

The Second Coming of the Public Interest into Patent Law

This is a pre-publication book review:

Danny Friedmann, The second coming of the public interest into patent law, *Journal of Intellectual Property Law and Practice*, Advanced Access, journal publication forthcoming number 8, Oxford University Press 2017.

The Access Regime, Patent Law Reforms for Affordable Medicines Ali, Feroz, Oxford University Press, 2016 ISBN-13: 978-0-19-946348-0 Hardcover, pp 263 + xxxviii

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The Republic of India, never a stranger to defining its own path of development,¹ realized that different jurisdictions have different needs. The leaders of this populous developing country have made full use of the policy space available to them to make long term decisions to guarantee affordable medicines and create a thriving generics pharmaceutical industry in the process. The book takes the reader from the Indian Patents and Designs Act of 1911 via the Chand and Ayyangar Committees in the sixties, when medicines were not affordable to most Indians, to the Patents Act 1970 and further. The Patents Act 1970 introduced a prohibition against granting product patents for medicines but allowed process patents for medicines. This prohibition, which lasted until 2005, helped create an indigenous pharmaceutical industry, where generics companies ingeniously worked around patented processes. The generics and active pharmaceutical ingredients were not only in great demand domestically, but also in developing countries that lacked the capacity to manufacture medicines.

Part I of *The Access Regime* brings us back to the early days of patent law when the public interest was still intricately connected. Although the inventor developed its invention in secrecy, a working model of the invention was needed as a requirement of patentability. This had the advantage that the public could take notice of it, by visiting Patent Offices that were crammed with working models or could be observed at exhibitions. However, this more participatory trend, essential for democracies, was replaced with the requirement of merely textualizing the invention. This intellectualizing of inventions via highly specialized and technical claims obscured most part of the public from taking notice of the latest patents.

After looking at the big picture, Part II zooms in on how India reinstated the public interest in the sphere of its patent system, implementing three trailblazing policy decisions to make use of pre-grant opposition; heightened patentability standards; and compulsory licensing. The author, the

¹ An example is India's Third Way movement as an alternative to both capitalism and socialism. See Stuart Corbridge and John Harriss, *Reinventing India: Liberalization, Hindu Nationalism and Popular Democracy*, Wiley and Sons 2013, unpaginated, Chapter 3.2 'The Developmental State'.

Ministry of Human Resource Development Intellectual Property Rights Chair Professor at the Indian Institute of Technology Madras, is well positioned to guide the reader through these complex concepts of patent law.

Chapter 3. Pre-grant opposition

The author demonstrates the advantages of effective public participation in patent prosecution that could curb for example endless amendments and the grant of frivolous or abstract patents. Besides, the patent prosecution process can affect the public at large as well. Since working models of patents are no longer needed, there is an information asymmetry at the prejudice of the Patent Office. The author cites Lemley who wrote that the Patent Office would spend on average 18 hours on the examination of a patent application.² The idea is that competitors of the patent applicant have more knowledge over the technology of the patent application than the Patent Office. Opposition procedures can be pre-grant or post-grant. The Chapter considers a peer-review system, now absent, that could enhance the disclosure standard of patents. The *ex ante* opposition can help the Patent Office prevent the grant of invalid patents. It might frivolously delay the grant of a patent, but then the erring opponent can be punished.

Chapter 4. Heightened patentability standards

This chapter is primarily focusing on the non-obviousness standard.³ Those interested in second and further medical use claims will find the part on the enhancement of efficacy exhilarating. Section 3(d) Indian Patents Act allows new forms of known substances where the applicant is able to demonstrate enhancement of efficacy. Scope, effect and constitutionality of Section 3(d) Patents Act were interpreted by the courts regarding Novartis' patent application for Glivec (beta crystalline form of Imatinib mesylate), all the way to the Supreme Court in 2013.⁴ The Supreme Court held that the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in case of a medicine the test of efficacy should be therapeutic efficacy. The Supreme Court deemed the more beneficial flow properties, better thermodynamic stability and lower hygroscopicity not relevant, because it did not refer to therapeutic efficacy and thus rejected the patent application.

Chapter 5. Compulsory licensing

The author notices that, despite the importance of compulsory licensing, no serious attempt was made to classify the different types. Compulsory licensing can be classified according to conduct into abuse and public interest based; or according to territory into local and international; or

² Mark Lemley, Rational Ignorance at the Patent Office, 95(4) Northwestern University Law Review 1500.

³ Indian Patents Act 1970, Section 2(1)(ja) defined inventive step as a feature of an invention that (a) involves technical advance as compared to the existing knowledge or; (b) having economic significance or; (c) both, and that makes the invention not obvious to a person skilled in the art.

⁴ *Novartis AG v Union of India* AIR 2013 SC 1311, 2013(54) PTC 1 (SC), (2013) 6 SCC 1.

according to needs into government use and market-initiated. The book deals comprehensively with the grant of the world's first compulsory license on Bayer's patented drug Nexavar.⁵

In 1995 India became a member of the World Trade Organization. It was given a ten year transition period to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁶ India has always made use of the flexibilities within TRIPS, also in regard to exporting patents under compulsory license to countries with insufficient or no pharmaceutical manufacturing sector.⁷ Part III is revisiting TRIPS as an access regime where India is showing the way.

The book, which was originally presented as the author's doctoral thesis at Duke University, is well structured and packed with insights. It includes a table of cases, bibliography and index. *The Access Regime* demonstrates that India's idiosyncratic patent system has concepts that other jurisdictions should take into account; especially the "enablers", *i.e.* countries, such as China, Brazil but also Canada, that have the capacity to manufacture patented drugs and are willing to provide them to countries in need.

This book is a celebration of India's bold long term decisions in the field of patent policy that have come to fruition and is an inspiration for other jurisdictions to calibrate their patent systems not just to accommodate their current circumstances but also to meet their future aspirations.

⁵ *Natco Pharma v Bayer Corp.* (Nexavar License) 38-39, Mumbai Patent Office (2012).

⁶ In the decade when India could exclude the granting of product patents, it did allow applications through the mail-box. These applications would be taken into consideration as of 2005.

⁷ India has been a trendsetting advocate for this concept, expressed in the waiver of the Doha Declaration of 21 November 2001 and formalized in the Ministerial Declaration of 6 December 2005, which introduces a protocol to permanently amend TRIPS for the first time. If two-thirds of the WTO members accept the Protocol before 2018, the amendments will be inserted into Article 31*bis* TRIPS. On 11 March 2007, 85 out of 164 members have ratified the Protocol, 24 members short of entry into force.