



Précis Paper

Implications of the extension of patent terms

A discussion on the recent decision of *Lundbeck AS v Commissioner of Patents* (2019) FCA 535.

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Implications of the extension of patent terms

In this edition of BenchTV, John Hennessy SC (Barrister, Tenth Floor Chambers, Sydney) and Angus Lang (Barrister, Tenth Floor Chambers, Sydney) discuss the recent decision of *Lundbeck AS v Commissioner of Patents* (2019) FCA 535.

Background

1. The case is a long-running matter which involves an antidepressant drug, the patent for which was owned by Lundbeck, a Danish pharmaceutical company.
2. The patent subsequently expired and generic pharmaceutical companies including Sandoz entered into market on the belief that an extension of time and term for the patent would not be granted. Lundbeck filed for an extension of time and term for the patent, 10 years out of time and against the backdrop of earlier litigation in which it had failed to obtain an extension of the patent term on another basis.
3. Some years later the extension of term was granted and the result was that Lundbeck obtained a retrospective extension of the patent term and brought infringement proceedings against Sandoz and other generic companies for the period of which they were in the market under section 223(2) of the *Patents Act 1990* (Cth).
4. Lundbeck acquired the extension under this provision which enables a patentee to apply for an extension of time, in order to apply for an extension of term for the patent. The provision also provides by way of counterbalance, for any third party affected by the extension of time to obtain a licence from the Patent Commissioner to protect itself from exposure to a patent infringement case
5. Lundbeck went ahead and sued Sandoz and the other companies who in turn applied to the Commissioner for a licence to try to protect themselves against the infringement suit.

The Commissioner's Licence

6. The licence exists to protect a person who has exploited a patent in circumstances whereby it has ceased and the extension of time has subsequently been granted by section 223 of the *Patents Act 1990* (Cth). Sandoz applied for a licence in the patents office but also pleaded in their defenses to infringement in the Federal Court proceeding that they had applied for such a licence
7. In the licence proceedings, Lundbeck took as a preliminary point the point that the application for the licence was not valid because a patent ceasing does not include

the expiry of a patent. The Commissioner did not agree that this was a preliminary point and Lundbeck took this on judicial review in the Federal Court.

8. Justice Beach of the Federal Court took the view that ceasing can include expiration and therefore the licence application by Sandoz was valid and could proceed to be determined by the Commissioner.

The Infringement Proceedings

9. Section 223(10) of the *Patents Act 1990* (Cth), is another form of safeguard which applies when a patentee makes an application for an extension of time and is a form of protection for someone who has exploited a patent in the meantime. This provision says that a patentee cannot take infringement proceedings in the period of time when the patent ceased and when it is restored.
10. Justice Jagot found that the defense did not apply and that under section 223(10) of the *Patents Act 1990* (Cth) the term ceasing did NOT including 'expiring' and therefore the patent was valid and infringed.
11. Her Honor however, could not determine Sandoz's defense that it had applied for and might obtain a Commissioner's Licence as at the time when Justice Jagot came to hand down her judgement, the Commissioner had not determined that question. Therefore, whilst those did ultimately make the final orders of a declaration of validity, infringement and orders to pay compensation, she also put in place some directions for Sandoz to apply for a stay of those orders pending the outcome of the Commissioner's licence.

The stay application

12. The basis of the stay application was that Sandoz argued that the obligation to pay \$27 million dollars by way of compensation should not be executed in circumstances where an available defense was still pending. Lundbeck resisted the stay application which was heard by Justice Beach in the Federal Court who ultimately granted the stay.

The Appeal

13. Shortly before the appeal was heard, the Commissioner handed down her decision granting Sandoz a licence under section 223(9) of the *Patents Act 1990* (Cth).
14. Lundbeck then sought a release from the undertaking it had provided to Justice Beach in the judicial review proceedings that it would not appeal his decision in relation to whether or not the requirements for an application before the Commissioner had been met until the licence application substantively was determined in full

15. Justice Middleton refused the application on the basis that nothing had changed from the time which the original undertaking was given, that is that the purpose of the original undertaking was not to fragment the Licence proceedings.

Grant of the Licence

16. Lundbeck's chief submission in respect of the licence was to emphasis the \$27 million figure that it had won in the infringement proceedings and to say that if the commissioner was now to grant a licence, it would be a \$27 million windfall for Sandoz. The Commissioner did not agree with that characterisation
17. Section 223(9) of the *Patents Act 1990* (Cth) and the regulations contain specific requirements that need to be fulfilled such as causation requirements and timing requirements and it was found that those requirements were satisfied and granted the licence.

General issues arising from application of case

18. One general issue that stems from the application of this case is the right of an exclusive licensee to sue for infringement in relation to a period of an extended term of a patent.
19. Another issue is in relation to a non-exclusive licensee. That is, that Lundbeck was a non-exclusive licensee who sought to have standing and entitlement to damages based on an allegation that failure to notify of the potential for infringement through the sale of products containing citalopram was a contravention of the Australian Consumer Law.
20. Most cases involving Australian Consumer Laws like this are usually tacked on to a patent claim, that is an entity that did otherwise have standing to sue for patent infringement also made an Australian Consumer Law claim, such as *Advanced Building Systems Pty Limited v Ramset Fasteners (Aust) Pty Limited* [1998] HCA 19.
21. Another question which arises in this case is when does a cause of action accrue in relation to an interest component, that is whether it is when the statute gives the right to sue or whether like a retrospective right to sue, there is a retrospective interest accrual.

BIOGRAPHY

John Hennessy SC

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Mr Hennessy is recognised as one of Australia's leading intellectual property silks according to Chambers & Partners Doyle's Guide to the Australian Legal Profession and World Trademark Review. He regularly appears in the Federal Court of Australia both at first instance and on appeal and has appeared in a number of leading intellectual property cases in the High Court of Australia. He also appears in the Australian Patent Office, the Australian Trade Marks Office, the Copyright Tribunal of Australia and in arbitral proceedings.

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Angus Lang was admitted/called to the Bar in 2006 after practising as a Senior Associate in the Intellectual Property Group at Herbert Smith Freehills. With over 20 years' experience in the field, Angus specialises in Intellectual Property across all divisions, including but not limited to, patents, copyright and trademarks. Offering his additional expertise in commercial litigation and consumer and completion law, Angus is recognised in the barrister rankings by multiple directors, Chambers and Partners, Doyle's Guide and the World Trademark Review. Angus is regularly briefed to appear in the Federal Court and Supreme Court, as well as the Copyright Tribunal and Patents and Trademarks Office.

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Focus Case

Lundbeck AS v Commissioner of Patents (2019) FCA 535

Cases

Advanced Building Systems Pty Limited v Ramset Fasteners (Aust) Pty Limited [1998] HCA 19

Legislation

Patents Act NSW 1990 (NSW)