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INTELLECTUAL PROPERTY LAW

Intellectual Property Alert:
The Safe Harbor for Divisional Applications Shrinks

By Sarah A. Kagan

February 2, 2018 — The U.S. Court of Appeals for the Federal Circuit affirmed on January 23, 2018, the U.S. Patent and Trademark Office Patent Trial and Appeal Board's decision that the re-examined claims of Janssen Biotech and New York University's U.S. Patent 6,284,471 ('471) are unpatentable under the doctrine of obviousness-type double patenting. *In re Janssen Biotech, Inc.*, No. 2017-1257.[1] The patent claims relate to Janssen's blockbuster drug Remicade®. See our previous alert about the oral argument for additional background information.

The key issue on appeal was whether the '471 continuation-in-part patent, by virtue of a re-designation as a divisional patent during the re-examination process, was protected from the doctrine of obviousness-type double patenting by the safe harbor provision of 35 U.S.C. §121. The court did not accept the U.S. Patent and Trademark Office's maximalist position that a divisional patent application must be filed as such. The court also rejected Janssen's minimalist position that a divisional application could be retroactively created in a post-issuance proceeding, so long as no claims had issued that relied on the subject matter added in the continuation-in-part. Rather, taking a middle road, the court decided that post-issue was too late to designate a divisional application entitled to the safe harbor of §121, but post-filing may not be too late. "For a challenged patent to receive safe-harbor protection, the application must be properly designated as a divisional application, at the very latest, by the time the challenged patent issues on that application." Slip opinion at pp.11-12. The court reserved some space for future disputes and clarifications. "[W]e do not decide whether such filing practices or amendments made prior to issuance—wherein an application is designated as a divisional application by the time the challenged patent issues on that application—would be sufficient to bring the challenged patent within the scope of the safe-harbor protections." *Id.* at p. 16.

[1] The validity of the '471 patent was also at issue in a second appeal. *Janssen Biotech, Inc., v. Celltrion Healthcare Co. LTD.*, No. 17-1120. That appeal was from the decision of the U.S. District Court for the District of Massachusetts in a patent infringement action. At oral hearing, the first question that the panel asked Janssen's counsel was whether affirmation of the U.S. Patent and Trademark Office Patent Trial and Appeal Board's decision in *In re Janssen Biotech, Inc.*, No. 2017-1257, would render the appeal from the district court case moot. Janssen indicated that it would. Thus, the U.S. Court of Appeals for the Federal Circuit is unlikely to issue a separate opinion in that appeal.

The court based its decision on a "strict application of the plain language of §121," *Id.* at p. 9. The court stated that by the literal terms of §121 "only divisional applications (or the original application) and patents issued on such applications" are protected. This strict application was coupled with its reasoning that post-issuance amendments do not retroactively change the nature of an application at the time it issues. Quoting *G.D. Searle LLC v. Lupin Pharm., Inc.*, 790 F.3d 1349 (Fed. Cir. 2015), the court stated, "Simply deleting that new matter from the reissue patent d[id] not retroactively alter the nature of the [CIP] application."

Janssen had tried to distinguish over *Searle*, stating that it had not "benefitted" from its new matter by issuing claims based on the new matter. Its issued claims did not rely on the subject matter added in the continuation-in-part application, it asserted, whereas Searle's claims had. The court rejected this difference, holding that Janssen had nonetheless benefitted from the new matter because over thirty patents issued claiming priority to the continuation-in-part applications, whether or not they actually relied on the added subject matter.

While the *Janssen* decision does not represent a large change in the scope of the safe harbor of §121, it underscores the risks of complicated patent family trees. The addition of subject matter to a pre-existing application is tempting. An applicant may be drawn to provide more data, more species of a disclosed genus, more details of a process, additional practical applications, broader scope of a genus, or combinations with other technologies. But these additions can preclude the benefit of the safe harbor and open a valuable patent to unnecessary double-patenting fallibilities. The *Janssen* decision warns applicants to think twice before succumbing to the temptation to add subject matter to a child or grandchild application.[2] On the other side of the aisle, the *Janssen* decision suggests that patent challengers look for continuation-in-part applications as potential defects to be exploited in a family tree.

Click here to download the decision in *In re Janssen Biotech, Inc.*

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[2] Note that this admonition does not apply to adding subject matter after a provisional filing, because a provisional filing does not generate patent claims to be used as a reference in a double-patenting rejection.