JONES DAY

COMMENTARY

JULY 2018

IN SHORT

The Situation: Roche, the originator of the biologic therapy rituximab, sought interlocutory orders to restrain Sandoz from launching its rituximab biosimilar in Australia, on the basis that supply of the biosimilar would infringe four patents relating to methods of use of rituximab to treat four specified immunology conditions ("patented indications").

The Outcome: Justice Burley granted an interlocutory injunction until the first expiry date of the patents.

The Reasoning: A factor his Honour took into consideration in limiting the grant of injunction to the earliest of the cascading expiry dates of the patents was the fragmented nature of the rituximab market and the risk that a blanket restraint may prevent legitimate sales.

Rituximab is sold by Roche under the brand name "MabThera". Sandoz registered its rituximab biosimilar, "Riximyo", on the Australian Register of Therapeutic Goods in November 2017 for the same indications as MabThera, including the patented indications. In March 2018, the Pharmaceutical Benefits Advisory Committee recommended that Riximyo be listed on the Australian Pharmaceutical Benefits Scheme ("PBS") and that it be "a"-flagged against MabThera (which would allow a dispensing pharmacist to substitute Riximyo for MabThera).

Roche filed an application for an interlocutory injunction to restrain the supply of Riximyo on the basis that such supply would constitute an infringement of the patents.

Interlocutory Injunction

The requirements for obtaining an interlocutory injunction under Australian law are:

- that there is a prima facie case of infringement; and
- that the balance of convenience favours the grant, including that, if no injunction is granted, the applicant will suffer irreparable harm for which damages will not be an adequate remedy.

Prima Facie Case. Sandoz conceded infringement but argued that the patents were invalid for lack of inventive step.

Where there are competing infringement and invalidity arguments, the court takes the view that unless the invalidity case is sufficiently strong to qualify the conclusion that there is a prima facie infringement case, this requirement will be satisfied.

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Unlike other grounds of invalidity, the question of inventive step is "nuanced, fact rich and involves balancing questions of fact and degree, akin to a jury question". Where an inventive step challenge involves competing issues of fact and opinion, it will often be difficult for a party to establish any more than that its case is arguable.

As both parties' expert evidence appeared rational and persuasive, and having regard to the differences between them, it was not possible for Burley J to conclude on a provisional view that Sandoz's "arguable" invalidity case was sufficiently strong to qualify Roche's prima facie infringement case.

Balance of Convenience. In arguing that an interlocutory injunction should be refused, Sandoz relied on a number of factors said to relate to the nature of biosimilars and their market.

First, Sandoz submitted that the costs and time taken to develop a new biosimilar meant that it was less likely for there to be a large number of competing biosimilars or radical price reductions (which, in the case of small molecule generics, could be up to 80 percent). However, there was no evidence of the pricing that Sandoz would adopt in Australia, and the UK market experience indicated a price drop of about 40 percent.

Secondly, Sandoz submitted that the uptake of a new biosimilar is slower than that of generics, and it

cannot be concluded that the introduction of a biosimilar would have swift market penetration despite the Australian government's initiatives to encourage biosimilar use.

Sandoz also argued that any assessment of its compensation claim (if an interlocutory injunction was granted but the patents were ultimately revoked) would be more complex than if Roche sought damages at the conclusion of any proceedings. Specific to biosimilars, Sandoz noted that the market was relatively new, making it more difficult to determine the impact of efforts to encourage the use of biosimilars and any advantages associated with being the first mover (which Sandoz submitted was more important because of the time required to educate clinicians and patients about biosimilars).

However, based on the evidence, Burley J considered it unlikely that the first mover advantage would be significant given that a second biosimilar was likely to launch within months of the proposed Riximyo launch.

Therefore, although his Honour considered that the matters raised by Sandoz made the balance "more finely tuned", he nevertheless concluded that the overall balance of the case and justice was in favour of the granting of interlocutory relief. In this regard, matters weighing in favour of Roche included the fact that Roche's monopoly in the rituximab market was well-established and commercially important to it, while Sandoz's proposed trade in Riximyo was new.

Form of Injunction. As the patented indications made up 92 percent of MabThera sales, Burley J held that there was sufficient justification for granting a blanket injunction while all the patents were in force. However, as the expiry of each patent may "materially alter the landscape of the balance of convenience and justice", the interlocutory injunction granted restrains Sandoz only until the first expiry date of the patents—11 August 2019. Upon that date, if the proceedings had not yet been finally determined, Roche has leave to apply to extend the term of the interlocutory injunction.

TWO KEY TAKEAWAYS

1. In an application for an interlocutory injunction to restrain patent infringement, where there are competing infringement and invalidity arguments, the court takes the view that unless the invalidity case is sufficiently strong to qualify the conclusion that there is a prima facie infringement case, this requirement will be satisfied.

2. Where a number of patents relating to methods of treating different diseases with cascading expiry dates are asserted, the court is highly attuned to the risk that a blanket restraint may prevent legitimate sales. In the *Roche* case, Burley J granted the interlocutory injunction on the basis that the patented indications made up 92 percent of MabThera sales. However, the injunction is to be reviewed at the first expiry date of the patents, after which time only 45 percent of MabThera sales will be infringing.


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