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Biosimilars: 180-day notice is mandatory

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Amgen Inc v Apotex Inc

On July 5 2016 the US Court of Appeals for the Federal Circuit in *Amgen Inc v Apotex Inc* held that a biosimilar product applicant must give notice to the reference product sponsor 180 days before commercially marketing its Food and Drug Administration (FDA)-licensed biosimilar, regardless of whether it had previously provided notice of the FDA review.

Facts

Apotex Inc had filed a Section 351(k) application for an FDA licence to market a biosimilar product for Neulasta, an FDA-licensed product owned and marketed by Amgen Inc, the reference product sponsor. Apotex complied with the steps of the 'patent dance' under the Biologics Price Competition and Innovations Act 2009, which established a timeline of steps for a biosimilar product applicant and the reference product sponsor to exchange patent and other information. These steps govern how the two parties must work out the patent infringement issues and typically leads to multiple stage litigation.

A key provision in the litigation stage is the Paragraph 8(A) requirement (found in 42 USC 262(l)(8)(A)) that requires a biosimilar product applicant to give at least 180 days' notice to the reference product sponsor before commercially marketing its licensed product. After receiving the notice, the reference product sponsor can then seek a preliminary injunction.

In an earlier case, *Amgen v Sandoz*, the Federal Circuit had held that the 180-day clock follows the licensure so that notice could not be given before licensing of the biosimilar. In that case, Sandoz had not provided notice of FDA review under the Biologics Act and the Federal Circuit held that participating in the patent dance was optional. However, it also held that the Paragraph 8(A) provision was a standalone notice requirement, not dependent on the earlier information exchange provisions.

In the present case, Apotex had not received an FDA licence for its biosimilar product. During the early stage of the patent dance, however, Apotex sent a letter to Amgen stating that it was providing notice of future commercial activity pursuant to Paragraph 8(A). The parties then negotiated and agreed to an immediate infringement action in a first stage of litigation.

Subsequently, Amgen filed a motion in the district court seeking a preliminary injunction that would require Apotex to provide an 8(A) notice if and when it received a licence, and to delay any commercial marketing for 180 days from that notice. Apotex contended that the notice requirement enforceable by injunction was not mandatory where the applicant had provided the proper notice to start the patent dance. The district court agreed with Amgen and granted the preliminary injunction.

Decision

The Federal Circuit affirmed, holding that the 180-day notice period, which can begin only on post-licensure notice, is mandatory for all applicants. It noted that the language of the provision is "categorical", and no other statutory language compelled a different treatment.

In response to an argument that this interpretation of Paragraph 8(a) effectively extended by six months the 12-year exclusivity period given to a reference product sponsor under the Biologics Act, the court noted that the 12-year date is only an earliest date (not the latest date) on which a biosimilar licence can take effect. It further posited the possibility of the FDA issuing a licence more than six months before the 12-year mark, but deeming the licence to take effect on the 12-year date. This would allow the applicant to send the Paragraph 8 (A) notice of commercial marketing as soon as the licence issues, even if not yet effective.

Biosimilar product applicants thus must provide at least 180 days' notice post-licensure, regardless of the path travelled. As a practical matter, this will lead to a substantial delay in commercial marketing activities of biosimilars.

Immersion Corp v HTC Corporation

On June 21 2016 in *Immersion Corp v HTC Corporation* the Federal Circuit approved the longstanding practice of 'same-day-continuation' filings in the United States. The district court had held that the Patent Act required continuation applications to be filed no later than the day before a patent issued in a parent application, an

approach that could have invalidated tens of thousands of otherwise valid patents. The appellate panel affirmed the interpretation that the US Patent and Trademark Office (USPTO) has followed for several decades, which permits a continuation application to be filed on the same day that the patent issues in the parent application.

US patent law allows for the filing of continuation applications, which have the benefit of an earlier parent application's filing date for priority. This has obvious benefits in a first-to-file system and shrinks the universe of prior art that can be used to determine patentability. A key condition for continuity under Section 120 of the Patent Act is that the continuation application has to be "filed before the patenting" of the parent application.

Decision

Starting with the statutory language, the Federal Circuit noted that the statute does not compel, although it could support, requiring filing a continuation on the day before the parent patent issues. However, the historical practice was decisively in support of same-day continuation filings. The Supreme Court had approved same-day continuations in 1863 and the Patent Act 1952, which introduced Section 120, has been broadly considered a codification of existing practices. Critically, the USPTO has interpreted Section 120 to allow same-day continuation filings since that time. In light of this "longstanding administrative construction", the court was justifiably reluctant to disturb more than 50 years of public and agency reliance of the legitimacy of same-day continuation filings.

The patent community can now, in effect, breathe a sigh of relief and return to business as usual.

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