Patent Law Update: Amgen v. Roche

September 16, 2009

Federal Circuit Clarifies Patent Application Standard

The Federal Circuit has clarified that in patent application filings, to protect against double patenting rejections, patent applications must be true divisional applications – filed in response to restriction requirements. Continuation and continuation-in-part applications are not divisional applications. The court recognized that the Manual of Patent Examining Procedure (MPEP) states the United States Patent and Trademark Office (USPTO) might recognize a continuation application as a divisional application – but concluded this recognition does not justify departing from a strict application of the plain language of the patent law, insofar as it affords benefits to divisional applications.

The clarification came in Amgen v. Roche litigation over the recombinant anemia drug erythropoietin (EPO). This litigation has been going on since 2005 when Amgen filed a declaratory judgment action against Roche in the United States District Court for the District of Massachusetts, alleging that Roche's product, Mircera, if imported into the United States, would infringe five of Amgen's patents to EPO.Roche asserted that Amgen's patents were invalid and not infringed. One of the defenses raised by Roche was obviousness-type double patenting of the asserted claims of the '933, '422 and '349 patents over the claims of an earlier issued and now expired patent – U.S. Patent No. 4,703,008.

In October of 2008, following rulings of summary judgment and judgment as a matter of law (JMOL), and a jury trial, the District Court entered judgment that four of the patents were infringed and not invalid, and that the fifth patent was neither invalid nor infringed. Amgen, Inc. v. F. Hoffman-La Roche Ltd. , Case No. 05-12237-WGY. Thereafter, the court granted Amgen declaratory relief and permanently enjoined Roche from marketing Mircera in the United States. Roche appealed.

Federal Circuit Upholds Injunction Against Roche

On September 15, 2009, the Court of Appeals for the Federal Circuit vacated "the court's grant of summary judgment and of JMOL to Amgen of no invalidity for obviousness-type double patenting" of certain patent claims. It also remanded to the District Court for an obviousness-type double patenting analysis of those claims in light of this opinion.

The Federal Circuit did not overturn the injunction barring Roche from selling its anemia drug in the U.S., but did revitalize at least a portion of the company's battle.

Under obviousness-type double patenting, a patent is invalid when it is merely an obvious variation of an invention disclosed and claimed in an earlier patent by the same inventor. Amgen's position on this issue was that the "safe-harbor" provision of 35 U.S.C. §121

protected the asserted claims of the patents from the disclosures and claims of several earlier issued patents. These patents were filed as continuation applications, and Section 121 affords protection to divisional applications, as follows:

Divisional Applications – … 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. …

Amgen sought to treat its continuation applications as "equivalent" to Section 121 divisional applications, relying upon the definition provided by the USPTO's Manual of Patent Examining Procedure (MPEP) – Section 201.06:

A later filed application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division."

Under this USPTO definition, Amgen claimed benefit of the Section 121 safe harbor from use of the earlier issued patents as a reference for obviousness-type double patenting.

Safe Harbor Protection of Section 121

The Federal Circuit noted that three of the Amgen patents were filed as continuations, and not as divisional applications and accordingly, the safe-harbor protection of Section 121 was not available. The court concluded that the statute, on its face, applied only to divisional applications. Simply stated, the Federal Circuit confirmed that a continuation application is not a divisional application – regardless of any contrary definition by the USPTO.

To obtain the safe-harbor protection of Section 121, an application must be a true divisional application – one filed in response to a restriction requirement issued by the patent examiner.

Please click here to view the Fed Circuit decision.

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