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STRATEGIC PATENTING OF PHARMACEUTICAL INVENTIONS AND THE PUBLIC'S RIGHT TO ACCESS MEDICINES: THE SOUTH AFRICAN CONTEXT

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ABSTRACT
Pharmaceutical firms' use of strategic patenting to influence the markets within which their patented inventions sit is legally questionable. Such patenting entails filing patents with the intention of blocking potential competitors from innovating and/or being granted patents within niche technology areas of interest to the patentee. Under this practice, patentees are potentially able to extend the breadth and duration of their monopoly power in the pharmaceutical market sub-sector within which that invention sits. Such practices take on a clear public interest element if they undermine affordable public access to medicines. This thematic report outlines forms of strategic patenting, analyses the degree to which the South African legal system provides remedies against such patenting, and proposes ways forward for South Africa to prevent such practices.

KEYWORDS
patents, pharmaceuticals, strategic patenting, public interest, access, compulsory licensing, competition, South Africa

INTRODUCTION: STRATEGIC PATENTING
Pharmaceutical companies use a wide range of strategic patenting approaches that are aimed at advancing their competitive positions in markets (Bader et al., 2012). Through these strategies, pharmaceutical companies use patents for purposes beyond protection of the technical subject matter of their inventions; they seek also to influence the business positions and behaviours of their competitors.

One of the foundational justifications – the incentive view – for how patents operate in relation to medicines is that companies engaged in pharmaceutical research and development will only be encouraged to continue developing new medicines if, in exchange for disclosure of their inventions, they are granted monopoly rights on a temporary basis (the current international standard is a 20-year duration) to enhance their ability to profit from the inventions they have spent time and resources developing.

From a public interest perspective, the incentive view is only credible if a patent serves the sole purpose of protecting the invention so that the patent holder, or his/her licensee or successor in title, can have an exclusive right to manufacture and commercialise the invented article, and nothing more. As Krishnan and Balachandran (2014) state, a "patent is for use and not for hoarding or exploitation" (2014, p. 175). The public interest is not being served when patents are used for more than just the protection of the specific subject matter of an invention. Potentially at stake is the public right of access to medicines, a key pillar of the global access to knowledge (A2K) movement seeking to ensure a fair, public interest-oriented balance between the rights of IP owners and the rights of users of IP-protected products.

A study by Sternitzke (2013) found clear evidence of a form of strategic patenting known as "fencing" in relation to PDE5 inhibitor drugs. According to Jackson (2007, p. 26),

> "[f]encing", or "surrounding", a competitor's core patents with a company's own patents for all conceivable improvements, is a method of forcing the competitor to enter into cross-licensing arrangements. […] This practice makes it difficult for a competitor to further expand on their original patents without infringing on patents held by the instigator of this tactic.

Also common in the pharmaceutical sector (Sternitzke, 2013, p. 549) is pre-emptive patenting, in which patents are filed to pre-empt competitors' behaviour, i.e., to prevent competitors from being granted exclusive rights in relation to certain markets and/or products. The evidence presented by Guellec, Martinez and Zuniga (2013) of pre-emptive patenting reveals the central role played by this strategy in the technology and market strategies of pharmaceutical companies. Another common practice is extension of the lifecycle of a drug patent by developing secondary patents (for minor changes to the drug) that serve to "evergreen" the original patent by increasing its term of protection (see Correa, 2011; Kapczynski et al., 2012; and *Novartis v Union of India (UOI) & Others*, 2013).

In the remainder of this article, I critically examine the legality, in the South African context, of using patents in a strategic manner to limit competition. I also suggest possible legal remedies that can be explored to address the adverse effects of such strategic patenting, e.g., in the event that public access to medicines is threatened by this practice.

SOUTH AFRICAN LAW
Article 28(1) of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides that a patent shall confer on its owner the exclusive right to prevent third parties not having the owner's consent from making, using, offering for sale, selling, or importing for these purposes that

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product (WTO, 1994). The corresponding provision in South African patent law, section 45(1) of the Patents Act, provides that

> [t]he effect of a patent shall be to grant to the patentee in the Republic, subject to the provisions of this Act, for the duration of the patent, the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention. (sect. 45(1), Patents Act of 1978)

The South African provision appears to be more liberal than its TRIPS equivalent. TRIPS simply lists the acts that third parties are excluded from, while the South African provision goes further, making reference to the patentee's entitlement to the "whole profit and advantage accruing by reason of the invention". Because of this wording, the provision can be afforded either a narrow or broad interpretation. A broad interpretation of "whole profit and advantage accruing by reason of the invention" could make strategic patenting permissible under section 45(1), i.e., if a court were to take a broad interpretation, the patentee could be permitted to use a patent to engage in any act he/she elected to in pursuit of "profit and advantage".

A narrow interpretation, however, of "whole profit and advantage accruing by reason of the invention" would be that the words apply only to the listed acts, i.e., to "making, using, exercising, disposing or offering to dispose of, or importing the invention […]". If a South African court were to adopt this narrow interpretation, strategic patenting practices would likely be ruled as falling outside the legal scope of the exclusive right provided to patentees.

I view the narrow interpretation as more plausible, because the broad interpretation appears to suggest that the exclusive right of the patentee is absolute and without limitations. In view of the fact that the South African Patents Act provides for significant public-interest limitations and exceptions permitted in terms of TRIPS – e.g., state walk-in rights (sections 4 and 78) and compulsory licensing (sections 55 and 56) – it is, in my view, inconceivable that the Act could, in section 45(1), provide for exclusive rights that would effectively threaten the public's right to access to medicines. The narrow interpretation establishes a balance between the private rights of the patentee and the public right of access; it protects the patent holder (against infringement of his/her patent rights by third parties) while ensuring that the exclusive rights of the patentee are exercised within clear, legally-defined boundaries (guarding against strategic patenting practices that threaten the public right of access to medicines).

PREVENTING STRATEGIC PATENTING

Based on a narrow interpretation of section 45(1) of the South African Patents Act, I see three possible legal remedies to be explored to ensure that strategic patenting practices do not adversely affect the right of the South African public to access medicines. These remedies are:

- a clear national position on strategic patenting, in both policy and law;
- implementation of compulsory licensing; and
- remedies for anti-competitive behaviour.

NATIONAL POSITION ON STRATEGIC PATENTING

The most relevant South African IP policy document at present is the Draft National Policy on Intellectual Property of 2013 (DTI, 2013). This Draft Policy is the South African government's effort to ensure that national IP laws not only meet international standards but are also in line with South Africa's needs as a developing country. The Draft Policy's Chapter 2, entitled "IP and Public Health", contains statements directly relevant to the focus of this article. The Chapter states that "IP protection regimes must not contradict public health policies and the two should be balanced", and that "South African legislation should allow strict rules to apply to patenting as competition principles may be undermined" (2013, p. 21). The essence of this argument is also echoed in the Draft Policy's Chapter 5 on "IP, Competition, Public Policy-Making, Compulsory Licensing and Technology Transfer". While neither chapter specifically addresses the issue of strategic patenting, they both emphasise the need for national patent law to safeguard the interests of the public and of patentees' competitors.

Assuming these parts of Chapter 2 and Chapter 5 remain unchanged in the eventual finalised National Policy, amendments should be made to the Patents Act to put the Act in line with the Policy. We have seen above that the current provisions in section 45(1) are potentially open to conflicting interpretations in respect of strategic patenting. It is therefore recommended that section 45(1) be amended so as to expressly provide that strategic patenting acts of the type discussed above are prohibited, i.e., that they fall outside the scope of rights granted to a patentee.

COMPULSORY LICENSING

Compulsory licensing is a mechanism by which a government limits the effect of a patent by granting a licence to a third party, without the consent of the patentee, so that the third party can work or exploit the invention on condition that the third party pays to the patentee a reasonable royalty (see Abbas, 2013, p. 245).

Both Article 5 of the Paris Convention on the Protection of Industrial Property and Article 30 of TRIPS provide for compulsory licensing as one of the possible exceptions to a patentee's exclusive rights, provided the implementation of the exception is "reasonable" (TRIPS, Art. 30) and takes into account the interests of both the patentee and

third parties, including the public. Wang (2014, p. 88) notes that compulsory licensing is a well-established IP legal instrument for facilitating affordable access, by breaking cartels and monopolies based on patent rights. Its most frequent use has been as a tool to secure public access to patented essential medicines. The South African Patents Act, in sections 55 and 56, provides for compulsory licensing in relation to two potential outcomes of strategic patenting: (1) non-working and non-licensing of a patent; or (2) existence of dependent patents.

NON-WORKING AND NON-LICENSING OF A PATENT

A compulsory licensing provision may be invoked when a patentee is found to be exhibiting behaviour deemed to be non-working, or inadequate working (without satisfactory reasons) of a patented invention on a commercial scale (in terms of section 56(2)(a) of the Patents Act).The legal precedent set in South Africa by the *Sanachem v British Technology Group plc* (1992) case regarding what it means to work a patent offers a relatively broad interpretation of "worked", as it not only considers local manufacturing of the patented articles but further includes importation as a means of working the patented invention. As patents may be worked not only when the patentee manufactures the patented invention but also through licensing, or assignment to the State or third parties, the non-working or abuse of patents may also be through the patentee's refusal to grant a licence to generics manufacturers. In the *Syntheta v Janssen Pharmaceutica & Another* (1998) case, it was held that the onus rests on the applicant for a compulsory licence to prove that the patentee has no satisfactory reason for not working (or licensing) the patent. The applicant therefore has to furnish the South African Commissioner of Patents with evidence of conducive conditions for working of the invention by the applicant under a compulsory licence.

EXISTENCE OF DEPENDENT PATENTS

Compulsory licensing can also be used, in terms of section 55 of the South African Patents Act, when there is evidence of dependency of other patents on a patentee's prior patent. In this regard, the prior patent is regarded as blocking the dependent patent, as the dependent patent may not be worked without infringing on the prior patent.This may oblige a prior patentee to grant a licence, or authorise use of his/her patent, in the working of the subsequent patent, or both parties to cross-license their patents to each other. To secure a compulsory licence, the holder of the dependent patent must prove that the proprietor of the prior patent is being uncooperative, i.e., the holder of the dependent patent must have unsuccessfully sought authorised access to the prior patent, on reasonable terms, from the prior patent's proprietor.

DIFFICULTIES WITH COMPULSORY LICENSING

Application for a compulsory licence must be done by a juristic person with technological capabilities to work the non-worked patent, and thus this is not a remedy that members of the general public can pursue. Another limitation is the burden of proof, which, outlined above, can be very challenging in relation to evidence of non-working of a patent. Firms' patenting strategies are not public documents, and therefore firms usually do not publicly disclose the reasoning that informs their approach. It is thus not surprising that on four occasions (all in the 1990s), the applicant's inadequate evidence was the reason cited by the Court of Commissioner of Patents for refusal of compulsory licensing applications.

REMEDIES FOR ANTI-COMPETITIVE BEHAVIOUR

Pre-emptive and blocking patenting strategies will often amount to anti-competitive behaviour, and thus qualify as prohibited acts (section 8) or abuse of dominance (sections 6 and 7) in terms of South Africa's Competition Act (RSA, 1998). A complainant lodging a complaint to the Competition Commission may allege a patentee's engagement in an exclusionary act (sect. 8(c)), or a patentee's refusal to give competitors access to an essential facility (sect. 8(b)), depending on the facts of the case at hand.

The advantage of using the competition regime is that, unlike patent law, it is available to the general public. In the *Hazel Tau & Others v GlaxoSmithKline and Boehringer Ingelheim* (2002) case before the Competition Commission, members of the general public were able to challenge the two multinational pharmaceutical firms on the grounds of alleged anti-competitive behavior or abuse of dominance, allegedly caused by excessive pricing of medicines and refusal to grant licences to generics manufacturers (able to produce the drugs at lower cost) on reasonable terms. Applicants who had no locus standi in the Court of the Commissioner of Patents, and so could not apply for a compulsory licence, were able to successfully seek and obtain relief through the competition law regime.

The outcome of the *Hazel Tau* case was that, after a detailed investigation, the Competition Commission found that GlaxoSmithKline and Boehringer Ingelheim abused their dominant positions in their respective anti-retroviral markets by engaging in prohibited anti-competitive acts (including denying a competitor access to an "essential facility", engaging in excessive pricing, and engaging in an exclusionary act). Thereafter, GlaxoSmithKline and Boehringer Ingelheim concluded separate settlement agreements with the complainants and the Competition Commission respectively, wherein they undertook to provide: voluntary licences to manufacturers of generic versions of the drugs protected by these companies' patents; importation of the drugs into South Africa; and export into other countries in sub-Saharan Africa.

CONCLUSIONS

Both the South African Patents Act and Competition Act offer possible remedies that could be used in cases of strategic patenting. The Patents Act offers remedies either through a narrow interpretation of its Section 45(1) or through use

of its compulsory licensing provisions in sections 55 and 56. But neither of these avenues is straightforward. It would appear that seeking remedy through the provisions of the Competition Act, against unfair competition and/or abuse of patent rights, would be more efficient and more sensitive to the public's rights. The outcome of the *Hazel Tau* case supports this view.

Regardless, the South African government should incorporate an explicit policy stand against strategic patenting in the final version of its National Policy on Intellectual Property and subsequent amendments to the Patents Act.

REFERENCES

Abbas, M. Z. (2013). Pros and cons of compulsory licensing: An analysis of arguments. *International Journal of Social Science and Humanity, 3*(3), 245-258.

Afrita (Pty) Ltd and Another v Carlton Paper of South Africa (Pty) Ltd, 1992 BP 331 (BP).

Bader, M. A., Gassmann, O., Ziegler, N., & Ruether, F. (2012). Getting the most out of your intellectual property – patent management along its life cycle. *Drug Discovery Today, 17*(7), 281-284.

Burrell, T. D. (1999). *Burrell's South African patent and design law* (3rd ed.). Durban: Butterworths.

Correa, C. M. (2007). Compulsory licensing: How to gain access to patented technology. In A. Krattiger (Ed.), *ipHandbook of best practices*. Retrieved from http://www.iphandbook.org/handbook/ch03/p10.

Correa, C. M. (2011). *Pharmaceutical innovation, incremental patenting and compulsory licensing*. South Centre Research Paper 41. Geneva: South Centre.

Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another, 1996 BP 455 (CP).

Department of Trade and Industry (DTI), (2013). Draft National Policy on Intellectual Property. Government of South Africa. Pretoria: *General Notice 918 of 2013*, 13 September.

Dolfsma, W. (2011). Patent strategizing. *Journal of Intellectual Capital, 12*(2), 168-178.

Guellec, D., Martinez, C., & Zuniga, P. (2013). Pre-emptive patenting: Securing market exclusion and freedom of operation. *Economics of Innovation and New Technology, 21*(1), 1-29.

Hazel Tau & Others v GlaxoSmithKline and Boehringer Ingelheim, Competition Commission Case No. 2002Sep226.

Jackson, P. J. (2007). The dangers of patents as weapons. LLM thesis. Canterbury, UK: University of Kent.

Kapczynski, A., Park, C., & Sampat, B. (2012). Polymorphs and prodrugs and salts (Oh My!): An empirical analysis of "secondary" pharmaceutical patents. *PLoS ONE, 7*(12).

Krishnan, R., & Balachandran, V. (2014).TRIPS Agreement and product patent – some issues. *International Journal of Advanced Research in Management and Social Sciences, 3*(4), 175-183.

Novartis AG v Union of India (UOI) and Others; Natco Pharma Ltd. v UOI and Others; M/S Cancer Patients Aid Association v. UOI and Others, Civil Appeal No. 2706-2716 of 2013.

Paris Convention for the Protection of Industrial Property of 1883, as last amended 28 September 1979.

Republic of South Africa (RSA). (1978). Patents Act of 57 of 1978, as last amended 15 January 2013.

Republic of South Africa (RSA). (1998). Competition Act 89 of 1998, as last amended 3 June 2013.

Sanachem (Pty) Ltd v British Technology Group plc, 1992 BP 276 (CP).

Sople, V. V. (2012). *Managing intellectual property: The strategic imperative* (3rd ed.). New Delhi: PHI Learning.

Sternitzke, C. (2013). An exploratory analysis of patent fencing in pharmaceuticals: The case of PDE5 inhibitors. *Research Policy, 42*(2), 542-551.

Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another, (449/96) [1998] ZASCA 74; 1999 (1) SA 85 (SCA); [1998] 4 All SA 445 (A).

Wang, R. L. (2014). Ancillary orders of compulsory licensing and their compatibility with the TRIPS Agreement. *Marquette Intellectual Property Law Review, 18*(1), 88-105.

World Trade Organisation (WTO). (1994). Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Yang, D. (2012). Compulsory licensing: For better or for worse, the done deal lies in the balance. *Journal of Intellectual Property Rights, 17*(1), 76-81.