

A Discussion in Support of Why the U.S. PTO Should Modify the Requirements for Terminal Disclaimers Based on Joint-Research Agreements

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Filing a terminal disclaimer is one option for overcoming a non-statutory double patenting rejection in a patent application. The applicant may either file a terminal disclaimer based on common ownership (“TD-CO”) or, when applicable, file a terminal disclaimer based on a joint-research agreement (“TD-JRA”).¹

The TD-CO and the TD-JRA have several common characteristics. However, the TD-JRA has a more restrictive enforcement constraint than the TD-CO. For example, unlike the TD-CO, the TD-JRA may affect enforcing the patent that forms the basis of the non-statutory double-patenting rejection. The TD-JRA should not place a larger burden on enforcing patents compared to the TD-CO. Accordingly, this article presents a proposal for modifying the TD-JRA’s requirements in order to make the TD-JRA more patent friendly.

Overview of TD-CO and TD-JRA

Table I summarizes the common requirements for the TD-CO and the TD-JRA, based on the USPTO forms in MPEP § 1490(IX).²

Table I – Common Requirements for the TD-CO and TD-JRA

Item	Description
Term Effect	Requires the patent applicant to disclaim the term of any patent that extends beyond the expiration date of another patent subject to the same terminal disclaimer.
Binding Effect	Requires the patent grantee, its successors, or assignees to comply with the terminal disclaimer.
Exceptions	Provides conditions that may void the terminal disclaimer.

The term effect ensures that patents subject to the same terminal disclaimer will expire on the same day. Back when patents had terms based on their issue date, a patent owner

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could extend its monopoly by filing serial continuation applications if each resulting patent had a later issue date.³ Today, patents based on applications filed after 1995 have terms based on their earliest US filing date. Therefore, the term effect matters less.

The binding effect ensures that a terminal disclaimer remains in place if the patent owner transfers its ownership to another party. As for the exceptions, the terminal disclaimer forms in MPEP § 1490(IX) include language that voids the terminal disclaimer if the prior patent expires for failing to pay a maintenance fee, is held unenforceable, is found invalid by a court, is statutorily disclaimed, has all of its claims canceled by a reexamination certificate, is reissued, or is terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

As shown in Table 2 below, the TD-CO and the TD-JRA include enforcement constraints that are designed to prevent an infringer from facing multiple lawsuits from different assignees for patents with claims that are patentably indistinct from each other.⁴ The TD-CO has a common-ownership constraint and the TD-JRA has a common-enforcement constraint.

Table 2 – Enforcement Constraints of the TD-CO and TD-JRA

TD-CO - 37 C.F.R. §1.321(c)(3)	TD-JRA - 37 C.F.R. §1.321(d)(3)
<p>(c) A terminal disclaimer, when filed to obviate judicially created double patenting in a patent application or in a reexamination proceeding . . . must . . .</p> <p>(3) Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting.</p>	<p>(d) A terminal disclaimer, when filed in a patent application or in a reexamination proceeding to obviate double patenting based upon a patent or application that is not commonly owned but was disqualified as . . . the result of activities undertaken within the scope of a joint research agreement, must . . .</p> <p>(3) Include a provision waiving the right to separately enforce any patent granted on that application or any patent subject to the reexamination proceeding and the patent or any patent granted on the application which formed the basis for the double patenting, and that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent and the patent, or any patent granted on the application, which formed the basis for the double patenting are not separately enforced.</p>

TD-JRA is more Restrictive than the TD-CO

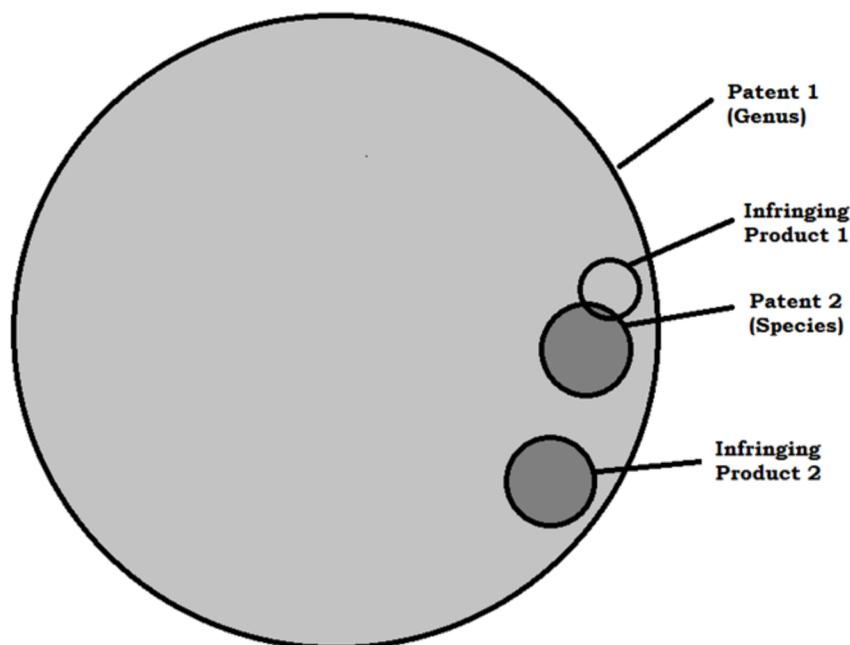
The TD-CO does not affect enforcing the patent that forms the basis of the double-patenting rejection, but the TD-JRA appears to. For example, 37 C.F.R. §1.321(c)(3) states that the patent granted on the application rejected for double patenting “shall be enforceable only for and during such period that said patent is commonly owned with the . . . patent which formed the basis for judicially created double patenting.” The language in 37 C.F.R. §1.321(c)(3) only affects enforcing the patent based on the application rejected for double patenting. Thus, if the common-ownership constraint in the TD-CO is breached, the patent that forms the basis of the double-patenting rejection still may be enforced.⁵

In contrast, the common-enforcement constraint of the TD-JRA is more restrictive than the common-ownership constraint of the TD-CO. For the TD-JRA, 37 C.F.R. §1.321(d) (3) requires that the patent owners waive the right to separately enforce any patent granted on the application rejected . . . [for] double-patenting and the patent granted on the application which forms the basis for the double patenting.

Additionally, some parties expressed concerns during the USPTO's rulemaking process that enforcing two patents subject to the same TD-JRA may be impossible if only one of the patents includes claims that read on the infringing product.⁶ The USPTO's Final Rule implementing the TD-JRA does not respond to those concerns.⁷

Figure 1 provides scenarios where the TD-JRA and TD-CO may affect enforcing patents differently. The genus claims in Patent 1 read on Products 1 and 2. The species claims in Patent 2 only read on Product 1. If the claims in Patents 1 and 2 are patentably indistinct, then the Examiner could reject the claims in Patent 2 for non-statutory double-patenting based on the claims in Patent 1.⁸

FIG. 1 – Claim Scope for Patents 1 and Products 1 and 2



The claims in Patents 1 and 2 both read on Product 1. Therefore, the common-enforcement constraint in the TD-JRA allows enforcing Patents 1 and 2 in the same lawsuit for infringement based on Product 1. Also, if Patents 1 and 2 are commonly owned, the common-ownership constraint in the TD-CO allows enforcing both Patents 1 and 2 for infringement based on Product 1.

However, the TD-CO and TD-JRA could make a difference for infringement based on Product 2. For example, the common-ownership constraint in the TD-CO allows enforcing Patent 1 by itself. In contrast, if Patents 1 and 2 are subject to the same TD-JRA, the owners of Patents 1 and 2 may be unable to bring an infringement lawsuit for infringement based on Product 2. As a defense against infringing Patent 2, the alleged infringer could argue that Product 2 does not directly infringe the claims of Patent 2. As a defense against infringing Patent 1, the alleged infringer could argue that the common-enforcement constraint in the TD-JRA prevents enforcing Patents 1 and 2 unless both Patents 1 and 2 are enforced in the same lawsuit (i.e., commonly enforced).

Now, in order to satisfy the common-enforcement constraint in the TD-JRA, the owner of Patent 2 could argue that Product 2 infringes the claims in Patent 2 based on the doctrine of equivalents.⁹ However, that makes enforcing Patent 1 more complex if Patents 1 and 2 are subject to a TD-JRA instead of a TD-CO. For example, if Patents 1 and 2 are subject to the same TD-CO, then Patent 1 may be enforced by itself. On the other hand, if Patents 1 and 2 are subject to the same TD-JRA, then Patents 1 and 2 have to be enforced in common. Additionally, prosecution history estoppel may limit the owner of Patent 2 from asserting that Product 2 infringes the claims in Patent 2 based on the doctrine of equivalents.¹⁰

Proposed Modification to the TD-JRA

Table 3 shows a proposed change that makes the enforcement constraint for the TD-JRA in 37 C.F.R. §1.321(d)(3) similar to the enforcement constraint for the TD-CO in 37 C.F.R. §1.321(c)(3).

Table 3 – Enforcement Constraints of the TD-CO and TD-JRA

TD-CO - 37 C.F.R. §1.321(c)(3)	Proposed Change to the TD-JRA - 37 C.F.R. §1.321(d)(3)
<p>(c) A terminal disclaimer, when filed to obviate judicially created double patenting in a patent application or in a reexamination proceeding except as provided for in paragraph (d) of this section, must ...</p> <p>(3) Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting.</p>	<p>(d) A terminal disclaimer, when filed in a patent application or in a reexamination proceeding to obviate double patenting based upon a patent or application that is not commonly owned but was disqualified as prior art as set forth in either § 1.104(c)(4)(ii) or (c)(5)(ii) as the result of activities undertaken within the scope of a joint research agreement, must ...</p> <p>(3) Include a provision waiving the right to separately enforce any patent granted on that application or any patent subject to the reexamination proceeding and separately from the patent or any patent granted on the application which formed the basis for the double patenting, and that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent <u>is not enforced separately from</u> and the patent, or any patent granted on the application, which formed the basis for the double patenting are not separately enforced.</p>

The proposed change modifies 37 C.F.R. § 1.321(d)(3) so the patent that forms the basis of the double patenting rejection may be enforced separately from a patent based on the application rejected for double-patenting. As a result, the proposed change to 37 C.F.R. § 1.321(d)(3) will have the same effect as 37 C.F.R. § 1.321(c)(3) on the patent that forms the basis of the double patenting rejection.

The proposed change to 37 C.F.R. § 1.321(d)(3) still includes a “provision waiving the right to enforce any patent granted on that application ... separately from the patent ... which formed the basis for the double patenting” to prevent an accused infringer from facing multiple lawsuits from different assignees for patents that are patentably indistinct from each other.

Conclusion

In its current form, the TD-JRA places more burdens on enforcing patents compared to the TD-CO. The key difference is the TD-JRA may limit enforcing the patent that serves as the basis for the double-patenting rejection. Accordingly, the USPTO should consider modifying the enforcement constraint for the TD-JRA based on the proposal in this article.

There is also precedent for changing the enforcement constraint of a terminal disclaimer. The TD-CO used to have a much harsher enforcement constraint. Before an amendment to 37 C.F.R. §1.321 in 1971, a patent granted on an application rejected for double-patenting would “expire immediately” if the patent at any time was not commonly owned with the patent that formed the basis of the non-statutory double-patenting rejection.¹¹ However, the USPTO recognized that the TD-CO does not need to be overly harsh as long it

serves the policy of objectives of double-patenting. The proposed change to the TD-JRA in this article just makes the TD-JRA more similar to the TD-CO by removing the part of the TD-JRA that limits enforcing the patent that forms the basis of the double-patenting rejection.

1. 37 C.F.R. § 1.321(c) and (d).
2. Manual of Patent Examining Procedure (MPEP) § 1490(IX) (9th ed., November 2014).
3. *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214-15 (Fed. Cir. 2014).
4. One of the policy justifications for double-patenting is preventing an accused infringer from facing multiple lawsuits from different assignees of related patents. *In re Van Ornum*, 686 F.2d 937, 944 (CCPA 1982).
5. For example, in *Voda v. Medtronic, Inc.*, 899 F. Supp. 2d 1188 (W.D. Okla. 2012), *aff'd* 541 Fed. Appx. 1003 (Fed. Cir. 2013)(per curiam without opinion under Rule 36), Voda successfully asserted an infringement claim for US Patent No. 6,083,213. Voda also tried to enforce US Patent No. 6,475,195. US 6,475,195 was subject to a first terminal disclaimer that required US Patent No. 6,475,195 would only be enforceable while it was commonly owned with US Patent No. 5,445,625 and a second terminal disclaimer that required US Patent No. 6,475,195 would only be enforceable while it was commonly owned with US Patent No. 6,083,213. During the lawsuit, the district court granted Medtronic's motion to dismiss the infringement claims for US Patent No. 6,475,195 because US Patent Nos. 6,475,195 and 5,445,625 were not commonly owned. Footnote 6 of the district court's order also suggests that Voda would be unable to enforce US Patent No. 6,475,195 because Voda did not own both US Patent Nos. 6,083,213 and 6,475,195 at the time the lawsuit was filed. *Voda v. Medtronic, Inc.*, Case No. CIV-09-95-L (W.D. Okla. Aug. 17, 2011).
6. Comments of Association of American Universities and Council on Government Relations on Interim Rule to Implement the Cooperative Research and Technology Enhancement Act of 2004, p. 2, Docket. No.: 2004-P-034, (February 10, 2005) (“[a] number of different fact scenarios make it impractical and unfair to require that both the rejected patent and the disqualified patent always be asserted together. For example, only one of two patents may have claims covering the infringing product or service.”); Comments of Sterne, Kessler, Goldstein & Fox P.L.L.C on Interim Rule to Implement the Cooperative Research and Technology Enhancement Act of 2004, p. 5, Docket. No.: 2004-P-034, (February 10, 2005). Both Comments are available at <http://www.uspto.gov/patent/laws-and-regulations/comments-public/comments-changes-implement-cooperative-research-and>.
7. Changes to Implement the Coop. Res. and Tech. Enhancement Act of 2004, 70 Fed. Reg. 54259, 54262-54264 (Sept. 14, 2005).

8. *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1379-81 (Fed. Cir. 2014).
9. *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1286-87 (Fed.Cir.2010)
10. See *id.* at 1290-92.
11. See *Merck Co, Inc. v. US Int'l Trade Comm'n*, 774 F. 2d 483 n. 21 (Fed. Cir 1985); MPEP § 804.02 (3rd ed., Rev. 22, October 1969), at http://www.uspto.gov/web/offices/pac/mpep/old/E3R22_800.pdf.