily have affected the patent term if the filings occurred prior to June 8, 1995, as such patent terms end 17 years from the date of issuance. However, on June 8, 1995, the General Agreement on Tariffs and Trade Act (GATT Act) took effect, which implemented Article 33 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). Under the GATT Act, the patent term still begins upon the date a patent issues, but it now expires 20 years from the earliest U.S. filing date.¹¹ Thus, by filing a CIP and claiming priority to both the first and second applications, the U.S. filing date for the purpose of calculating the patent term becomes the filing date of the first

⁹ "A CIP is an application filed during the lifetime of an earlier [nonprovisional] application by the same applicant, repeating some substantial portion or all of the earlier [nonprovisional] application and *adding matter not disclosed* in the said earlier [nonprovisional] application." *In re Klein*, 1930 C.D. 2, 393 O.G. 519 (Comm'r Pat. 1930).

¹⁰ Section 120 of the Patent Act states the following:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States . . . which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120.

¹¹ *See* 35 U.S.C. § 154(a)(2).

application, which would cause a one year loss of patent term for claims specifically directed to the improvement. If Antigen A/Adjuvant X turns out to be a multimillion dollar a year therapy, a one year loss in patent term could be worth millions of dollars.¹² On the other hand, this monetary loss is perhaps mitigated by the following consideration: by combining the first and second applications into a CIP, Company is able to obtain claims specifically directed to the improvement and also generic claims that would potentially dominate Antigen A in combination with any other compound, which makes it difficult for a competitor to invent around the commercial embodiment simply by using a different adjuvant.

The above strategy for overcoming Company's own § 102(e) prior art was made possible by the enactment of the Patent Law Amendments Act of 1984,¹³ which amended the first paragraph of 35 U.S.C. §116 to read:

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 (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.¹⁴

Thus, in the above hypothetical, it is possible to prosecute the initial discovery and the improvement in the same CIP application even though inventor γ did not make a conceptual contribution to every claim of the CIP.¹⁵

Avoiding a § 102(e) rejection by combining two commonly owned applications into one CIP was specifically approved by the PTO in published explanatory comments when it

¹² An alternative would be to simply not claim priority to the first application. This would result in the generic claims to Antigen A only being entitled to the second application's filing date, but would extend the patent term for both inventions further into the future. However, this strategy would risk the invalidity of the generic claims to Antigen A based on prior art published or otherwise available subsequent to the first filing date. Therefore, it would be rare that this risk would be justified.

¹³ Pub. L. No. 98-622, § 104(a), 98 Stat. 3384, 3385 (1984) (codified as amended at 35 U.S.C. § 116).

¹⁴ 35 U.S.C. § 116, para. 1.

¹⁵ 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.

promulgated rules under amended § 116.¹⁶ However, as a caveat, at least one commentator has urged caution before following this strategy in light of the traditional collaboration requirement of joint inventorship under certain circumstances.¹⁷ Citing Donald Chisum,¹⁸ other statutes and the legislative history of the Patent Amendments Act of 1984, this commentator concludes that "Congress's relaxation of the strict 'all claims' rule does not show an intent to abrogate the collaboration, or joint manner, requirement."¹⁹ Indeed, retaining the collaboration requirement for joint inventorship would appear to be supported by Federal Circuit case law since 1984.²⁰

Prior to 1984, at least in certain circuits, all the inventors named in an application were also inventors of every claim in the application. Thus, the named inventors must have collaborated on every claim of the application. Following the 1984 amendment, the inventors of a particular claim in an application can differ from the named inventors of the application.²¹ While it is clear that the collaboration requirement survives the 1984 amendment of section 116, it is not clear whether compliance with the collaboration requirement is determined for the application as a whole or on a claim-by-claim basis.

If the collaboration requirement is determined for the application as a whole, there must be some minimal collaboration between all named inventors even if different inventors contributed to

¹⁶ See Final Rules For Miscellaneous Patent Provisions, 1053 O.G. 10 (1985).

¹⁷ 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, 207-08 (1992).

¹⁸ See 7 DONALD S. CHISUM, PATENTS § 2.02[2], at 2-13 (July 1998) ("There is no evidence that Congress intended to discard the fundamental requirement [when enacting the Patent Law Amendments Act of 1984] that there be some form of collaboration between the joint inventors in the development of the final invention.").

¹⁹ See Fasse, *supra* note 17, at 179.

²⁰ See *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., Inc.*, 973 F.2d 911, 917, 23 U.S.P.Q.2d 1921, 1926 (Fed. Cir. 1992) ("[T]here must be some element of joint behavior, such as collaboration or working under common direction. . . . Inventors cannot be totally independent of one another and be joint inventors.").

²¹ If claim 1 was invented by a and β and claim 2 was invented by a, β, and γ, the inventorship named on the application would be a, β, and γ, which differs from the inventors of claim 1 (a and β).

separate, perhaps patentably distinct, claims.²² However, if compliance with the collaboration requirement is determined on a claim-by-claim basis, it would only be necessary that joint inventors of a particular claim collaborate, but not that all inventors named on the application collaborate.

In our hypothetical, the collaboration requirement would be satisfied under either the application as a whole or the claim-by-claim analysis. Under the application as a whole analysis, the issue would be whether all the named inventors of the application at least minimally collaborated with each other in some way. For example, in the above hypothetical, assume that claim 1 in the CIP is directed to the Antigen A compound and claim 2 is directed to the Antigen A/Adjuvant X composition. Because α , β , and γ all collaborated in the joint invention of claim 2, under the application as a whole analysis, the collaboration requirement is satisfied. Under the claim-by-claim analysis, one looks to the inventorship of each claim, including assessing compliance with the collaboration requirement separately for each claim. Once inventorship is determined for each claim, the inventors named on the application are merely the summation of the inventors named for each claim. In the hypothetical, since α and β collaborated during the conception of the invention defined by claim 1, and α , β , and γ collaborated during the conception of the invention defined by claim 2, the collaboration requirement would also be met under the claim-by-claim analysis.

However, this would change if our hypothetical is modified so that a claim 3 is added directed to Antigen B, which was solely and independently conceived by δ . If we assume that δ did not collaborate with α , β , or γ during the conception of Antigen B, the collaboration requirement would presumably not be satisfied based on the application as a whole analysis, but would be satisfied under a claim-by-claim approach.

²² Under current P.T.O. practice it is possible for claims to patentably distinct inventions to be included in the same patent application if the examination of these claims would not constitute an undue burden on the examiner. *See, e.g.*, MANUAL OF PATENT EXAMINING PROCEDURE § 803, at 800-3 (7th Ed.1998)(For a restriction requirement to be proper, the inventions must be independent or distinct as claimed, *and* examining the inventions together must place a serious burden on the examiner).

A claim-by-claim approach appears to have been favored by the PTO when it promulgated 37 C.F.R. § 1.45(c),

[i]f multiple inventors are named in a nonprovisional application, each named inventor must have made a contribution, *individually* or jointly, to the subject matter of at least one claim of the application and the application will be considered to be a joint application under 35 U.S.C. 116.²³

This suggests that the claim-by claim approach to the collaboration requirement is proper absent evidence to the contrary.

In summary, a viable strategy for Company to overcome a potential obviousness rejection based on prior art under § 102(e) is to abandon the first and second applications after filing a CIP and prosecuting both the initial discovery and the improvement in one application. However, Company should keep in mind that naming multiple inventors in one application may only be proper if there was at least some minimum element of collaboration between each of the named individuals even though they may not have contributed conceptually to every claim.

III. Collaborations with an Industrial Partner

In the above hypothetical, assume that α and β are employed by Company, but γ is employed by Industrial Partner (IP).²⁴ Thus, the initial discovery claimed in the first application (the Antigen A compound) would be assigned to Company. However, since γ is employed at IP,

²³ 37 C.F.R. § 1.45(c) (1997) (emphasis added).

²⁴ Due to the obstacles associated with identifying and developing a potential drug, alliances in Biotechnology have become a necessity for many companies whose platform is based on a vast set of data which provides a seemingly endless number of potential targets or compounds that need screening. According to Ernst & Young, LLP, from 1995 to 1997 the following Biotech alliances were formed by technology: 10 in Carbohydrates/Cell Adhesion; 48 in Gene/Cell Therapy; 44 in Genomics; 56 in Molecular Diversity; 27 in monoclonal antibodies; 12 in Antisense; 5 in photodynamic therapy; 48 in rDNA; 29 in signal transduction; and 8 in Transgenics. See ERNST & YOUNG, LLP, BIOTECH 97: ALIGNMENT, THE ELEVENTH INDUSTRY ANNUAL REPORT, at 26 (1996). The following are examples of a few of the specific alliances formed in 1997, as reported by Ernst & Young, LLP: Hybridon and G.D. Searle & Co, entered into an agreement worth nearly \$200 million to develop antisense drugs for immune system regulation. Searle also announced a deal with CoCensys for \$80 million to develop insomnia drugs. Pfizer entered into an agreement with Megabios for \$50 million for developing gene therapy treatments of lung cancer; Myriad Genetics and Bayer Corp. signed a \$71 million partnership to search for genes related to osteoporosis, obesity and asthma; and Ophidian and Eli Lilly entered into a deal potentially worth more than \$12 million to develop therapeutics for gastrointestinal infections. See *id.* at 29.

the improvement (the Antigen A/Adjuvant X composition) would be assigned to both Company and IP.²⁵ Thus, not only would there be a potential obviousness rejection under §§102(e)/103 against a claim to the improvement in the second application if the first application were to issue as a patent, there would also potentially be an obviousness rejection under §§ 102(g)/103 based on the prior reduction to practice of Antigen A by a and β. Further, if communications between co-inventors during the development of an invention can constitute prior art, there would potentially also be an obviousness rejection under §§ 102(f)/103 based on a and β's communication of Antigen A to γ. Moreover, the obviousness rejections based on §102(f) and §102(g) could not be overcome by combining the first two applications into a CIP.²⁶ Sections 102(f) and 102(g) of the patent statute and their applicability to the present hypothetical are discussed in more detail below.

A. *Are Sections 102(f) and 102(g) Prior Art Sections?*

Whether § 102(f) is indeed a prior art section,²⁷ making 102(f) art available in obviousness determinations, has been the subject of much controversy. The literal wording of §102(f) provides that a person shall be entitled to a patent unless "he did not himself invent the subject matter sought to be patented."²⁸ This has traditionally been considered a derivation provision, the purpose of which is to prevent someone from obtaining a patent on that which was invented by someone else.

²⁵ In the eyes of the PTO, Company is a different "ownership entity" than the joint entity of Company-IP Final Rules for Miscellaneous Patent Provisions, 50 Fed. Reg. 9368, 9373 (1985)(codified at 37 C.F.R. § pt. 1). This issue is discussed in greater detail below at pages 17-18.

²⁶ When joint inventors are named in an application, the PTO presumes that all claims are assigned to single "ownership entity". See MANUAL OF PATENT EXAMINING PROCEDURE § 706.02 (m), ¶ 7.20.02 (7th Ed.1998) ("In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).").

²⁷ If § 102(f) is a prior art section then, if certain circumstances are met, communications of less than the complete invention as claimed can be relied on to reject or invalidate a claim. In other words, viewing § 102(f) as a prior art section means that the contents of a communication can be combined with "traditional" prior art disclosures (journal articles, patents, prior uses, etc.) to render a later claimed invention obvious under § 103.

²⁸ 35 U.S.C. § 102(f).

It does not only pertain to public knowledge, but also applies to private communications, even those made under a secrecy agreement.

According to case law, two elements are required for establishing derivation under § 102(f). First, "the named inventor in the patent [must have] acquired knowledge of the claimed invention from another."²⁹ Second, there must have been a prior conception of the invention, and the conception must have been communicated.³⁰ In patent law, an invention is deemed to have been conceived when there is a "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention."³¹ Thus, a prior reduction to practice of the invention by another is not required to establish derivation under § 102(f), provided that there was a prior conception and a communication.

However, the case law has been in a state of disarray concerning whether a derivation under § 102(f) can be combined with other prior art in an obviousness rejection under § 103. For example, the Federal Circuit stated in dictum in *New England Braiding*³² that "[t]o invalidate a patent for derivation of invention, a party must demonstrate that the named inventor in the patent acquired knowledge of the claimed invention from another, or *at least so much of the claimed invention as would have made it obvious to one of ordinary skill in the art.*"³³ This dictum in *New*

²⁹ *New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 970 F.2d 878, 883, 23 U.S.P.Q.2d 1622, 1626 (Fed. Cir. 1992).

³⁰ *See McSherry v. Giannuzzi*, 227 U.S.P.Q. 868, 872 (Bd. Pat. App. & Int. 1985), *aff'd*, 790 F.2d 95 (Fed. Cir. 1986); *see also Price v. Symsek*, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d 1031, 1033 (Fed. Cir. 1993).

³¹ *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 U.S.P.Q. 81, 87 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947, 107 S. Ct. 1606 (1987). However, conception of a chemical compound requires more than just a conception of biological activity. It requires the ability of an inventor to describe his or her invention with sufficient particularity to structurally distinguish the compound from other compounds. *See Fiers v. Revel*, 984 F.2d 1164, 1169, 25 U.S.P.Q.2d 1601, 1605 (Fed. Cir. 1993).

³² 970 F.2d at 878, 23 U.S.P.Q.2d 1622.

³³ *Id.* at 883, 23 U.S.P.Q.2d at 1626 (emphasis added)

England Braiding conflicts with dictum in *In re Bass*³⁴ and also conflicts with the dissenting opinion in *Lamb-Weston, Inc. v. McCain Foods, Ltd.*³⁵.

Further confusion appears in *Gambro Lundia AB v. Baxter Healthcare Corp.*³⁶ In *Gambro*, while referring to the dictum in *New England Braiding*, the lower court concluded that to invalidate Gambro's patent, "Baxter did not need to prove communication of the entire conception, but rather only so much of the invention 'as would have made it obvious to one of ordinary skill in the art.'"³⁷ However, the Federal Circuit held that, its dictum in *New England Braiding* notwithstanding, the lower court's holding was clearly erroneous and "applied the wrong legal standard" because it "introduces incorrectly an obviousness analysis into the test for derivation."³⁸ According to the Federal Circuit, the proper standard for finding communication of a prior conception was enunciated by the Supreme Court over 125 years ago in *Agawam Woolen Co. v. Jordan*,³⁹ wherein the Court required a showing that the communication "'enabled an ordinary mechanic, without the exercise of any ingenuity and special skill on his part, to construct and put the improvement in successful operation.'"⁴⁰ Further, the Federal Circuit pointed out that this *enablement* standard for finding communication of a prior conception had been consistently applied by the Federal Circuit's predecessor, the CCPA.⁴¹

³⁴ 474 F.2d 1276, 1290, 177 U.S.P.Q. 178, 189 (C.C.P.A. 1973) (§102(f) has "no relation to § 103 and no relevancy to what is "prior art" under § 103"). This decision is discussed in greater detail below at page 15.

³⁵ 78 F.3d 540, 548-49, 37 U.S.P.Q.2d 1856, 1863 (Fed. Cir. 1996) ("Derived knowledge can indeed be invalidating [under § 102(f)], but this is not properly described as "prior art", which is defined as actual or presumed public knowledge.")(dissenting opinion).

³⁶ 110 F.3d 1573, 42 U.S.P.Q.2d 1378 (Fed. Cir. 1997).

³⁷ *Id.* at 1577, 42 U.S.P.Q.2d at 1382.

³⁸ *See id.*

³⁹ 74 U.S. (7 Wall.) 583 (1868).

⁴⁰ *Gambro Lundia*, 110 F.3d at 1577, 42 U.S.P.Q.2d at 1382 (quoting *Agawam Woolen*, 74 U.S. (7 Wall.) at 602-603).

⁴¹ *See Gambro Lundia*, 110 F.3d at 1577, 42 U.S.P.Q.2d at 1382 ("Communication of a complete conception must be sufficient to *enable* one of ordinary skill in the art to construct and successfully operate the invention.") (emphasis added) (quoting *Hedgewick v. Akers*, 497 F.2d 905, 908, 182 U.S.P.Q. 167, 169 (C.C.P.A. 1974)); *see also DeGross v. Roth*, 412 F.2d 1401, 1406, 162 U.S.P.Q. 361, 365 (C.C.P.A. 1969).

The panel in *Gambro*, which was decided in April of 1997, included Circuit Judge Rader, Chief Judge Archer and Circuit Judge Lourie. Later, in August of 1997, a different panel of the Federal Circuit (Circuit Judges Michel, Lourie, and Rader) again turned the derivation standard on its head in *OddzOn Products, Inc. v. Just Toys, Inc.*⁴² While citing §103(c) of the patent statute,⁴³ the *OddzOn* panel stated that

[w]hile the statute [§ 103(c)] does not expressly state in so many words that § 102 (f) creates a type of prior art for purposes of §103, nonetheless that conclusion is inescapable; the language that states that § 102(f) subject matter is not prior art under limited circumstances clearly implies that it is prior art otherwise. That is what Congress wrote into law in 1984 and that is the way we must read the statute.⁴⁴

Interestingly, the Federal Circuit in *OddzOn* did not cite *Gambro*, which was decided four months earlier, even though *Gambro* enunciated a different legal standard for derivation.⁴⁵ According to

⁴² 122 F.3d 1396, 43 U.S.P.Q.2d 1641 (Fed. Cir. 1997).

⁴³ In the Patent Law Amendments Act of 1984, Congress amended § 103 to disqualify events that fall exclusively within §§ 102(f) or (g) from use as prior art under § 103, if specific conditions are met. Pub. L. No. 98-622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103). This amendment can now be found in subsection (c) of § 103, which provides:

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.

35 U.S.C. §103(c).

⁴⁴ 122 F.3d at 1403-02, 43 U.S.P.Q.2d at 1646.

⁴⁵ However, as discussed in Chisum, "[i]t is not clear whether this standard [i.e, the enablement standard enunciated in *Agawam Woolen*] means enablement of a mechanic with presumed knowledge of all the prior art (as with Section 103) . . . or simply enablement of a mechanic with the ordinary level of skill (as with the disclosure standard of Section 112) If it means the former, then Section 102(f) would itself contain an obviousness standard." 2 DONALD S. CHISUM, PATENTS § 5.03[3], at 5-177 n.59 (July 1998). Thus, depending on the scope given to the enablement standard in *Gambro*, it is possible that there may be some overlap between the *Gambro* and *OddzOn* legal standards for derivation when applied to a particular fact situation.

the Federal Circuit in *Newell Co., Inc. v. Kenney Manufacturing Co.*,⁴⁶ where there is a conflict in statements of Federal Circuit law, the earlier statement prevails unless or until it has been overruled *en banc*.⁴⁷ Thus, if the issue of whether § 102(f) is a prior art section is again before the Federal Circuit, it would appear that a subsequent panel (if it followed *Newell*) would presumably be forced to hold in the negative and follow the enablement standard as enunciated by the panel in *Gambro*. In our view, an *en banc* decision will be necessary to fully resolve this issue.

In contrast to § 102(f), the case law is rather well settled that art qualifying under § 102(g) is available as prior art in an obviousness analysis, subject to the limitations discussed in subsections B and C below. Under the first sentence of § 102(g), a person is not entitled to a patent if "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it."⁴⁸ While § 102(g) is typically associated with interferences, it may also be a grounds for invalidity in other contexts such as a defense in patent infringement litigation and during *ex parte* prosecution.⁴⁹ In order to constitute prior art under §102(g), the invention must have been reduced to practice in the United States and it cannot have been abandoned, suppressed or concealed. The reduction to practice can be an actual reduction to practice, by actually completing the invention, or a constructive reduction to practice, by filing a patent application that satisfies the requirements of 35 U.S.C. § 112, first paragraph.⁵⁰

⁴⁶ 864 F.2d 757, 9 U.S.P.Q.2d 1417 (Fed. Cir. 1988).

⁴⁷ *See id.* at 765, 9 U.S.P.Q.2d 1423 (stating that subsequent panel opinions may elaborate and refine and thus advance the evolution of judge made law, but they cannot change the law as established in prior rulings)(citing *U.M.C. Elec. Co. v. U.S.*, 816 F.2d 647, 652 n.6, 2 U.S.P.Q.2d 1465, 1468 n.7 (Fed. Cir. 1987)).

⁴⁸ 35 U.S.C. § 102(g).

⁴⁹ *See Checkpoint Sys., Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761, 35 U.S.P.Q.2d 1042, 1046 (Fed. Cir. 1995)(affirming an ITC decision that held patent claims invalid as anticipated by art qualifying as prior art only under section 102(g)).

⁵⁰ *See In re Katz*, 687 F.2d 450, 454, 215 U.S.P.Q. 14, 17 (C.C.P.A. 1982) ("No possible barrier is created by § 102(g) unless another has either actually reduced the invention to practice or has constructively reduced it to practice by filing a patent application."); *see also Ex parte Osmond*, 191 U.S.P.Q. 340, 341 (P.T.O. Bd. App. 1976).

A reduction to practice (actual or constructive) does not constitute prior art under §102(g) if the invention was abandoned, suppressed, or concealed.⁵¹ In order to constitute an actual reduction to practice the invention must be reduced to a physical or tangible form.⁵² With few exceptions, the invention must have been tested to confirm that it works for its intended purpose.⁵³ Moreover, §102(g) does not contain a "personal knowledge requirement" or a "known to the art requirement."⁵⁴ Thus, provided that there has been no abandonment, suppression, or concealment, under § 102(g) the prior work of another can constitute secret prior art against the work of a second inventive entity even where the prior work was not publicly known in the art and second inventive entity had no knowledge of it.⁵⁵

B. The § 103(c) Exception to 35 U.S.C. §§ 102(f) and 102(g) as Prior Art Sections.

35 U.S.C. §103 states in part that "[a] patent may not be obtained [even though the claimed invention may be novel] . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art" Thus, a claimed invention must not only be novel, but also nonobvious to be patentable. Importantly, a combination of prior

⁵¹ If an application describing the invention is subsequently abandoned, the right to rely on a constructive reduction to practice is lost. With respect to an actual reduction to practice, "[t]he courts have consistently held that an invention, though completed, is deemed abandoned, suppressed, or concealed if within a reasonable time after completion, no steps are taken to make the invention publicly known. Thus, failure to file a patent application; to describe the invention in a publicly disseminated document; or to use the invention publicly have been held to constitute abandonment, suppression, or concealment." *International Glass Co., Inc. v. United States*, 408 F.2d 395, 403, 159 U.S.P.Q. 434, 441 (Ct. Cl. 1968) (citations omitted); *see also See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.* 849 F.2d 1430, 1436 n.5, 7 U.S.P.Q.2d 1129, 1134 n.5 (Fed. Cir.), *cert. denied*, 488 U.S. 986, 109 S. Ct. 542 (1988) ("[T]he filing of a United States patent application maintains the secrecy of work, but is a factor cutting against abandonment, suppression, or concealment.").

⁵² *See Wetmore v. Quick*, 536 F.2d 937, 941, 190 U.S.P.Q. 223, 227 (C.C.P.A. 1976).

⁵³ *See Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593, 44 U.S.P.Q.2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose.").

⁵⁴ *See E.I. du Pont de Nemours*, 849 F.2d at 1437, 7 U.S.P.Q.2d at 1134-35.

⁵⁵ *See id.* (prior secret invention of Witt and Leatherman is relevant to validity of patent to Andersen and Stumatoff under 35 U.S.C. §§ 102(g)/103.)

art references or prior art "events" (e.g., a prior reduction to practice by another) can be used to formulate an obviousness rejection under § 103.

In *In re Bass*⁵⁶, the PTO rejected claims in a patent application naming Bass, Jenkins, and Harvat as co-inventors as being obvious over previously filed issued patents to Bass and Jenkins.⁵⁷ The PTO's rationale was that the claims in the later filed patent application were merely an obvious variation of what had been reduced to practice in the earlier filed issued patents and thus the patent application was properly rejected under § 103 by virtue of § 102(g). Importantly, one of the two earlier filed issued patents was ultimately deemed to be by "another" for purposes of the § 102(g) analysis even though there was an overlapping inventor.⁵⁸ In other words, the rejection was deemed to be applicable because the "inventive entity" of the earlier filed issued patents was not identical to the "inventive entity" of the later filed patent application. Also, the rejection was deemed appropriate even though the invention and the earlier reduction to practice occurred within the same company. The PTO's rejection was upheld by the Court of Customs and Patent Appeals (CCPA), which was the predecessor court of the Court of Appeals for the Federal Circuit (Federal Circuit).

In 1984, Congress amended § 103 to disqualify events that fall exclusively within §§ 102(f) or (g) from use as prior art under § 103, if specific conditions are met.⁵⁹ This amendment can now be found in subsection (c) of § 103, which provides in pertinent part:

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.

⁵⁶ 474 F.2d 1276, 177 U.S.P.Q. 178.

⁵⁷ *See id.* at 1277, 177 U.S.P.Q. at 179.

⁵⁸ The disclosure in the second patent was excluded from consideration as prior art, since the disclosure in that patent and in the rejected claims were part of the same research and development program and were invented simultaneously.

⁵⁹ Pub. L. No. 98-622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103).

13 U.S.C. §103 (c).

This amendment was reportedly in direct response to the *Bass* decision, which arguably created a disincentive to file patents early and discouraged communication between co-workers.⁶⁰ In support of the amendment, commentators argued that "[s]uch encouragement of ignorance defeats a fundamental principle of corporate research - the free exchange of ideas between corporate employees. Moreover, it runs counter to both the policy and the spirit of the patent laws because it discourages both invention and the prompt disclosure of new inventions."⁶¹ Thus, recognizing the value of team research within corporations, businesses, and universities, Congress amended §103 to eliminate these obstacles to team research.

Interestingly, the enacted version of the 1984 amendment to § 103 is considerably different from the version first proposed by Representative Kastenmeir in the House of Representatives on November 18, 1983.⁶² The original bill, entitled H.R. 4525, provided that "[p]rior art shall not include unpublished information which is developed by the applicant singly or jointly with others, or which is known to the applicant only by virtue of his or her employment."⁶³ Thus, the original version of the amendment disqualified two types of art:

- 1) that "developed by the applicant singly or jointly with others," and
- 2) that "known to the applicant only by virtue of his or her employment."

Apparently, both types of disqualified prior art were to be limited to unpublished information.

⁶⁰ See *Section by Section Analysis: Patent Law Amendments of 1984*, *supra* note 7, at 5833.

⁶¹ *Patent Law Improvements Act: Hearing on S. 1535 and S. 1841 Before the Subcommittee on Patents, Copyrights, and Trademarks of the Senate Committee on the Judiciary*, 98th Cong., 157 (1984)(prepared statement of John E. Maurer).

⁶² See H.R. 4525, 98th Cong. (1983).

⁶³ *Id.*

However, the original version was objected to both by the American Intellectual Property Law Association (AIPPLA) and the PTO as being vague and overly broad. In particular, the AIPPLA proposed redrafting the original version of the bill because:

We believe that [the original draft] in addition to modifying subparagraphs (f) and (g) of Section 102 of Title 35 might be interpreted as eliminating other prior art bars. Also, some of the words in [the original draft] are unnecessarily vague. The purpose of the amendment is to precisely define the needed remedy.⁶⁴

The PTO's reason for supporting a revision was as follows:

Drafting an appropriate provision . . . has proven to be an elusive and complex task [The original draft of the amendment to section 103] is too broad. It is not limited, for example, to exchanges of background information among co-workers in a single organization. [Under the original draft] [i]nformation learned from or transmitted to outsiders could be disqualified as prior art.⁶⁵

Congress' own explanation of the differences between the original and enacted versions of the amendment to §103 was that "the language in [the adopted version] is parallel to but also is more precise than the language of [the originally proposed version]. For example, [the enacted version] makes clearer that information learned from or transmitted to persons outside the inventor's immediate organization is not disqualified as prior art."⁶⁶

Thus, the enacted version of the amendment to § 103 (now § 103(c)) disqualifies "subject matter developed by another person" if it meets the following criteria:

- 1) it falls only within the definitions of sections 102(g) or (f); and

⁶⁴ *Hearing on S. 1535 and S. 1841, supra* note 61, at 67 (prepared statement of Bernarr R. Pravel, president, AIPPLA).

⁶⁵ *Id.* at 32 (prepared statement of Gerald J. Mossinghoff, Assistant Secretary and Commissioner of Patents and Trademarks).

⁶⁶ *Section by Section Analysis: Patent Law Amendments of 1984, supra* note 7, at 5833.

2) the subject matter of the prior art and of the claimed invention were:

a) commonly owned,

b) "at the time the [second] invention was made."

When the PTO implemented § 103(c) by amending 37 C.F.R. §1.104, it explained that common ownership by the same "person" or "organization" "would include circumstances where the ownership resided in more than one person and/or organization as long as the applications are owned jointly by the same owners."⁶⁷ In other words, for the § 103(c) exception to apply, there must be an identical "ownership entity" between the subject matter which would otherwise qualify as prior art under §§ 102(f) or (g) and the subsequent invention claimed in the later filed patent application. In other words, to receive benefit of § 103 (c), if the prior art subject matter was owned by companies A and B, then the subsequent invention must also have been owned by companies A and B at the time the subsequent invention was made.

This interpretation by the PTO of "commonly owned" appears to be consistent with Congress when it amended the original bill in order to "make clearer that information learned from or transmitted to persons outside the inventor's immediate organization is not disqualified as prior art."⁶⁸

C. An Inventor's Own Prior Work as Prior Art Under 35 U.S.C. §§ 102(f) and 102(g).

Assuming that the holding in *OddzOn* is adopted by the Federal Circuit generally, it means that

an invention, A', that is obvious in view of subject matter A, derived from another, is also unpatentable. The obvious invention, A', may not be unpatentable to a third party who did not receive the

⁶⁷ Final Rules for Miscellaneous Patent Provisions, *supra* note 25.

⁶⁸ *Section by Section Analysis: Patent Law Amendments of 1984*, *supra* note 7, at 5833.

disclosure of A, but it is unpatentable to the party who did receive the disclosure.⁶⁹

The standard enunciated in *OddzOn* is perhaps workable where the subject matter is derived from a non-inventor. However, it becomes problematic where the subject matter is derived from a co-inventor. For example, in our hypothetical, α , β and γ are co-inventors of the improvement (i.e., the Antigen A/ Adjuvant X composition), which is potentially obvious over the initial discovery of Antigen A by α and β . Since the second inventive entity (α , β and γ) is considered to be "different" than the first inventive entity (α and β),⁷⁰ the second inventive entity could be said to have derived subject matter (the initial discovery Antigen A) from the first inventive entity that renders the improvement obvious when combined with other prior art documents.⁷¹

Thus, an important unanswered question is whether the Federal Circuit's holding in *OddzOn* would apply to communications between inventors.⁷² In 1982, the Fifth Circuit in *Shields v. Halliburton Co.*⁷³ held that the prior work of one inventor does not constitute prior art against a later joint invention between the inventor and another.⁷⁴ In reaching this conclusion, the Fifth

⁶⁹ *OddzOn*, 122 F.3d at 1403, 43 U.S.P.Q.2d at 1646.

⁷⁰ *See supra* note 7.

⁷¹ Note that the § 103(c) exemption does not apply here since the "ownership entities" are also different — the initial discovery is solely owned by Company whereas the improvement is co-owned by Company and IP. *See* Final Rules for Miscellaneous Patent Provisions, *supra* note 25. This issue was discussed in greater detail above at pages 17-18.

⁷² As indicated in note 24 *supra*, alliances between biotech partners have become an integral part of the industry. It is our view that applying the *OddzOn* decision to discussions between co-inventors at collaborating biotech institutions would serve to frustrate, rather than promote, discoveries in biotechnology in the same fashion as the decisions in *In re Bass* and *In re Clemens*, 622 F.2d 1029, 206 U.S.P.Q. 289 (C.C.P.A. 1980), decisions that many commentators, at the time, argued created a disincentive to file patents early and discouraged communication between co-workers at a single institution. The amendment to § 103 (which can now be found as § 103(c)) was made to legislatively overrule *Bass* and *Clemens*. *Section by Section Analysis: Patent Law Amendments of 1984*, *supra* note 7, at 5833. If the present day realities of biotech research had been known when Congress enacted the Patent Law Amendments of 1984, it is possible that the § 103(c) exemption would not have been limited to commonly owned inventions, but may have been extended to inventions arising out of collaborative research. *See* discussion *supra* pp. 17-18. The value of team research between present day collaborating biotech institutions is arguably as great as was the value of team research within corporations in 1984.

⁷³ 667 F.2d 1232, 216 U.S.P.Q. 1066 (5th Cir. 1982).

⁷⁴ *See id.* at 1235, 216 U.S.P.Q. at 1069.

Circuit relied heavily on the fact that no patent had been filed directed to the first inventor's initial discovery.⁷⁵ While Chisum criticizes the rationale behind the Fifth Circuit's holding,⁷⁶ Chisum agrees that communications between co-inventors should not constitute prior art under § 102(f).

In at least one instance derived knowledge should not be treated as "prior art." This is the case of joint invention. The prior knowledge in fact developed by a joint inventor as part of a prior invention should not be "prior art" under Section 102(f) as to the joint invention. This would be an exception to the normal concept of separate "inventive entities." Thus, the prior secret work of one joint inventor would be prior art as to the later invention of joint inventors only under Section 102(g)—which assumes reduction to practice and no abandonment, suppression or concealment.⁷⁷

Arguably, applying the *OddzOn* standard to discussions between co-inventors at collaborating biotech institutions would serve to frustrate, rather than promote, discoveries in biotechnology.⁷⁸ This is particularly true since, in order to be joint inventors, there must have been some degree of

⁷⁵ See *id.* at 1236, 216 U.S.P.Q. at 1069 ("Had Bassett sought a patent for his [prior] work . . . he must have claimed that process he had developed was an invention. Had Bassett then collaborated with Olsen, and sought a patent for their joint product they would have been declaring that their work constituted an invention. In such a situation each process would have to be the first of its kind. Accordingly, the validity of Bassett and Olsen's patent application would have to be established against Bassett's earlier one. However, as here, where Bassett does some work, seeks no patent, collaborates with Olsen, and subsequently they together seek a patent, the joint application declares that their work submitted as a whole is a single invention—the first of its kind. Because they declare their work to be single, and first invention, as between the joint inventors there is no earlier invention or prior art against which the joint invention need be established.").

⁷⁶ See 1 DONALD S. CHISUM, PATENTS § 3.08[2], at 3-155 (July 1998) ("It should be noted that the language of the relevant statute—Section 102—provides no basis for distinguishing between patented and unpatented prior invention insofar as the definition of 'another' is concerned. The holding in *Shields* could easily have been reached by either construing the prior unpatented work and later patented work as part of a single joint invention or by ruling that the prior work by 'another' was abandoned, suppressed or concealed within the meaning of Section 102(g).") (footnotes omitted). Construing an initial discovery by one inventor and an improvement resulting from a later collaboration as a single joint invention was the approach taken by the Sixth Circuit in *General Motors Corp. v. Toyota Motor Co.*, 667 F.2d 504, 212 U.S.P.Q. 659 (6th Cir. 1981), when considering a situation factually similar to that in *Shields*.

⁷⁷ See CHISUM, *supra* note 45, at 5-180 (footnotes omitted).

⁷⁸ See *supra* note 72.

collaboration among the inventors.⁷⁹ As the Fifth Circuit said in *Shields*, "if the first inventor's initial work . . . constitutes an earlier invention to any subsequent effort with a collaborator, no valid joint invention would be possible. Theoretically every joint invention would have to be the result of simultaneous inspiration of the collaborators."⁸⁰ However, like Chisum's admonishment of the Fifth Circuit's rationale in *Shields* on the grounds that § 102 "provides no basis for distinguishing between patented and unpatented prior invention insofar as the definition of 'another' is concerned,"⁸¹ the patent statutes provide no basis for making a distinction between prior art under §102(f) versus prior art under §102(g) insofar as the prior work of one of the inventors is concerned.⁸² In other words, we fail to see a statutory basis for the Federal Circuit to "carve out" an exception where an inventor's prior work qualifies as prior art under § 102(f), but not recognize a similar exception where the inventor's prior work qualifies as prior art under § 102(g).

In our hypothetical, since Company and Company-IP are different ownership entities and thus § 103(c) would not apply, obviousness issues could be presented under §§ 102(g)/103 against the improvement invented by α , β and γ based on the prior reduction to practice of Antigen A by α and β .⁸³ Thus, even if the Federal Circuit were to adopt Chisum's recommendation and recognize the exception that "knowledge developed by a joint inventor as part of a prior invention should not be 'prior art' under Section 102(f) as to the joint invention,"⁸⁴ patenting improvements arising out of collaborations between companies would still prove problematic unless this exception is extended to reach a joint inventor's previous reduction to practice that qualifies as prior art against the joint invention under § 102(g). However, if applied generally, the holding in *In re Bass*, discussed

⁷⁹ See *Kimberly-Clark*, 973 F.2d at 917, 23 U.S.P.Q.2d at 1926 ("[T]here must be some element of joint behavior, such as collaboration or working under common direction."); see also *infra* text accompanying note 20.

⁸⁰ See *Shields*, 667 F.2d at 1235, 216 U.S.P.Q. at 1069.

⁸¹ See *CHISUM*, *supra* note 76, at 3-155.

⁸² 35 U.S.C. § 103.

⁸³ Even though the first application filed in the U.S. by Company directed to the initial discovery is secret, filing a patent application can rebut a presumption of abandonment, suppression, or concealment. See *supra* note 51.

⁸⁴ *CHISUM*, *supra* note 45, at 5-180.

supra, would appear to militate against recognizing such an exception to prior art under § 102(g)⁸⁵. Thus, another important question is whether the holding in *In re Bass* creates a *per se* rule of unpatentability under §§ 102(g)/103 based on a joint inventor's previous reduction to practice.

In *General Motors Corp. v. Toyota Motor Co., Ltd.*⁸⁶, decided prior to the enactment of § 103(c), at issue before the Sixth Circuit was the obviousness of a catalytic converter that had been developed at General Motors (GM) in at least three stages. While citing *In re Land*⁸⁷ and *In re Bass*, Toyota argued that the "three steps are discrete inventions because the first two steps did not result from the collaboration of the patentees"⁸⁸ and thus the first two steps constituted prior art against the patented catalytic converter. GM countered with the argument that "there was only one invention, the patented converter, and the two earlier steps in its development should be seen as merging into the final product."⁸⁹ The Sixth Circuit sided with GM,⁹⁰ and "explained around" the CCPA's holdings in *In re Land* and in *In re Bass*:

Neither *Land* nor *Bass* indicates that the prior inventions were in any way the product of concerted effort within a business entity. Under the facts of this case, where numerous "inventors" all worked under the aegis of one employer toward a common goal, it is appropriate to define the concept of joint invention broadly. It is not realistic to require in such circumstances that joint inventors work side-by-side,

⁸⁵ The enactment of § 103(c) legislatively overruled *In re Bass* for situations where the initial discovery and the improvement were owned by the same entity at the time the improvement was made. *See supra* notes 66 and 68 and accompanying text, and note 72. However, where the initial discovery and the improvement were made at different institutions, it would appear that the holding of *In re Bass* still applies.

⁸⁶ 667 F.2d 504, 212 U.S.P.Q. 659 (6th Cir. 1981).

⁸⁷ 368 F.2d 866, 151 U.S.P.Q. 621.

⁸⁸ *General Motors*, 667 F.2d at 506, 212 U.S.P.Q. at 662.

⁸⁹ *Id.* "Put another way, GM contend[ed] that the patented converter is a 'joint invention' of most or all of the above GM employees, and that an intermediate step by a subset of this inventive group should not be considered disabling prior art." *Id.*

⁹⁰ *See id.* ("GM's argument has the virtue of realism . . .").

and that each step in the inventive process be taken by all the firm's collaborators.⁹¹

If it is not realistic to require that each step in the inventive process be taken by all the collaborators while working at a single institution, it is arguably even less realistic to require this where the collaborators are employed at different institutions. However, it is presently unclear whether the Federal Circuit would follow the Sixth Circuit's rationale in *General Motors* and extend it to situations involving collaborators working toward a common goal or goals while employed at different institutions. In our view, recognizing α and β 's initial discovery as prior art under §§102(g)/103 against α , β and γ 's improvement places an unreasonable burden on both Company and IP. It places Company in the unenviable position of having to decide whether to abandon, suppress, or conceal the initial discovery to better ensure that patent protection will be obtained for a potentially more commercially viable improvement and, for the same reason, gives the collaborating IP an incentive to seek such assurances from Company prior to entering into the collaboration agreement.⁹² Further, creating a legal setting whereby the abandonment, suppression, or concealment of an initial discovery can, in certain circumstances, be beneficial runs contrary to a stated purpose of the patent system, which is to encourage the early disclosure of inventions to the public.⁹³

In sum, it is our view that the prior art effect of the previous knowledge or previous reduction to practice of an inventor against a later joint discovery by the inventor and another

⁹¹ *Id.*; see also, *Clairol, Inc. v. Save-Way Industries, Inc.*, 210 U.S.P.Q. 459, 464 (S.D. Fla. 1980) ("The Court concludes . . . that Burian and Sempliner are joint inventors, and on the basis of this conclusion, holds that the Sempliner prototype is not prior art with the meaning of 35 U.S.C. § 103. Prototypes created by a co-inventor do not constitute prior art within 35 U.S.C. § 103.").

⁹² While abandoning, suppressing, or concealing α and β 's initial discovery would be helpful to avoid § 102(g) prior art against the improvement, it would be detrimental if applications relating to the invention are involved in an interference. In an interference context, the ability to rely on a prior actual reduction to practice for priority is lost if that actual reduction to practice is abandoned, suppressed, or concealed. Therefore, as a general strategy, it would be preferable to avoid § 102(g) prior art in ways other than relying on abandonment, suppression, or concealment.

⁹³ See *Hearing on S. 1535 and S. 1841*, *supra* note 61, at 157

remains uncertain. Important unanswered questions include whether the Federal Circuit's holding in *OddzOn* (that prior art under § 102(f) can be relied on in an obviousness determination under § 103) would apply to communications between joint inventors and whether the CCPA's holding in *In re Bass* creates a *per se* rule of unpatentability under §§ 102(g)/103 based on a joint inventor's previous work. In light of the present day reality that collaborative research between biotech and pharmaceutical institutions is an integral part of the industry, the Federal Circuit may want to consider recognizing the equity on a case-by-case basis of defining joint invention broadly to encompass the previous knowledge and work of each joint inventor, which would arguably be in agreement with, or at least a logical extension of, the Fifth Circuit's holding in *Shields* and the Sixth Circuit's holding in *General Motors*.

D. Recommendations

In our hypothetical, to avoid encountering potential obviousness rejections under § 102(f) and § 102(g), Company and IP should have at least considered an agreement whereby IP would contractually agree to assign its rights to all inventions arising out of the collaboration to Company. This would have invoked § 103(c) of the statute, which disqualifies §102(f) and §102(g) from use as prior art under § 103 if, at the time the improvement was made, the improvement and the initial discovery were "owned by the same person or subject to an obligation of assignment with the same person."⁹⁴ If such a common assignment or an obligation to assign the improvement to Company had been in place, § 102(f) and § 102(g) prior art issues based on the initial discovery would be resolved. (The Company patent attorney could then combine the first and second applications into a CIP to prosecute claims to both the initial discovery and the improvement in one application as we discuss in Section II above to avoid any § 102(e) issues.) Thus, from a patent law perspective, crafting collaboration agreements such that § 103(c) applies best ensures that claims are obtained to both the initial discovery and the improvement because, when prosecuting the improvement, it removes the obstacle of having to overcome an obviousness rejection on the merits based on the initial discovery.

⁹⁴ 35 U.S.C. § 103(c).

However, from a business standpoint, agreeing to assign all inventions arising out of the collaboration to Company may not be acceptable to IP. This is because each joint owner (also called a co-owner or a tenant-in-common) is an owner of an undivided one-half interest in the patent⁹⁵ and is said to be at the mercy of the other joint owners.⁹⁶ 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 the patented invention into the United States without the consent of and without accounting to the other owners.⁹⁷

Additionally, all co-owners must join in a patent infringement suit. Further, a "primary interest" of a co-owner is "the interest . . . in being able to license third parties under his or her patent without harassing suits by other co-owners."⁹⁸ Thus, clear advantages flow from being a joint owner of a patent, which may make IP reluctant to enter into an agreement assigning its rights to inventions arising out of the collaboration to Company. However, this notwithstanding, many of IP's concerns could presumably be addressed contractually, such as, for example, with an exclusive licensing arrangement.

Alternatively, to avoid having to fashion a licensing arrangement that compensates for IP's lack of ownership status, Company and IP could have agreed to assign Company's initial discovery

⁹⁵ Drake v. Hall, 220 F. 905, 906 (7th Cir. 1915).

⁹⁶ See 5 E. LIPSCOMB'S WALKER ON PATENTS § 19:39 at 464-65 ("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.") (footnotes omitted). See generally Robert P. Merges and Lawrence A. Locke, *Co-Ownership of Patents: A Comparative and Economic View*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 586 (June 1990).

⁹⁷ 35 U.S.C. § 262.

⁹⁸ Willingham v. Lawton, 555 F.2d 1340, 1344, 194 U.S.P.Q. 249, 252 (6th Cir. 1977).

and all inventions arising out of the collaborative research to a joint venture, incorporated by Company and IP especially for the purpose of the collaboration.⁹⁹ Another option would be for Company to agree, prior to the start of the collaboration, to assign to IP an undivided, one-half interest in any patent application directed to Company's initial discovery, with the assignment conditioned upon the development of a patentable improvements from the collaboration. Thus, at the time of the invention of Antigen A/Adjuvant X, because of Company's obligation to assign rights in Antigen A, and due to the collaboration in the development of Antigen A/Adjuvant X, both inventions would be under an obligation to be assigned to the same ownership entity: Company-IP. Therefore, under either alternative, at the time of the invention both the potential "prior art" under § 102(f) or (g)/§ 103 of Antigen A, and the improvement invention of Antigen A/Adjuvant X would be under an obligation of assignment to the same ownership entity, and would fall within the exception in § 103(c). However, one caveat of both alternatives is that Company may not be willing to share its rights in Antigen A with IP for only the possibility of the development of valuable improvements from the collaboration. Thus, none of the alternatives we have discussed completely abrogate the § 102(f) or (g)/§ 103 prior art problem that plagues collaborations between companies.

IV. Conclusions

If a first patent application, directed to an initial discovery, and a later filed second patent application, directed to an improvement, do not name identical inventors, the disclosure of the first application may become available as prior art upon issuance into a patent against the second application under § 102(e). Thus, before permitting the first application to issue, the possibility of incorporating the text of both applications into a CIP that claims the initial discovery and the improvement should be considered. As a caveat, caution should be exercised before following this strategy in light of the traditional collaboration requirement for joint inventorship.

⁹⁹ This was previously suggested in an article by Virginia C. Bennett and Sorojini J. Biswas in *Protecting the patentability of your collaborative research*, 15 NATURE BIOTECHNOLOGY 472, 473 (1997).

If the second application is assigned to a different ownership entity than the first application, §§102(e)/103 may apply as above against a claim to the improvement in the second application once the first application issues as a patent. In addition, §§ 102(g)/103 may also apply based on the prior reduction to practice of the initial discovery. This is because § 103(c) does not apply where the initial discovery and the later discovered improvement are not commonly owned, or at least under an obligation of common assignment, at the time the improvement is made. Further, if communications between co-inventors during the development of an invention can constitute prior art, §§ 102(f)/103 may also apply. While the law remains unsettled regarding the propriety of obviousness rejections under § 102(f) or §102(g) based on a joint inventor's previous knowledge or work, we agree with others in recommending that the Federal Circuit recognize that prior knowledge developed by one inventor should not constitute prior art under §102(f) as to later joint discoveries by the inventor and another. However, in our view, recognizing such an exception for § 102(f) but not for § 102(g) could promote the abandonment, suppression, or concealment of initial discoveries to avoid them from becoming secret prior art as to later discovered improvements arising out of the collaboration.

Strategies for ensuring that § 103(c) applies to collaborative research include having the industrial partner agree to assign all rights to inventions arising out of the collaboration to the company making the initial discovery. Alternatively, the company and the industrial partner could agree to assign the initial discovery and all inventions arising out of the collaboration to a joint venture, formed especially for purposes of the collaboration, or the company could agree to conditionally assign an undivided, one-half interest in its first application to the industrial partner.

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