DOUBLE PATENTING
The April 22, 2014 decision in Gilead Sciences, Inc v Natco Pharma Inc (Gilead) emphasises that obviousness-type double patenting (ODP) is a concern not just during the examination of a patent before the US Patent and Trademark Office (USPTO) but is a viable basis for invalidating an issued patent despite the presumption of validity that a patent has under 35 USC §282. In the case, Gilead owned two patents: the ‘483 and the ‘375. After being sued for infringement of the ‘483 patent, Natco asserted that the claims of the ‘483 patent were invalid for ODP as being obvious given the claims of the ‘375 patent.

Unlike statutory double patenting under 35 USC §101 (stating in the singular that an inventor
In the Gilead case, Gilead focused its arguments on the respective issue dates of the '483 and '375 patents, rather than their expiration dates. Gilead argued that because the '375 patent was issued after the '483 patent, the '375 patent cannot serve as the basis for an ODP rejection. The Gilead situation was unusual, but not unheard of, in that the later-filed application (the '483 patent) was actually issued first. In Gilead, the '483 patent had a later priority filing date than the '375 patent and thus a longer patent term; the '483 patent was issued first despite being filed later.

Gilead did file a terminal disclaimer but it was filed in the '375 patent in view of the '483 patent, which had no effect on the term of the '375 patent as the '483 patent had a later expiration date. Gilead asserted that the terminal disclaimer was properly filed in the '375 patent because the '483 patent had been issued first. However, the Court of Appeals for the Federal Circuit (CAFC) disagreed and held that the '483 patent was invalid for ODP over the '375 patent.

Important dates

The focus of the court in Gilead was on the respective expiration dates of the '483 and '375 patents, rather than on their issue dates as argued by Gilead. The court noted that filing dates and issue dates will often correlate, with the later-filed application typically issuing later. However, in determining whether an ODP rejection is proper, it is not the respective issue dates of the patents but rather their respective expiration dates that matter. As the court stated: "It is the comparison of Gilead's patent expiration dates that should control, not merely the issuance dates."

The analysis used by the CAFC in Gilead is consistent with the approach taken by the USPTO when considering ODP issues. The Manual of Patent Examining Procedure (MPEP) §804(I)(B)(1) states, in part:

If a "provisional" non-statutory ODP rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

Thus the policy followed by the USPTO is also based on the patent term, meaning an ODP rejection cannot be withdrawn from a later-filed (and therefore later-expiring) application without a terminal disclaimer being submitted in the later-filed application. The Gilead decision makes it clear that it is possible for a later-issued, but earlier-expiring, patent to serve as the basis for ODP of an earlier-issued, but later-filed patent. The key consideration is the expiration dates of the respective patents, rather than their issue dates.

Aside from clarifying this issue for future cases, the Gilead decision also serves to reinforce the
argument that ODP is a serious consideration that patent owners should keep in mind during the examination of an application or in performing due diligence on a patent portfolio. Indeed, MPEP §2001.06(b) states, in part: “The individuals covered by 37 CFR 1.56 [Duty to disclose information material to patentability] have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other co-pending US applications which are ‘material to patentability’ of the application in question.”

The Gilead case is not the first time a patent has been held invalid for ODP. On May 8, 2014 the US District Court for the Eastern District of Virginia held that Pfizer’s patent covering Celebrex (RE 44,048) is invalid in part for ODP over an earlier issued patent, GD Searle v Lupin Pharmaceuticals, No. 2:13cv121 (EDVA May 8, 2014).

To prevent these assertions of invalidity during litigation, it is prudent for applicants to notify the USPTO of applications containing related subject matter. Even if the applications are being handled by the same examiner, the applicant cannot assume that the examiner is aware of both related applications.

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