

Balancing Inequities: Overcoming Double Patenting in Today's World

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Obviousness-type double patenting ("OTDP") is a rare beast in the realm of patent law – in a regime dominated by statutes and rules, OTDP arises from equity. Like patent misuse, implied license, and the doctrine of equivalents, OTDP was judicially created to right perceived wrongs allowed by those statutes and rules. In the case of OTDP, those wrongs are easy to understand.

One of the underlying wrongs is unjust extension of patent term. If a patentee seeks to obtain a second patent to essentially the same invention as an earlier patent, the second patent should last no longer than the first.

The second and less obvious wrong is subjecting an alleged infringer to multiple lawsuits by different parties on patents arising out of the same inventive activities. Such duplicative lawsuits unfairly penalize potential infringers and complicate the path to market for the patented technology, so patentees seeking multiple patents to essentially the same invention should not be permitted to separate the related patents from one another.

The United States Patent and Trademark Office ("USPTO") rejects applications for OTDP as a way of preempting the granting of multiple indistinct patents. The standard cure for OTDP is to file a terminal disclaimer ("TD") with two key provisions: (1) any term of the later patent that outlasts a prior patent is disclaimed and (2) the affected patents must be commonly owned or enforced. Although the name "terminal disclaimer" suggests only the first of these requirements, the second provision is an inextricable part of a TD.

OTDP is a critical issue for patents. In recent years, the pharmaceutical industry has run afoul of OTDP in high-profile cases for blockbuster drugs. The result? The only remaining patent protecting a lucrative drug is invalid. The economic consequences are predictably severe.

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The World Has Changed

The law of OTDP was born in time when U.S. patents lasted 17 years from their issue date, and filing a TD in a subsequent application with patentably indistinct claims invariably addressed the inevitable result that the second patent would last longer.

Times have changed. Patents granted on applications filed since June 8, 1995, when the General Agreement on Tariffs and Trade ("GATT") took effect, are entitled to a term that lasts 20 years from their earliest claimed PCT or U.S. utility priority filing date, regardless of when they issue.

Thus, setting aside the potential for accruing patent term adjustments due to delay in prosecution,¹ the vast majority of patents issuing today have a term that depends entirely on their priority date. Yet the USPTO's guidelines for requiring TDs, based primarily on pre-GATT case law, read as though we still live in a 17-years-from-issue world, and even the courts seem quite attached to the rules they created in days gone by.² Consequently, TDs work smoothly only in the simplest and most straightforward scenarios; in complex situations, bizarre outcomes may result.

Under the pre-GATT patent term system, each patent in a string of continuations was entitled to its own 17 years of patent term, with little to prevent an infinite succession of patents to the same basic invention from stretching endlessly into the future. TDs provide a perfectly reasonable solution to the problem, both preventing the incremental extension of patent term for an invention, and protecting potential infringers from the risk of being sued by multiple parties wielding similar patents arising from the same inventive acts.

For a series of continuation applications, this requirement is still reasonable post-GATT. After all, later patents in a series of continuations all claim the same priority date and thus will expire simultaneously by their very nature. Other than the often acceptable requirement to maintain common ownership, an applicant loses nothing by filing a TD.

Of course, not all patentably indistinct patents arise from continuations of a common ancestor application. In the U.S., it is sometimes possible to obtain a patent for the most modest of improvements, because prior patents of the same inventors are not prior art³, and prior patents of the same owner are partially excluded from being prior art.⁴ Nonetheless, if the claimed improvement is obvious over the claims of an earlier patent, the application will still be rejected for OTDP, meaning that the modest improvement gets no more patent term than the original invention.

This, too, makes theoretical sense in both pre-GATT and post-GATT regimes. After all, whether the later-filed application expires later by virtue of being later issued or by being later filed, the excess will be relinquished by the filing of a TD. However, in real life, there is no guarantee that the later-filed application will issue second. And OTDP scenarios grow even more complex from there.

Current USPTO Practice

Whenever two applications or an application and a patent have an inventor in common or are commonly owned, the examiner applies OTDP analysis. The Manual of Patent Examining Procedure ("MPEP") details the USPTO's approach to this analysis.⁵

When considering an application and a patent, one of two analyses is performed. If the application has the earlier filing date, a two-way test is used, so long as the applicant could not have filed the patented claims in the earlier-filed application and administrative delay is solely responsible for the earlier-filed application not issuing first. Satisfying the two-way test requires finding the application claims obvious over the patent claims *and vice versa*. For all other applications, a one-way test is applied, looking only at the obviousness of the application's claims over those of the patent. A finding of obviousness mandates an OTDP rejection.

Finally, the MPEP establishes how an applicant can overcome an OTDP rejection.⁶ Unless the applicant argues that the claims are not in fact obvious or amends the claims to remove the obvious subject matter, the applicant *must* file a TD, addressing both the disclaimer of term and the common enforcement of the patents, in the application in which the rejection is made.

This framework is based on the governing case law, and reflects how courts currently examine OTDP issues as well.

Real Life Happens

Real-world situations illuminate the mischief that these seemingly reasonable rules can create. Although these hypotheticals consider the issues from the standpoint of an applicant at the USPTO, the same principles and possible solutions pertain to double patenting issues raised against a patent holder in litigation.

i) A company and a university professor, under an obligation to assign patent rights to the university, collaborate without a joint research agreement. They jointly file a patent for a composition comprising two types of agents, A and B. The company licenses the university's rights. After the collaboration ends, the company, working alone, identifies a particular kind of B that offers unique advantages in the composition and files an application for this composition, A+B'. Patents issue for both inventions, and a continuation of the first application is properly filed. The continuation application is rejected for obviousness-type double patenting over the patent for the second invention, on the grounds that the application and the patent have an inventor in common and claims to A+B are anticipated by the patented claims to A+B', making A+B indisputably obvious.

Notice that the second invention is patentable over the first, but because the USPTO's analysis is based on the *filing* date, rather than the *priority* date, a one-way analysis is applied. No harm, one might say, since the application expires earlier anyway. But here, the application is jointly owned by the company and the university, while the patent is owned solely by the company. Because a terminal disclaimer cannot be filed without common ownership or at least a joint research

agreement,⁷ the only option recognized by the USPTO rules is to amend the claims to avoid the problem. However, as the specification for the first invention was drafted before the second invention was conceived, there may be no support in the application for any satisfactory amendment that preserves meaningful claim scope.

The best course of action is, of course, to avoid this situation entirely. Had the parties entered into a joint research agreement ("JRA"), Section 1.321(d) would permit the filing of the requested TD, requiring simply that the parties agree to commonly enforce the patents. In the above situation, had the company and the university entered into a JRA, a TD could have been filed with little consequence.

However, without the JRA, the USPTO rules provide no clear path to overcome the rejection. But all hope is not lost if the situation is viewed not through the lens of the MPEP but from the grounding principles and concerns of OTDP. Viewed in this way, since time-wise extension of patent rights is arguably not at play in this circumstance, simple cooperation between the university and the company could resolve any inequities occasioned by the granting of the second patent to the joint invention. The parties might, for example, present to the USPTO a signed contract agreeing that the patents to the first and second invention will be commonly enforced.⁸ This agreement should eliminate the threat of multiple parties suing an infringer on related patents no less effectively than the corresponding provision of a standard TD. Even if a patent term adjustment made patent term an issue as well, any excess term could be handily disclaimed using an ordinary disclaimer.⁹ Because OTDP law rests firmly in equity, there is no obvious reason that such an approach would not find approval in the courts, if not in the USPTO.

Not all OTDP issues arise from complex ownership situations, though, as the second hypothetical demonstrates.

ii) A company screens molecules, identifies a genus of drug candidates, and files an application for the genus. Before this application publishes, the same inventors identify a subgenus including a few surprisingly efficacious compounds and a lead compound within this subgenus. The company files an application for the subgenus and the lead compound. The first application issues as a patent, and the claims of the second application are found patentable over the prior art, which under Section 102(e) does not include the company's earlier patent. However, although the lead compound is not obvious over the claims of the patent, the dependent claims of the earlier patent include a claim that renders the subgenus obvious, and so an OTDP rejection is made. For reasons unrelated to patentability, the company wants the lead compound to be the subject of its own patent, separate from the subgenus. The company then has two options:

1. cancel the claims to the subgenus, take the patent to the lead compound without disclaiming term, and pursue the subgenus in a continuation; or
2. cancel the claim to the lead compound, take the patent to the subgenus with the disclaimer, and pursue the lead compound in a continuation.

If the company chooses option 1, the continuation will require a TD over both patents, but the term of the compound patent will be unshortened, an obvious

advantage. However, examination of the continuation may not go as smoothly as in the parent, putting the broader scope of the subgenus at risk.

With option 2, the term of the compound patent will likely have to be disclaimed over the subgenus patent, whose term is already disclaimed over the original genus patent. A set of patented claims identical to those of option 1 would result. The risk that examination of the narrow lead compound claims goes poorly is comparatively small, yet the patent term advantage for the compound patent is forfeited.

The asymmetry here arises from the provision of the USPTO's form TD that disclaims the term of a patent that extends past the expiration date of the earlier patent, *as the earlier patent may itself be terminally disclaimed over earlier patents*. The equitable need for this indirect disclaimer is suspect, as it is not demonstrably unfair for the compound patent to last longer than the original genus patent. Faced with this situation, an applicant might try filing a TD that, without referencing the original genus patent, disclaims any term that extends past the *undisclaimed* expiration date of the subgenus patent. This tactic arguably achieves the dual goals of avoiding unjust extensions of patent term and risk of multiple lawsuits, although it may encounter hurdles in the USPTO or the courts.

Another possible solution is to follow option 2, but respond to the double-patenting rejection in the continuation to the compound by filing a TD *in the subgenus patent* referencing the compound application. This filing would cement the requisite common ownership, and if a patent term adjustment in the later patent would cause the term to exceed the undisclaimed term of the patent, that excess could be disclaimed by a straightforward disclaimer without specifically referencing the subgenus patent, thus avoiding the arguably unnecessary indirect disclaimer over the original genus patent. Unfortunately, this type of solution is also not to be found in the MPEP; the creative applicant that wishes to pursue it may end up having to appeal to the Board of Patent Appeals and Interferences, if not the courts.

Over recent years, OTDP practice has switched from a sensible approach to resolving equitable concerns into an arcane and rigid set of rules ill-adapted to a modern post-GATT world in which employees are increasingly mobile and companies routinely engage in complex collaborations. Despite legislative interventions, such as the Cooperative Research and Technology Enhancement Act, that help to inject the law with a dose of the flexibility modern business requires, OTDP still creates traps for the unwary and pitfalls for the merely unlucky. Until the law adapts to modern realities, such difficulties will remain. However, by stepping back to focus on the equitable issues, applicants faced with a seemingly insurmountable obstacle can design a creative remedy to suit the occasion. With persuasion and a little luck, success may still be within reach.

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¹ For simplicity, the complicating effects of patent term adjustment will not be considered in this article.

² See, for example, *In re Fallaux*, 564 F.3d 1313 (Fed. Cir. 2009).

³ 35 U.S.C. § 102(e)

⁴ 35 U.S.C. § 103(c)

⁵ MPEP § 804

⁶ MPEP § 804.02

⁷ 37 C.F.R. § 1.321(d)

⁸ Indeed, such a provision might be inserted into the license agreement between the university and company, in case the relationship might sour later on.

⁹ See, for example, 37 C.F.R. § 1.321(b).