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A Look At The U.S. Doctrine of Obviousness-Type Double Patenting

Courtenay C. Brinckerhoff (Foley&Lardner LLP) · Wednesday, June 13th, 2012

While many countries have laws against “double patenting” that prevent an Applicant from obtaining more than one patent on the same invention, the U.S. also bars Applicants from obtaining a second patent on an invention that is deemed to be an obvious variation of an invention claimed in a granted patent. The judicially created doctrine of “obviousness-type double patenting” (OTDP) is one of the most complex areas of U.S. patent law, but there are underlying principles that can serve as guideposts when navigating through an OTDP analysis.

Obviousness-Type Double Patenting

In a recent case addressing OTDP in the pharmaceutical patent context, [Otsuka Pharmaceutical Co. v. Sandoz, Inc.](#), the Federal Circuit explained that the doctrine of obviousness-type double patenting (also referred to as “non-statutory double patenting”) is “grounded in public policy that prevents the extension of the term of a patent . . . by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent.”

In accordance with the USPTO’s [Manual of Patent Examination and Procedure \(MPEP\)](#), the language you might see in an Office Action explains it this way:

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent.

[Section 804](#) of the MPEP includes a complex flow chart illustrating when an OTDP rejection should be raised, but there are three basic requirements:

1. There must be a common inventor or owner or a joint research agreement linking the cited patent/application and the patent application at issue.
(The USPTO guidance provides for OTDP rejections even when the patents/applications are not owned by the same entity, but this specific fact pattern has not been directly upheld by the Federal Circuit.)
2. The subject matter claimed in the application at issue must be obvious in view of the subject matter claimed in the cited patent/application, or vice versa.
3. There must not have been a Restriction Requirement that resulted in the subject matter at issue being pursued in separate patent applications.

The OTDP Analysis

As the Federal Circuit explained in *Otsuka*, an OTDP situation “is analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. § 103 [but] [i]mportant differences remain.”

- First, “the patent principally underlying the double patenting rejection need not be prior art.” This means that the asserted patent/application may have been filed earlier, simultaneously with, or after the application at issue.
- Second, the claims at issue are not evaluated in view of the specification of the cited patent/application, although the specification may be consulted to determine the meaning of the cited claims, and “may be considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent.” See MPEP § 804.

The MPEP provides the following guidance to USPTO Examiners:

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claim relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations.

In *Otsuka*, the Federal Circuit explained that an OTDP analysis for a new chemical entity under the “lead compound” framework analysis differs from the prior art obviousness analysis because the OTDP analysis starts with the assumption that the compound claimed in the granted patent is a “lead compound.” Thus, the OTDP inquiry turns on the identification in the prior art of “some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success.”

Typical Scenarios

While OTDP must be evaluated on a case by case basis, there are some scenarios that arise frequently:

- granted claims to a species are likely to give rise to an OTDP rejection against claims to an

encompassing genus *but*

- claims to a species might be patentably distinct from earlier claims to an encompassing genus if, for example, the species exhibits unexpected results (but see discussion of “Difficult OTDP Questions” below)
- granted claims to a method of making or using a compound or composition are likely to give rise to an OTDP rejection against claims to the compound or composition itself *but*
- claims to a specific method of using a compound or composition may be patentably distinct from earlier claims to the compound or composition (unless the later claimed method would preempt the only disclosed use for the earlier patented compound or composition. *See, e.g., Geneva Pharms., Inc. v. Glaxosmithkline, PLC* (Fed. Cir. 2003))

Difficult OTDP Questions

One difficult OTDP question is whether claims that do not recite overlapping subject matter nevertheless can give rise to an OTDP situation if the subject matter is not patentably distinct. Take for example (i) claims to a composition comprising Formulation A with Drug X and (ii) claims to a composition comprising Formulation A with Drug Y.

If the purpose of the doctrine is used as a guiding principle, such a scenario should not give rise to OTDP, because there is no “timewise extension of the right to exclude.” The patentee could not use the claims that recite Drug X to prevent commercialization of a composition with Drug Y. On the other hand, if only the usual principles of obviousness are applied, such a scenario could give rise to OTDP if, for example, once Formulation A is known it would have been obvious to prepare a composition with Drug Y instead of Drug X.

Although recent case law emphasizes the obviousness analysis, earlier decisions that are directly on point indicate that claims that do not recite overlapping subject matter do not give rise to OTDP. *See, e.g., In re Vogel* (CCPA 1970) (pork vs. beef); *General Foods v. Studiengesellschaft Kohle* (Fed. Cir., 1992) (decaffeinating coffee vs. obtaining caffeine).

Another difficult question is whether secondary indicia of non-obviousness (such as unexpected results) can be considered in an OTDP analysis. While the MPEP says yes, a 2001 decision of the USPTO Board of Patent Appeals and Interferences cited dicta from earlier Federal Circuit decisions and said no. *In re Lee*, No. 2011-002616 (BPAI Dec. 14, 2011).

There also is some uncertainty as to whether OTDP can arise between applications/patents that have common inventors but that are not commonly owned or the subject of a joint research agreement. While the MPEP instructs Examiners to make OTDP rejections in such circumstances, the Federal Circuit has not directly affirmed this policy. This situation is problematic because when the applications/patents are not commonly owned or the subject of a joint research agreement, any OTDP rejection cannot be overcome with a Terminal Disclaimer, because a [Terminal Disclaimer](#) requires the applications/patents to be commonly owned to be enforceable.

Avoiding OTDP Scenarios

There are several steps that Applicants can take to avoid OTDP rejections. First, Applicants should consider their overall patent strategies when filing and prosecuting multiple patent applications surrounding a common core technology. While it might be logical to file multiple patent

applications from the start, filing a single application with claims directed to different inventions may be advantageous from an OTDP perspective, particularly in view of [35 USC § 121](#), which can shield the claims of later-filed applications from OTDP rejections:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

This statute comes into play only when there has been a Restriction Requirement. Thus, Applicants should consider filing different types of claims in their patent applications in order to trigger multi-way Restriction Requirements. Moreover, the Federal Circuit has indicated that it can be important to file the later applications as “divisional” applications in order to ensure that the statute is available. Thus, Applicants should identify applications as “divisional” applications when it is appropriate to do so. Additionally, the statute applies only when the claims presented in the later applications are consonant with the claims that were subject to the Restriction Requirement, thus care should be taken when drafting the claims of any applications intended to be shielded by the statute.

The protections of the statute may not be available if a Restriction Requirement is withdrawn. Thus, Applicants should consider retaining “withdrawn” claims in an application if it is possible that the Examiner will withdraw the Restriction Requirement during the examination process, such as if a generic linking claim may be determined to be patentable.

The Impact of OTDP On Patent Term

If an OTDP rejection cannot be overcome on the merits (e.g., by establishing that the claims are patentably distinct), it usually is possible to remove an OTDP rejection by filing a [Terminal Disclaimer](#).

A Terminal Disclaimer must disclaim the term of any patent granted on the application at issue that would extend beyond the term of cited application or patent. A Terminal Disclaimer takes precedence over any Patent Term Adjustment that the application at issue may have accrued due to USPTO delays in prosecution, but does not prevent the extended rights of a patent that has obtained a Patent Term Extension under 35 USC § 156 (e.g., for regulatory review of a drug product) from enduring beyond the term of the cited patent/application.

As noted above, a Terminal Disclaimer also must provide that any patent granted on the application at issue “shall be enforceable only for and during such period that said patent is commonly owned” with the cited patent/application.

The Rising Significance of OTDP

It is important that practitioners and Applicants understand the U.S. doctrine of obviousness-type double patenting, because it is a complex issue of growing importance. Between the evolving doctrine of obviousness and USPTO examination delays that can result in significant awards of Patent Term Adjustment, avoiding OTDP scenarios or at least minimizing their impact can be essential to maximizing the value of a patent portfolio.

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This entry was posted on Wednesday, June 13th, 2012 at 1:25 am and is filed under [United States of America](#)

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