Incorporating a Model of Human Rights into the Adjudication of Pharmaceutical Patent Cases (Part Two) South Africa as a Case Study - Book Review

By:

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Oke's book Patents, Human Rights and Access to Medicines, is a timely and valuable contribution to the literature in this area. Its timeliness is due to the global context of the COVID-19 pandemic since 2019. The discussion of the import of patents to access to medicines, from a human rights lens is a critical endeavour which has been undertaken by several scholars. The seminal Intellectual Property, Human Rights and Access to Medicines-A Selected and Annotated Bibliography, now in its 3rd edition (Velásquez, Correa and Ido, 2020) curates the majority of this literature. The sections on Human Rights and Access to medicines (pp. 121 – 133) and African studies (pp. 134 – 145) are of specific interest to this review. Other relevant literature on Africa, human rights

and access to medicines not included in the bibliography includes Owoeye's Intellectual Property and Access to Medicines in Africa-A Regional Framework for Access (2019) which considers patents, access to medicines and the human right to development in its chapter 9, Vawda and Baker (2018) and Pieterse (2014). Since the publication of this bibliography in 2020, several other works on patent law making have been added to the literature. These include Ragavan and Vanni's edited volume Intellectual Property Law and Access to Medicines - TRIPS Agreement, Health, and Pharmaceuticals (2021) (which includes a chapter by Oke), Vanni's Patent Games in the Global South : Pharmaceutical Patent Law-Making in Brazil, India and Nigeria (2020) and Dutfield's That High Design of Purest Gold: A Critical History of the Pharmaceutical Industry, 1880-2020. Oke's book adds to this literature through its focus on South Africa, India and Kenya as case studies. This review focuses specifically on chapter five, the South African case study.

Chapter five has five sections, including an introduction and conclusion. The introduction succinctly locates the chapter within the book. The first of the three longer substantive sections (section 5.2.) summarises the patent legislation and highlights some of the shortcomings that have been identified, such as the lack of substantive patent examination and the lack of opposition procedures. Oke notes that the legislation "contains key flexibilities that can be utilized to facilitate access to affordable medicines… include compulsory licensing, permitting the parallel importation of patented pharmaceutical products, and regulatory review exemptions for generic drug manufacturers." (p. 119). The chapter does not expound on these aspects probably because its focus is on the courts' development of a model of human rights to the selected cases discussed in section 5.3. Readers will be familiar with the discussion of South Africa's use of these flexibilities through other scholarly works (e.g. on compulsory licensing : Forere 2019, Owoeye 2019 pp. 68 – 69; Vawda 2019). They will be equally familiar with the difficulties South Africa encountered in its bid to provide for parallel imports in its Medicines and Related Substances Act (e.g. Abbas 2021, Ncube 2021, Azam 2016, Heywood 2016, Ndlovu, 2014).

Section 5.2 notes that South Africa's ongoing patent reform process has been long in coming, with a draft national Intellectual Property (IP) policy being released for comment in 2013. Thereafter, following consultation, Phase One of the IP Policy it was adopted by Cabinet in 2018. As Oke notes, four years later,

in 2022 this policy remains unimplemented as the country continues to await a legislative reform process. The IP policy's recommendations include the phased introduction of substantive examination of patent applications and the introduction of opposition processes, which have been discussed in literature published in South Africa (e.g. Tomlinson et al (2019), Berger and Rens 2018, Tomlinson et al 2015, Ncube 2014). The discussion of these recommendations by Oke in juxtaposition with the Kenyan and Indian case studies amplifies the need for their implementation. His views find resonance with several other scholars. For instance, it has been consistently argued in the local literature that swift implementation of the IP Policy's reforms would enhance access to medicines.

The following section (5.3) considers the jurisprudence on the right to health in South Africa with a close scrutiny of the Constitutional Court's decisions in *Soobramoney* [1]*, Minister of Health v Treatment Action Campaign* [2] and the *New Clicks* [3] case, which have also received attention in other scholarly works as part of larger collections of litigation (e.g. DiStefano, Karim and Krubiner 2022, Sellin 2014 pp. 293-346, Pieterse 2014). Similar to the findings of these scholars, Oke characterises the courts as "a reasonableness approach" to the right to health. The essence of this approach is that "the right to health care in South Africa, which includes the right to have access to affordable medicines, imposes an obligation on the government to facilitate access to affordable medicines through the adoption of reasonable measures, although this obligation can only be fulfilled within the limits of available resources." (p. 126).

Section 5.4 considers how South African courts have applied this model of human rights to selected cases. Oke begins by noting that the South African constitution does not contain provisions specific to the protection to intellectual, unlike the Kenyan constitution (at p. 126). He then considers two cases and finds that in *Pfizer v Cipla* [4] the court failed to apply the model due to its failure to "see the tension between patent rights … and the need to facilitate access to medicines" (p128). He argues that the second case, *Aventis v Cipla* [5] also fell short because even though the court saw the tension it "was willing to hold that the denial of access to generic drugs should be considered as part of the price the society pays for securing monopoly rights through the grant of patents". (p.131). He argues that a full incorporation of the model of human rights would have rendered the same result but with the advantage of

making it clear that a case on different facts, may be resolved differently. This would then create a powerful template for deciding future cases. As stressed by the author, in his conclusion, “the incorporation of a model of human rights does not necessarily translate to the abrogation of patent rights, it only means that the courts should not permit patent rights on pharmaceutical products to be exercised and enforced in a manner that impedes the enjoyment of the human right to health. Where there is no risk that the exercise or the enforcement of patent rights will impede the enjoyment of the right to health, there is no need to prevent a patentee from exercising or enforcing its patent rights.” (p.132).

As shown by the above commentary, embedded within a broader literature review on patents, human rights and access to medicines in South Africa, Oke’s work accords with prevailing views on the topic. This chapter is a valuable addition to the topic through its evaluation of the South African courts’ application of a human rights approach to the selected cases and its demonstration of how the deployment of a model of human rights would render more justiciable results. This will continue to be a critical aspect of the state’s strides towards ensuring access to medicines, in compliance with their duties to respect, protect and fulfil the right to health (Chirwa 2003, p. 565).

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[1] Soobramoney v Minister of Health (CCT32/97) [1997] ZACC 17; 1998 (1) SA 765 (CC)

[2] Minister of Health & Ors v. Treatment Action Campaign & Ors (No. 2), (CCT8/02) [2002] ZACC 15; 2002 (5) SA 721

[3] Minister of Health v. New Clicks [2005] ZACC 14; 2006 (8) BCLR 872 (CC)

[4] Pfizer Ltd. v. Cipla Medpro (Pty) Ltd. (2005) BIP 1 [2005] ZACCP 1.

[5] Aventis v. Cipla (Court of the COmmissioner of Patents, Unreported Case No. P39/8936, Judgment delivered on 20 October 2011)

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