Keywords: continuation-in-part; restriction; obviousness-type double patenting; 35 U.S.C. § 121

General: Claims in a continuation-in-part application filed after a restriction requirement in a parent application can be found invalid based on obviousness-type double patenting in view of the parent application.

Pfizer Inc. v. Teva Pharmaceuticals USA Inc.
86 U.S.P.Q.2d 1001 (Fed. Cir. 2008)
Decided March 7, 2008

I. Facts

The present patent infringement suit relates to a non-steroidal anti-inflammatory drug ("NSAID"), such as Celebrex. Traditional NSAIDs, such as aspirin, ibuprofen, and naproxen, are effective in treating pain, yet they have various gastrointestinal side effects. In the 1970's, it was discovered that the traditional NSAIDs inhibit the cyclooxygenase ("COX") enzyme in the body, including both the COX-1 enzyme that produces molecules associated with good gastrointestinal physiology and, also, the COX-2 enzyme that produces molecules associated with pain and inflammation.

By 1993, Pfizer had discovered several new compounds that were believed to selectively inhibit COX-2 without inhibiting COX-1, thereby eliminating the side effects of traditional NSAIDs. On November 30, 1993, Pfizer filed U.S. Patent Application No. 08/160,594 ("the '594 application"), which disclosed and claimed various compounds to inhibit COX-2. In an Office Action, the Examiner restricted the claims to the chemical compounds, the compositions with the compounds, or the methods of using the compounds. The Examiner also included an election of species requirement. In response, Pfizer elected the compound claims and the single compound species celecoxib. The '594 application subsequently issued as U.S. Patent No. 5,466,823 ("the '823 patent") with these compound claims. In addition, Pfizer filed a divisional application and a continuation-in-part ("CIP") application, which later issued as U.S. Patent No. 5,563,165 ("the '165 patent") and 5,760,068 ("the '068 patent"), respectively.

After issuance of these patents, Teva filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") for a drug identified as "Celecoxib Capsules." In response, Pfizer filed a patent infringement suit against Teva in district court. Teva filed an answer asserting affirmative defenses, including invalidity for a best mode violation, invalidity for obviousness-type double patenting, and unenforceability for inequitable conduct. However, Teva did not argue that its ANDA was outside the scope of the patent claims.

In the district court, various arguments were made about Teva's affirmative defenses. Specifically, Teva asserted that the '068 patent claims are invalid based on obviousness-type double patenting in view of the '165 patent. As noted above, the '068 patent is a CIP of the '823 patent, and the '165 patent is a divisional of the '823 patent. The district court disagreed with Teva's arguments, and held that the '165 patent could not be used as prior art against the '068 patent in accordance with the safe-harbor provision of 35 U.S.C. § 121. Ultimately, the district court held that Teva infringed claims of all three patents, and also held that the asserted claims were not invalid based on any of Teva's asserted grounds.

II. Issue

Can a parent application be used as prior art against a continuation-in-part (CIP) application to support obviousness-type double patenting?

III. Discussion

Yes. An obviousness-type double patenting rejection is proper in the case of a CIP application.

On appeal, the court spent a considerable amount of time discussing 35 U.S.C. § 121 and its history, the difference between divisional and CIP applications, and general fairness. The third sentence of Section 121 states:

> 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. 35 U.S.C. § 121 (2000).

The court emphasized that Section 121 refers only to divisional applications, not CIP applications. Pfizer argued that the CIP application was filed based on the original restriction requirement, and asserted that a divisional application broadly refers to any type of continuing application, including a divisional, continuation, or CIP. The court disagreed, and emphasized the repeated use of the term "divisional" in Section 121. The court discussed the legislative history of Section 121, emphasizing that its purpose was to eliminate the inequity of obviousness-type double patenting rejections in the event of *divisional* applications (i.e., specifically caused by an Examiner's restriction requirement). The court also emphasized that CIPs include new matter, whereas divisional applications do not. Thus, if Section 121 included CIPs, then the court suggested that Section 121 could be read to give the earlier priority date to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application. Thus, the court concluded that the safe-harbor provision of Section 121 applies only to divisional applications, not CIP applications.

The court then evaluated whether the claims of the '068 patent are patentably distinct from the claims of the '165 patent. The court noted that obviousness-type double patenting analysis involves two steps: (1) construe the claims in both patents and determine the differences; (2) determine whether those differences render the claims patentably distinct. The court noted that the claims at issue in the '068 patent merely recite methods of administering a "therapeutically-effective amount" of the compositions recited in claim 5 of the '165 patent, and that claim 1 of the '165 patent also recites the term "therapeutically-effective amount." The parties also stipulated that "therapeutically-effective amount" means the same thing in both patents. Thus, the court found that the asserted claims of the '068 patent are not patentably distinct over the claims of the '165 patent.

IV. Conclusion

A parent application can be used against a subsequent CIP application for a finding of obviousness-type double patenting. Section 121 is limited to divisional applications, not CIP applications.