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Landmark Federal Court decision sets a new benchmark for damages in patent infringement claims

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The Federal Court of Australia has handed down its first detailed damages decision in a long time in a patent infringement claim against a generic pharmaceutical company. In doing so, it sets a new benchmark for damages claims by innovator companies whose products have been illegally copied.

In *Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd* [2017] FCA 250, Bayer was awarded damages of over \$25m plus interest, assessed on Bayer's pre-tax losses. However, it is Justice Jagot's detailed decision, including her finding on "one for one" substitutability, that is most interesting.

Background

Bayer holds a patent which protects an oral contraceptive which it markets as "Yasmin". In 2012 Generic Health entered the market with a competing oral contraceptive product known as "Isabelle". Subsequently, Bayer also marketed its own generic product under the name "Petibelle". Justice Jagot had previously found that Bayer's patent was infringed as a result of the sale of "Isabelle".

A factual twist in the case was that Bayer sought to amend some of the original claims of the patent after Isabelle entered the market. Patent infringement proceedings were already on foot. The proposed amendments were tailored to focus more directly on the features of the "Isabelle" product, specifically as to dose, dosage form and testing for solubility. These amendments were approved by Justice Yates in late 2012 under section 105 of the *Patents Act 1990*.

Bayer's damages claim

Bayer elected to seek damages for patent infringement, rather than an account of profits. In support of its claim, it argued that every sale of Isabelle, and of its own generic Petibelle, was in reality a lost sale for Yasmin.

Generic Health contended that Bayer's claim for damages was excessive because:

- under section 115(1)(a) of the *Patents Act 1990*, Bayer should not be entitled to damages before the date the patent was amended (14 December 2012) because the original specification was not framed in good faith and with reasonable skill and knowledge;
- damages should not be calculated on that basis that each sale of Isabelle and Petibelle was a lost

sale of Yasmin;

- there should be a discount to Bayer's standard costings to reflect that risk that Bayer would have incurred more costs in producing additional Yasmin tablets; and
- interest should be calculated on post-tax losses.

The original claim and the effect of the later amendment

Justice Jagot concluded that the original claims regarding dosage range, dosage form and parameters of the dissolution test were framed in good faith and with reasonable skill and knowledge. In arriving at this conclusion, she noted that:

- the later amendments were not sought because Bayer considered that the original claims might be invalid;
- the limitations introduced by the amendment were not left out in error given the state of the common general knowledge; and
- the evidence disclosed that the skilled addressee would have known the parameters of the dissolution test limitation introduced by the amendments.

Accordingly, losses incurred by Bayer before 14 December 2012 were compensable by an award of damages.

Lost sales and substitutability

Bayer's evidence demonstrated that Isabelle was only obtainable by a woman who held a prescription for Yasmin. In other words GPs write prescriptions for Yasmin. Curiously, Generic Health offered no contrary evidence.

The Court held that, on the evidence, the possible class of women who would have bought Isabelle but not Yasmin was immaterial.

It also held that, but for the sale of infringing Isabelle by Generic Health, Bayer would not have introduced its own generic Petibelle. Thus, Bayer's loss should be assessed on the basis that every sale of Isabelle, and every sale of Petibelle until 30 June 2016, was a lost sale of Yasmin at Yasmin's original price point, not the reduced price after the generic product was launched.

The discount to standard costings

On the issue of the level of discount to be applied to Bayer's standard costings used to assess Bayer's loss, Justice Jagot had regard to the fact that Generic Health was the wrongdoer and the evidence from each party's expert accountant. Having regard to these matters, she allowed a discount of 2%.

Pre-or post-tax losses?

Justice Jagot rejected Generic Health's submission that interest should be calculated on post-tax losses.

In doing so, she noted that there is no guidance in either the *Patents Act 1990* nor the Federal Court Practice Note on whether interest is applied to pre-tax or post-tax sums. She also pointed out that any damages payable to Bayer would be subject to income tax to the same extent as if Bayer had

made the lost Yasmin sales.

The Bayer decision's effect on future patent infringement claims

It is rare for patent infringement claims against generic companies to make it as far as judicial calculation of damages ? it is far more common for them to be resolved by settlement. This decision is thus a valuable one for multiple reasons.

First, it sets a benchmark for Australian damages awards in this space.

Secondly, Justice Jagot's finding on substitutability in particular will not only be influential in future litigation, but could change the commercial attractiveness for generic companies of a new product.

Thirdly, it demonstrates the downside risks for generic companies launching before the patent position is clear.

However, this almost certainly won't be the last word on the matter. Given the importance of the issues, and the quantum of the damages award, it is most likely that this decision will be appealed, so watch this space.

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