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The effect of obviousness-type double patenting on patent term extension and patent term adjustment in the biotech and pharma industry needs careful consideration, as Gaby L. Longsworth and Eric K. Steffe report.

A blockbuster drug can generate revenues of more than $5 billion per year. Each day that a patent encompassing such a drug prevents a competitor from entering the market translates into millions of dollars for a company. Patent term extension (PTE) and patent term adjustment (PTA) can significantly lengthen the term of patents. However, without careful prosecution, patent term can be lost due to the doctrine of obviousness-type double patenting (ODP). Provided below is a discussion of the interplay of ODP, PTA and PTE and the impact on drafting and prosecuting patent applications.

Obviousness-type double patenting

The doctrine of ODP was judicially created to prevent the issuance of claims in a second patent that are not 'patentably distinct' from the claims of a first patent. According to the doctrine, a patent owner should not be able to obtain a second patent with a longer patent term claiming the same or similar invention as an earlier patent. In addition, ODP arose to prevent multiple lawsuits by different patent owners based on essentially the same invention.

The US Patent and Trademark Office (USPTO) often rejects one or more pending claims over the claims of an issued patent or patent application that has at least one common inventor or that is commonly owned. An ODP rejection can be made even if the reference patent or patent application is not otherwise available as prior art.

To obviate an ODP rejection, an applicant may file a terminal disclaimer (TD) to disclaim the term of the later patent extending beyond the term of the reference patent, if the reference patent and the pending application are commonly owned or subject to a joint research agreement (JRA) as set forth in 35 USC §103(c)(2)(3). Thus, if there is a common inventor but different ownership and no JRA, a TD cannot be filed to obviate the rejection as was the case in *In re Hubbell*, where the Federal Circuit affirmed the USPTO's decision to reject CalTech's patent application for ODP.

If only one claim in an issued patent is anticipated or held obvious over a claim in an earlier issued reference patent, the patent owner must file a TD over the reference patent. Thus, filing a TD truncates the term of the entire patent based on an ODP rejection of a single claim. In addition, while a TD can be filed during litigation after a finding that the challenged patent is invalid for ODP, a TD cannot be filed if the earlier-issued reference patent has already expired, as in *Boehringer Ingelheim Int'l GmbH v Barr Labs, Inc*.

In addition, in *Otsuka Pharmaceuticals Co, Ltd v Sandoz, Inc*, the Federal Circuit held that a lead compound argument need not be advanced for ODP, making it potentially easier for competitors to allege invalidity of a chemical compound for OPD.

Avoiding double patenting rejections

If a restriction requirement (RRQ) is issued in an application, all divisional applications are shielded from an ODP rejection in accordance with 35 USC §121. However, §121 protection is available only to divisional applications properly filed in response to the RRQ, but not continuation or continuation-in-part applications. Thus, it is essential to specify, when possible, that a child application is a divisional and not a continuation application (see *Pfizer Inc v Teva Pharmaceuticals Inc* and *Amgen Inc v F. Hoffmann-La Roche Ltd*).

Also, for §121 to apply, consonance with the claim groupings in the original RRQ must be maintained in all future divisional applications. In other words, the later application or applications must strictly follow the USPTO's restriction requirement (see *Symbol Techs, Inc v Opticon, Inc* and *Gerber Garment Tech, Inc v Lectra Sys, Inc*).

While it is well settled that ODP rejections must be based on the claims of a reference patent, an exception to this rule is where a later-filed application attempts to claim a 'method of use' described in the reference patent. In such a scenario, the Federal Circuit has upheld ODP rejections even where the described 'method or use' was not claimed in the reference patent (*Geneva Pharmaceuticals, Inc v GlaxoSmithKline PLC, Pfizer, Inc v Teva Pharmaceuticals USA, Inc*, and *Sun Pharmaceutical Industries, Ltd v Eli Lilly & Co*). Thus, careful consideration should be given before including a 'laundry list' of uses when drafting patent applications.

Moreover, the USPTO often asserts ODP rejections against pending earlier-filed applications over later-filed, but earlier-issued patents. It is not uncommon for a later-filed application narrowly claiming a species to proceed more quickly through the USPTO than an earlier-filed application claiming a genus. Because a species anticipates a genus, such a rejection could not be overcome on the merits and filing a TD would present the only option for obviating the rejection.

However, as filing a TD requires disclaiming any patent term extending beyond the expiration date of the reference patent, any PTA that had accrued in the earlier-filed application would be lost. Thus, to avoid such ODP rejections, care should be taken to prosecute applications to issuance in the order that they are filed. This is of paramount importance where there is no common ownership or JRA such that a TD could not be relied on to obviate the rejection.

Can ODP rejections be based on later-issued, earlier-expiring patents?

In *Ex Parte Pfizer Inc*, the Board of Patent Appeals and Interferences held that a later-issued but earlier-expiring patent is available for use in an ODP rejection against an earlier-issued, but later-expiring patent. However, in *Abbott Labs v Lupin Ltd* (D.Del), *Brigham & Women's Hosp Inc v Teva Pharm USA, Inc* (D.Del), and *Gilead Sciences, Inc*

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v Natco Pharma Ltd (D.NJ), the district court reached the opposite conclusion. In a recent surprise decision, the Federal Circuit in *Gilead* sided with the USPTO and invalidated a later-filed, later-expiring, but earlier-issued patent over an earlier-filed, earlier-expiring, but later-issued patent for ODP.

The *Gilead* decision is likely to have major ramifications for the term of a significant number of existing patents. This is particularly true in the biotech and pharma industries, where prosecution of multiple families of related applications is common.

The interplay of ODP, PTA and PTE

To avoid the potential loss of patent term, a TD should be filed only after careful consideration. In this example, a patent issues claiming a drug compound that is the subject of regulatory approval by the FDA. A second application is prosecuted and, due to USPTO-caused examination delays, could be entitled to 1,095 days of PTA. During prosecution of the second application, the USPTO rejects certain claims but not others for ODP over claims in the first patent and the rejection cannot be overcome on the merits, ie, by arguing non-obviousness.

If a TD were filed to obviate the rejection, all 1,095 days of PTA would be lost. To avoid losing PTA, an alternative would be to cancel the rejected claims and pursue them in a continuation application. The non-rejected claims in the second application would then issue as a second patent with 1,095 days of PTA, resulting in a patent with significant additional term over the first patent. A third patent could also issue out of the continuation of the second application with a TD over the first patent.

Upon approval of the drug, the patentee may be entitled to PTE due to patent term lost during the regulatory review period. The USPTO's rules permit a drug approval holder to file applications for PTE in multiple patents, although only one patent may ultimately be extended for PTE. In this hypothetical case, which of the three patents should be chosen for PTE would be based on a consideration of multiple factors, including:

- The relative strength of each patent from a validity perspective;
- Which patent provides the most robust infringement position against competitors;
- The relative expiration dates of each patent taking into account PTA and/or PTE;
- The statutory caps set forth in 35 USC §156(c)(3) and (g)(6), which provide that the patent term remaining after the date of approval of the drug product cannot exceed 14 years and the period of extension may not exceed five years;
- The right to exclude during the PTE extension period only encompasses the FDA-approved product whereas the right to exclude during the PTA extension period encompasses the entire claim scope; and
- Filing a TD does not truncate PTE whereas filing a TD truncates PTA.

Thus, if the approval holder elected the second patent for PTE, the extended term would be the sum of the PTA period plus the PTE period (subject to the 14- and five-year statutory caps). If, however, there was little or no benefit associated with further extending the second patent, the approval holder could choose to apply the PTE extension to either the first or third patent resulting in two patents having an extended term (one with PTA and one with PTE).

It can be seen that the interplay of ODP, PTA and PTE when drafting and prosecuting patent applications in the biotech and pharma industries requires careful consideration. ■

Gaby L. Longsworth is a director at Sterne, Kessler, Goldstein & Fox PLLC. She can be contacted at: glongs@skgf.com

Eric K. Steffe is a director at Sterne, Kessler, Goldstein & Fox PLLC. He can be contacted at: esteffe@skgf.com

Gaby L. Longsworth, PhD, is sought out by both innovator and generic pharmaceutical companies for her insights and knowledge of IP and brand product lifecycle management strategies. She counsels innovator pharmaceutical clients from around the world in all areas of patent procurement, including domestic and foreign patent preparation, and lifecycle management strategies. She also represents generic pharmaceutical companies in patent cases involving Abbreviated New Drug Applications that include a Paragraph IV certification to one or more *Orange Book* listed patents.

Eric K. Steffe heads the firm's patent prosecution practice and counsels domestic and foreign clients in various matters involving biotechnology patent law. He leads teams who create and manage complicated patent portfolios protecting pipeline and FDA-approved products for companies in the areas of immunology, antisense, protein therapy, personalised medicine and diagnostics, therapeutic antibodies, small molecules and vaccines. He also has significant expertise representing clients involved in contested case proceedings before the USPTO, including *inter partes* review proceedings, *ex parte* and *inter partes* patent reexaminations and interferences.