

Patent term and double dipping

Pharmaceutical companies have dreamed up numerous strategies to forestall the loss of profits when a patent expires. But one simple way to maximise profits is to ensure a correct patent term calculation

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It should be no surprise that drug profits are inextricably linked to patent protection. Likewise, it should be no surprise that drug development is very expensive. Of the millions of compounds investigated for therapeutic use in humans, only a small fraction will eventually receive regulatory approval. Each year, only about 25 new drugs are approved for marketing. Without solid patent protection, it is difficult – perhaps impossible – for pharmaceutical and biotechnology companies to recoup their massive investments. Thus, securing and maintaining maximum patent term is critical to the profitability of a drug and to reward innovation in the pharmaceutical and biotechnology industries. For example, it is estimated that Bristol-Myers earned \$253 million in the four months it took Mylan Pharmaceuticals to invalidate a new patent relating to Bristol-Myers' Buspar product, so that it could introduce a generic equivalent when the original patent expired. Prilosec earns AstraZeneca \$11 million every day, which may explain why the company has filed more than 11 additional patents over a 20-year period to protect the product. The patent protecting GlaxoSmithKline's Zantac product is estimated to be worth £2 million to £3 million a day in profits. By unofficial estimates, three patent extensions on its Claritin product translated into additional

revenues of \$13 billion for Schering Plough. GlaxoSmithKline's sales of its Zofran product declined 88% in 2007, reflecting generic competition after its patent protection expired in December 2006. When Pfizer's patent on its Zoloft product expired in 2006, worldwide revenues declined from over \$3 billion in 2005 to about \$500 million in 2007.

There are a number of strategies that pharmaceutical companies employ to forestall the loss of profits when a patent expires, including pre-emptive launch of a generic, layering innovations and line extensions. However, there has been considerable focus on something rather less sexy than these creative strategies to ensure profits – ensuring a correct patent term calculation.

Patent term adjustment: how did we get here?

In 1994 the term for a utility patent, which protects pharmaceutical and biotech products as well as other types of technology, was changed from 17 years, measured from the date of issuance of the patent, to 20 years, measured from the date on which the application was first filed. One of the goals of this change was to discourage intentional prosecution delays by the applicant to extend patent term unfairly. Since patent term was measured from issuance, delays in prosecution never had a negative impact on the full term of the patent. In fact, patent applicants were sometimes accused of intentionally delaying the prosecution to delay issuance and, in turn, extend their patent term. However, it was also recognised under the new statutory regime that the pendulum had perhaps swung too far and that delays by the US Patent and Trademark Office (PTO) would unfairly cut into the patentee's term. Thus, in 1999 Congress enacted the Patent Term Guarantee Act of 1999, as part of the

American Inventors Protection Act, which provides for certain adjustments to compensate for these delays.

As currently codified, 35 USC § 154(b) provides three guarantees of patent term for the following types of delay:

- If the PTO fails to take certain actions within specified timeframes (“14+4+4+4 Rule”; “Type A delay”).
- If the PTO fails to issue a patent within three years of the actual filing date of the application (“Three-Year Rule”; “Type B delay”).
- For delays due to interference, secrecy order or successful appellate review (“Type C delay”).

The 14+4+4+4 Rule establishes four “time clocks” for certain actions by the PTO. If the PTO fails to meet any of the enumerated time clocks, the term of the patent is adjusted one day for each day by which the PTO misses the timeframe, with certain exceptions. The first time clock is for the PTO initially to act on the application within 14 months of the filing date. The second time clock is for the PTO to respond to an applicant’s reply or appeal within four months of the date on which the reply was filed or the appeal was taken. The third time clock is for the PTO to act on an application within four months of the date of a decision by the Board of Patent Appeals and Interferences or by a federal court in an application in which allowable claims remain. A fourth time clock is that the PTO must issue a patent within four months of the date on which the issue fee is paid and all outstanding formal requirements are met.

The guarantee relating to Type B delays provides for term adjustment if the PTO does not issue a patent within three years of the actual filing date of the application. A one-day term extension is granted for every day beyond three years after the filing date that it takes for the patent to issue.

The extensions granted for Type A, B and C delays are subject to reductions in some cases for the applicant’s own delay. In addition, to the extent that these delay periods overlap, the period of any adjustment must not exceed the actual number of days for which issuance was delayed, so that there is no double counting and a potential windfall to the patentee.

Wyeth checks the maths

While the maths above may seem straightforward (and it generally is), it does not answer the question of what does and does not constitute overlap. In its action

against the PTO, Wyeth won a summary judgment that the PTO had misconstrued the language of the statute and thereby denied Wyeth of additional patent term to which it was entitled for PTO delays (*Wyeth v Dudas*, 580 F Supp 2d 138 (DDC 2008)).

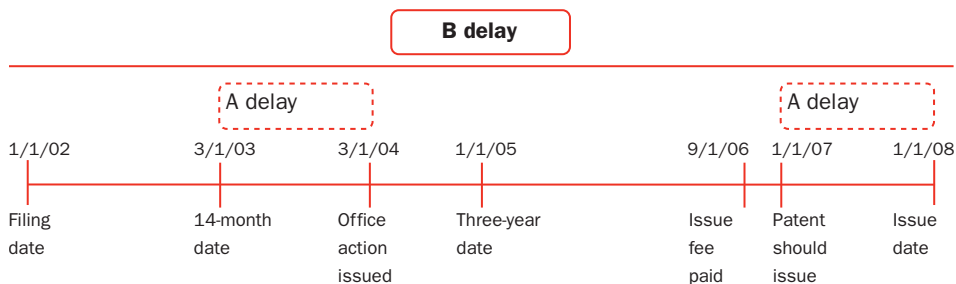
The delays that occurred in the prosecution of the *Wyeth* patent involved Type A delays and Type B delays only. The arguments presented by both sides are best summed up by viewing the hypothetical example used by Wyeth and adopted by the court, shown below.

The PTO considered the period of Type B delay to be the entire period during which the application was pending before the office (from filing date to issue date), because to interpret otherwise would permit double counting in the delays prior to the three-year date. Thus, Type B delays would necessarily overlap any Type A delays. In the example above, the PTO would calculate a patent term adjustment of three years.

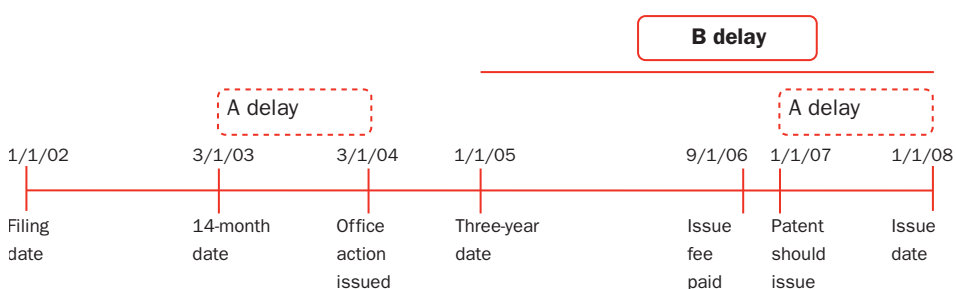
On the other hand, Wyeth argued that Type A delays and Type B delays overlap only if they occur on the same calendar day or days. Since Type B delays are not counted until the period following the three-year date, Type A delays occurring before the three-year date cannot occur on the same calendar day or days. Thus, Wyeth counts Type A delays occurring prior to the three-year date plus Type B delays. In the example above, Wyeth

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PTO’s view: patentee entitled to three-year patent term adjustment



Wyeth’s view: patentee entitled to four-year patent term adjustment



Company	Patent term adjustment challenged
Biogen Idec Inc	2,058 days (not 1,409 days)
Ironwood Pharmaceuticals, Inc	702 days (not 411 days)
Molecular Insight Pharmaceuticals, Inc	1,303 days (not 634 days)
Napo Pharmaceuticals, Inc	1,007 days (not 453 days)
Purac Pharmaceuticals BV	949 days (not 386 days)
Solvay Pharmaceuticals GmbH	633 days (not 534 days)

would calculate a patent term adjustment of four years.

The district court judge acknowledged the reasonableness of the PTO's argument that patentees would be awarded a "windfall extension", in that any Type A delays during the first three years of an application's pendency inevitably would lead to Type B delays in later years because one cause of delay would be counted twice. Furthermore, while the court concluded that the PTO presented a reasonable argument that was perhaps even consistent with Congress's intent, the PTO's interpretation did not "square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy," not the PTO.

The PTO has filed a notice of appeal to the US Court of Appeals for the District of Columbia Circuit.

Others follow suit

Following Wyeth's lead, at least six other pharmaceutical companies have filed complaints alleging miscalculation of their patent term, as outlined in table 1.

Recommended actions and conclusions

Unfortunately, thousands of other patents may have been denied their proper term. However, applicants that have received a notice of allowance with notification of the estimated patent term adjustment should carefully review the patent term adjustment calculation and request reconsideration prior to payment of the issue fee. For issued patents, patentees must request reconsideration by the PTO of the patent term adjustment indicated on the patent within two months of the date on which the patent was issued. If the patentee is outside this window but within 180 days of grant of the patent, the patentee should consider filing a civil action against the director of the PTO in the US District Court for the District of Columbia. Finally, the patentee should also consider filing a certificate of correction to obtain a corrected patent term adjustment.

If upheld on appeal, the *Wyeth* decision will provide a greater patent term for many US patents that have undergone or will undergo prosecution lasting more than three years. This would be a particular and significant benefit for patents in the field of pharmaceuticals, biotechnology, chemistry and medical devices, where the patentee is most likely to experience significant delay during prosecution and wish to maintain the patent for its full term. As each additional day of patent term affords considerable economic and competitive advantage to the patentee, it appears that there will be a major effort to correct and ensure proper patent term in the future. **iam**



Wendy Choi's practice primarily focuses on patent prosecution for clients in the chemical, pharmaceutical and biotechnology industries. They range from start-ups to large corporations in both domestic and international patent matters. Ms Choi's practice benefits from extensive first-hand knowledge of the business world. Prior to joining Woodcock Washburn, Ms Choi spent more than 10 years working on patent matters for firms in the chemical, biotechnology and mechanical industries. Combined with an academic grounding in chemistry, Ms Choi's knowledge of the patent process in scientific industries is substantial.

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