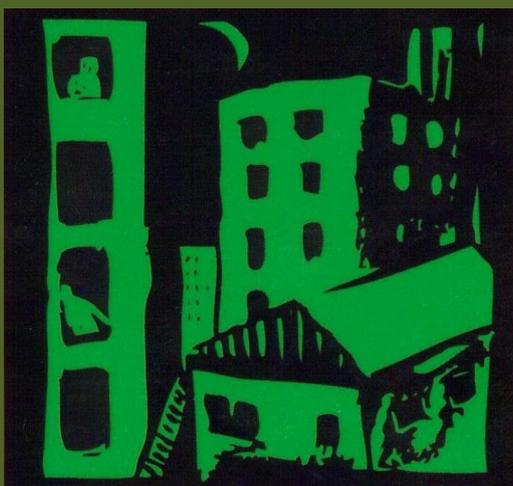


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After the *Novartis* judgment - 'Evergreening' will never be the same again!

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1 INTRODUCTION

For South Africa, the decision handed down by the Indian Supreme Court in the *Novartis*¹ case could not be more timely. As South Africa's legislators and policymakers ponder a new draft intellectual property (IP) law², they would do well to take heed of the import of this decision. While on the face of it the case involved "evergreening"³ – the

¹ *Novartis AG v Union of India & Others* Civil Appeals Nos 2706-2716, 2728 and 2717-2727 of 2013 Supreme Court of India (1 April 2013).

² On 3 September 2013, the Minister of Trade and Industry by publication in the Government Gazette, invited the public to comment on the policy. See Department of Trade and Industry "The Draft National Policy on Intellectual Property, 2013" GG No. 36816 of 4 September 2013. Available at www.gov.za/documents/download.php?f=198116 (accessed 28 August 2014).

³ "Evergreening" refers to "the submission of a new application for an ostensibly novel product, which is in fact only very slightly different from the one which is about to lose its patent protection. The 'new' product can then receive a further 20 years of patent protection." Jackson E *Law and the regulation of medicines* (Oxford: Hart Publishing 2012) at 81.

claim for a patent on an incremental improvement of an existing cancer drug (as opposed to a “genuine” innovation)⁴ – the decision has significance far beyond the question of which medicines ought to be patented. It is instructive in that it impacts the discourse on a wide range of issues, such as: a country’s ability to design a patent regime according to its specific conditions and context; the role of the courts and whether patent disputes may be resolved on narrow legal and technical arguments, or whether the wider context of the interests of society at large is to be considered; and the ramifications of this decision on the role of India’s generic manufacturers in facilitating the accessibility and affordability of much-needed medicines in developing and least developed countries.

This article traces the genesis of Indian patent law with regard to the protection of product patents for medicines, reviews the changes brought by the TRIPS Agreement and India’s measures to become compliant with this international regime, reviews the legal and policy arguments raised in the *Novartis* case, and discusses the implications of this decision on other developing and least developed countries in terms of access, policy considerations and legislative choices when crafting appropriate laws.

2 WHY INDIA?

India became the site for this contestation of intellectual property rights for a number of reasons. It is widely known that India’s manufacturers of generic medicines are among the world’s major providers of affordable medicines – with their exports reputed to total some US\$10 billion annually.⁵ Less obvious are the reasons for this. Until it was obliged to provide protection on medical products with the advent of the TRIPS Agreement,⁶ the Indian patent legislation did not permit patenting of, among others, pharmaceutical products, and restricted patenting only to the processes by which such products were manufactured.⁷ This significant departure from the existing legislation imposed during the period of British colonialism, was the result of the recommendations contained in the 1959 Ayyangar Report.⁸

⁴ “Incremental innovations” are minor modifications, namely, improvements to or adaptations of existing products or processes. “Irrespective of their practical usefulness, such improvements may be obvious to develop for a person having ordinary skills in the art.” Correa C *Guidelines for the examination of pharmaceutical patents: Developing a public health perspective* WHO-ISTSD-UNCTAD Working Paper (2007) at 28. Available at http://www.ufrgs.br/antropi/lib/exe/fetch.php?media=correa_pharmaceutical-patents-guidelines.pdf (accessed 20 December 2014).

⁵ Harris G & Thomas K “Low-cost drugs in poor nations get a lift in Indian court” *The New York Times* 1 April 2013. Available at <http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?adxnnl=1&pagewanted=all&adxnnlx=1374671022-Vnzdiw6lMJu8lber4FvP8A> (accessed 24 July 2013).

⁶ *WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994). Available at www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs (accessed 8 June 2013).

⁷ S 5(a) of the Patents Act, 1970, which barred the patenting of “substances intended for the use, or capable of being used, as food or as medicine or drug”.

⁸ Ayyangar NR *Report on the revision of the patents law* (1959) India Ministry of Commerce and Industry.

As observed by the Court in the *Novartis* judgment, the rationale for this approach was that the existing law had “benefited foreigners far more than Indians”⁹ – necessitating the need to “clearly identify certain inventions, the grant of patents to which would retard research, or industrial progress, or be detrimental to the national health or well-being, and to make those inventions not patentable.”¹⁰ This amendment to the then existing legislation opened the door to the development of a robust generic industry, as local manufacturers were able to sidestep the protected process patent for a medicine mainly through the use of “reverse engineering”, and could freely make copies of pharmaceutical products patented elsewhere in the world. In a little over two decades, India gained its reputation as the “pharmacy of the poor.”

The TRIPS Agreement contains special provisions for countries such as India, which did not allow the patenting of medicines, to transition to the new regime.¹¹ Effectively, India was granted until 1 January 2005 to become compliant with this aspect of the TRIPS Agreement. In terms of the Agreement, members are obliged to grant patents for any inventions that are “new, involve an inventive step and are capable of industrial application.”¹² Beyond this general prescription, the TRIPS Agreement does not define the scope and meaning of these criteria for patentability. Indian legislators exploited the latitude or flexibility allowed in the Agreement to exercise their freedom “to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”¹³ Thus, when crafting their amended patent law in 2005,¹⁴ in addition to defining “invention” and “medicine or drug”,¹⁵ the legislature refined the patentability criteria in respect of the inventive step requirement, by substituting the existing sub-section 3(d) with a new sub-section which is clearly designed to counteract the effect of ‘evergreening’.

While the repealed sub-section¹⁶ disallowed patents for new properties or new uses of known substances, or the mere use of a known process, the amended provision¹⁷

⁹ *Novartis* para 31.

¹⁰ *Novartis* para 39.

¹¹ Art 65 TRIPS Agreement.

¹² Art 27(1) TRIPS Agreement.

¹³ Art 1 TRIPS Agreement.

¹⁴ The Patents Act 1970 (as amended).

¹⁵ Ss 2(1)(j) and 2(1)(l) respectively the Patents Act, 1970 (as amended).

¹⁶ It reads as follows:

“3. The following are not inventions within the meaning of this Act,-

(d) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in new product or employs at least one new reactant;”

¹⁷ It reads as follows:

“(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives

extends the exclusion to ‘new forms’ of a known substance. Additionally, it requires that in order to be patentable, the new form of the known substance must “result in the enhancement of the known efficacy of that substance.” Helpfully, the explanation attached to the amended provision elaborates the range of ‘forms’ which will be considered to be the same substance, except if it is shown that they “differ significantly in properties with regard to efficacy.” Notably, the term “efficacy” is not defined in the amendments, and this issue generated much debate regarding its interpretation, in the case under review.

3 WHAT WAS THE CASE ABOUT?

In essence, it was about whether the Switzerland based pharmaceutical company Novartis should be granted a product patent in India for a specific compound, which was the beta crystalline form of imatinib mesylate, which is marketed as “Glivec” or “Gleevec” and is used to treat chronic myeloid leukaemia. The Indian Patent Office did not think a patent should be granted, and rejected Novartis’ application in 2006, on the basis that it failed to meet the required standards for patentability under Indian law.¹⁸ Some background to the history of this compound is instructive.

In 1994, Novartis applied for a patent in the United States for the drug “Imatinib” and other derivatives, which application also covered pharmaceutically acceptable salts. This patent (called the Zimmermann patent, after its inventor) was granted in May 1996.¹⁹ The following year, Novartis applied for a patent for a specific variation of the imatinib mesylate salt, the beta crystalline form – which was eventually granted under the lax US patenting standards. In July 1998, Novartis filed an application for a patent on the beta crystalline form of imatinib mesylate with the Chennai Patent Office in India.²⁰ By the time this application came up for examination by the Indian patent authorities, section 3(d) had been amended, as elaborated on above, and Novartis (hereafter the appellant) was required to demonstrate enhanced efficacy. The drug manufacturer thus undertook some studies to satisfy this statutory requirement. The authorities, after hearing several objections made possible through procedures in the law for pre-grant opposition to patent applications,²¹ rejected the application on two grounds: that the invention claimed by the appellant was anticipated by prior publication, and that the alleged invention was disallowed by section 3(d) of the amended Act.²² What followed was a series of legal challenges over the next seven years, which culminated in the decision of the Supreme Court.

of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;”

¹⁸ This article does not elaborate on how the patent application came to be in the ‘mailbox’ awaiting examination prior to the recognition of product patents on 1 January 2005, and pursuant to the provisions of Arts 65(4) and 70(8) of TRIPS.

¹⁹ *Novartis* para 5.

²⁰ *Novartis* para 8.

²¹ S 25(1) of the Patents Act 1970 (as amended).

²² *Novartis* para 14.

The Supreme Court Justices Alam and Desai had, once again, to decide on these issues. First, whether the invention claimed qualified as a new product in terms of sections 2(1)(j) and (ja) of the amended Act and secondly, whether it adequately constituted an inventive step in terms of an enhancement of efficacy, as required by section 3(d).²³

In arriving at its decision, the Court undertook a comprehensive analysis of the genesis of the imatinib compound, in order to ascertain whether the appellant had satisfied the novelty requirement. It concluded that the original Zimmermann patent had claimed and covered both forms of the compound (imatinib mesylate and imatinib),²⁴ and that the salt form had been disclosed and was therefore publicly known, prior to 1997. In order to decide whether the beta crystalline form satisfied the test of enhanced efficacy, it had to be compared to the known and previously-marketed mesylate salt form, and not the “free base” form of imatinib which was not soluble and thus not marketed. However, the appellant’s studies revealed the beta crystalline form evinced a 30% increase in bioavailability (more beneficial flow properties, better thermodynamic stability and lower hygroscopicity) in comparison only to the “free base” form.²⁵ Clearly it had thus not demonstrated these improvements in relation to the mesylate salt form.

Whether the above improvements in the physical properties of the chemical compound amounted to enhanced “efficacy”, and what the precise meaning of the term was, engaged much of the Court’s attention, and counsel for all the parties addressed the Court at some length thereon.²⁶ After considering the possible meanings of the term “efficacy” – which ranged from curative effects, to improved safety to reduced toxicity – the Court interpreted the notion to mean “therapeutic efficacy”, concluding that “in the case of a medicine that claims to cure a disease, the test of efficacy can only be ‘therapeutic efficacy.’”²⁷ However, the Court declined to pronounce on the appropriate definition of the term, as the case could be decided without doing so.²⁸

In arriving at its above conclusions, the Court recognised that the Indian legislation had set the threshold for its patentability standards significantly higher than other jurisdictions, in respect of medicines and drugs and other chemical substances.²⁹ Significantly, in reaching its conclusion as to the true purport of the requirements of section 3(d) namely to prevent “evergreening”, the Court embarked on a substantial analysis of the legislative history of the amended Act.³⁰ It carefully analysed the compelling interests of public health – both local and global – that Parliament had to consider, and took judicial notice of the representations of various UN agencies and civil society organisations. These spoke to the crucial role of India’s generic manufacturers in

²³ *Novartis* para 3.

²⁴ *Novartis* paras 133 and 157.

²⁵ *Novartis* para 172.

²⁶ *Novartis* paras 175-189.

²⁷ *Novartis* para 180.

²⁸ *Novartis* para 186.

²⁹ *Novartis* para 104.

³⁰ *Novartis* paras 76-85.

supplying affordable medicines to the world's poor, and the threat that the type of patent sought by the appellant would pose to global public health.

Finally, the Court chided the appellant, as it appeared that what it was selling in India was imatinib mesylate, and not the beta crystalline form. It remarked that "the case of the appellant appears in rather poor light and the claim for patent for beta crystalline form of Imatinib Mesylate would only appear as an attempt to obtain patent for Imatinib Mesylate, which would otherwise not be permissible in this country."³¹

4 IMPLICATIONS OF THE JUDGMENT

Reactions to the decision, as expected, were divided. Predictably, Novartis and other pharmaceutical companies were joined by the US Chamber of Commerce in criticising the judgment – claiming that it would negatively affect the future of innovation in medicines, as well as foreign direct investment. Mark Elliot, a representative of the US Chamber of Commerce, was quoted as saying: "This is not the first incident of this kind in India. There's a pattern of behaviour over many years that is of concern to the business community."³² Consumer advocates, public health campaigners and leading economists welcomed the decision. Nobel laureate Joseph Stiglitz and his co-author Arjun Jayadev lauded the judgment – commenting that the claims of the pharmaceutical industry and its lobbyists "are wildly overstated."³³ They further observe:

There is a curious incoherence in the argument that the Indian decision undermines property rights. A critical institutional foundation for well-functioning property rights is an independent judiciary to enforce them. India's Supreme Court has shown that it is independent, interprets the law faithfully, and does not easily succumb to global corporate interests. It is now up to the Indian government to use the TRIPS agreement's safeguards to ensure that the country's intellectual-property regime advances both innovation and public health.

Indeed, many analysts are in agreement that far from reflecting any bias or "errant" behaviour, the judgment is a balanced one. The Court stood firm on its interpretation of the law, and refused to be intimidated by multinational corporations and their Western government supporters, which have striven to foist interpretations of global patent rules on developing and least developed countries, which were most favourable to such corporations and often at the expense of the general public.³⁴ Clearly, the implications of this decision are far reaching, and provide five important lessons for other jurisdictions:

³¹ *Novartis* para 194.

³² Akshita "Consumer advocates hail, US trade lobby decries Novartis verdict" *India Talkies* 3 April 2013. Available at <http://www.indiatalkies.com/2013/04/consumer-advocates-hail-trade-lobby-decries-novartis-verdict.html> (accessed 20 December 2014).

³³ Stiglitz J & Jayadev A "India's patently wise decision" (April 2013) *Project Syndicate – A world of ideas*. Available at <http://www.project-syndicate.org/commentary/the-impact-of-the-indian-supreme-court-s-patent-decision-by-joseph-e--stiglitz-and-arjun-jayadev> (accessed 11 June 2013).

³⁴ See Chaudhuri S "The larger implications of the Novartis-Glivec judgment" (2013) 48(17) *Economic & Political Weekly* at 17. Available at <http://www.epw.in/authors/sudip-chaudhuri> (accessed 20 December 2014); Baker BK "Analysis: India's Supreme Court upholds strict patent standards and patient's right to access to affordable medicines; court dismisses unmeritorious court challenge by drug giant Novartis" (April 2013) *Health GAP*. Available at <http://healthgap.org/blog/2013/4/1/aids-activists-applaud-indian-supreme-court-novartis-decision> (accessed 20 December 2014); Abbott F "The judgment in

First, the Court's analysis of India's patent laws drew substantially upon the intent of the legislature, as deliberated in Parliament – foregrounding the objective of limiting practices, such as evergreening which affect access to affordable medicines.³⁵ It confirmed the notion of the will of Parliament as an important tool of judicial interpretation. Secondly, it adopted an expansive approach to deciding legal questions, placing the dispute in a larger economic and political context, venturing beyond the specific technical and legal questions raised by the challenge to the patent legislation, and linking patenting with “net benefits to society”.³⁶ Thirdly, it underscored the value and critical role of an independent judiciary which can stand up to both executive authority, as well as powerful transnational corporate interests.³⁷ Fourthly, it interpreted the term “efficacy” to mean therapeutic efficacy in the context of pharmaceutical products, providing patent offices with clear guidelines for determining the scope of this legal requirement. As Chaudhuri has observed: “(l)inking patenting to therapeutic benefit is a simple but powerful idea.”³⁸ It re-opens the debate about the “best time along a continuum for granting a patent” which, as Abbott suggests, may well be “after researchers have demonstrated that drugs will accomplish something significant in terms of curative effect”.³⁹ Finally, the judgment makes a strong case for taking cognizance of the specific conditions of a country in determining the most appropriate patenting regime, and that even under the TRIPS provisions “countries have some flexibility to frame their own patent laws to suit their national interests.”⁴⁰

5 HOW DOES THE INDIAN LAW COMPARE TO THAT OF OTHER JURISDICTIONS?

“Evergreening” is commonplace in many countries. Jurisdictions, such as, the US and EU, have generally adopted relatively low (or lax) standards of patentability, and have routinely permitted new patents for minor, incremental innovations. For instance, the revised provisions of the European Patent Convention of 2000 made it possible to obtain such patents.⁴¹ The TRIPS Agreement permits its members the freedom to do

Novartis v India: What the Supreme Court Of India said” (April 2013) *Intellectual Property Watch*. Available at <http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/> (accessed 11 June 2013).

³⁵ Abbott (2013) at 1.

³⁶ Chaudhuri (2013) at 10.

³⁷ Stiglitz & Jayadev (2013) at 2; Baker (2013) at 2.

³⁸ Chaudhuri (2013) at 11.

³⁹ Abbott (2013) at 3.

⁴⁰ Chaudhuri (2013) at 10.

⁴¹ Sterckx S & Cockbain J “Pharmaceutical product claims under the revised European Patent Convention.” Available at http://academia.edu/243632/Pharmaceutical_product_claims_under_the_revised_European_Patent_Convention (accessed 15 July 2013).

so.⁴² Temmerman, however, after reviewing a series of decisions in European domestic courts, concludes that this practice constitutes a category of “abuse of patent system.”⁴³

In addition, as the somewhat perverse consequences of this practice have become evident, particularly where its impact on public health is concerned, governments and courts in these jurisdictions have become alive to its problematic nature. Thus, following several prior studies arising from concerns about the economic and social costs of “low patent quality”⁴⁴, the US government has introduced new measures to improve patent quality.⁴⁵ The US Supreme Court has itself, in recent times, imposed restrictions on what may be considered to be patentable in a series of decisions⁴⁶, culminating in the landmark *Myriad Genetics*⁴⁷ case, which confirmed the strict patentability criteria of the US patent authorities around the patenting of genes. In arriving at its judgment, the court recognised the importance of public health considerations, and the need for competitive markets for medical (in this instance, diagnostic) products. Justice Clarence Thomas might well have been echoing the Indian Supreme Court when he said: “As we have recognized before, patent protection strikes a delicate balance between creating “incentives that lead to creation, invention and discovery” and imped[ing] the flow of information that might permit, indeed spur, invention.”⁴⁸

Therefore, while Indian patent provisions on evergreening may have had a distinctly different trajectory from that of the US and EU statutes, the latter jurisprudence may itself be developing in the direction of eschewing protection for secondary patents, as is evident in the recent US Supreme Court decisions. A frequent criticism levelled against the *Novartis* judgment and section 3(d) of the Indian Patents Act is that the provision is not TRIPS compliant. It has routinely been a target of the US Trade Representative, appearing in successive Special 301 Reports. For example, one recent report has this to say:

The United States is concerned that the recent decision by India’s Supreme Court with respect to India’s prohibition on patents for certain chemical forms absent a showing of ‘enhanced efficacy’

⁴² Art 1 TRIPS Agreement.

⁴³ Temmerman M “The legal notion of abuse of patent rights” Swiss National Centre of Competence in Research Working Paper No 2011/23, (May 2011) at 17. Available at http://www.nccr-trade.org/fileadmin/user_upload/nccr-trade.ch/wp3/3.5/The%20Legal%20Notion%20of%20Abuse%20of%20Patent%20Rights.pdf (accessed 15 July 2013).

⁴⁴ See, for example, Hall BH Graham SJH Harhoff & D Mowery DC “Prospects for improving U.S. patent quality via post-grant opposition” NBER Working Paper No. 9731(2003). Available at http://www.nber.org/papers/w9731.pdf?new_window=1. (accessed 15 July 2013).

⁴⁵ See Henderson N “White House recommends legislative action to curb patent troll abuse” *Web Host Industry Review* 4 June 2013. Available at

<http://www.thewhir.com/web-hosting-news/white-house-recommends-legislative-action-to-curb-patent-troll-abuse> (accessed 15 July 2013). “Patent trolling” is the practice whereby patents are registered not for use but merely for the purpose of anticipating infringements and engaging in litigation. See also “Peer to Patent.” Available at <http://www.peertopatent.org/> (accessed 15 July 2013).

⁴⁶ See, for example, *Bilski v Kappos* 561 US (2010), and *Mayo v Prometheus* 566 US (2012).

⁴⁷ *Association for Molecular Pathology v. Myriad Genetics* 569 U.S. (2013).

⁴⁸ *Myriad Genetics* at 11.

may have the effect of limiting the patentability of potentially beneficial innovations. Such innovations would include drugs with fewer side effects, decreased toxicity, or improved delivery systems. Moreover, the decision appears to confirm that India's law creates a special, additional criterion for select technologies, like pharmaceuticals, which could preclude issuance of a patent even if the applicant demonstrates that the invention is new, involves an inventive step, and is capable of industrial application.⁴⁹

This criticism fails to appreciate that “drugs with fewer side effects, decreased toxicity, or improved delivery systems” might still fail the test of patentability if the innovation was obvious to a person with ordinary skills in the art, thus not satisfying the requirement of inventiveness. Thus, while the provisions of the Indian Patents Act may not find favour with the US Trade Representative, it does not mean that it is not TRIPS-compliant. Indeed, no complaint has to date been lodged with the Dispute Settlement Body of the WTO, challenging the validity of the impugned section.

Understandably, this judgment appears to be anathema to “IP maximalists” – those governments, agencies, industries, lawyers and supporters who wish to ensure ever-increasing protection for intellectual property rights holders, protection which goes well beyond the requirements of the TRIPS Agreement.⁵⁰

6 IMPLICATIONS FOR SOUTH AFRICA

In considering the implications of this judgment for South Africa, its impact on public health, and the availability of affordable medicines, there is a role for both the legislature and the judiciary, as well as for civil society.

The immediate question arising from the *Novartis* judgment is: can South Africa reap the benefits of the strict standards of patenting applied by the Indian Supreme Court? The answer is: most definitely – if Macdonald Netshitenzhe, Head of Policy in the Department of Trade and Industry has his way. “We have a policy position that says ‘Let us have a strong system that will not grant easy patents’”, Netshitenzhe said in a recent interview in response to the Indian Supreme Court’s ruling on the issue of evergreening.⁵¹ South Africa’s Draft National Policy on Intellectual Property 2013, is now in the public domain. Its objectives are, among others: to develop a legal framework to empower all strata of citizens; to provide a conducive environment for economic opportunities; to ensure that such a framework applies alongside other government policies to contribute to development; to interface with related new emerging issues; and to improve and strengthen enforcement.⁵² On the anticipated

⁴⁹ US Trade Representative “2013 Special 301 Report” (2013). Available at <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf> (accessed 17 July 2013).

⁵⁰ For an elaboration of the “IP maximalist agenda”, see, for example, Sell S “The global IP upward ratchet, anti-counterfeiting and piracy enforcement efforts: The state of play” (June 2008) *Third World Network*. Available at <http://www.twinside.org.sg/title2/FTAs/info.service/fta.info.service132.htm> (accessed 24 July 2013).

⁵¹ Roelf W “South Africa seeks to close drug patent loophole” *Reuters* 22 April 2013. Available at <http://www.reuters.com/article/2013/04/22/us-safrica-medicines-idUSBRE93L0M420130422> (accessed 12 June 2013).

⁵² At p 4.

opposition by the pharmaceutical industry to the proposed reforms of the law, Netshitenzhe had this to say:

South Africa, an emerging economy with pressing public health needs, wanted to improve access to medicines, including generics, and was ready should drug firms come out fighting against the proposed patent law changes. They can lobby but nobody will be able to withstand this tsunami of access to medicine.⁵³

Chapter 1 of the Draft National Policy includes: recommendations to amend legislation to incorporate the flexibilities available in the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001⁵⁴; the establishment of a system of substantive search and examination of patents; incentive schemes in areas of IP that advance developmental goals, such as, poverty alleviation and health, the necessity for competition law to be applied to patent law where there is over-concentration, dominance or abuse by IP holders, and a commitment to the protection of clinical trial and other data, but not data exclusivity. Interestingly, the document identifies the need to explore alternatives to IP, such as subsidies or prize funds.⁵⁵

Chapter 2 deals with the impact of the protection of IP on public health. The document recommends the use of mechanisms, such as, compulsory licences and parallel importation, in order to enhance access to medicines; proposes that IP, competition and trade policies should be in harmony with health policy objectives; recommends the inclusion of provisions to facilitate generic competition in the medicines market; and suggests that stricter rules ought to apply to patenting.⁵⁶

The proposal for stricter patenting rules provides scope for South Africa to contemplate changes of the kind that the Indian Supreme Court deliberated upon. In other words, the prospect of incorporating the equivalent of section 3(d) of India's amended Patents Act into South African law. Patenting standards are a particular concern, as studies have demonstrated that South Africa's lax patenting requirements – including the lack of a system of substantive examination of patent applications – have resulted in a proliferation of 'weak' patents.⁵⁷ South African patent authorities granted a mammoth 2442 pharmaceutical patents in one year alone (2008).⁵⁸ Our patent system

⁵³ Roelf (2013).

⁵⁴ WTO "Declaration on the TRIPS Agreement and Public Health" (14 November 2001). Available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. (accessed 12 June 2013). The Doha Declaration stresses that the TRIPS Agreement should not prevent member countries from taking measures to protect public health.

⁵⁵ Gray A, Vawda YA & Jack C "Health policy and legislation" in: Padarath and English (eds) (2013) *South African Health Review 2012/13*.

⁵⁶ Gray, Vawda & Jack (2013).

⁵⁷ See: Correa CM "Pharmaceutical innovation, incremental patenting and compulsory licensing" (2011) South Centre Research Paper 41 (2011). Available at <http://www.uns.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf> (accessed 11 June 2013); Vawda YA "Pharmaceutical innovation, incremental patenting and compulsory licensing country case study: South Africa" (2011). Available at <http://www.tac.org.za/userfiles/file/Vawda%20SA%20patenting.pdf> (accessed 11 June 2013); Pouris A & Pouris A "Patents and economic development in South Africa: Managing intellectual property rights" (2011) *South African Journal of Science* 107.

⁵⁸ Vawda (2011).

contains several other flaws in addition to the lack of examination. These include, for example, the acceptance of overly-broad claims, weak disclosure requirements, and the lack of the requirement of the international, non-proprietary name for drugs.⁵⁹

With the publication of the Draft National Policy, legislators, policymakers and the general public will have an opportunity to craft a new IP law, and, most critically, a new patent regime for medicines that balances the interests of patent holders with those of consumers. Indeed, approximately 100 submissions have already been filed by representatives of industry, civil society and academia⁶⁰.

The specific areas in which South Africa can benefit from the Indian experience include the following:

1. Adopting strict standards for granting patents, and in the case of medicines, writing in the requirement of enhanced therapeutic efficacy to counteract the possibility of evergreening.
2. Permitting interest groups to file an opposition to patent applications for medicines, in the interests of public health. Provision must be made for such opposition – both before and after the grant of the patent.⁶¹
3. Strengthening compulsory licensing provisions to extend them to instances where the reasonable requirements of the public with respect to the patented invention have not been satisfied, or the patented invention is not available to the public at a reasonably affordable price.
4. Establishing patent office capacity to conduct substantive examinations to determine the merits of patent applications, particularly for medicines, in order to eliminate the grant of patents for inventions that are not genuine innovations. The feasibility and cost effectiveness of this option have been discussed elsewhere.⁶²

There are, in addition to the above, other “flexibilities” that South Africa can write into law, drawn from experiences in India and elsewhere.⁶³ The judiciary, for example, can also take a leaf out of the book of the Indian Supreme Court, which, as it demonstrated in the *Novartis* case, has not been averse to considering public policy arguments in

⁵⁹See Vawda YA “Who benefits from pharmaceutical patents? Why SA needs to use TRIPS flexibilities” (2012). Available at www.tac.org.za/sites/default/files/resources/.../Vawda%20presentation.pdf (accessed 12 June 2013).

⁶⁰ *Intellectual Property Watch* “Comments received for South Africa’s process for new IP policy” (18 November 2013). Available at <http://www.ip-watch.org/2013/11/18/comments-received-to-south-africas-process-for-new-ip-policy/> (accessed 28 August 2014).

⁶¹ *Novartis* para 8.

⁶² See, TAC, MSF & RIS “Why South Africa should examine pharmaceutical patents - How legislative reform could boost the affordability and accessibility of medicines for South Africans” (December 2012). Available at <http://www.tac.org.za/news/patent-examination-viable-and-necessary-south-africa-important-new-paper-describes-why-and-how> (accessed 12 June 2013).

⁶³ These include parallel importation under the international exhaustion regime; several permissible exemptions from patentability, as well as exceptions for research, early working and other purposes; and the freedom to exclude data exclusivity rules which bar drug regulators from referencing clinical trial data already on file, and consequently blocking generic competition. These aspects are treated extensively in the literature.

interpreting and applying patent law. In contrast, South African courts have missed opportunities to break new ground in this regard. A case in point is the recent decision of the Supreme Court of Appeal involving the cancer drug “Docetaxel.”⁶⁴ While essentially a dispute about whether the holder of a pharmaceutical patent can obtain an interdict against an alleged infringer, this was a significant test case for the extent to which courts are required to apply broad constitutional principles (in this case, the right of access to health-care services and medicines) in IP disputes. The Court accepted an amicus submission that the broader public interest, and not merely the interests of the litigating parties, ought to be considered in determining the balance of convenience in interdict proceedings, but did not go far enough to hold that this principle applied on the facts of that case. While making a concession to the principle, the Court took a rather narrow view of the issue of awarding damages (royalties) should the patent ultimately be found to be valid – holding that this would be tantamount to granting a compulsory licence. Such an approach is indicative of the reluctance on the part of South African courts and the patent authorities to countenance the grant of compulsory licences,⁶⁵ and is out of step with other jurisdictions, such as, India and the USA.⁶⁶

7 CONCLUSION

The *Novartis* decision has demonstrated the extent to which a judiciary – which is alive to the broader context in which IP regimes operate – can deliver outcomes that are fair, balanced, and which prioritise the most vulnerable and indigent. South Africa’s legislators, too, have a powerful tool in their hands, when considering the Draft National Policy – to correct the imbalances resulting from the existing IP regime. They can, furthermore, empower the judiciary with unambiguous legal provisions to draw the curtain on practices which place lifesaving medication out of the reach of those needing it. The project of attaining full access to medicines for all is a complex and multi-faceted task, requiring a range of interventions, including prudent policy choices and various developmental initiatives. Indian legislators and the Indian Supreme Court have shown us the way in this regard. Evergreening will never be the same again.

⁶⁴ *Cipla Medpro (Pty) v Aventis Pharma SA, Aventis Pharma SA & others v Cipla Life Sciences (Pty) Ltd & others* 2013 (4) SA 579 (SCA).

⁶⁵ As a matter of record, no compulsory licence has ever been issued in South Africa in respect of a pharmaceutical product. See Vawda (2011).

⁶⁶ For a fuller discussion of this case, see Gray, Vawda & Jack (2013) at 12-13.