

## Double Patenting: The Ticking Time Bomb

01 April 2010

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**Changes in patent term calculation have outpaced the law of double patenting in the US, leaving the validity of some issued patents in question, warns David Halstead**

IPREVIEW

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Obviousness-type double patenting (OTDP) is a rare beast in the realm of patent law. In a regime dominated by statutes and rules, OTDP arises from equity. Like patent misuse, implied licence and the doctrine of equivalents, OTDP was judicially created to right perceived wrongs allowed by those statutes and rules.

One of the underlying wrongs is unjust extension of patent term. OTDP law was created when US patents lasted 17 years from their issue date. Routine practices like filing a continuation application and pursuing additional claims to an invention could have been used to effectively extend patent term indefinitely. But requiring a terminal disclaimer (TD) in subsequent applications that claim patentably indistinct inventions eliminates this possibility.

The second, less obvious wrong is the risk that an infringer would be subject to multiple lawsuits with different parties on patents arising out of the same inventive activities. Such duplicative lawsuits unfairly increase the risk for potential infringers and deter competition, so multiple patents to essentially the same invention should not be separated from each other.

The current practice for resolving OTDP issues is to file a TD with two key provisions: (1) that the patentee agrees to commonly own or enforce affected patents, and (2) that any term of the patent that outlasts the cited patent is disclaimed.

Unresolved OTDP is a serious flaw. In recent years, the pharmaceutical industry has run afoul of OTDP in some high-profile cases over blockbuster drugs – In re Fallaux (2009) being a key example – defending their exclusivity with one last, late-expiring patent. The worst-case scenario is that the only remaining claims protecting a lucrative drug proves invalid – the economic consequences of which are predictably severe.

## **The world has changed**

Patents granted on applications filed since June 1995 – when the General Agreement on Tariffs and Trade (GATT) took effect – are entitled to a term that lasts 20 years from their earliest claimed Patent Co-operation Treaty (PCT) or US utility priority filing date, regardless of when they are issued. Thus, if we set aside the potential for accruing patent term adjustments due to US Patent and Trademark Office (USPTO) delays in prosecution, the vast majority of patents being issued today have a term that depends solely on their priority date. Yet the USPTO's guidelines for requiring TDs – based primarily on pre-GATT case law – read as though we still live in a 17-years-from-issue world, and even the courts seem quite attached to the rules they created at a different time.

According to the Manual of Patent Examining Procedure (MPEP), section 804, whenever two applications or an application and a patent have an inventor in common or are commonly owned, the examiner applies OTDP analysis. As a result of this analysis, the USPTO requires an applicant to file a TD in an application rejected for OTDP, even when it is rejected over a patent issued from a later-filed application. In other words, even where the patent resulting from the application will expire sooner than the previously issued patent – even without the TD – the disclaimer is required to be filed in the application, not in the later-expiring patent. So, by judiciously controlling the order in which related applications are issued, a patentee can obtain patents with extended term in a way that simply wasn't possible under pre-GATT law. If OTDP is meant to correct the inequity of time-wise extension of patent term that the law otherwise permits, current practice seems to miss the mark. If courts reach the same conclusion, this analysis will be applied retroactively to post-GATT patents that received an inequitable time-wise extension of patent term because of continued adherence to the old system. In the end, this may mean that many patentees are holding invalid patents – or at least patents that will expire sooner than expected.

## **Preparing for the future**

Patentees should review their portfolios from the perspective of a world in which a court, faced with two patentably indistinct patents, requires that the longer term be disclaimed to match the shorter – regardless of the order in which they were issued. While the filing of a TD that references a patent with a later priority date, and thus a later expiration date, can serve as a warning sign for a latent issue of this type, not all OTDP risks will be so conveniently labeled. Furthermore, some scenarios may not actually represent an OTDP issue for the patent with the later priority date – either because its claims can be defended as patentably distinct over the earlier-expiring patent, or because the specific facts do not evoke inequity.

On the other side of the table, potential or accused infringers might want to take a fresh look at competitors' portfolios to see where such issues might be raised in litigation, in order to either invalidate a troublesome patent or shorten its term. Similarly, potential acquirers of companies or their intellectual property (IP) may want to consider this possibility in their due diligence. In many industries, even a few days' variance in patent term can have significant economic consequences that affect the value of the underlying IP.

Those engaged in ongoing prosecution of patent applications might want to consider these issues as well, for very different reasons. The USPTO is in the habit of requiring TDs, out of continued adherence to outdated case law, in situations where the equitable considerations may not require it. An applicant faced with filing an unwanted TD might consider whether the TD is also unwarranted, appealing the issue to the courts if necessary. Indeed, some unfortunate situations – such as where applications and patents are not co-owned and not subject to a joint research agreement – make

the filing of a TD impossible, and thus creative approaches based on the underlying equitable considerations may be the only way to secure a patent.

Over recent years, OTDP law seems to have evolved from a sensible equitable doctrine into an arcane and rigid set of rules, ill-suited to a modern, post-GATT world. However, analyzing the underlying equitable issues may expose hidden flaws in a patent or suggest a creative remedy to a seemingly insurmountable obstacle.

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