

3 KEY TAKEAWAYS

Challenges and Strategies for Patenting Pharmaceutical Formulations

A recent Kilpatrick Townsend presentation on pharmaceutical patent law included these key takeaways on double patenting:

1

No recapture of double patenting safe harbor after issue: In *In re Janssen Biotech, Inc.*, the Federal Circuit stated that to receive the 35 U.S.C. § 121 protection from an obviousness-type double patenting (ODP) rejection based on a related application, a patent application had to be designated as a divisional before issue. However, the Court's statements indicate that a continuation's designation could be changed if the application had not yet issued as a patent. If you have a continuation application with claims that could properly be included in a divisional application, consider changing the application's status to guard against a later ODP challenge.

2

No recapture of double patenting safe harbor for continuation-in-part: The Federal Circuit's holding in *In re Janssen Biotech, Inc.* rejected the conversion of a continuation-in-part application to a divisional application after issuance. To avoid an ODP rejection during reexamination, the patentee Janssen tried to convert a continuation-in-part application to a divisional application by deleting any added disclosure from the issued patent. The Federal Circuit held that a patent with matter not disclosed in the original application cannot qualify for the divisional safe harbor from ODP even if the additional matter is later deleted. If you have a pending continuation-in-part application with claims that could legitimately be filed in a divisional application, consider filing the claims in a new divisional application.

3

Lower court factual findings provide bulwark against close art for obviousness-type double patenting: In *UCB, Inc. v. Accord Healthcare, Inc.*, the Federal Circuit upheld a patent against very close ODP art based on the lower court's factual finding of no reasonable expectation of success in predicting the claimed compound's activity. Because the district court's finding was supported by expert testimony and carefully considered the contrary evidence on the record, the majority of the Court viewed it as not clear error. This case illustrates the power of a favorable factual finding in dictating the results of an ODP challenge on appeal. Although the feasibility of this strategy will depend on the specific disclosure in any art cited against you, consider the defensive value of factual findings if you face an ODP challenge.

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