HERBERT SMITH FREEHILLS

DAMAGES FOR PHARMACEUTICAL PATENT INFRINGEMENT: FEDERAL COURT GIVES LONG AWAITED GUIDANCE

24 March 2017 | Australia
Legal Briefings – By **Shaun McVicar** and **Rachelle Downie**

Last week, the Federal Court handed down the important decision in *Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd* [2017] FCA 250[1] regarding the assessment of damages for pharmaceutical patent infringement. Being the first reported Australian case on this issue, the decision is commercially significant for both originator and generic pharmaceutical companies.

LESSONS

The decision confirms that product substitutability is critical to the assessment of damages in pharmaceutical patent infringement cases and provides guidance on the type of financial records that may be relied on to establish the damage suffered. The decision also provides guidance on the 'good faith and with reasonable skill and knowledge' requirement in the context of patent amendments under s 115 of the Patents Act. This brief article focuses on the assessment of damages, in which Bayer was awarded more than AUD25 million in damages (plus interest on Bayer's pre-tax losses).

BACKGROUND

The question of damages arose as a result of the Federal Court's finding in 2013 that Generic Health's generic product, Isabelle, infringed Bayer's patent covering the oral contraceptive pill, Yasmin. In 2012, Generic Health began selling in Australia its generic version of Yasmin, Isabelle. Isabelle was registered as being bioequivalent to Yasmin and thus substitutable for Yasmin. In 2014, Generic Health was required to cease selling Isabelle and shortly after, Bayer launched its own generic version of Yasmin, Petibelle. The impact this had on the damages assessment is discussed below.

SUBSTITUTABILITY – THE SPECIAL CASE FOR PHARMACEUTICALS

The decision confirms that for prescription pharmaceuticals, the issue of substitutability is critical to the assessment of damages.

In contrast to the assessment of damages for infringement of other IP rights (such as copyright), the issue of substitutability is not determined by consumer choice. Like other prescription drugs, Yasmin could only be obtained on prescription. The Court accepted that the prescription would be for a specific brand and the consumer will seek the doctor's advice in relation to the brand which best met the consumer's needs.

In relation to the sales of Generic Health's infringing product, Isabelle, the Court held that every sale of Isabelle was a lost sale of Bayer's Yasmin product. Relevant factors that underpinned the Court's reasoning included:

- Isabelle entered the market as a pill that was bioequivalent to Yasmin
- Doctors would not prescribe by reference to the brand Isabelle and continued to prescribe Yasmin
- A woman could only obtain Isabelle if she held a prescription for Yasmin
- Women generally do not change the type of oral contraceptive pills (OCs) regularly or without good reason

The Court was also required to consider whether Bayer could also claim the loss associated with its sale of Petibelle. As to the legal question of causation, the Court considered that there was a 'sufficient causal connection' between Bayer's launch of Petibelle and Generic Health's infringement of the patent. This connection arose as Bayer successfully argued that, but for the infringement, it would not have introduced the lower priced Petibelle. On this basis, the Court accepted that the sales of Petibelle amounted to a lost sale of Yasmin, noting that Bayer was entitled to take reasonable steps to rectify the brand damage which Isabelle's unlawful entry into the market had caused Bayer.

FINANCIAL EVIDENCE – WHEN IS STANDARD COSTING IS ACCEPTABLE?

In relation to the financial evidence required to support the damages claim, the Court accepted Bayer's evidence on standard costing. This evidence was accepted on the basis that Bayer (a large company) relies on standard costing in the normal course of its business. It was against this background, that the Court considered that any discounting associated with inaccuracies in the standard costing and the assignment of fixed versus variable costs, should be resolved in favour of Bayer, not Generic Health - the infringing party.

LESSONS FOR THE PHARMACEUTICAL INDUSTRY

With the decision being the first in which the Federal Court has given detailed consideration of the approach to the assessment of damages for patent infringement it is goes without saying that this is an important decision for the pharmaceutical industry.

The Court's assessment of the question of substitutability is notable, with product and consumer specific factors being critical to the ruling. The importance placed by the Court on context raises the question whether the decision would have been the same had the medicine in question been a more readily substitutable product with a broader patient base, a non-prescription medicine or medical device.

The decision also provides guidance for both originator and generic pharmaceutical companies. The Court's inclusion of the Petibelle sales in the damages calculation suggests that it is acceptable for originators to take reasonable steps to rectify brand damage due to unlawful market entry.

At the date of this article it is unclear whether either party intends to appeal.

ENDNOTES

1. *Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd* [2017] FCA 250.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

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