Current Intelligence

Patents

Patents Court maintains injunction protecting Warner-Lambert's second medical use patent for pregabalin

Warner-Lambert Company LLC v Sandoz GmbH, High Court for England and Wales (Chancery Division), [2016] EWHC 3317 (Pat), 21 December 2016

In the latest decision in the long-running 'pregabalin' litigation, the Patents Court has refused to vary an interim injunction restraining Sandoz from proceeding with the launch of its full label generic pregabalin product, thereby maintaining protection for Warner-Lambert's second medical use patent.

Legal context

Second medical use patents are widely used by pharmaceutical companies to extend patent protection beyond the expiry of the patents for the drugs themselves. However, several cases have diminished the value of second medical use patents, and the realities of the pharmaceutical market mean such patents can be difficult to enforce. Doctors commonly prescribe drugs without reference to a brand name and with no indication of the condition the drug is being used to treat, with the result that pharmacists often unwittingly dispense generic products to treat conditions covered by the second medical use patent where the branded product should instead be dispensed. In the latest in a series of cases concerning Warner-Lambert's second medical use patent for the use of pregabalin, Arnold J provided further insight on the value of second medical use patents in preserving the market for originators.

Facts

Warner-Lambert's subsidiary, Pfizer, markets pregabalin under the brand name 'Lyrica' for use in the treatment of neuropathic pain. Patent protection for pregabalin itself expired in 2013, but Warner-Lambert holds a second medical use patent with claims in Swiss form for the use of pregabalin in the treatment of pain. Of most relevance to the latest decision are claim 1, which covers use of pregabalin for treating pain, claim 3, which covers neuropathic pain, and claims 10 to 12, which cover specific types of peripheral neuropathic pain.

In September 2015, Arnold J ruled on the validity of the patent in revocation proceedings brought by other generics manufacturers, Actavis and Mylan. Shortly after, on 2 October 2015, Sandoz notified Warner-Lambert that it had started to supply a full-label pregabalin product, for which it had received marketing authorization in June 2015. This prompted Warner-Lambert to apply for an urgent injunction restraining Sandoz from dealings in its full-label product. The interim injunction was granted against Sandoz in November 2015.

Arnold J's decision on validity was upheld by the Court of Appeal in October 2016. Warner-Lambert has applied for permission to appeal this decision to the Supreme Court and is currently awaiting the outcome of that application. Subject to any further appeal to the Supreme Court, claims 1 and 3 have been held to be invalid while claims 2, 5 and 7 to 12 have been found to be valid.

In February 2015, NHS England had issued guidance to GPs and pharmacists that, where pregabalin is prescribed for the treatment of neuropathic pain, the branded form of pregabalin, Lyrica, should be prescribed and dispensed wherever possible. After the Court of Appeal's ruling, Warner-Lambert wrote to NHS England proposing that the NHS guidance be limited to prescribing and dispensing Lyrica for the types of pain in those patent claims upheld as valid by the Court of Appeal (ie claims 2, 5 and 7 to 12). It proposed revised guidance which covered *all* of the conditions listed in the valid claims, while Lyrica's marketing authorization only includes use in *some* of them: Lyrica is authorized for treating neuropathic pain (claims 10 to 12), but not for treatment of the types of pain covered by claims 2 and 5 and 7 to 9. The NHS initially appeared to agree to revise its guidance to the form proposed by Warner-Lambert. However, after objections from a number of generics manufacturers that the guidance might raise issues of promotion of unlicensed use, the NHS indicated that it needed to consider the issues further.

As well as seeking to have the NHS guidance changed, Warner-Lambert made a concession to allow generic companies to obtain variations to their skinny-label marketing authorizations to extend the authorizations to *central* neuropathic pain but not to *peripheral* neuropathic pain. Sandoz did not, however, wish to amend its full-label marketing authorization. It chose instead to apply to vary the terms of the interim injunction to allow it to launch its full-label pregabalin product (but not for treatment of licensed indications that are covered by patent claims which were held by the Court of Appeal to be valid). Sandoz's application was heard in December 2016.

Analysis

Material change in circumstances

The threshold condition Sandoz had to satisfy was that there had been a material change in circumstances since

the interim injunction was granted. While the Court of Appeal's decision to uphold Arnold J's earlier decision on validity constituted a change in circumstances, Arnold J did not consider this to be a *material* change in circumstances sufficient to meet the threshold condition. He did, however, consider that Warner-Lambert's change of position with regard to the enforcement of claim 3 by injunction was a material change in circumstances. In the original interim injunction hearing in October 2015, Arnold J had assessed the balance of the risk of injustice on the basis that Warner-Lambert had a real prospect of success on claim 3. Since Warner-Lambert no longer relied on claim 3, this constituted a material change in circumstances.

Serious issue to be tried

Arnold J then proceeded to conduct a fresh assessment as to Warner-Lambert's entitlement to an interim injunction. He held that Warner-Lambert's claims for infringement of claims 10 to 12 of the Patent (for types of peripheral neuropathic pain) raised a serious issue to be tried. Sandoz's full-label pregabalin product was plainly indicated for the treatment of peripheral neuropathic pain, including the conditions covered by claims 10, 11 and 12. There could be little dispute that Sandoz intended its full-label product to be dispensed to patients who have been prescribed pregabalin for the conditions for which it is authorized. Consequently, Arnold J concluded that Warner-Lambert had a strong case that dealings in Sandoz's full-label product would infringe claims 10 to 12 if valid.

Balance of the risk of injustice

The court considered the potential harm that would be done to both parties by the grant or otherwise of the varied order. In doing so, he noted that the conditions covered by claims 10, 11 and 12 represented only a small percentage of the market (only 1.13 per cent or around £2.3 million until the expiry of the patent). Notwithstanding the small size of the market, he concluded that, if the marketing of Sandoz's full-label product infringed those claims, Warner-Lambert was prima facie entitled to an injunction to prevent such marketing. If Sandoz was permitted to market its full-label product, it would be quickly followed by other generic companies and within a couple of months there would be a 'free for all' in the full-label market. The consequence would be further pressure on the market price of pregabalin. The loss Warner-Lambert would suffer as a result would be very difficult to quantify.

Sandoz had offered to take steps to publicize the NHS guidance and to try to ensure that its full-label product would not be dispensed if pregabalin had been prescribed for one of the conditions covered by claims 10 to 12. However, Arnold J did not consider that these offers materially affected the assessment of the harm Warner-Lambert would suffer and concluded that Warner-Lambert was at greater risk of irremediable harm than Sandoz. He held that Sandoz's failure to clear the path and preservation of the status quo were factors that favoured the grant of the injunction.

Proportionality

Sandoz had focused its arguments largely on proportionality in light of the size of the market involved. However, Arnold J did not consider this to be a 'trump card' for Sandoz because the market covered by claims 2, 5, 7, 8 and 9 was considerably larger (over 13.8 per cent). It was 'immaterial' that Lyrica was not authorized for the conditions covered by those claims such that Warner-Lambert only reached that part of the market through off-label prescribing. Furthermore, it was a problem that certain pharmacy chains have to stock full-label product. Even though the conditions covered by claims 10 to 12 represented a small percentage of the total market, Warner-Lambert was prima facie entitled to use its monopoly to protect the full-label market for pregabalin (as distinct from the skinny-label and intermediate-label markets).

In light of all the factors, Arnold J dismissed Sandoz's application to vary the interim injunction. He noted, however, that the position might be different when it comes to considering the grant of a final injunction.

Practical significance

This decision will be welcomed by originators as confirming that second medical patents are of some value in protecting the market for innovators. Arnold J proceeded on the basis of a presumption of valid rights and it is clear that the burden remains on generic companies to clear the path before launching a generic product. It is conceivable that doctors will 'play it safe' and prescribe Lyrica whenever a prescription for pregabalin is required even where the condition to be treated is not covered by Warner-Lambert's patent. Originators and generic companies alike, as well as those involved in prescribing and dispensing drugs, will no doubt be eagerly awaiting the next instalment of the pregabalin litigation.

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