Article Information

Authors: Tim O'Callaghan, Travis Shueard, Zara Cox
Service: Corporate & Commercial, Dispute Resolution & Litigation, Intellectual Property & Technology
Sector: Health & Life Sciences

Is it Obvious? Sandoz v Bayer and a Patent's Inventive Step

The validity of a patent relies, amongst other things, on the claimed invention involving an inventive step. This requires the claimed invention to not be obvious to a person skilled in the relevant art, in light of the common general knowledge. A recent Full Court decision clarifies the test for obviousness in relation to the development of pharmaceutical drugs.

Background Facts

Bayer Australia Limited (**Bayer Australia**) is the exclusive licensee of the following patents in Australia:

- Australian Patent No 2004305226, entitled "Method for the production of a solid, orally applicable pharmaceutical composition" with a priority date of 27 November 2003; and
- Australian Patent No 2006208613, entitled "Prevention and treatment of thromboembolic disorders" with a priority date of 31 January 2005.[1]

(together, the **Bayer Patents**)

Bayer Australia markets and sells PBS-listed products comprising rivaroxaban under the trade name XARELTO.[2]

Before the primary judge, Sandoz AG sought to revoke the Bayer Patents for various reasons, one being that they were obvious in light of the common general knowledge together with a prior art specification, being the compound patent International Patent Publication No WO 01/47919 (WO 919).[3]

For a patent to be valid, the claimed invention must involve an 'inventive step'.[4] Under section 7(2) of the *Patents Act 1990* (Cth), an "*invention is taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed before the priority date of the relevant claim*".[5]

WO 919

Bayer was also the owner of the compound patent WO 919, which describes a novel therapeutic approach for the treatment and prophylaxis of thromboembolic disorders.[6] It discloses a variety of compounds that should be suitable for more efficient treatment of thromboembolic disorders.[7]

Importantly, WO 919 gives "very particular preference" to rivaroxaban as the compound to be used.[8]

WO 919 expired in Australia in November 2023.

Decision of the Primary Judge

At first instance, the primary judge, Rofe J, held that the inventions claimed in each of the Bayer Patents involved an inventive step in light of the common general knowledge together with WO 919.[9]

The primary judge found that a skilled person reading WO 919 was likely to have selected rivaroxaban as the lead

candidate to take into further drug developments.[10] However, the nature of the drug development process and the real inherent risks meant that the skilled person would not have the requisite expectation of success at the time of selecting rivaroxaban that it would pass through all the drug development stages and result in a safe and effective drug to treat thromboembolic disorders.[11]

In doing so, the primary judge considered that:

- each step of the drug development process provides new data that can halt the process or lead to revision or modifications; and
- according to literature provided by Bayer, there is only around a 10% chance that a candidate drug will progress the entire way from pre-clinical testing to approval.[12]

Therefore, the patents were not obvious and involved the requisite inventive step to remain valid.

Sandoz appealed this decision to the Full Court of the Federal Court of Australia.

Decision of the Full Court

On appeal, the Full Court rejected the primary judge's findings.

The Full Court pointed out the importance of the primary judge's finding that a skilled person reading WO 919 was likely to select rivaroxaban as a lead candidate to take further into drug development.[13]

However, because any consideration of obviousness needs to be measured against the ordinary level of expectation and risk inherent in routine work in the relevant field, the selection of rivaroxaban as a lead candidate was *notwithstanding* the risks associated with drug development, even in the "*high risk field of thrombosis involving a novel, first in class drug.*"[14] Any risk of failure or change in direction is "*common to the field*" and does not mean that an inventive step has occurred.[15]

The Full Court held that the correct test for obviousness to be used is not that the skilled person has to *know* that steps will, would or even may well work, but that the skilled person merely *expects* that the steps may well work.[16] It is not necessary for the skilled person to know a particular outcome at the outset in order to be obvious.[17]

Further, the Full Court pointed to a lack of evidence that any issues would have been expected to have arisen during the drug development process and that the formulation of rivaroxaban or its dosage regime, as claimed in the patents, would *not* have been identified during the course of the drug trials.[18]

In light of the above, the Full Court upheld the appeal, finding that the patent did not involve and inventive step because a person skilled in the art in light of the common general knowledge (including WO 919), "*would have directly been led, as a matter of course, to try to develop rivaroxaban in the expectation that it might well produce a useful alternative*" to the treatment of thromboembolic disorders.[19]

Key Takeaways

This decision has clarified the threshold that needs to be met to prove obviousness. Whether a patent involves an inventive step will very much depend on the ordinary level of expectation in the relevant field. In the case of drug development, just because there are risks and unknowns in the drug trial process does not mean that a drug that does in fact proceed to approval involves the necessary inventiveness.

Patentees must take care to ensure that any claimed invention is not obvious in light of the prior art and common general knowledge in the relevant. Failure to take such care may render a patent invalid.

Piper Alderman has a nationally recognised practice in intellectual property enforcement and protection, with experience in all jurisdictions. Please contact Tim O'Callaghan and his team if you require patent advice.

[1] *Sandoz AG v Bayer Intellectual Property Gmbh* [2024] FCAFC 135 [2]-[3], [10]-[18].

[2] Ibid [3].

[3] Ibid [4].

[4] *Patents Act 1990* (Cth) s 18(1)(b)(ii).

[5] Ibid s 7(2).

[6] *Sandez v Bayer* (n 1) [63].

[7] Ibid.

[8] Ibid [64].

[9] Ibid [62].

[10] Ibid [76].

[11] Ibid [86].

[12] Ibid [72], [85].

[13] Ibid [76]-[77].

[14] Ibid.

[15] Ibid [92].

[16] Ibid [101].

[17] Ibid [103].

[18] Ibid [90]-[91].

[19] Ibid [106].