IP Alert: Is the Safe Harbor for Divisional Applications Shrinking?

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By Sarah A. Kagan

In October, the U.S. Court of Appeals for the Federal Circuit heard arguments in a pair of related cases that may add yet another boundary to the safe harbor of §121. One suit was an appeal from an ex parte reexamination in the U.S. Patent and Trademark Office (In re Janssen Biotech, Inc., No. 17-1257) and the other was an appeal from the U.S. District Court for the District of Massachusetts in a patent infringement action (Janssen Biotech, Inc., v. Celltrion Healthcare Co. LTD., No. 17-1120).

Since 1952, patent statute 35 U.S.C. §121 has sweetened the sting of the Patent and Trademark Office's restriction practice by providing a safe harbor from subsequent rejections between patents that result from the restriction. Typically, such rejections present as obviousness-type double patenting rejections. The safe harbor statute provides:

> 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 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. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

Over the past decade, the Federal Circuit has construed the statute and delineated situations where it does not apply. In 2008, the Federal Circuit barred the use of the §121 safe harbor for a patent that was designated as a continuation-in-part. Pfizer, Inc., v. Teva Pharmaceuticals, USA, Inc., 518 F.3d 1353. The court held that the protection of §121 is limited to divisional applications. Pfizer at 1362.

In 2009, the Federal Circuit again blocked the use of the §121 safe harbor. This time it barred application of the §121 safe harbor to patents whose parent applications were designated as continuations, even though they may have been filed in response to a restriction requirement. Amgen v. Hoffman-La Roche, Ltd., 580 F.3d 1340. Following the reasoning of the Pfizer opinion, the court held that on its face the statute only applied to divisional applications, and a continuation application, like a continuation-in-part application, is not a divisional application. Amgen at 1353. The court harmonized its decision with prior cases that permitted the §121 safe harbor to continuation applications, as long as they descended from a proper divisional application.

In 2015, the Federal Circuit again denied the application of the §121 safe harbor to a patent. This time the patent was designated as a divisional application, but it had gained this designation through the reissue of a patent initially designated as a continuation-in-part. G.D. Searle LLC v Lupin Pharmaceuticals, Inc., 790 F.3d 1349 (2015). The court held that deleting the new matter during reissue did not alter the nature of the underlying application. The court reasoned that the patent had enjoyed the benefit of the new matter in the form of issued claims (before their cancellation in the reissue process). The court presented this as an issue of fairness and equity. Additionally, the court denied the safe harbor because the target and reference patents did not result from a common restriction requirement.

Now Janssen comes to the court with a continuation-in-part patent that it tries to redesignate as a divisional using the reexamination process. Janssen filed a patent application, which matured into

U.S. 6,284,471 (’471), designating it as a continuation-in-part. During an ex parte reexamination, the ’471 claims were rejected as obvious over the issued claims of a sister application and over the issued claims of a continuation-in-part of the ’471 itself. In order to obtain the benefit of the §121 safe harbor generated by a restriction requirement in a common parent application, Janssen amended the specification to delete new subject matter that had rendered the ’471 a continuation-in-part and amended the priority claim to indicate that the ’471 was a divisional of the common parent application. Despite these amendments, the Patent Trial and Appeal Board maintained the rejection that the ’471 claims were unpatentable for obviousness-type double patenting. Janssen appealed to the Federal Circuit.

The Federal Circuit heard arguments on October 3, 2017. Janssen argued that Searle did not create a per se rule that late designations of divisional status are ineffective to gain the benefit of the §121 safe harbor. Unlike Searle, Janssen argued, it did not have any issued claims that relied on the new subject matter, so it had not enjoyed any benefit of the continuation-in-part status as Searle had. Janssen also pointed to §120 (which is incorporated into §121), which explicitly mentions amending priority claims and designating a status for those amended priority claims. This statutory provision, Janssen argued, is inconsistent with the Patent and Trademark Office’s position that an application must be filed as a divisional to gain the benefit of the §121 safe harbor.

The Federal Circuit may be poised to continue down the path of increasing stringency in requirements to obtain the benefit of the §121 safe harbor. However, during the hearing, the panel asked the Patent and Trademark Office solicitor whether there should be a bright-line rule that §121 only applies to applications filed as divisional applications. The solicitor replied that it already was a bright-line rule. The panel noted that the Federal Circuit’s bright-line rules had not fared well upon Supreme Court review. We will see whether this was merely a quip or a genuine concern that will inform the Federal Circuit’s decision.

Posted: November 6, 2017