

Rule changes at the USPTO

Proposed rule change to the USPTO practice on terminal disclaimers and obviousness double patenting stemming from joint research agreements. By **Connor McGregor** and **Tim McAnulty**.

The US Patent and Trademark Office (USPTO) proposed a rule change affecting applicants subject to joint research agreements. The proposed rule expands the ability of parties to a joint research agreement to file terminal disclaimers and overcome double patenting rejections. And it further allows parties to preemptively file terminal disclaimers to expedite prosecution. This article provides a backdrop for the rule change and discusses potential benefits to applicants.

Double patenting

The USPTO considers two types of double patenting rejections: statutory double patenting, when the USPTO considers claims in an application to be drawn to the same invention as claims in another application or patent, and obviousness-type double patenting (ODP), when the USPTO considers claims in an application to be different but not 'patentably distinct' from claims in another application or patent. See, e.g., *Eli Lilly v Barr Labs*.¹ ODP rejections may be based solely on the reference application or patent, or include one or more secondary references similar to an obviousness rejection based on prior art.

Statutory double patenting is based on the principle that an inventor is entitled to only one patent per invention.² ODP is based on this same principle but is a judicially created doctrine to prohibit an inventor from extending the term of a first patent by introducing inconsequential differences and to limit the risk of multiple infringement suits by different assignees asserting separate patents for essentially the same invention.³ Statutory double patenting rejections are generally less frequent than obviousness double patenting rejections and typically require amending the claims to overcome. ODP rejections, on the other hand, can be overcome in various ways. For example, applicants can amend or argue to further differentiate the pending claims

and show they are patentably distinct from the reference claims. ODP can arise during prosecution as well as litigation, and the Finnegan team has discussed the changing state of the law on ODP in several earlier articles.⁴ While the law is still somewhat unsettled, this article focuses on overcoming ODP rejections during prosecution by using terminal disclaimers when the inventions are generated from a joint research programme.

While ODP rejections can be overcome by filing a terminal disclaimer,⁵ there are potential drawbacks. A terminal disclaimer surrenders the portion of patent term (if the underlying application is granted) which extends beyond the expiration date of the referenced patent or application.⁶ And the referenced patent or application and the underlying application must be commonly owned when the terminal disclaimer is filed, and throughout the term of both patents.⁷

Joint research agreements

It is not uncommon for different entities to cooperate on research or product development. Often, these joint ventures lead to new inventions and one or more patent applications. Generally, if these separate entities cooperate and share information, they could limit each other's ability to obtain a patent on subject matter derived from the information shared during the venture. For example, if one party files a patent application after another party, the first-filed application might be prior art against the second-filed application. Additionally, if two different parties file patent applications for different but not patentably distinct inventions, the applications may have double-patenting concerns relative to one another. If the applications were commonly owned, an ODP rejection could be overcome by filing a terminal disclaimer. But, if the applicants are distinct entities cooperating through a joint enterprise, strict co-ownership may not be possible.

In 2004, the United States passed the CREATE Act, which had

a goal to encourage disclosures and promote cooperative research between universities, the public sector, and private enterprises.⁸ The Act amended the pre-AIA patent statute to exempt certain prior art from being used to render claims obvious, including: previously filed published US patent applications, previously issued US patent applications, or previously published PCT applications that designate the United States, where they name another inventor.⁹ To accomplish this, the Act treats qualifying applications, created under a joint research agreement,¹⁰ as if they were commonly owned. Thus, an applicant of a qualifying application can overcome obviousness grounds for rejection if:

1. the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
2. the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
3. the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.¹¹

An applicant of a qualifying application may also be able to file a terminal disclaimer to overcome an ODP rejection.¹² But because they are not actually commonly owned, the terminal

disclaimer must be accompanied by a provision stating that any patent granted will be unenforceable if either the challenged application or the referenced patent or application are ever separately enforced.¹³

Reason for the rule change

In 2011, the United States passed the Leahy-Smith America Invents Act (AIA), changing the patent system from first-to-invent to first-inventor-to-file.¹⁴ The AIA effectively maintained the exceptions of certain prior art for purposes of obviousness, but moved them from the obviousness statute to the novelty (or enumerated prior art) statute.¹⁵

The current federal rule for filing of terminal disclaimers to overcome ODP rejections is limited to instances where the referenced patent or application is exempted as prior art against the challenged patent or application.¹⁶ Effectively, the rule is aligned with the statutory exemption of prior art for obviousness, i.e., if a reference patent or application was exempted for purposes of obviousness, a terminal disclaimer could also be filed to overcome an ODP issue. But the rule did not explicitly permit terminal disclaimers if the reference patent or application was not exempted.¹⁷ This led to unintentional consequences.¹⁸

For example, ODP issues are not limited to prior art, i.e., earlier disclosures. As the Federal Circuit stated in *Gilead*

Notes and references

1. *Eli Lilly & Co. v Barr Labs., Inc.* 251 F.3d 955, 967 (Fed. Cir. 2001).
2. See 35 U.S.C. §101 ('Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, **may obtain a patent therefor**, subject to the conditions and requirements of this title.')[emphasis added] (interpreted as providing one patent per invention).
3. *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013).
4. Double Patenting, Timothy P. McAnulty and Arpita Bhattacharyya, Ph.D., January/February [2017] *CIPA* 25; Double Patenting in the US, Jeffrey M. Jacobstein, Rhianna L. Lindop, Ph.D., and Erin M. Sommers, Ph.D., December [2017] *CIPA* 20; US Update: Double Patenting, Timothy P. McAnulty and Arpita Bhattacharyya, Ph.D., April [2019] *CIPA* 35.
5. 37 C.F.R. §1.321(c).
6. See MPEP §804.02.
7. 37 C.F.R. §1.321(c)(3).
8. The Cooperative Research and Technology Enhancement Act of 2004 (the CREATE Act), Public Law 108– 453, 118 Stat. 3596.
9. See id.; see also 35 U.S.C. § 103(c)(2004) (Pre-AIA).
10. The USPTO considers a joint research agreement to be a written contract, grant, or cooperative agreement entered into by two or more persons for the performance of experimental, developmental, or research work in a specific art field. See MPEP § 717.02.
11. 35 U.S.C. § 102(c).
12. 37 C.F.R. § 1.321(d).
13. Id.
14. Leahy-Smith America Invents Act (the AIA), Public Law 112–29, 125 Stat. 284 (2011).
15. Common-ownership provisions moved from Pre-AIA 35 U.S.C. §103(c)(1) to AIA 35 U.S.C. §102(b)(2)(C) and the joint research agreement provisions moved from Pre-AIA 35 U.S.C. §103(c)(2) to AIA 35 U.S.C. §102(c).
16. 37 C.F.R. §1.104(c)(4)(ii).
17. 37 C.F.R. §1.321(d).
18. Disclaimer Practice in Patents and Patent Applications, 85 Fed. Reg. 86,518 (30 December 2020), available at: www.federalregister.gov/documents/2020/12/30/2020-27676/disclaimer-practice-in-patents-and-patent-applications.
19. *Gilead Sciences, Inc. v Natco Pharma Ltd.* 753 F.3d 1208 (Fed. Cir. 2014).
20. Id. at 1215, 1217.
21. 35 U.S.C. §102(a)(2).
22. Disclaimer Practice in Patents and Patent Applications, 85 Fed. Reg. 86,518 (30 Dec 2020), available at: www.federalregister.gov/documents/2020/12/30/2020-27676/disclaimer-practice-in-patents-and-patent-applications.
23. Id.
24. Id.
25. Id.
26. Petitions typically do not toll the required response periods set forth during prosecution. MPEP §710.
27. Disclaimer Practice in Patents and Patent Applications, 85 Fed. Reg. 86,518 (30 December 2020), available at: www.federalregister.gov/documents/2020/12/30/2020-27676/disclaimer-practice-in-patents-and-patent-applications.

Sciences v Natco Pharma,¹⁹ a patent that issues after but expires before another patent can qualify as an ODP reference for an earlier-issued, later-expiring patent.²⁰ Thus, in some instances a referenced patent or application may not qualify as a prior art reference to the underlying application yet it may still qualify as an ODP reference.

For example, if the challenged application has the same, or an earlier, filing date as a referenced application, the referenced application would not qualify as prior art under the current statute and the applicant could not file a terminal disclaimer to overcome an ODP rejection. Similarly, the statute requires that the prior art reference 'names another inventor.'²¹ So, if the inventive entities are the same but the applications themselves are not commonly owned (not an uncommon situation for joint research agreements), the referenced patent or application would not qualify as prior art under the statute, yet the applicant could not file a terminal disclaimer to overcome the rejection.

The USPTO recognizes that the current rule narrows the benefit of joint research agreements and thus potentially hinders the objective of the CREATE Act (to encourage research and similar disclosures under such agreements). For that reason, the USPTO has routinely granted petitions to waive the specific prior art requirement in these circumstances and allow applicants to file terminal disclaimers.²² The USPTO's proposed rule change now seeks to formally adopt this practice.

The proposed rule revises the introductory text to permit the filing of a terminal disclaimer by a party to a joint research agreement even where the referenced application or patent is not prior art to the challenged application.²³ It removes the language which requires that the referenced application or patent first be disqualified as prior art.²⁴ The requirements for establishing a joint research agreement and the requirement that the claimed inventions result from activities within the scope of that agreement are unchanged. In addition, the new rule will allow applicants to preemptively file terminal disclaimers, before any ODP rejections have been raised.²⁵

Thus, qualifying entities sharing information under a joint research agreement will not bar each other's different but patentably indistinct inventions. Furthermore, it allows qualifying applicants to file applications at the same (or close to the same) time without risking ODP implications. The rule change also eliminates the need for applicants to file petitions requesting the USPTO to waive the specific prior art requirement, which was necessary under the old rule. This should provide a more efficient use of USPTO resources by eliminating the need to review and grant such petitions and saves applicants the cost of preparing and filing petitions, as well as the possible delay in prosecution while petitions are pending.²⁶ Furthermore, allowing preemptive filing of the terminal disclaimers will likely benefit parties and the USPTO. The rule should streamline prosecution (if terminal

disclaimers are filed early) by avoiding time associated with the USPTO and applications in considering, issuing, and overcoming ODP rejections by filing terminal disclaimers.

Conclusion

The proposed rule change was published by the USPTO on 30 December 2020. Comments on the rule change must be received by 22 March 2021 to be considered.²⁷ After considering the comments, the USPTO will issue its final rule, though there is no due date for the USPTO to act. Stay tuned as we continue to follow changes to USPTO regulations and double patenting in the United States. □

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