PATENT PRIMER

Obviousness-type double patenting

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The doctrine of obviousness-type double patenting has been used with considerable success in recent years to defeat later-issued claims in the patent estates of new drug innovators (see box). This judicially created doctrine is grounded in policy, rather than the language of the Patent Statute, with the explicit goal of preventing the 'unjustified time-wise extension' of a patent owner's right to exclude others from practicing the patented invention.

Beyond prior art

US courts have long recognized that a patent owner's own prior patents can escape consideration as prior art to its later-filed patent applications, even though the earlier patents, if invented or owned by others, would have served as invalidating prior art to the later-filed application.

For example, an earlier-filed, but later-published, patent does not qualify as prior art with respect to either the novelty or non-obviousness of a later application filed by an identical set of inventors; the earlier-filed patent is not 'by another', as required by statute. Common ownership at the time the later invention is made defeats use of the earlier-filed, but later-published, patent as prior art for the purpose of assessing non-obviousness, even if the inventive entity of the later-filed application differs, and even though the earlier-filed patent is effective as of its filing date as prior art for assessing novelty and obviousness of third-party inventions.

Because a patentee is entitled in its first-filed patent to claim both the invention as described and its obvious variants, courts have found it inequitable to permit the patentee later to obtain an additional patent on such obvious modifications, with such later patent's potential for extending the effective patent monopoly beyond the expiry of the first patent. To prevent such an outcome in circumstances in which the earlier patent is not available as prior art to the later, the courts have fashioned a non-statutory prohibition against obviousness-type double patenting.

Restriction and division

The US Congress recognized, however, that invalidating a later-filed patent over one's own earlier-filed patent on non-statutory grounds can also lead to inequities.

For example, the US Patent and Trademark Office (USPTO) can, as an administrative convenience, restrict the examination of a patent application to one of several independent and distinct inventions, thereby obliging the applicant to file one or more subsequent divisional applications drawn to the inventions not originally elected for prosecution. To prevent the original application from barring the patenting of the later divisional (or vice versa) the Patent Statute precludes the assertion of one against the other, either as prior art or for the purpose of double patenting.

In the absence of an explicit restriction requirement, however, an applicant's voluntary filing of a continuation application does not trigger this statutory exemption from double patenting. Nor does the filing of a divisional application that fails to strictly adhere to the subject matter demarcation set forth in the restriction requirement.

Demonstrating such 'concordance' is no longer as straightforward, however, as had long been understood. Unsettling long-established expectations, the Court of Appeals for the Federal Circuit held last year that restriction requirements do not necessarily propagate through the chain of priority, and on that basis held that certain of Bristol-Myers Squibb's carboplatin claims would not be entitled to statutory protection against double patenting (BMS versus Pharmachemie B.V. (Fed. Cir. 2004).)

Terminal disclaimer practice

The principal policy concern motivating the double patenting doctrine — time-wise extension of a patentee's exclusionary rights — would be allayed by the concurrent expiration of both patents on the earlier of the two expiration dates.

In practice, this result is achieved by the filing of a terminal disclaimer, a formalized relinquishment of so much of the term of the later-issued patent as would extend beyond the statutory expiry of the earlier-issued patent.

With US patent term now measured from the earliest effective US filing date, rather than from issuance, the term-reducing consequences of a terminal disclaimer are often less onerous than in the past. Nonetheless, a terminal disclaimer acts to disclaim term as to all of the claims in the later-issued patent, even though double patenting is itself assessed on a claim-by-claim basis.

Furthermore, terminal disclaimers also require that the later and earlier patents be maintained in common ownership. This satisfies the secondary concern that an infringer might otherwise be subject to multiple lawsuits by separate owners of related, but patentably indistinct, patents. With the recent expansion of common ownership constructively to include research collaborators, a change effected by the 2004 Cooperative Research and Technology Enhancement (CREATE) Act, the requirement of common enforcement ensures that the decision to file a terminal disclaimer continues to retain a certain gravity.

THE POLICY IMPERATIVE

With policy as its explicit doctrinal basis, obviousness-type double patenting becomes a formidable weapon when an accused infringer is able to convince a court that the patentee has acted abusively to extend its exclusionary rights:

- **"After its filing, the '379 application engendered a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy. When the last patent stemming from the '379 application issued in December 1986, the application had spawned four divisional applications, three continuation applications, and six patents. During that twelve-year period, Lilly obtained six patents relating to fluoxetine hydrochloride." Eli Lilly & Co. versus Barr Labs., Inc. (Fed. Cir. 2001) (affirming invalidity of a PROZAC claim).**
- **"GSK took about a quarter-century to prosecute the 1985 and 2000/01 patents to issue. This record does not explain that delay ... [which] could potentially extend patent protection for the invention in the original ... application .... [T]his thin and insufficient record simply does not operate to shield these patents ... against double patenting rejections." Geneva Pharms., Inc. versus GlaxoSmithKline PLC (Fed. Cir. 2003) (invalidating AUGMENTIN patents).**

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doi:10.1038/nrd1855