Patent Invalidation Procedures in the WTO Member BRICS Countries: India Provides a Model Legislation

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Abstract. Eighty percent of the world's population lives in emerging markets, and a significant portion of this population is not receiving healthcare or at least is not receiving the healthcare they need. This is an issue experienced in all of the BRICS countries as well. The BRICS countries particularly need drugs for the treatment and management of infectious and communicable diseases. The affordability of healthcare is one of the key priorities of the BRICS countries. These goals may not necessarily be in line with the patent laws of the BRICS countries which are also members of the World Trade Organization (WTO). This article examines the patent invalidation procedures of the four WTO member BRICS countries, namely India, China, Brazil, and South Africa with the aim of evaluating the strengths and weaknesses of their procedural safeguards and learning from their experiences. The presence of a functional patent opposition model is of utmost importance for the BRICS countries, since this allows for the invalidation or opposition of patents that have been granted in their respective jurisdictions. However, except for India, none of the other WTO member BRICS countries have developed a well-thought-out patent opposition model. This study argues that the BRICS group provides a viable forum for India to promote its distinguished patent invalidation model. In turn, the WTO member BRICS countries can learn from India's pro-health patent opposition model and reform their national patent laws to align with their public health priorities. This is especially important in the context of the pandemic like COVID-19, for example.

Keywords: Brazil; China; India; South Africa; patent opposition; public health; TRIPS; WTO.

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Introduction

In 1995, the World Trade Organization (WTO) linked intellectual property protection with trade because signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is a prerequisite condition to becoming a WTO member.[1] Prior to the TRIPS Agreement, pharmaceuticals were excluded from patent protection under the domestic laws of approximately fifty countries.[2] The TRIPS Agreement provided mandatory patent protection to inventions in all fields of technology for a period of twenty years.[3] It was anticipated at the time of the drafting of the TRIPS Agreement that the exclusive rights granted under patent law may have serious practical implications for poorer countries in accessing affordable medicines. Public health safeguards were therefore included in the original draft of the TRIPS.[4]

Patent opposition is one of the safeguards embedded in the TRIPS Agreement. The definition of "patent opposition" has not been provided either in international treaties or in national patent laws. According to the Médecins Sans Frontières (MSF) Patent Opposition,

> patent opposition is a general term to refer to the ways in which it is possible to challenge the validity of a patent – both during the period

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1 Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* 64 (2012).

2 Germany excluded pharmaceuticals from patent protection until 1968, Switzerland until 1977, Italy until 1978, Norway, Portugal, and Spain until 1992, and Finland until 1995. *See* F.M. Scherer & Jayashree Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries*, Commission on Macroeconomics and Health (November 2001), at 4 (Jan. 20, 2024), available at http://www.icrier.org/pdf/jayawatal%20.pdf.

3 TRIPS Agreement, Arts. 27(1) & 33.

4 Muhammad Zaheer Abbas & Shamreeza Riaz, *TRIPS Flexibilities: Implementation Gaps Between Theory and Practice*, 2013(1) Nord. J. Commer. L. 1 (2013).

> when a patent application is being reviewed and after the patent has been granted.[5]

The World Intellectual Property Organization (WIPO) has defined the term "opposition" as

> a request, presented by the opposing party (a person or entity other than the applicant or the owner of the industrial property right) to the industrial property office [patent office] to refuse the application or to revoke the industrial property rights.[6]

The patent opposition is a time-bound administrative process within a patent office that allows for third parties, such as competitors, suppliers, or customers of the patentee, to raise arguments and provide evidence against the validity of a patent.[7] This procedure is used as a safeguard to make sure that only those inventions are granted patents that meet the requirements of patentability under national patent laws.

It is important to know how patent opposition works in key jurisdictions in the developing world. Patents are jurisdiction-specific territorial rights. Patent rights awarded by the patent office of a particular country protect the invention only within the territorial jurisdiction of that issuing country and not in other parts of the world. Patents granted in individual jurisdictions need to be invalidated or opposed in the same individual jurisdictions. It is important to develop a global or regional strategy for patent opposition because this procedural safeguard is essential to protecting the public interests across different jurisdictions. Because of its limited scope, this study focuses on the patent invalidation regimes of four key jurisdictions in the developing world.

In 2001, Brazil, Russia,[8] India, and China (BRIC) were identified by Jim O'Neill as the top tier of emerging economies.[9] Later, South Africa was added to this list in December 2010.[10] In 2006, Brazil, Russia, India, and China formed a formal BRIC group, which became BRICS in 2011 when South Africa formally joined the group.[11] In 2024 the BRICS

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5 How to Build an Opposition?, Patent Opposition Database (Jan. 20, 2024), available at http://www.patentoppositions.org/en/how_to_build_an_opposition?.

6 *See* World Intellectual Property Organization, *WIPO Handbook on Industrial Property Information and Documentation* (Jan. 20, 2024), available at https://www.wipo.int/standards/en/handbook.html.

7 Kimberlee Weatherall et al., *Patent Oppositions in Australia: The Facts*, 34(1) U.N.S. Wales L.J. 93 (2011).

8 Russia still remains outside the WTO. *See* Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 Am. J. L. & Med. 348 (2008).

9 Maya Tannoury & Zouhair Attieh, *The Influence of Emerging Markets on the Pharmaceutical Industry*, 86 Curr. Therapeutic Res. 19 (2017).

10 *Id.*

11 Frederick M. Abbott et al. (eds.), *Emerging Markets and the World Patent Order* 23 (2013).

group admits new member countries – Egypt, Ethiopia, Iran, and the United Arab Emirates.[12] The BRICS countries face common challenges in terms of providing affordable access to medicines to their citizens.[13] One of the primary rationales for providing patent invalidation procedures in these countries is to address this common issue of access to essential medicines. The procedures adopted by each of these countries are, however, distinctively different. This study evaluates the patent invalidation procedures of the following four WTO-member BRICS countries, namely India, China, Brazil, and South Africa, with the aim of evaluating the strengths and weaknesses of their procedural safeguards and learning from their experiences.

The BRICS countries "need drugs against infectious diseases and communicable diseases such as sexually transmitted diseases."[14] According to the BRICS Health Ministers Declaration, issued after the first BRICS Health Ministers' Meeting in 2011, the affordability of healthcare is one of the key priorities of BRICS countries.[15] In 2014, the first BRICS Science, Technology and Innovation Ministerial Meeting highlighted the need for

> people-centred and public-good driven science, technology and innovation, supporting equitable growth and sustainable development.[16]

That same year, the BRICS countries met on the sidelines of the 67th World Health Assembly (WHA) in Geneva and reaffirmed their commitments to cooperate in terms of promoting health under the BRICS Framework for Collaboration on Strategic Projects in Health.[17]

The positions of the other BRICS countries are very much in line with India's stance on the relationship between IP, trade, and public health.[18] The reason for choosing these countries as comparators is the fact that these countries are facing roughly similar challenges in terms of access to medicines and public health. It is important to investigate how these varied models compare because sometimes different regimes may face similar problems but adopt different substantive and procedural rules to

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12 *Expansion of BRICS: A quest for greater global influence?*, European Parliament, 15 March 2024 (Jan. 20, 2024), available at https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI(2024)760368.

13 Tannoury & Attieh 2017.

14 *Id.*

15 BRICS Health Ministers' Meeting: Beijing Declaration, Beijing, China, 11 July 2011, BRICS Information Centre (Jan. 20, 2024), available at http://www.brics.utoronto.ca/docs/110711-health.html.

16 *Id.*

17 Joint Communiqué of the BRICS Member States on Health on the Sidelines of the 67th WHO, Geneva, 20 May 2014, BRICS Information Centre (Jan. 20, 2024), available at http://www.brics.utoronto.ca/docs/140520-health.html.

18 *Id.*

address them. This study argues that the BRICS countries need to consider their public health needs and adopt tailor-made procedures in relation to addressing patent opposition. The legislative choices of the BRICS countries should not only comply with the requirements of the TRIPS Agreement but also align with domestic needs and constitutional obligations in terms of public health. India's legislative choices appear to be informed by this very approach of making optimal use of the policy space provided under the TRIPS agreement to customise the national laws in line with their country's domestic needs. The remaining three WTO member BRICS countries, that is, China, Brazil, and South Africa, can learn from the Indian approach and reform their patent laws with a key focus on their respective countries' public health goals.

1. India: A Well-Thought-Out Patent Opposition Model

After joining the WTO in 1995, India had to amend its patent laws because implementing the TRIPS Agreement is a mandatory requirement for WTO membership.[19] As a developing country, India was given a grace period up to 1 January 2005, to comply with the TRIPS regulations.[20] Since 2005, India has developed a detailed legislative framework for both pre-grant and post-grant patent opposition to fully avail itself of this TRIPS' procedural flexibility. Previously, beginning in 1970, India had provided only a pre-grant opposition system.[21] In 2004, under the Patents (Amendment) Ordinance 2004, the Indian patent regime provided for pre-grant representation and post-grant opposition proceedings.[22]

This study supports India's decision to set in place a less formal *ex-parte* pre-grant opposition procedure. The pre-grant opposition mechanism, provided under section 25(1) of the Patents Act 1970 and r. 55 of the Patents Rules 2003, is not designed to make the opponent a party to the proceedings.[23] The role of an opponent in pre-grant opposition proceedings is to help or aid the Controller by providing information in the form of grounds of opposition and supporting evidence. As a result, the

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19 The Agreement Establishing the World Trade Organization, Art. II.2. It stipulates the following: "The agreements and associated legal instruments included in Annexes 1, 2, and 3 (hereinafter referred to as 'Multilateral Trade Agreements') are integral parts of this Agreement, binding on all Members."

20 *Id.* Art. 65(2).

21 Previously, the pre-grant opposition could be filed only by an "interested person." After the 2005 amendment, pre-grant opposition can be filed by "any person."

22 Patents (Amendment) Ordinance 2004, sec. 25.

23 Patents (Amendment) Ordinance 2004 provided for pre-grant representation under sec. 25. Sec. 25(2) of the Ordinance specifically stated that "the person making a representation referred to in that sub-section shall not become a party to any proceedings under this Act only for the reason that he has made such representation." Though sec. 25 was amended under the Patents (Amendment) Act 2005 to provide for pre-grant opposition proceedings and the new provision was silent on whether or not the pre-grant opponent is a party to the proceedings, the previous provision can still be used to show the intent of the legislature.

Controller can make a more informed decision on the patent application in light of the information supplied by the opponent(s).

India has also set in place the additional safeguard of a more formal *inter-partes* post-grant opposition procedure. As compared to pre-grant opposition procedures, post-grant opposition procedures are more formal and detailed. As these proceedings are instituted after the grant of the patent, unlike pre-grant opposition, they are not an extension of the patent application procedure. The rights of the opponent are not dependent on the discretion of the Controller. The opponent is a party to the post-grant proceedings and, if either party is not satisfied with the Controller's decision, that party gets a proper opportunity to make his or her case and to appeal the decision.

As per sections 25(1)(f) and 25(2)(f), one of the grounds for invoking patent opposition proceedings in India is that

> the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act.[24]

This ground for opposing patents links the Indian patent opposition proceedings with section 3(d) which provides a notable exception to patentability in India. Section 3(d) excludes trivial modifications of known substances from patent eligibility in India unless they satisfy the condition of "enhanced efficacy."[25] Moreover, under sections 25(1)(e) and 25(2)(e), patents can be opposed on the grounds of obviousness or lack of an inventive step. This ground links the Indian opposition proceedings with section 2(ja) which defines the inventive step and adds additional requirements of "technical advance" and "economic significance" to the inventive step threshold. Sections 3(d) and 2(ja) are, therefore, very important components of the Indian patent opposition proceedings.[26] This nexus of two distinct TRIPS flexibilities is a distinctive feature of the Indian patent opposition model. India has thus used its procedural mechanisms of patent opposition to reinforce its heightened patentability requirements.

2. China: Still Experimenting to Strike a Proper Balance

In 1984, China adopted the Patent Law of the People's Republic of China.[27] Under this law, which entered into force on 1 April 1985, China introduced its pre-grant

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[24] The Patents Act 1970, sec. 25(1)(f).

[25] *Id.* sec. 3(d).

[26] Muhammad Zaheer Abbas, *Patent Laws and the Public Health Puzzle: Comparing India's Patent Opposition Model with the US and EU Model*, 13 Ind. J. Intellect. Prop. L. 1 (2023).

[27] China excluded pharmaceutical products from patent protection under the Patent Law of the People's Republic of China of 1984. *See* Hans Löfgren & Owain Williams (eds.), *The New Political Economy of Pharmaceuticals: Production, Innovation and TRIPS in the Global South* 48 (2016). *See more* Jing Chen et al., *TRIPS-Plus and Access to Medicines in China*, 34(2) J. Publ. Health Pol'y 229 (2013).

opposition procedure.[28] The procedure was abolished in 1992, possibly due to the discouragingly low opposition rate of only one percent.[29] In 1992, China revised its patent laws[30] and established two procedures: a post-grant opposition procedure and a post-grant invalidation procedure.[31] The post-grant opposition procedure not only overlapped with the invalidation procedure but also added to the burden of the Patent Office.[32] In 2000, when China revised its patent laws in order to comply with TRIPS requirements, it decided to eliminate the post-grant opposition procedure.[33] In 2008, China revised its patent laws again, this time with the aim of improving the balance between patent protection and the public interest. The 2008 amendments expanded the scope of compulsory licensing,[34] allowed parallel importation, and provided Bolar exemption for clinical trials.[35] No changes were, however, made this time to China's patent invalidation procedures.

China's current IP regime provides *inter partes* post-grant invalidation procedures as the sole means of invalidating patents. Once a patent is granted, any person may present a petition to have the patent invalidated.[36] China allows the petitioner to be anonymous or a "strawman," as petitions can be brought without the requirement to disclose the identity of the true party in interest. The petitions are made to the State Intellectual Property Office's (SIPO) Patent Re-examination Board.[37] In the event of an adverse decision, either party can appeal to the Beijing No. 1 Intermediate People's Court within three months of the Board's decision.[38] If either party is not satisfied

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28 Haitao Sun, *Post-Grant Patent Invalidation in China and in the United States, Europe, and Japan: A Comparative Study*, 15 Fordham Intell. Prop. Media & Ent. L.J. 286 (2004).

29 Kevin Greenleaf et al., *Beyond Our Borders: Comparing the Opposition Proceedings of Europe, China, and the United States*, 5(6) Landslide 36 (2013).

30 In 1992, China, faced with the threat of trade sanctions by the U.S. Trade Representative, signed the "Memorandum of Understanding on the Protection of Intellectual Property" with the U.S. The 1992 revision extended patent protection to pharmaceutical products. *See* Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines* 123 (2018).

31 Bonan Lin et al., *Overview of Chinese Patent Law*, in 35th International Congress of the PIPA, 19–22 October 2004, at 10 (Jan. 20, 2024), available at https://ipo.org/wp-content/uploads/2013/04/China_Overview_ChinesePatentLaw_Sept20040425.pdf.

32 *Id.*

33 *Id.*

34 The 2008 revision clarified that a national emergency includes a public crisis. China has, however, never invoked its compulsory licensing provisions to issue a compulsory license. *See* Chen et al. 2013, at 232. *See more* Sundaram 2018, at 128–9.

35 Löfgren & Williams (eds.) 2016, at 49. There is little evidence to suggest that China has made effective use of its parallel importation or Bolar exemption provisions in terms of facilitating access to medicines. *See* Sundaram 2018, at 131.

36 Patent Law of the People's Republic of China, Art. 45.

37 *Id.* Arts. 41, 45 & 46.

38 *Id.* Art. 46(2).

with the Intermediate People's Court's decision, that party can further appeal to the Beijing Higher People's Court.[39]

China, which initially relied on legal transplants, is still experimenting not only with its invalidation procedures but also with its overall patent regime. On one hand, China has adopted certain flexibilities, such as compulsory licensing and bolar exceptions, and on the other hand, China still allows patent protection for incremental innovations under its utility model or petty patents model.[40] China's current patent invalidation procedures generate legal estoppels, which make them less attractive to third parties.[41] Furthermore, China has not provided any mechanism for pre-grant invalidity challenges. When compared to India, China is struggling to devise a balanced system for itself, let alone provide a model for other jurisdictions.

3. Brazil: Dual Patent Examination but No Full-Fledged Pre-Grant Opposition Model

The re-democratization movement in Brazil began in the late 1980s, following a period of twenty-one years under military control.[42] In 1988, Brazil approved a new constitution that provided the legal basis for a universal healthcare system and a universal pharmaceutical assistance program.[43] Under its new constitution, referred to popularly as "the Citizens' Constitution,"[44] Brazil provided the right to health as a fundamental constitutional right.[45] Since the adoption of the new constitution, Brazil, a country with a population of over 200 million that exhibits profound social inequalities,[46] has consistently demonstrated a very clear pro-patient stance on public health matters. In Brazil, "the right to health is not an abstract goal to be eventually achieved, but rather a highly concrete undertaking."[47] Brazil's highly skilled state-based health activists have played a huge role in shaping Brazil's approach to public health.[48]

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39 Sun 2004.

40 Abbott et al. (eds.) 2013.

41 Chinese rules on estoppel are similar to the U.S. doctrine of collateral estoppel.

42 Elize Massard da Fonseca, *The Politics of Pharmaceutical Policy Reform: A Study of Generic Drug Regulation in Brazil* 30 (2014). The military rule ended in Brazil in 1985 as a result of a lengthy democratic struggle. *See* Duncan Matthews, *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements* 125 (2011).

43 *Id.* at 30.

44 Joseph Harris, *Achieving Access: Professional Movements and the Politics of Health Universalism* 77 (2017).

45 Constitution of the Federal Republic of Brazil, 1988, Arts. 196 to 200.

46 Edison de Paula Moura & David Petla Moura, *The Challenges of Providing Affordable Healthcare in Emerging Markets – The Case of Brazil*, 17(2) J. Mgmt. Pol'y & Prac. 35, 35–36 (2016).

47 Rochelle Dreyfuss & César Rodríguez-Garavito (eds.), *Balancing Wealth and Health* 94 (2014).

48 Harris 2017, at 152.

Brazil, a country that has one of the highest burdens of AIDS,[49] is often quoted as an example or recognized as a model for providing free and universal access to antiretrovirals (ARVs) through its national program.[50] Brazil adopted its first AIDS program in 1983.[51] In 1994, only 16 percent of HIV/AIDS patients in Brazil were receiving antiretroviral (ARV) drugs under the national program.[52] This situation gave rise to the emergence of new mobilizations in a country with "more than 600 different non-governmental organizations (NGOs) working on issues related to HIV/AIDS."[53] These NGOs used "human rights principles to frame the health policy on the right to health care as a right for all."[54] As a result of NGO mobilization, in 1996, Brazil adopted legislation that mandated Sistema Único de Saúde (SUS) to provide free and universal access to ARV drugs.[55] That same year, in order to comply with the TRIPS requirements, Brazil also adopted legislation that provided patent protection for pharmaceutical products.[56]

Brazil established post-grant administrative nullity procedures under its Industrial Property Law (Lei da Propriedade) of 1996.[57] As a result, any person having a legitimate interest may initiate these proceedings within a period of six months from the grant of the patent.[58] The proceedings are conducted by the National Institute of Industrial Property (Instituto Nacional da Propriedade Industrial or INPI).[59] The decision of INPI's president has a retroactive effect from the filing date of the application.[60] Moreover, the decision of the president can be appealed in the Federal Court forum within a period of sixty days.[61]

Brazil allows for the extremely limited participation of third parties before a patent is granted. Rather, it has established a mechanism known as "subsidies" for the submission of information by third parties.[62] Third parties are allowed, at any

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49 Harris 2017, at 153.

50 da Fonseca 2014, at 37.

51 Harris 2017, at 153.

52 *Id*. at 155.

53 Matthews 2011, at 126.

54 *Id.* at 127.

55 Federal Law 9.313/96 (Brazil). *See* Federal Laws 8.080/90 and 8.142/90.

56 The Law on Industrial Property (Law No. 9.279 of 14 May 1996) (Brazil).

57 *Id.*

58 *Id.* Art. 51.

59 In Brazil, the INPI is the federal governmental body in charge of the examination and grant of patents.

60 The Law on Industrial Property (Law No. 9.279 of 14 May 1996) (Brazil), Art. 48.

61 *Id.* Arts. 56, 57 & 212.

62 *Id.* Art. 31.

time from the publication of the patent application until the end of the examination, to present information and documents, free of charge, in order to subsidize the substantive examination.[63] This participation of the third party is limited to the presentation of information and documents (if any). Moreover, the examination of subsidies is not mandatory for INPI's examiners.[64] As compared to pre-grant opposition, this "input for examination" mechanism is extremely restricted in terms of its scope and effectiveness. There is a strong presence of civil society organizations in Brazil. Non-profit organizations, like the Brazilian Interdisciplinary AIDS Association (ABIA), can play a crucial role in defending the public interest if provided with proper opportunities to challenge low-quality patents in Brazil.

Since 2001, Brazil's patent laws have incorporated a unique practice of "prior consent" (anuência prévia).[65] Before the grant of a drug patent, prior consent from the Brazilian national health surveillance agency (Agência Nacional de Vigilância Sanitária or ANVISA) is required. The role played by ANVISA in terms of taking into account public health considerations in the patent examination is unprecedented in the history of patent regulation not only in Brazil but also in the rest of the world. This national agency is seen as a guarantor of the social function of IP rights as its involvement in the examination of drug patent applications is aimed at striking a balance between industrial and public health interests by "controlling the quality, safety, usefulness, and accessibility of health products."[66]

The examination of patent applications for therapeutic products and methods is divided between the INPI and the ANVISA. The INPI's examination focuses on the legal and technical aspects of a patent application, while the ANVISA's second analysis, which is carried out for the purpose of making sure that the patent examination has been performed rigorously, focuses on protecting and promoting public health. The rationale for adopting this practice of health-oriented examination is to control the price of drugs by deterring awards of inappropriate patents to incremental innovations in the pharma sector that do not meet stringent standards of novelty and inventiveness, while also keeping in view the implications of such patents for public health.[67]

Brazil's unique approach to patents has been subjected to extensive external pressure. For example, PhRMA considers the prior consent requirement as an additional

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63 The Law on Industrial Property (Law No. 9.279 of 14 May 1996) (Brazil), Art. 31..

64 Ricardo Nunes, *Brazilian Patent Statute under Attack (Part IV) Proposal for Pre-grant Opposition Mechanism in Respect of Patent Applications*, 005 Prevail 2 (2015).

65 The Law on Industrial Property (Law 10.196 of 14 February 2001) (Brazil), Art. 229(c).

66 Jean-Paul Gaudillière & Volker Hess (eds.), *Ways of Regulating Drugs in the 19th and 20th Centuries* 290 (2012).

67 Kenneth C. Shadlen, *The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil*, 39(2) Pol. & Soc'y 145 (2011).

"fourth criterion"[68] for patentability in Brazil.[69] The USTR has also criticized this approach in its annual Special 301 reports.[70] On the other hand, the NGOs involved in battles over IP rights support ANVISA's coordination of IP rights.[71] The prior consent system is supported by MSF-Brazil, as well as civil society groups such as the ABIA, the National Aids Program, and the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples.[72] ANVISA enjoys the support of public health groups since it believes that patents on a second therapeutic application of a known molecule are

> detrimental to public health and to the country's scientific and technological development, and could impede access to medicines.[73]

According to the official data provided in ANVISA's 2011 report, this national agency has been much stricter than the INPI in its patent application examinations, consenting to patent protection only for inventions that have achieved high levels of novelty and inventiveness.[74]

In addition to external pressures, the practical implementation of the dual examination system has been problematic. The system has caused much tension between the institutions that carry out the dual examination. It has been noted that INPI consistently seeks to "minimize ANVISA's participation in patent examination."[75] The INPI insists that, keeping in view its institutional purpose, "ANVISA should focus on analysing eventual risks to public health only."[76] In the majority of cases where ANVISA disagrees with the primary examination and refuses to grant the patent, INPI simply freezes the patent application instead of formally rejecting it.[77] This practice of

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68 Brazil's prior consent system is corroborated by the principles of the TRIPS Agreement established in Articles 1 and 8. The freedom afforded to the WTO member states to institute differentiated mechanisms in certain fields has been confirmed by the WTO dispute settlement body. *See* World Trade Organization, WT/DS114/R, 17 March 2000, para. 7(92).

69 Shadlen 2011, at 146.

70 *Id. See more* Maurice Cassier & Marilena Correa (eds.), *Health Innovation and Social Justice in Brazil* 168 (2019).

71 Gaudillière & Hess (eds.) 2012.

72 Shadlen 2011, at 164.

73 Gaudillière & Hess (eds.) 2012, at 292.

74 Cassier & Correa (eds.) 2019, at 171.

75 Hans Löfgren (ed.), *The Politics of the Pharmaceutical Industry and Access to Medicines: World Pharmacy and India* 291 (2017).

76 Newton Lima et al., *Brazil's Patent Reform: Innovation Towards National Competitiveness*, Center for Strategic Studies and Debates (2013), at 133 (Jan. 20, 2024), available at https://www2.camara.leg.br/a-camara/estruturaadm/altosestudos/pdf/brazils_patent_reform_eng.pdf.

77 Shadlen 2011, at 153. ANVISA is not authorized to directly deny a patent. It sends its final decision to INPI, which proceeds with the final decision and subsequent publication thereof. *See also* Lima et al., *supra* note 76, at 148.

allowing patent applications to remain open when they should have been rejected goes against the very rationale that led to the establishment of the preventative prior consent institution. As noted by Kenneth C. Shadlen,

> [t]he state of non-decision provides effective protection, and has the same effect as granting the patent in terms of warding off competitors, because third parties fear retroactive damages in the case of the patent eventually being granted.[78]

Keeping in view its constitutional obligations in terms of providing universal health care, Brazil needs to address the problems associated with the practical implementation of its prior consent or dual examination system. More importantly, Brazil, as a developing country facing serious challenges in terms of providing affordable healthcare to its citizens, should learn from India and implement a full-fledged pre-grant opposition procedure that provides third parties with a better opportunity to challenge pending patent applications. This will offer more feasible opportunities for Brazil's active health groups to challenge the validity of questionable drug patents.

4. South Africa: The Highest Grant Rates in the Absence of Patent Examination

South Africa has been a member of the WTO since 1 January 1995.[79] The South African government, under the 1996 Constitution, is obligated to facilitate access to healthcare services,[80] including access to medicines.[81] The underlying preconditions of health are also covered under South Africa's Constitution.[82] Previously, in the apartheid era, access to health care was not a right.[83] However, in the post-apartheid era, South Africa's democratically elected government made pro-health amendments to the Medicines and Related Substances Act[84] aimed at creating a legal framework to enforce the constitutional right to health.[85]

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78 Lima et al., *supra* note 76, at 148.

79 Jennifer A. Sellin, *Access to Medicines: The Interface Between Patents and Human Rights. Does One Size Fit All?* 293 (2014).

80 The Constitution of the Republic of South Africa, secs. 12, 14, 24, 27, 28 & 35.

81 *Minister of Health v. Treatment Action Campaign* (No. 2) 2002 (5) SA 721 (CC).

82 *Lindiwe Mazibuko and Ors. v. City of Johannesburg and Ors*, (2009) CCT 39/09.

83 Harris 2017, at 89.

84 The Medicines Act (Act 101 of 1965) (South Africa). Section 15C was introduced in the Act in order to adopt an international exhaustion regime. *See also* Sellin 2014, at 330.

85 Sundaram 2018, at 191.

The government of South Africa, a country severely affected by HIV/AIDS and characterised by a high burden of tuberculosis, faced numerous budgetary constraints at one juncture in terms of fulfilling its constitutional obligations. The government thus made the decision to restrict the dispensation of Nevirapine, an ARV drug, to only eighteen pilot sites. The Treatment Action Campaign (TAC), a leading civil society organization in South Africa, however, brought an action against this decision of the government. The High Court held that the government's program fell short of its constitutional obligations. The Constitutional Court, upon appeal, upheld the High Court's decision and ordered the government to remove restrictions on the drug's dispensation at public health facilities.[86] As a result of such efforts by the TAC and other HIV/AIDS NGOs, South Africa currently has the largest AIDS treatment program in the world.[87]

South Africa's government has failed to make full use of the public health flexibilities provided under TRIPS. Theoretically speaking, South Africa allows the grant of a compulsory license;[88] but in practice, it has yet to grant a compulsory license for any drug patent.[89] Furthermore, South Africa has adopted lenient patentability standards, and it has provided neither a patent examination[90] nor a patent opposition system to monitor and prevent the grant of frivolous patents.[91] In the absence of a substantive examination system,

> thousands of patents have been registered in the country to cover minor or trivial developments that can block local production or importation of low-priced generic medicines.[92]

As a non-examining country, South Africa has one of the highest grant rates in the world.[93] A comparative analysis showed that, between 2000 and 2002, South

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86 *Minister of Health and Others v. Treatment Action Campaign and Others*, (2002) (10) BCLR 1033 (CC).

87 Harris 2017, at 170.

88 Compulsory licensing for dependent patents and in instances of abuse of patent rights is allowed under secs. 55 and 56 of the 1978 Patents Act, respectively. *See* Löfgren & Williams (eds.) 2016, at 192.

89 Alexander Ward, *The BRICS Wall of Protection: What South Africa's Patent Policy Means for the Future of National Health*, The Yale Global Health Rev., 16 March 2014 (Jan. 20, 2024), available at https://yale-globalhealthreview.com/2014/03/16/the-brics-wall-of-protection-what-south-africas-patent-policy-means-for-the-future-of-national-health.

90 The South African Patent Office grants a patent without a full examination as to the merits of the application if the patent applications meet the necessary formalities required under sec. 34 of the 1978 Patents Act. *See* IPO, *Intellectual Property Guide South Africa* (2016).

91 Ward, *supra* note 89.

92 Peter Drahos et al. (eds.), *Kritika: Essays on Intellectual Property* 68 (2015).

93 Companies and Intellectual Property Commission, *Submission by South Africa; Exceptions and Limitations* 13 (2017).

Africa granted 66 percent more pharmaceutical patents than the United States and the European Union.[94]

There is a high probability of exclusive rights being granted, with broad invalid claims for inventions that do not necessarily meet the substantive patentability requirements.[95] Moreover, questionable patents that are overturned in other countries through opposition or legal procedures are often unchallenged or upheld by courts in South Africa.[96] As noted by Lonias Ndlovu,

> Introducing patent searches and [substantive] examinations will make life-long saving medicines and drugs available and accessible to South Africans because pharmaceutical companies will no longer be able to file multiple patents for the same drug.[97]

Mara Kardas-Nelson, an Access and Innovation Officer with the MSF Access Campaign in South Africa, rightly noted that

> [p]atent oppositions are an important tool to bring checks and balances to the patent system and improve access to essential medicines. But the current South African law means we have our hands tied behind our backs.[98]

In the absence of administrative invalidity procedures, South Africa's defenders of the public interest are left with the sole option of patent litigation, "a process that may well be more expensive, more time-consuming, and less expert in testing post-issue validity."[99] Patent litigation is a less attractive option for civil society organizations with limited resources and lacking financial incentives to challenge questionable patents.

South Africa has a strong presence of civil society organizations and HIV/AIDS NGOs. These organizations have been proactive in terms of framing the right to

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94 Catherine Tomlinson et al., *Reforming South Africa's Procedures for Granting Patents to Improve Medicine Access*, 105(9) S. Afr. Med. J. 741 (2015).

95 *Id.*

96 Fix the Patent Laws, *Patent Barriers to Medicine Access in South Africa: A Case for Patent Law Reform*, Publication of the Fix the Patent Laws Campaign (September 2016), at 8 (Jan. 20, 2024), available at https://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf.

97 Lonias Ndlovu, *Why South Africa Should Introduce Patent Searches and Substantive Examinations to Improve Access to Essential Medicines*, WIPO-WTO Colloquium Papers (2015) (Jan. 20, 2024), available at https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_9_2015_e.pdf.

98 Kate Ribet, *New Patent Opposition Database Highlights Gaps in South African Patent Law*, Fix the Patent Laws, 12 October 2012 (Jan. 20, 2024), available at https://www.fixthepatentlaws.org/new-patent-opposition-database-highlights-gaps-in-south-african-patent-law/.

99 Wesley M. Cohen & Stephen A. Merrill (eds.), *Patents in the Knowledge-Based Economy* 85 (2003).

health as a fundamental human right. In 1998, South Africa's civil society played an active role when the Pharmaceutical Manufacturers Association of South Africa (PMA) challenged South Africa's pro-health amendments to its Medicines and Related Substances Act.[100] However, due to an unprecedented civil society mobilization, PMA (a group of 39 multinational drug companies) decided to withdraw the case against the South African government.[101] In the 2000s, the TAC and the AIDS Law Project brought court actions against GlaxoSmithKline, Merck, and Boehringer Ingelheim over the prohibitively high costs of their ARV drugs.[102] The generic entry of key ARVs was possible as a result of these actions, which relied on South Africa's competition law rather than IP laws, and the prices dropped dramatically.[103]

South Africa's civil society is still playing an active role in the areas of health and IP. In the wake of affordability issues[104] resulting from a corporate-friendly patent regime, public health activists in South Africa started the "Fix the Patent Laws" campaign in 2011.[105] The main focus of this advocacy campaign has been on the need to fully enact the TRIPS public health safeguards into South Africa's national patent laws.[106] As a result of these advocacy efforts, the country is undergoing a process of reviewing and amending its national IP laws and policies. The Intellectual Property Consultative Framework (IPCF), approved by the South African cabinet in July 2016, recommended the adoption of a substantive examination in order to strike an appropriate balance between public health and the grant of patent rights.[107] The Draft Intellectual Property Policy (DIPP), published in August 2017 by South Africa's Department of Trade and Industry, went one step ahead and recommended the adoption of a pre-grant opposition system in addition to a substantive examination.[108] As of this writing in early 2021, no mechanisms for opposing the grant of a patent exist in South Africa.

Thus, it can be noted that, instead of using TRIPS flexibilities in an effective manner, South Africa has mainly relied on its competition (anti-trust) law[109] as a legal

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100 Sundaram 2018, at 175.

101 Ribet, *supra* note 98.

102 *Drug companies withdraw HIV drug lawsuit against South Africa*, HIV i-Base, 17 May 2001 (Jan. 20, 2024), available at https://i-base.info/htb/4380.

103 Ribet, *supra* note 98.

104 South Africa has higher medicine prices as compared to other developing countries. *See* Sellin 2014, at 298.

105 Companies and Intellectual Property Commission, *supra* note 93, at 11.

106 Fix the Patent Laws, *supra* note 96, at 9.

107 Companies and Intellectual Property Commission, *supra* note 93, at 18.

108 *Id.*

109 The Competition Act No. 89 of 1998 (South Africa), secs. 4–9.

lever for affordable access to medicines.[110] Many of South Africa's public health and socio-economic problems could have been addressed in a much better way through a wise and well-thought-out use of TRIPS flexibilities. Not providing a substantive examination is clearly an unreasonable decision, keeping in view South Africa's domestic challenges as a country with distinctively higher disease burdens. South Africa needs to revamp its current patent laws and policies without any further delay, drawing inspiration from India's example in this regard. Providing not only a viable substantive examination system but also pre-grant opposition procedures[111] would be a far superior policy option for South Africa. It would offer South Africa's active civil society, public health NGOs, and generic drug companies[112] with much more feasible and affordable opportunities to challenge pending patent applications.

Conclusion

Having a viable patent opposition model is critical for the BRICS countries because it provides a means for the invalidation or opposition of patents granted within their individual jurisdictions. However, with the exception of India, no other WTO member BRICS country has developed a well-thought-out patent opposition model. China, which initially relied on legal transplants, is still experimenting with its invalidation procedures as well as its overall patent regime. South Africa's IP regime has major flaws, as it still does not allow patent applications to be examined, let alone challenged. As compared to China and South Africa, Brazil has shown more clarity in terms of enacting public health safeguards into its national legislation, but Brazil has not yet implemented a full-fledged pre-grant opposition safeguard. India's tailor-made patent opposition model outperforms all other jurisdictions discussed in this study. The BRICS group provides a suitable platform for India to take on the role of intellectual property policy leader and help other BRICS countries develop intellectual property regimes that are not only TRIPS compliant but also in line with the individual national goals of these countries.

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110 Löfgren & Williams (eds.) 2016, at 185.

111 Currently, under u/s 61(1) of the 1978 Patents Act, South Africa provides only one type of third-party intervention, i.e. an application for revocation of a granted patent. The cost of such actions is too high for the members of the public to be able to afford. *See* Caroline B. Ncube, *The Draft National Intellectual Property Policy Proposals for Improving South Africa's Patent Registration System: A Review*, 9(10) J. Intell. Prop. L. & Prac. 828 (2014).

112 South Africa has an established generic drug manufacturing industry. *See* Löfgren & Williams (eds.) 2016, at 185.

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