

Kluwer Patent Blog

Tribunal grants Sandoz a section 223(9) patent licence, in long-running Lexapro litigation

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On 18 September 2024, the Honourable Justice Jackman, in his capacity as a Deputy President of the Administrative Appeals Tribunal (**AAT**), granted Sandoz a licence pursuant to section 223(9) of the *Patents Act 1990* (Cth) (**Act**). In doing so, his Honour set aside an earlier, 2019 decision, in which the Commissioner of Patents (**Commissioner**) had also granted Sandoz a licence but on different terms. As discussed in this update, his Honour preferred a licence that was limited to the number of units Sandoz had imported by 12 June 2009 – within the period of time extended under section 223(2).

The case is significant, because it represents the first decision by a Federal Court judge (albeit sitting as the AAT), in which a licence under section 223(9) has been granted.

Background to the litigation

This proceeding is the latest instalment in a lengthy and complex web of litigation, concerning a patent owned by Danish company, H Lundbeck A/S (**Lundbeck**), relating to escitalopram, a drug used for treating depression and related conditions (**Patent**).

The standard 20-year term of the Patent expired on Saturday, 13 June 2009, but on the Friday before the Patent expired, Lundbeck filed an application for an extension of term, together with an application under section 223(2) of the Act for an extension of time in which to do so. Lundbeck needed the extension of time because, by then, the extension of term application was nearly 10 years late. By this stage, Sandoz had already exploited the invention (pursuant to a contractual, two-week early-entry licence), and taken definite steps towards a planned product launch of its generic escitalopram product, “ESITALO”, on the Monday, 15 June 2009. The Patent did expire on 13 June 2009, Sandoz proceeded with its planned launch, and continued selling its products at all material times ever since.

Years later, on 25 June 2014, Lundbeck was granted a retrospective extension of term by the Commissioner, which extended the term of the Patent to 9 December 2012. The extension was ultimately upheld on appeal, which was finally determined in 2016. The Lundbeck parties sued for patent infringement in respect of acts occurring during the extended term of the patent. At first instance, the Federal Court determined that Sandoz’s sales during the extended term of the Patent constituted patent infringement and statutory misleading or deceptive conduct. Justice Jagot made declarations, and orders for damages, interest and costs, accordingly. On appeal, the Full Federal

Court reversed the primary judge’s rulings, holding that Sandoz had a complete defence to infringement: a contractual licence pursuant to a settlement agreement Sandoz had entered into with Lundbeck in February 2007. The High Court subsequently granted special leave to appeal, and, in March 2022, held that Sandoz’s contractual licence did not include the extended term of the Patent, and remitted the proceeding back to the primary judge.

On 4 July 2023, the Federal Court granted a stay of the proceeding that had been remitted by the High Court, pending the final determination of all appeals concerning Sandoz’s section 223(9) statutory licence application, as discussed below.

Section 223(9) and regulation 22.21

As noted above, in order to pursue the retrospective extension of term application, Lundbeck also needed to obtain an extraordinary extension of time under section 223(2) of the Act of nearly 10 years. The extension of time application was ultimately determined in Lundbeck’s favour – by a bare majority of the High Court, in December 2014.

For extensions of time of that magnitude, the Act provides for licences to be granted by the Commissioner, to protect or compensate eligible persons affected by the lengthy extension of time. In particular, section 223(9) of the Act provides in relevant part:

(9) Where the Commissioner grants:

(a) an extension of more than 3 months for doing a relevant act; ...

the prescribed provisions have effect for the protection or compensation of persons who, before the day on which the application for extension of time is advertised under subsection (4), exploited (or took definite steps by way of contract or otherwise to exploit) the invention concerned because of the failure to do the relevant act within the time allowed, ... or the ceasing of the patent, as the case may be.

The “prescribed provisions” are found in regulation 22.21 of the *Patents Regulations 1991* (Cth), which relevantly provides:

(2) Persons who availed themselves of or exploited, or took definite steps by contract or otherwise to avail themselves of or exploit, inventions: ...

(c) in the case of inventions to which subsection 223(9) of the Act applies—within the period of time extended under that subsection;

may apply, in the approved form, to the Commissioner for the grant of licences to exploit the inventions. ...

(5) The Commissioner, if reasonably satisfied that the application should be granted, must grant a licence to the applicant on such terms as the Commissioner thinks reasonable.

In reliance on the above provisions, and in light of the extension of time Lundbeck had been granted, Sandoz applied to the Commissioner for a licence to exploit the invention claimed in the Patent.

The Commissioner’s decision under review

On 11 April 2019, the Commissioner granted Sandoz's application for a licence to exploit the Patent for the full extended term. The Commissioner found that Sandoz had in fact exploited the Patent during the relevant time, including by reason of an importation of ESITALO stock that occurred in late May 2009.

The statutory provisions had received limited consideration in case law to date. Putting to one side the escitalopram litigation, there has been only one other case in which a licence has been granted pursuant to section 223(9), namely the Commissioner's decision in *HRC Project Design Pty Ltd v Orford Pty Ltd* (1997) 38 IPR 121 (*HRC*). In the current proceeding, the Commissioner found no reason to depart from the terms of the licence that had been granted in *HRC*, and granted the licence to Sandoz accordingly.

Lundbeck applied to the AAT for review of the Commissioner's 2019 decision. The AAT proceeding was effectively stayed for a number of years, but the stay was lifted in late 2023 following events in the parallel infringement proceedings. The Tribunal heard the matter in late August 2024.

The AAT develops the law on statutory licences

On 18 September 2024, the Tribunal delivered judgment. After setting out the complex factual background in some detail, the Tribunal's reasoning primarily focussed on two main issues:

- whether Sandoz was entitled to apply for a statutory licence; and
- if the Tribunal exercises its discretion to grant Sandoz a licence, what terms would be reasonable.

On the first issue, the Tribunal concluded that Sandoz was eligible to apply for a statutory licence on the basis of its importation and keeping of the ESITALO product before 12 June 2009.

The Tribunal considered that, picking up language from the statute itself, the principal question on entitlement was whether Sandoz had exploited or taken definite steps to exploit the invention concerned "*because of*" Lundbeck's failure to apply for an extension of term within the time allowed. In reaching its conclusion that Sandoz was eligible, the Tribunal rejected several arguments put forward by Lundbeck, including a submission that a person may only apply for protection or compensation under section 223(9) if their acts of exploitation/definite steps were unauthorised or constituted an infringement. The Tribunal also held that, if Lundbeck had applied for an extension of term of the Patent by the applicable deadline (26 July 1999), then the ultimate expiry date of 9 December 2012 would have been established well before 2009. The Tribunal found that, as a direct result of Lundbeck's default, Sandoz was led to expect (in the period leading up to 13 June 2009) that the Patent would expire on 13 June 2009, which it ultimately did.

In its reasoning on this issue, the Tribunal cast some doubt on comments previously made by a single judge of the Federal Court, Justice Bennett, in *Law v Razer Industries Pty Ltd* (2010) 190 FCR 166, about the requisite level of causation required by the "*because of*" language of section 223(9). In that case, Bennett J had opined that "*There must be a link between the fact that the particular patent has ceased and reliance upon that fact by the person seeking to obtain the protection.*" The Tribunal considered that the "*because of*" language did not necessarily require reliance, as Bennett J had found, and could also be satisfied by a lower threshold of causation, such as "*active indirect causation*" and "*passive indirect causation*" as those terms have been used in case authorities concerning the legal causation test relevant to statutory misleading or deceptive conduct. Absent the *Law v Razer* authority, his Honour would have held that the "*because of*"

language of section 223(9) could have been satisfied by an applicant simply showing that the failure had made a “*material contribution*” to their conduct and decision-making. However, in the present case, the Tribunal, as an administrative body, considered itself bound by Justice Bennett’s decision in the Federal Court. On the facts of this case, these conflicting views about the requisite threshold did not affect the result, because the Tribunal was satisfied that Sandoz had established the higher threshold of reliance, in any event.

Despite finding (as the Commissioner had done) that Sandoz was entitled to a statutory licence, the Tribunal preferred a different approach with respect to the terms upon which the licence would be granted.

The Tribunal did not adopt the Commissioner’s licence terms (which had been consistent with the Commissioner’s previous decision, in *HRC*) which involved a licence for the complete extended term of the Patent. Instead, the Tribunal was influenced by its preferred construction of section 223(9) and regulation 22.21. The Tribunal considered that the licence should be limited to only the exploitation that had occurred during the period of time extended (i.e., between 26 July 1999 and 12 June 2009). Despite making findings that Sandoz’s conduct in launching its ESITALO product on 15 June 2009 had been reasonable, the Tribunal did not consider it appropriate that the terms of the licence should protect Sandoz from allegations of infringement during the whole extended term of the patent following that product launch. The Tribunal considered the protection should be limited to exploitation of units that had already been imported or ordered from overseas by 12 June 2009.

Clayton Utz acts for Sandoz in the ongoing escitalopram litigation with Lundbeck.

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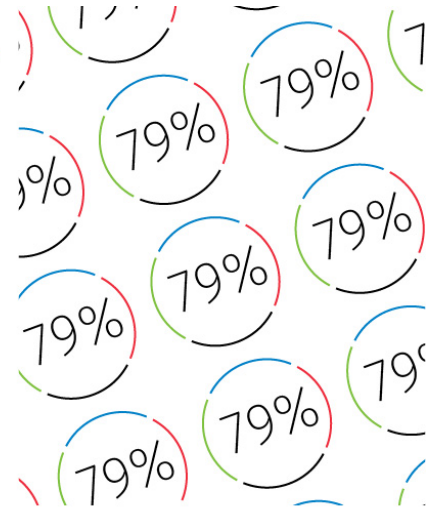
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