Obviousness-Type Double Patenting

A recent case addressing OTDP in the pharmaceutical patent context, Otsuka Pharmaceutical Co., Ltd. v. In re Lee, No. 2018-1354 (Fed. Cir. Mar. 25, 2019), focused on the issue of whether to grant a Restriction Requirement that would result 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 obviousness requirement of 35 U.S.C. § 103...[but] important differences remain." Thus, "the patent principally underlying the double patenting rejection need not be prior art." A look at the U.S. doctrine of obviousness-type double patenting is one of the most complex areas of U.S. patent law.

In Graham v. John Deere Co., 383 U.S. 1 (1966), the Supreme Court enunciated the "lead compound" framework analysis, which states that the obviousness-type double patenting rejection can arise when the claims directed to a new chemical entity under the "lead compound" framework analysis differ from the prior art in significant respects.

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

1. Identify the relevant prior art.
2. Determine the subject matter to which the prior art relates.
3. Consider the prior art against the subject matter of the claim.
4. Compare the subject matter of the claim and the subject matter of the prior art.
5. Make the final determination.

The obviousness-type double patenting rejection can arise when the claims directed to a new chemical entity under the "lead compound" framework analysis differ from the prior art in significant respects. A look at the U.S. doctrine of obviousness-type double patenting is one of the most complex areas of U.S. patent law.
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 the 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 delay in prosecution, but does not extend the enforceability of a patent that has obtained a Patent Term Extension under 35 USC § 156 (e.g., for regulatory review of a drug product) that extends 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.