Chapter 6: A Valuable Contribution in Understanding the Influence of the Right to Health on Modern Indian Patent Law

By:

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In his illuminating book ‘Patents, human rights, and access to medicines’, Emmanuel Oke provides a lucid exposition of the intersection between patent law and the human right to health, through an exploration of judicial engagement with this intersection by courts in three developing countries: India, Kenya and South Africa. The book represents a thorough and comprehensive evaluation of a vitally important subject that has not received the kind of sustained scholarly attention that Oke bestows on it. In this post, I shall review chapter 6 of the book, titled ‘India as a case study’.

Oke begins by outlining the contextual peculiarities in India that informed the framing of modern Indian patent law, in the form of the Indian Patents Act of 1970 [‘1970 Act’]. A key concern that has consistently been at the forefront of

debates about Indian patent law is the need to modulate the law to meet the public health needs of India's predominantly economically disadvantaged population. As Oke notes: "Thus, for India, its patent regime must necessarily take into consideration the public health challenges in the country and not focus alone on protecting the rights of patent owners such as pharmaceutical companies."

Oke devotes, for good reason, considerable attention to the report of the Justice Ayyangar Committee that formed the blueprint for modern Indian patent law. He notes Justice Ayyangar's bold and visionary recommendation that Indian patent law should not allow for the grant of product patents on food and medicinal substances but should only allow for such grants on the process of manufacturing them. Justice Ayyangar's recommendations found expression in Section 5 of the 1970 Act which disallowed the grant of patents on products relating to food, medicine, or drugs or substances produced by chemical processes.

As I reference in my thesis 'Towards Using the Right to Health to Prevent Constitutionally Intolerable Denial of Access to Patented Drugs in India', this move created a facilitative environment for the generic industry in India to flourish. By 2004, the generic industry had assumed control over 77% of the Indian pharmaceutical market, as compared to 23% control by multinational companies.

In 2005, however, by virtue of the obligations imposed on it under the TRIPS Agreement, India had to amend its patent law. Indian patent law was therefore amended to allow for the grant of patents on pharmaceutical products. As Oke notes, this Amendment was coupled with the introduction of Section 3(d) which prohibits patent grants on incremental inventions, called evergreening. Further, Indian patent law also contains other exceptions to offset the impact of the overbroad legal monopoly granted by patents on pharmaceuticals, as indeed on other patented inventions. These are in the shape of compulsory licenses, regulatory review, parallel importation and an exception for research.

Disappointingly [from my perspective] Oke does not focus on the fact that these flexibilities have remained signally unutilized thus far. Despite having a robust right to health ['RtH'] jurisprudence, Indian courts and civil society have

not been able to use the RtH as an instrument to address this sorry state of affairs.

In the next segment, titled ‘the right to health in india’, Oke traces the evolution of the RtH as an element of Article 21 – the right to life clause in the Indian Constitution. He discusses at length the ground-breaking judgment of the Delhi High Court in *Mohd. Ahmed v. Union of India*. At issue in Mohd. Ahmed was the question as to whether a child belonging to an economically weaker segment is entitled to free medical treatment for a rare and chronic disease called Gaucher when the treatment is likely to help the child lead a normal life.

In Mohd. Ahmed, the Delhi Government argued that the state cannot be expected to prioritize the health of one individual over the health of the public at large. The High Court rejected this argument. It held that “every person has a fundamental right to quality health care -- that is affordable, accessible and compassionate.”

Even though the Ahmed judgment did not deal with a patented treatment, Oke is right in asserting that the judgment has enormous implications for the interaction between the RtH and Indian patent law. As he notes, if the approach on the RtH adopted by the Ahmed Court is adopted in the adjudication of patent law cases, “it will ensure that owners of patent rights on pharmaceutical products are not allowed to exercise their patent rights in a manner that impedes the enjoyment of the right to health.”

Equally, Oke does not deal with the unintended consequences of the court’s holding that the RtH includes every individual’s right to access the life-saving medicines that she needs. From a distributive justice standpoint, [i.e. ensuring that the state’s health budget is utilized in the most effective manner from the perspective of the public at large], the individual-centric conception of the RtH that the court proffers may be problematic. As the pioneering work by UCL scholar Octavio Ferraz shows in the context of Brazilian case law on access to medicines, adopting an individual-centric interpretation of the RtH can skew the state’s health budget and result in several second order unintended consequences. And so it would have been interesting to read Oke’s reflections on how the RtH can be applied in the area of patent law in a manner that does not give rise to the consequences seen in Brazil.

Oke concludes this segment of the chapter by distilling the following three principles that emerge from Indian case law on the rtH:

- Absence of adequate resources is not a permissible justification for the state's failure to provide medical facilities;
- The court is likely to adopt a hands off approach on any health policy that the state enacts and will only interfere if the policy is unreasonable, arbitrary or unconstitutional.
- Finally, the state has a core obligation to provide access to essential medicines at affordable prices.

In section 6.4, Oke discusses the four judgments in which an Indian court incorporated a human rights model into the adjudication of a patent law dispute. These are:

- *Novartis v. Union of India*, involving the interpretation of Section 3(d). The Madras High Court directly, and the Supreme Court indirectly, drew on the RtH in arriving at its interpretation.

- *Natco v. Bayer*, the case concerning the grant of India's first CL under the 1970 Act. The Controller General of Patents and Intellectual Property Appellate Board determined whether Bayer's drug was available at a 'reasonably affordable price' in light of the RtH of the patients needing access to the drug.

- *Bayer v. Union of India*, in which the Delhi High Court was called on to decide if it should recognize the doctrine of patent linkage. In turning down this invitation, the Court was mindful of the RtH-based consequences of judicially creating a regime of patent linkage.

- *Roche v. Cipla*, involving Roche's plea for the grant of an injunction against Cipla's production of the generic equivalent of Roche's anti-cancer drug, Erlotonib.

Equally, as Oke points out, even as Indian courts have been cognizant of the RtH in patent law disputes, they have not allowed the RtH to disrupt the integrity of the patent system. The RtH has just been one of the factors considered by the court. To illustrate, in *Novartis v. Cipla*, in which the Delhi

High Court granted an injunction against Cipla for infringing Novartis' patent on Indacaterol (a drug Used to treat chronic obstructive pulmonary disease), Cipla resisted the injunction by arguing that the injunction would violate the RtH of the patients of its generic equivalent. In rejecting this argument, the Court held: "Article 21 cannot be pressed into service by an infringer seeking to justify the infringement of a valid patent and the statutory rights conferred by the statute."

It would have been interesting to read Oke's views on how Indian courts can deepen the relationship between patent law and the RtH in future cases and build on the jurisprudence that he painstakingly documents. In my thesis, for instance, I point to one possible way in which this can be done. I argue that Indian courts can use the RtH as a resource to urge the executive to utilize patent law flexibilities, such as compulsory licenses, to secure affordable access to a patented drug when it is established, based on evidence and arguments, that the drug is generally unaffordable.

Notwithstanding this minor quibble, I found Oke's contribution very thorough, thoughtfully written and enlightening. The book in general, and this chapter in particular, will be a valuable resource for scholars who want to study the patent law and RtH relationship more deeply.

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