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Interpretation of TRIPS provisions in a manner consistent with human rights instruments: a policy option for the exploration of south-south judicial cooperation

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The rigid interface between the enforcement provisions of patents under TRIPS standards and the institutional, technical and human resource capacity deficiencies means that political decisions to exploit the TRIPS flexibilities to promote access to medicines in the context of Africa is almost an exercise in futility. Notably, the Development Agenda under the auspices of WIPO often follows the North-South model, and the failings are well-documented in the empirical literature, as this has brought little institutional change. For instance, the judiciary that could help to provide an interpretation of the TRIPS flexibilities to promote public health simply lacks capacity. At the same time, the Indian judiciary, through the lens of human rights norms, is widely known for its functional activism in the interpretation of the TRIPS provisions consistent with public health protection, and is the best example for African countries. It is on this basis that this paper attempts a critical exploration of judicial cooperation based on a South-South model with a view to underlining its doctrinal significance for African countries. Therefore, the author questions the rationality of African countries' exclusive reliance on so-called North-South capacity building and argues that the South-South judicial cooperation model would provide a logical platform that could operate alongside the conventional North-South system for building institutional, technical and human resource-based aspects of capacity for its judiciary to interpret TRIPS in a manner consistent with human rights norms to promote access to medicines.

Key words: Africa; Access to Medicines; Human Rights; South-South Cooperation; TRIPS Agreement

A INTRODUCTION

Intellectual Property (IP) is protected in law under the presumption that it should foster innovations to improve socio-economic welfare.¹ The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), in Article 7, is clear on this definitive objective,² except that the language adopted by that Article, which is the 'objective' provision of the Agreement, suggests that the protection of IP alone does not automatically produce welfare gains.³ With this, TRIPS seemingly presumes that something other than the simple strengthening of patent

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¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 7.

² Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 91.

³ *ibid* 97.

laws may be necessary to achieve the welfare gains that the members expect from the Agreement.⁴ Importantly, implicit in TRIPS—apart from the notion of socio-economic welfare objectives—are essential public interests, which the Agreement envisages as its major principles.⁵

Still, this is not automatic, and the TRIPS Agreement maintains a basic principle that preserves the underlying public policy objectives of members' discretion to adopt consistent measures necessary to protect the public interest.⁶ Nevertheless, it remains a challenging task for predominantly developing countries to put in place IP regimes capable of maintaining the TRIPS principles. The IP policymaking process is complex and technical,⁷ and these countries have a limited understanding of IP norms in general and the implications of instituting an effective IP protection system.⁸

In fact, internal capacity constraint arguments are acknowledged to have substantial merit in explaining this failure, as standards often fail to strike the right balance between the interests of innovators and the wider public interest.⁹ Consequently, the protection of human rights is undermined, although the primacy of human rights obligations over economic policies and agreements is the settled principle.¹⁰ Importantly, the right to health is a notion well-founded

⁴ Michael Halewood, 'Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law' (1997) 35 *Osgoode Hall Law Journal* 243, 259.

⁵ Antony Taubman, Hannu Wager, Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (CUP 2012) 13.

⁶ United Nations Conference on Trade and Development (UNCTAD), 'The TRIPS Agreement and Developing Countries' (1996) UNCTAD/ITE/1, 54.

⁷ Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (2002) 139.

⁸ George M Sikoyo, Elvin Nyukuri, and Judi W Wakhungu, *Intellectual Property Protection in Africa: Status of Laws, Research and Policy Analysis in Ghana, Kenya, Nigeria, South Africa and Uganda* (Acts Press 2006) 9.

⁹ Commission on Intellectual Property Rights (n 7) 138.

¹⁰ United Nations Commission on Human Rights (UNCHR) (Sub-Commission on the Promotion and Protection of Human Rights) Resolution (Res) 7 (2000) UN Doc E/CN.4/Sub.2/Res/2000/7, cls 2, 3.

in international human rights instruments;¹¹ it is also a settled understanding that access to essential medicines remains a significant component of the right to health.¹²

Nevertheless, it is well-documented in the empirical literature that, while a shortage of essential medicines generally appears to be a global issue,¹³ the implications of this are worse in Africa, even though the continent shoulders a disproportionate burden of diseases.¹⁴ In particular, the patent standards under TRIPS¹⁵ and its enforcement provisions are held to be a consequential factor.¹⁶ Significantly, there are several flexibilities inherent in the TRIPS Agreement, all of which could be implemented to counterbalance the impact of exclusive rights in order to reduce prices and increase the affordability of medicines.¹⁷

Compulsory licensing is one of the flexible instruments that could be interpreted to promote access to essential medicines.¹⁸ Compulsory licensing as an instrument of government policy remains a significant part of the global IP regime and is consistent with TRIPS. The World Trade Organisation (WTO)¹⁹ confirmed this position in the Doha Declaration on TRIPS

¹¹ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 12. See also African Charter on Human and Peoples' Rights (adopted 27 June 1981, entered into force 21 October 1986) 21 ILM 58 (Banjul Charter) art 16; Universal Declaration on Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 25; Charter of Fundamental Rights of the European Union [2012] OJ C326/391 (CFREU) art 35.

¹² Stephen P Marks, 'Access to Essential Medicines as a Component of the Right to Health' in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health* (Rüffer & Rub 2009) 80, 88.

¹³ World Health Organization (WHO) (Executive Board), 'Addressing the global shortages of medicines, and the safety and accessibility of children's medication: Report by the Secretariat' (18 December 2015) WHO Doc EB138/41 [1].

¹⁴ WHO (Regional Committee for Africa), 'Tackling Neglected Tropical Diseases in the Africa Region' (15 June 2009) WHO Doc AFR/RC59/10 [3].

¹⁵ TRIPS (n 1) pt II, s 5.

¹⁶ TRIPS (n 1) pt III. See also World Trade Organization (WTO) (Council for TRIPS), 'TRIPS and Public Health' (20 June 2001) WTO Doc IP/C/W/296 [5].

¹⁷ World Intellectual Property Organization (WIPO) (Committee on Development and Intellectual Property (CDIP)), 'Patent-Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels' (18 August 2010) WIPO Doc CDIP/5/4 Rev [30].

¹⁸ Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (3rd edn, Kluwer Law International 2010) 174.

¹⁹ The WTO was established by the Marrakesh Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement).

and Public Health (Doha Declaration).²⁰ Notwithstanding this, African countries have generally failed to utilise compulsory licensing as an instrument of government policy to promote access to affordable medicines, and this is a political decision failure.

Unless human-rights advocates provide an effective intellectual and organisational counterweight to economic interests, the IP landscape will be reshaped in the years ahead without adequate consideration of the impact on human rights.²¹ The central thrust is that IP policymaking still remains a sweeping exercise across the globe.²² This has occurred in several ways,²³ and in most cases the interest of the right-holders is enhanced at the expense of the general public.²⁴ Apart from the IP domains under TRIPS, the new wave of IP standard-setting under Bilateral Trade Agreements (BTA) is complex and has continually become expansive.²⁵

These international trade deals have set up powerful legal structures to seal corporate power into the enforcement of trade rules.²⁶ Under this approach, developing countries' policymakers are under political pressure to draw up stringent IP regimes in the interest of the right-holders and they often ignore the incorporation of public safeguards.²⁷ Notably, restrictions and limitations that previously excluded specific types of subject-matter from patenting are gradually being eliminated.²⁸ In most cases, these arrangements contain

²⁰ WTO (Ministerial Conference), Doha Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2 (Doha Declaration)
<http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 23 June 2016.

²¹ Audrey R Chapman, 'Approaching intellectual property as a human right: obligations related to Article 15(1)(c)' (2001) 35 Copyright Bulletin 4, 6.

²² Peter Drahos, 'Expanding Intellectual Property's Empire: the Role of FTAs' (November 2003)
<<http://www.ictsd.org/downloads/2008/08/drahos-fta-2003-en.pdf>> accessed 23 November 2016.

²³ John Braithwaite and Peter Drahos, *Global Business Regulation* (CUP 2000) ch 24.

²⁴ Peter Drahos, 'BITs and BIPs: Bilateralism in Intellectual Property' (2001) 4 *The Journal of World Intellectual Property* 791, 804.

²⁵ Susan Sell, 'The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play' (2010) PIJIP Research Paper No 15
<digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1016&context=research> accessed 29 November 2016.

²⁶ Jagdish Bhagwati, *Termites in the Trading System: How Preferential Agreements Undermine Free Trade* (OUP 2008) 73.

²⁷ Ruth L Okediji, 'Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection' (2003-04) 1 *University of Ottawa Law & Technology Journal* 125, 140.

²⁸ Chapman (n 21) 9.

additional demands on these countries beyond what is required from them under the multilateral trading regime.²⁹

With the complex environment in which IP policymaking subsists, the emergent consensus within the international development community is that the ability of developing countries, particularly those in Africa, to stimulate socio-economic growth via the conduits of the IP regime hinges on capacity building initiatives.³⁰ The WTO recognises this presumption.³¹ Within this notion, the Development Agenda (DA) was prompted in 2005 by the initiative of Argentina and Brazil under the auspices of the World Intellectual Property Organisation (WIPO).³² The DA initiative follows the view that, as developing countries continue to implement IP-related treaties such as TRIPS and participate in new negotiations at the bilateral, regional, and multilateral levels, appropriate and effective technical capacity will be crucial if these countries are to use IP as a tool for the promotion of human and socio-economic development sustainably.³³ As a specialised agency, the United Nations (UN) supports WIPO's DA.

²⁹ Mohammed K El Said, *Public Health related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the Eastern Mediterranean Region* (World Health Organisation and International Centre for Trade and Sustainable Development 2010) 46; Sisule Musungu and Graham F Dutfield, 'Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Organisation (WIPO)' (TRIPS Issues Papers 3, Quaker United Nations Office and Quaker International Affairs Programme 2003) 2 <www.iprsonline.org/ictsd/docs/WIPO_Musungu_Dutfield.pdf> accessed 24 November 2016.

³⁰ Thaddeus Manu, 'Essential Medicines and the Complexity of Implementing Nationally Based Compulsory Licensing: On the Need for a Regional System of Compulsory Licensing in Sub-Saharan Africa' (2014) 36 *European Intellectual Property Review* 39, 47; Robert Dibie, Felix Moses Edoho, and Josephine Dibie, 'Analysis of Capacity Building and Economic Growth in Sub-Saharan Africa' (2015) 6 *International Journal of Business and Social Science* 1, 4.

³¹ WTO (Ministerial Conference), 'Ministerial Declaration' (14 November 2001) WTO Doc WT/MIN(01)/DEC/1 [33].

³² WIPO was established by the Convention establishing the World Intellectual Property Organisation (adopted 14 July 1967, entered into force 26 April 1970, amended 28 September 1979) 21 UST 1749, 828 UNTS 3 (WIPO Convention). See also Christopher May, *The World Intellectual Property Organisation (WIPO): Resurgence and the Development Agenda* (Routledge 2007) 85. The WIPO Development Agenda can be found at <www.wipo.int/ip-development/en/agenda/> accessed 1 July 2016.

³³ Tom Pengelly, 'Technical Assistance for the Formulation and Implementation of Intellectual Property Policy in Developing Countries and Transition Economies' (ICTSD Programme on IPRs and Sustainable Development, Issue Paper No 11, International Centre for Trade and Sustainable Development 2005) 5 <www.iprsonline.org/unctadictsd/docs/Pengelly_TA_FINAL.pdf> accessed 24 November 2016.

As per Article 1 of the agreement between the UN and the WIPO, the former recognises the latter as one of its specialised agencies responsible for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to developing countries in order to accelerate economic, social, and cultural development, subject to the competence and responsibilities of the United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme, and the United Nations Industrial Development Organisation, as well as the United Nations Educational, Scientific and Cultural Organisation and other constituent agencies within the UN system.³⁴

Within this recognition, the UN takes a conceptual view that to harness the socio-economic welfare embedded in the IP system may require capacity from a typical developing country perspective.³⁵ The DA has adequate legal backing. Its legal foundation can be inferred from several provisions, in particular the Preamble to the TRIPS Agreement and Articles 66(2) and 67 of TRIPS. Given that the notion of capacity building is conditioned against the implementation of TRIPS obligations, this has resulted in several layers of capacity building initiatives directed towards developing countries in general.³⁶ Importantly, consistent with Article 66(1) of TRIPS, the WTO/TRIPS Council has extended, until January 2033, the period during which key provisions of the TRIPS do not apply to pharmaceutical products in least developed countries (LDCs).³⁷

This decision follows the adoption of the new UN Sustainable Development Goals, which affirm the right of developing countries to utilise the TRIPS Agreement flexibilities to ensure access to medicines for all.³⁸ The decision also keeps open the option for further

³⁴ Agreement between the World Intellectual Property Organisation and the World Trade Organisation (signed 22 December 1995, entered into force 1 January 1996) (WIPO and WTO Agreement) <www.wipo.int/treaties/en/agreement/trtdocs_wo030.html> accessed 13 July 2016.

³⁵ Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 197.

³⁶ Commission on Intellectual Property Rights (n 7) 137.

³⁷ WTO (Council for TRIPS), 'Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with respect to Pharmaceutical Products' (6 November 2015) WTO Doc IP/C/73 cl 1.

³⁸ United Nations General Assembly (UNGA) Res 70/1 (25 September 2015) UN Doc A/RES/70/1 (Sustainable Development Goals) Goal 3.

extensions beyond that date.³⁹ It is important to acknowledge that, under Article 66(1) of TRIPS, many African countries are classified as LDCs, and therefore countries can choose whether or not to protect pharmaceutical patents and clinical trial data before 2033. In fact, the latest extension, which is specifically applied to pharmaceutical products for LDCs, is in line with the well-established principles set by the Doha Declaration in 2001 and the objectives of the WIPO DA.

Importantly, several intergovernmental Organisations and Non-Governmental Organisations continue to support developing countries and LDCs in assuring development gains from the international trading system.⁴⁰ With respect to TRIPS, UNCTAD plays a significant role in recognising the need to rebalance the IP rules and rule-making to make them more flexible and more in line with the public interests, as well as a development-oriented framework.⁴¹ Usually, technical assistance under WIPO's mandate reflects a measure that appears to be a central component of the organisation's deliberations, particularly in the context of its DA.⁴²

Despite WIPO playing a leading role in stimulating awareness of the importance of IP protection in terms of the socio-economic needs of countries, contributing to the creation of IP infrastructure, and enhancing governance mechanisms at the national, regional, and global levels towards the implementation and protection of regimes,⁴³ various procedures and outputs of the organisation have become increasingly sophisticated.⁴⁴ Some developed countries have

³⁹ WTO (Council for Trips) (n 37) cl 2.

⁴⁰ See, eg, the UN Development Programme, the WHO, OECD, World Bank, UN Educational, Scientific and Cultural Organisation, South Centre, International Centre for Trade and Sustainable Development, Quakers, The Consumer Project on Technology, Médecins Sans Frontières, Oxfam, etc.

⁴¹ UNCTAD, 'Intellectual Property in the World Trade Organisation: Turning it into Developing Countries' Real Property' (2010) UN Doc UNCTAD/DITC/TNCD/2006/8 20.

⁴² Carolyn Deere Birkbeck and Santiago Roca, 'An External Review of WIPO Technical Assistance in the Area of Cooperation for Development' (Final Report, prepared for WIPO's CDIP, submitted 31 August 2011) 90.

⁴³ Carolyn Deere Birkbeck, *The World Intellectual Property Organization (WIPO): A Reference Guide* (Edward Elgar 2016) 8.

⁴⁴ Christopher May (n 32) 56.

noted the shortcomings within WIPO's technical assistance and have called for efficiency in delivering capacity building initiatives.⁴⁵

The chief concern is that WIPO's patent agenda is to substantially disseminate to developing countries the patent systems modelled around the current standard-setting of key developed countries' regimes. However, the majority of this technical assistance is sponsored by the patent offices of developed countries.⁴⁶ Consequently, in delivering technical assistance to modernise the legal and administrative infrastructures, the suspicion is that WIPO's main focus is more on the strict compliance of patent provisions than on helping countries to implement key flexibilities.⁴⁷

Therefore, the time has come where reading human rights norms into IP regimes is critical if countries are to neutralise the impact of the stringent IP laws being put in place. Importantly, the judiciaries in all countries are called upon to address delicate issues concerning liberty, property, and the protection of public interests. Therefore, as an institution, the judiciary could help in the promotion of access to medicines in Africa, and in affirming its claim as a human right. This is backed up by the fact that domestic courts in some countries outside Africa have displayed a growing willingness to use human rights laws to reinterpret and even strike down IP laws that impede access to medications.⁴⁸

In the same vein, human right arguments can be used to invalidate detrimental IP laws in Africa. In other words, human rights standards could serve as a powerful counter-measure to the political and economic motives that keep harmful IP laws in place. Significantly, judicial

⁴⁵ WIPO (CDIP), 'Proposal by Spain' (14 April 2016) proposition 3 <www.ip-watch.org/weblog/wp-content/uploads/2016/04/CDIP-New-Spanish-Proposal-April-2016.pdf> accessed 12 August 2016.

⁴⁶ WIPO Convention (n 32).

⁴⁷ Carlos Correa, 'Formulating Effective Pro-Development National Intellectual Property Policies' in Christopher Bellman, Graham Duffield, and Ricardo Meléndez-Ortiz (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (Earthscan Publications 2003) 209, 214 (condemning WIPO for only highlighting the social benefits and largely ignoring the costs of IP rights protection and also failing to present the ranges of policy options available for developing countries).

⁴⁸ Ole Frithjof Norheim and Bruce M Wilson, 'Health Rights Litigation and Access to Medicines: Priority Classification of Successful Cases from Costa Rica's Constitutional Chamber of the Supreme Court' (2014) 15 *Health and Human Rights* 47, 52, find that in Costa Rica, approximately 500 cases concerning the right to health have been filed in the courts since 2008. Of those cases, 192 were claims for medications, with approximately 50 per cent of claimants winning their cases.

articulation of the relationship between the right to health and IP law can not only mitigate the detrimental impact of IP law but also legitimise the broader political actions that prioritise the right to health over IP protection.

However, as highlighted earlier, the interface between IP and human rights norms is complex. This complexity is compounded by the fact that technological development has outstripped legal development. The conceptual thinking is that judges have to apply ‘old’ laws to ‘new’ situations, laws adopted without the foresight of how technology will develop.⁴⁹ Moreover, cases that use human rights language substantively to attack patent laws are much more recent.⁵⁰

Additionally, given the complication within which the IP standard-settings subsists—which sometimes lacks transparency⁵¹—a more moderate claim here is that capacity issues may render the judiciary less proactive in offering interpretations in defence of access to medicines as a significant component of human rights law.⁵² This is because determining the validity of human rights questions of IP regimes often demands difficult value judgments, premised on high moral authority. That is, it will be difficult to delineate the specifics of human rights obligations in new domains, such as health and IP, and this drawback in turn may feed the courts’ fear that IP standards are limitless due to the presumption against conflicts in international law.

Meanwhile, India is a country that has a long history of IP policy which protects the domestic health needs of its people.⁵³ More importantly, its judiciary has been a strong

⁴⁹ WIPO (Advisory Committee on Enforcement), ‘The Role of the Judiciary in Enforcement of Intellectual Property Rights: Intellectual Property Litigation under the Common Law System with Special Emphasis on the Experience in South Africa’ (19 May 2004) WIPO Doc WIPO/ACE/2/4 Rev [13].

⁵⁰ Hannah Brennan and others, ‘A Human Rights Approach to Intellectual Property and Access to Medicines’ (Global Health Justice Partnership Policy Paper 1, Yale Law School and Yale School of Public Health, September 2013) 20.

⁵¹ Cary Coglianese, Heather Kilmartin, and Evan Mendelson, ‘Transparency and Public Participation in the Rulemaking Process: A Nonpartisan Presidential Transition Task Force Report’ (University of Pennsylvania, July 2008) 2 <www.hks.harvard.edu/hepg/Papers/transparencyReport.pdf> accessed 17 February 2017

⁵² WIPO (Advisory Committee on Enforcement) (n 49) 13 states that IP enforcement is about a conflict between the strong and the weak, the rich and the poor.

⁵³ Rajesh Sagar, ‘Introduction of Exclusive Privileges/Patents in Colonial India: Why and for Whose Benefit’ [2007] *Intellectual Property Quarterly* 164, 173.

protector of public health and maintains a global record for the interpretation of IP rules consistent with human rights norms. Notably, in 2012, the Indian Controller utilised the compulsory licensing provision under its TRIPS-compliant patent regime to grant a compulsory licence to Natco Pharma Limited (Natco), an Indian generic manufacturer, to market generic copies of ‘sorafenib tosylate’—marketed as ‘Nexavar’,⁵⁴—exclusive rights to which are held by Bayer.⁵⁵

The use of compulsory licensing in India exerted a downward pressure on prices and increased the manufacture of affordable generic alternatives of Nexavar for distribution.⁵⁶ Not satisfied with the Indian Intellectual Property Appellate Board (IPAB)⁵⁷decision,⁵⁸ Bayer subsequently took the case to the High Court,⁵⁹ and then to the Indian Supreme Court,⁶⁰ but lost, as the courts interpreted the provisions of its IP regime as being consistent with human rights norms. The question is whether the judiciary in African countries will be similarly resolute in interpreting patent law in a manner consistent with the reasonable requirements of

⁵⁴ *Natco Pharma Ltd v Bayer Corp*, CLA 1 of 2011, 9 March 2012 (Indian Controller of Patents).

⁵⁵ ‘Sorafenib Tosylate’ is a pharmaceutical therapeutic compound patented by the Bayer Corporation, marketed as Nexavar, and used in the treatment of the advanced stages of kidney cancer (Renal Cell Carcinoma) and liver cancer (Hepatocellular carcinoma). It stops the growth of new blood vessels and impacts other cellular growth mechanisms. The drug can extend the life of a patient by between 6 months and 5 years. See American National Cancer Institute, ‘FDA Approval for Sorafenib Tosylate’ (13 November 2013) <www.cancer.gov/cancertopics/druginfo/fda-sorafenib-tosylate> accessed 28 June 2016.

⁵⁶ Médecins Sans Frontières, ‘Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries’ (15th edn, Médecins Sans Frontières 2012) 11. See also United Nations Human Rights Council (UNHRC), ‘Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, including the Right to Development: Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (31 March 2009) UN Doc A/HRC/11/12, [20], citing Brazil, India, South Africa, and Thailand.

⁵⁷ Note that IPAB exercises appellate jurisdiction against the decisions of the Controller General of Patents, Registrar under the Trade Marks Act, 1999 and the Geographical Indications of Goods (Registration and Protection) Act, 1999.

⁵⁸ *Bayer Corp v Union of India and Others*, OA/35/2012/PT/MUM, IPAB, 4 March 2013 (Intellectual Property Appellate Board, Chennai, India).

⁵⁹ *Bayer Corp v Union of India and Others*, WP 1323 of 2013, 15 July 2014 (Bombay High Court (BHC)).

⁶⁰ *Bayer Corp v Union of India and Others*, SLP 30145 of 2014, 12 December 2014 (Indian Supreme Court (ISC)).

the public. Notably, recent activities by WIPO indicate that African judges lack the capacity to enforce IP standards and interpret the flexibilities.⁶¹

*Aventis v Cipla*⁶² (South Africa) and *Pfizer Inc v Cosmos Limited*⁶³ (Kenya) confirm this conclusion. As already reiterated, Africa has many needs with regard to institutional, technical and human resources-based aspects of capacity.⁶⁴ More importantly, training and human resource development of various kinds, typically aimed at the development of professional capacities in IP administration and enforcement, has been a major focus in IP-related technical assistance programmes.⁶⁵ Consequently, the traditional norm on which these capacity building initiatives sits follows the North-South model, despite the importance of the South-South model capable of meeting some of the fundamental development needs of developing countries.⁶⁶

The framework of operational guidelines on UN support for South-South and triangular cooperation defines South-South cooperation as:

[A] process whereby two or more developing countries pursue their individual and/or shared national capacity development objectives through exchanges of knowledge, skills, resources and technical know-how, and through regional and interregional collective actions, including partnerships involving Governments, regional organisations, civil society, academia and the private sector, for their individual and/or mutual benefit within and across regions. South-South cooperation is not a substitute for, but rather a complement to, North-South cooperation.⁶⁷

⁶¹ WIPO has recently, in March 2014, held a national colloquium on building respect for IP for the judiciary in Ghana. The Colloquium, which was attended by 18 High Court Judges and two Circuit Court Judges, had the purpose of examining the minimum standards and flexibilities contained in Part III of the TRIPS Agreement, discussing topical issues, including consumer awareness raising and the equitable disposal of infringing goods, addressing recent case law developments, and working towards effective inter-agency cooperation at the national level. For the programme of the colloquium see WIPO, 'WIPO National Colloquium on Building Respect for IP for the Judiciary' (27 March 2014) WIPO Doc WIPO/IP/ACC/14/INF/2.

⁶² *Cipla Medpro v Aventis Pharma* (139/12); *Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (South African Supreme Court of Appeal (SASCA)). Decision of the Supreme Court of Appeal, 26 July 2012.

⁶³ Case No 49 of 2006, 25 April 2008 (Kenyan Industrial Property Tribunal).

⁶⁴ Thaddeus Manu, 'Locally Working Patents and the Grant of Compulsory Licences: The Need for Stronger Statutory Provisions in Africa' (2014) 3 *Global Journal of Comparative Law* 203, 234 (referring to the absence of institutional immaturity and competence issues).

⁶⁵ Commission on Intellectual Property Rights (n 7) 137.

⁶⁶ Developing countries can support each other through South-South cooperation to transfer, adapt, acquire, and pool knowledge and experience to achieve economic growth and poverty reduction.

⁶⁷ UNGA (High-level Committee on South-South Cooperation), 'Note by the Secretary-General on the Framework of Operational Guidelines on United Nations support to South-South and Triangular

The definitions of South-South and triangular cooperation are based on the Nairobi Outcome Document, negotiated at the UN High-Level Conference on South-South Cooperation and adopted by the UN General Assembly in December 2009.⁶⁸ Therefore, despite the idea of South-South cooperation having already influenced revolutionary thinking in the field of development, African countries often neglect this⁶⁹ because of the resulting opportunity for lucrative market access with a more developed north.⁷⁰ While this is both the norm and practice, evidence suggests that there exist inconsistent motivations in delivering capacity programmes, where on most occasions capacity building initiatives focus too much on ratcheting up stronger IP regimes to cement the export interests of developed countries.⁷¹ In the end, the failings in the system mean that the institutional change required to promote IPRs standard-setting that is capable of meeting the fundamental interests of this category of countries has not been attained rapidly.⁷²

It is on this basis that this paper attempts a critical exploration of judicial cooperation based on the South-South model with a view to underlining its doctrinal significance for African countries to build capacity in the interpretation of the safeguard provisions within TRIPS consistent with human rights norms in a health-sensitive way to promote access to medicines. Therefore, the author questions the rationality of Africa countries' exclusive reliance on so-called North-South capacity building and argues that the South-South judicial cooperation model would provide a logical platform that could operate alongside the conventional North-South system for building institutional, technical, and human resource-based aspects of capacity for its judiciary to interpret TRIPS in a manner consistent with human rights norms to promote access to medicines.

Cooperation' (12 April 2012) UN Doc SSC/17/3 4 (providing an operational definition of South-South cooperation).

⁶⁸ UNGA Res 64/222 (21 December 2009) UN Doc A/RES/64/222 (Nairobi Outcome Document) annex, cls 18–20.

⁶⁹ *ibid.*

⁷⁰ Manu (n 30) 48 cites the African Growth and Opportunity Act 2000 (US) and states that African countries do not hesitate to trade off stringent enforcement of IP in negotiating BTAs for market access.

⁷¹ Drahos (n 24) 797.

⁷² Deere Birkbeck and Roca (n 43) 2 (Box 2).

B IMPLICATIONS OF TRIPS AND ACCESS TO MEDICINES IN DEVELOPING COUNTRIES

Significantly, the relevant justification for IP protection follows economic paradigms. Not only have IP regimes become globalised, but the scope of the subject-matter has also been expanded exponentially. Therefore, the current IP policymaking under the ambiance of the WTO takes on board no human rights values. While TRIPS embodies certain public interest safeguards, none of its 73 articles specifically makes reference to human rights norms.

As a matter of empirical logic, countries have historically developed their patent regimes in accordance with their own interests and levels of development.⁷³ For instance, at the start of the Uruguay Round,⁷⁴ about fifty member states did not grant protection to pharmaceutical products at all, and some also excluded pharmaceutical processes and products from protection.⁷⁵ Thus, before TRIPS, countries had more freedom to design their national IPR regimes under the Paris Convention.⁷⁶ They could exclude from protection entire fields of technology, determine the patent term, and define many other aspects of such regimes.

The foremost restrictions on manufacturing and supply were not of a formal legal character, except for the prevailing conditions of legal uncertainty affecting technology transfer, which generally may have inhibited investment in, or the flow of, medicines benefiting

⁷³ Carlos M Correa, 'Intellectual Property Rights and Inequalities in Health Outcomes' in Roland Labonté, Ted Schrecker, Corinne Parker, and Vivien Runnels (eds), *Globalization and Health: Pathways, Evidence and Policy* (Routledge 2009) 263, 264.

⁷⁴ The Uruguay Round was launched by General Agreement on Tariffs and Trade (GATT), 'Ministerial Declaration' (20 September 1986) GATT Doc Min(86)/W/19 (Punta del Este Declaration). See also Kendall Stiles, 'Negotiating Institutional Reform: The Uruguay Round, the GATT, and the WTO' (1996) 2 *Global Governance*, 119–48; Alan Winters, 'The Road to Uruguay' (1990) 100 *The Economic Journal*, 1288–1303.

⁷⁵ Some of the countries that did not grant pharmaceutical product patents include Portugal, Spain, Brazil, India, Mexico, and Egypt. See Juan C Ginarte and Walter G Park, 'Determinants of patent rights: A cross-national study' (1997) 26 *Research Policy* 283. Before TRIPS, many countries provided only process, but not product, patents. Product patents provide for absolute protection of the product, whereas process patents provide protection in respect of the technology and the process or method of manufacture. Protection for process patents would not prevent the manufacture of patented products by a process of reverse engineering, where a different process or method from that which has been invented (and patented) is used. For example, national legislation requiring only process patent protection has enabled manufacturers in certain countries to make generic versions of patented medicines. See, Germán Velásquez and Pascale Boulet, 'Globalization and access to drugs: perspectives on the WTO/TRIPS Agreement' (Health Economics and Drugs Series No 7, 2nd rev edn, WHO 1999) 19.

⁷⁶ Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, last amended 28 September 1979) 21 UST 1583, 828 UNTS 305.

these countries. Rather, the key factors depended on the reverse engineering capacities.⁷⁷ In this environment, the ability of developing countries to obtain essential medicines varied with respect to their procurement methods, local manufacturing capabilities, public health policies, and general financial resources.⁷⁸

This is no longer the case, as the adoption of TRIPS changed this dramatically.⁷⁹ Backed by its strong enforcement mechanism, TRIPS appeared to put an end to the significant leeway that countries had in designing their national patent systems in line with their domestic socio-economic conditions.⁸⁰ Notably, TRIPS contains standards relating to patents and covers both substantive principles as well as specific issues of enforcement that are generally applicable to patents.⁸¹

Thus, with the incorporation of the TRIPS Agreement as one of the multilateral agreements of the WTO, members are bound to observe a set of minimum standards of IPRs protection,⁸² and failure to do so may lead to sanctions under the rules of the Dispute Settlement Understanding system.⁸³ The outcome of the negotiation of TRIPS in 1994 resulted in the

⁷⁷ Frederick M Abbott and Jerome H Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 *Journal of International Economic Law* 921, 928.

⁷⁸ Peter Drahos, 'Securing the Future of Intellectual Property: Intellectual Property Owners and Their Nodally Coordinated Enforcement Pyramid' (2004) 36 *Case Western Reserve Journal of International Law* 53, 76; Cícero Gontijo, 'Changing the Patent System from the Paris Convention to the TRIPS Agreement: The Position of Brazil' (Andrea Carina Ceschi (tr), Global Issue Papers No 26, Heinrich Böll Foundation 2005) 6
<www.boell.de/sites/default/files/assets/boell.de/images/download_de/internationalepolitik/GIP26.pdf> accessed 26 November 2016.

⁷⁹ Carlos Correa and Duncan Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health' (Discussion Paper, United Nations Development Programme, Bureau of Development Policy 2011) 5.

⁸⁰ Gail E Evans, 'Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries' (2008) 34 *American Journal of Law & Medicine* 175, 180.

⁸¹ UNCTAD (n 6) [111–114].

⁸² Correa and Matthews (n 79) 6.

⁸³ Understanding on Rules and Procedures Governing the Settlement of Disputes (adopted 15 April 1994 as Annex 2 to the WTO Agreement (n 19), entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (Dispute Settlement Understanding). For additional analysis of the WTO dispute resolution rules see Ernst-Ulrich Petersmann, *The GATT/WTO Dispute Settlement System: International Law, International*

Agreement unambiguously strengthening the scope of patent rights, declaring in part, under its Article 27, that ‘patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application’.

Moreover, Article 27(1) in part provided that patent rights would be ‘enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced’.⁸⁴ The controversial interpretation is that the foregoing provision completely prohibits WTO members from mandating within their national patent regimes the reasonable requirements of the public concerning the general principles applicable to the working of patented inventions locally as an independent condition for the granting of compulsory licences.⁸⁵

Admittedly, while there are many factors that may contribute to the problem of limited access to essential medicines,⁸⁶ patents on pharmaceutical products are often blamed for the lack of access to medicines.⁸⁷ Importantly, there is another school of thought that generally agrees that patents on pharmaceutical medicines provide a very strong incentive for research.⁸⁸ Remarkably, African countries, that are mostly LDCs, have a special dispensation not to enforce patents on pharmaceutical products until 2033.⁸⁹ Still, they in a way enforce pharmaceutical patents via the legal conduits of BTAs⁹⁰ while the pharmaceutical industry has

Organizations and Dispute Settlement (Kluwer International Law 1997) 117 (discussing the new dispute settlement system of the 1994 WTO Agreement).

⁸⁴ *ibid.*

⁸⁵ Maria Victoria Stout, ‘Crossing the TRIPS Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1’ (2008) 14 *Boston University Journal of Science & Technology Law* 177, 180.

⁸⁶ Ellen ‘t Hoen, ‘TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha’ (2002) 3 *Chicago Journal of International Law* 27, 28.

⁸⁷ Amir Attaran, ‘How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?’ (2004) 23 *Health Affairs* 155, 159.

⁸⁸ Henry Grabowski, ‘Patents, Innovation and Access to New Pharmaceuticals’ (2002) 5 *Journal of International Economic Law* 849, 850.

⁸⁹ WTO (Council for TRIPS) (n 37).

⁹⁰ Okediji (n 27).

failed to innovate medicines that can be used to treat tropical diseases, often citing commercial reasons.⁹¹

In fact, critics point to high prices resulting from patent protection as the reason why essential medicines are less affordable for people in developing countries.⁹² Thus, by preventing cheap generic copies of essential medicines under patent from being produced and distributed, the TRIPS Agreement has had serious ramifications for public health.⁹³ Importantly, while access to affordable essential medicines could be achieved through a variety of different mechanisms, the use of compulsory licensing remains the foremost feasible means to promote access to affordable medicines.⁹⁴

C COMPULSORY LICENSING AS AN INSTRUMENT OF PUBLIC POLICY TO REALISE ACCESS TO MEDICINES

The adoption of the TRIPS Agreement standards resulted in the creation of diverse options for WTO members to implement their TRIPS obligations, while taking into account different considerations such as the country's stage of development and specific national interests (e.g. public health).⁹⁵ This is significant, as the Preamble of the TRIPS Agreement recognises the underlying public policy objectives of national systems for the protection IP. Thus, the TRIPS Agreement incorporated compulsory licensing as one of the flexibilities that members may use to such an extent as their national regimes make provision for its use.

⁹¹ Thaddeus Manu, 'Exploring a Regional Pharmaceutical Innovation Network as a Possible Solution to the Market Failure in the Innovation of Essential Medicines for Tropical Diseases in sub-Saharan Africa' (2014) 6 *African Journal of Science, Technology, Innovation and Development* 111, 117.

⁹² UNHRC (n 56) [19]; Philippe Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health' (2003) 79 *International Affairs* 139, 160.

⁹³ WHO, *Progress on Global Access to HIV Antiretroviral Therapy: A Report on "3 by 5" and Beyond* (World Health Organisation 2006) 60.

⁹⁴ Robert Weissman, 'A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 *University of Pennsylvania Journal of Economic Law* 1069, 1124.

⁹⁵ WHO, WIPO, and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (WHO, WIPO, and WTO 2013) 71 <www.wto.org/english/res_e/booksp_e/pantiwhowipowtoweb13_e.pdf> accessed 22 July 2016.

The compulsory licensing regime finds its legal basis in Article 31 of TRIPS. The general purpose of that provision is to allow any WTO member state to grant a compulsory licence.⁹⁶ Put differently, Article 31 of TRIPS essentially provides for a distinct balancing act, establishing a government's right to issue compulsory licences, while attempting to safeguard the rights of the patent-holder whenever possible.⁹⁷ Remarkably, the Paris Convention can be a good starting point for outlining the legal provisions that frame any discussion of the legality of compulsory licensing as an instrument of government policy.

As a matter of discretion reserved for the member states, the Paris Convention does not pursue any substantive grounds on which to grant such licences.⁹⁸ Moreover, it is a matter of legal prudence that Article 5(A)(2) of the Paris Convention recognises one example whereby members may grant compulsory licences, that is, to remedy failure to work, which the Convention contemplates as an abuse of the exclusive rights. In fact, the restrictions are based on substantive conditions only.

With this requirement, members may not grant any licences before the expiration of a period of four years from the date of the filing of the patent application or three years from the date of the granting of the patent, whichever period expires last.⁹⁹ Complementing the language in Article 5(A) of the Paris Convention, which is directly incorporated into TRIPS by virtue of Article 2, the TRIPS Agreement does not use the term 'compulsory licensing'. However, in reference to patent usage, Article 31 does allow for 'use without authorisation of the right holder', thus allowing a compulsory licence to be issued.¹⁰⁰

⁹⁶ Richard Hunter, 'Compulsory Licensing: A Major Issue in International Business Today?' (2009) 11 *European Journal of Social Sciences* 370, 372.

⁹⁷ Sara M Ford, 'Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents' (1999-2000) 15 *American University International Law Review* 941, 960.

⁹⁸ Georg Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* (WIPO Publication No 611(E), United International Bureaux for the Protection of Intellectual Property (BIRPI) 1969) 70.

⁹⁹ Paris Convention (n 76) art 5(A)(4).

¹⁰⁰ Letter from the Consumer Project on Technology to the Congressional Black Caucus regarding the African/AIDS/Patent Trade Dispute (29 June 1999) <www.cptech.org/ip/health/sa/clyburn.html> accessed 25 July 2016; Michael Blakeney, *Trade Related Aspects of Intellectual Property: A Concise Guide to the TRIPS Agreement* (Sweet & Maxwell 1996) 90.

Along the same legal premise as the Paris Convention, Article 31 of TRIPS does not state specifically the grounds upon which compulsory licences can be issued. In fact, with the single exception of semiconductor technology, Article 31 of TRIPS does not limit the grounds on which WTO members can implement compulsory licences. This is also qualified by the same understanding that as far as their domestic laws allow them, members can pursue compulsory licences, and thus have the freedom to determine the grounds on which such licences are based.¹⁰¹

However, although some grounds are expressly mentioned in Article 31 of TRIPS, these are only examples that are meant to guide members. Article 31 of TRIPS, thus, describes two situations where compulsory licences can be used. Nevertheless, these two situations—where the licence is required to address an overriding public interest, and where the patent rights are being used in an anticompetitive manner—remain within the remit of the national laws of member states. TRIPS does not limit the possibility of, or WTO members' independence in, granting compulsory licences on any other substantive grounds.¹⁰²

Article 31 of TRIPS contains a detailed set of substantive conditions and procedural requirements that must be satisfied when members are to grant compulsory licences. Therefore, in as much as the procedural requirements and other substantive conditions are met, the TRIPS Agreement does not limit members' possibility to grant compulsory licences on any grounds, such as failure to work or public health considerations, and leaves open cases in which such licences can be granted.¹⁰³ This is confirmed by the Doha Declaration.¹⁰⁴

In this spirit, the TRIPS Agreement also allows member states to make virtually all decisions regarding the granting of compulsory licences, including those regarding compensation or appeals, through administrative processes, provided that the process is fair and transparent.¹⁰⁵ Therefore, WTO members are left with a very broad scope of action with

¹⁰¹ Daniel Gervais, *The TRIPS Agreement: Drafting Analysis and Negotiating History* (1st edn, Sweet & Maxwell 1998) 165.

¹⁰² Correa (n 2) 311.

¹⁰³ Frederick M Abbott, Thomas Cottier, and Francis Gurry, *International Intellectual Property Integrated World Economy* (2nd edn, Aspen Publishers 2011) 196.

¹⁰⁴ Doha Declaration (n 20) cl 5(b).

¹⁰⁵ TRIPS (n 1) art 31(c), (i), (j), and (k).

regard to the grounds on which they can grant compulsory licences.¹⁰⁶ These include the need to authorise such use on its individual merit,¹⁰⁷ non-exclusivity,¹⁰⁸ the need for a prior request to the patent holder on reasonable commercial terms, and the obligation to pay adequate compensation.¹⁰⁹

The requirement to request a voluntary licence is not applicable in cases of emergency and public non-commercial use.¹¹⁰ It is also important to note that TRIPS specifically does not require governments to grant injunctive relief to patent holders¹¹¹ in cases where government authorisations of patent use satisfy the Article 31 framework.¹¹² Article 31, therefore, makes it obvious that the TRIPS Agreement leaves members with a wide discretion as to the granting of compulsory licences and the grounds on which to do so. In other words, the restrictions are not strictly legal in nature, but member states must satisfy certain substantive conditions in relation to the application of the procedural requirements.¹¹³

Compulsory licensing as an instrument of government policy is not new to the patent system. This instrument has formed a common and integrated part of most patent systems,¹¹⁴ even though it is not often put into practice for various reasons, including human resource constraints, political considerations, inadequate infrastructure, and high operating costs due to small market size, which makes the practice of compulsory licensing difficult in developing countries.¹¹⁵ In other words, the concept and practice of compulsory licences are not new, even

¹⁰⁶ Velásquez and Boulet (n 75) 35.

¹⁰⁷ TRIPS (n 1) art 31(a).

¹⁰⁸ TRIPS (n 1) art 31(d).

¹⁰⁹ TRIPS (n 1) art 31(h).

¹¹⁰ TRIPS (n 1) art 31(b).

¹¹¹ TRIPS (n 1) art 44(2).

¹¹² James Love, *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord* (Third World Network 2004) 1.

¹¹³ Thaddeus Manu, 'Building National Initiatives of Compulsory Licences: Reflecting on the Indian Jurisprudence as a Model for Developing Countries' (2015) 14 *Journal of International Trade Law & Policy* 23, 35.

¹¹⁴ Compulsory licensing provisions were included, eg, in the first patents statute of Australia, the Patents Act 1903 (Cth) (Australia) s 87.

¹¹⁵ Warren A Kaplan, *Local Production and Access to Medicines in Low- and Middle-Income Countries: A literature review and critical analysis* (prepared for the WHO Department of Public Health, Innovation and Intellectual Property, World Health Organisation 2011) 3.

in developed countries.¹¹⁶ They have a long history and have remained a prominent feature of the general philosophy of patent regimes for over a century. Many patent law regimes provide for the granting of compulsory licences in a variety of situations.¹¹⁷ Many countries have used, or threatened to use, compulsory licensing for public interest purposes. Specific situations in which compulsory licences may be issued are set out in the relevant statutes of each patent system.¹¹⁸

D JUSTIFICATION OF ACCESS TO MEDICINES ON THE FRAMEWORK OF THE RIGHT TO HEALTH

International human rights standards have transformed the nature of the relationship between governments and individuals and made public authorities far more accountable. For instance, the right to health is also recognised in numerous regional and international human rights instruments and declarations as a fundamental human right and is a core obligation that states are obliged to fulfil.¹¹⁹ Examples in this regard are the United Nations Universal Declaration of Human Rights,¹²⁰ the Convention on the Rights of the Child,¹²¹ the Convention on the Elimination of Discrimination against Women,¹²² the International Convention on the Elimination of all Forms of Racial Discrimination,¹²³ the International Covenant on Economic,

¹¹⁶ The Belgian Patent Law (28 March 1984, last amended 28 January 1997), arts 31, 33, and 35, eg concern compulsory licences. See also Friedrich-Karl Beier, 'Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law' (1999) 30 *International Review of Intellectual Property and Copyright Law* 251, 259–260.

¹¹⁷ Cole Fauver, 'Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come' (1987) 8 *Northwestern Journal of International Law & Business* 666, 671.

¹¹⁸ UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD), *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (CUP 2005) ch 25.

¹¹⁹ United Nations Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant)' (14 December 1990) UN Doc E/1991/23 [2]; CESCR, 'General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4 [36]. See also John Tobin, *The Right to Health in International Law* (OUP 2012) 194.

¹²⁰ UNDHR (n 11) art 25.

¹²¹ Convention on the Rights of the Child (adopted 20 November 1989, entered into force 2 September 1990) 1577 UNTS 3 (CRC) art 24.

¹²² Convention on the Elimination of Discrimination against Women (adopted 18 December 1979, entered into force 3 September 1981) 1249 UNS 13 (CEDAW) arts 11(1)(f), 12.

¹²³ International Convention on the Elimination of All Forms of Racial Discrimination (adopted 21 December 1965, entered into force 4 January 1969) 660 UNTS 195 (ICERD) art 5(e).

Social and Cultural Rights (ICESCR),¹²⁴ and the African Charter on Human and Peoples' Rights.¹²⁵

The preamble to the constitution of the World Health Organisation (WHO) also declares that it is one of the fundamental rights of every human being to enjoy 'the highest attainable standard of health.'¹²⁶ The ICESCR is the most important international instrument relating to socio-economic rights. Article 12 of ICESCR provides for the 'enjoyment of the highest attainable standard of physical and mental health conducive to living a life of dignity'. This provision has been interpreted to include access to essential medicines.¹²⁷

Essential medicines, according to the WHO, are those that 'satisfy the priority health care needs of the population' and 'are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford'.¹²⁸ The UN Development Group defines 'access' in this context as 'having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population'.¹²⁹ The normative view is that access to health care, including access to essential medicines, is a prerequisite for realising that right.¹³⁰ Thus, a central principle underpinning the framework of access to medicines as a human rights matter has been interpreted broadly as including a right to treatment and, more specifically, a right to access to medicines.¹³¹

¹²⁴ ICESCR (n 11) art 12.

¹²⁵ Banjul Charter (n 11) art 16.

¹²⁶ Constitution of the World Health Organisation [1946] 14 UNTS 185. UN General Assembly Resolution A/RES/131, second session, hundred and seventeenth plenary meeting, 17 November 1947.

¹²⁷ CESCR, 'General Comment No. 14' (n 119) [12(a)], [12(b)]; Linda Muswaka, 'The Impact of Patent Protection and Lack of Generic Competition on the Right of Access to Medicines in South Africa: Explicating Corporate Responsibilities for Human Rights' (2014) 5 *Mediterranean Journal of Social Sciences* 229, 230.

¹²⁸ WHO, 'Essential Medicines and Health Products' (2016) <www.who.int/medicines/services/essmedicines_def/en/> accessed 1 July 2016.

¹²⁹ MDG Gap Task Force, *Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals: MDG Gap Task Force Report 2008*, (United Nations 2008) 35.

¹³⁰ *ibid* 42.

¹³¹ CESCR, 'General Comment No. 14' (n 119) [12]; UNHRC Res 12/24 (2 October 2009) UN Doc A/HRC/RES/12/24, cl 7.

The concept of access to essential medicines as a human right is generally not a disputed notion in the academic literature.¹³² Theoretically, the mainstream international human rights instruments support its practical underpinnings.¹³³ In fact, several resolutions and declarations at the international level, including those under the UN and its constituent agencies, have placed adequate scope on access to medicines as a significant component of the right to health.¹³⁴ The domains of this norm have been transposed into some regional instruments and national legal provisions.¹³⁵ The background to making access to medicines a shared norm backed by law at the international level follows a useful framework underpinning the basic principles of the overriding objective of public health protection.¹³⁶

While its underlying rationale is straightforward in theory in the empirical literature, its realisation has not gained any serious momentum at the national level, in particular in developing countries, which predominantly shoulder a disproportionate burden of diseases.¹³⁷ The spread of diseases continues to challenge the authority of political establishments in this category of countries, and although many of these diseases could easily be prevented if essential medicines were readily available within the public health setting, this is not the case.¹³⁸

The Commission on Human Rights adopted a resolution in 2001 in which it recognised that ‘access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the

¹³² Thomas Pogge, ‘Montréal Statement on the Human Right to Essential Medicines’ (2007) 16 *Cambridge Quarterly of Healthcare Ethics* 97–108.

¹³³ UDHR (n 11); ICESCR (n 11); Banjul Charter (n 11).

¹³⁴ UNGA Res S-26/2 (27 June 2001) UN Doc A/RES/S-26/2, annex.

¹³⁵ Constitution of Azerbaijan, art 41; Constitution of Cameroon, art 25; Constitution of Cuba, art 50. See also S Katrina Pehudof, ‘Health, Essential Medicines, Human Rights & National Constitutions’ (World Health Organisation 2008) 61.

¹³⁶ *Barcelona Traction, Light and Power Company, Limited Case* [1970] ICJ Rep 32 [33], [34] found that ‘all States can be held to have a legal interest’ in the protection of obligations to the international community as a whole in view of the ‘importance of the rights involved’. See also Centre on Global Health Security Working Group on Health Financing, *Shared Responsibilities for Health: A Coherent Global Framework for Health Financing* (Final Report, The Royal Institute of International Affairs 2014) 7.

¹³⁷ World Health Assembly (WHA) Res 67.22 (24 May 2014) WHO Doc A67/VR/9, 2.

¹³⁸ Manu (n 64) 234.

enjoyment of the highest attainable standard of physical and mental health'.¹³⁹ Among a list of measures, it called on states 'to refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them'¹⁴⁰ and, clearly with TRIPS in mind, requested them

[T]o ensure that their actions as members of international organisations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceuticals and medical technologies.¹⁴¹

In 2001, the Office of the High Commissioner prepared a report on the impact of the TRIPS Agreement on human rights,¹⁴² and the Sub-Commission on the Promotion and Protection of Human Rights took this up in its resolution in the same year on 'Intellectual Property Rights and Human Rights'.¹⁴³ The resolution, adopted by consensus, referred to the 'actual or potential conflict... between the implementation of the TRIPS Agreement and the realisation of economic, social and cultural rights'.¹⁴⁴ In other words, access to medicines in the context of the human rights framework means that governments have a legal obligation to adopt reasonable measures to obtain access to affordable essential medicines for public health protection.

A human rights orientation is predicated on the centrality of protecting and nurturing human dignity and the common good. By extension, the rights of the creator or the author are conditional on contributing to the common good and welfare of the society and not undermining the latter.¹⁴⁵ A human rights approach also takes the implicit balance between the rights of inventors and creators and the interests of the wider society within IP paradigms and

¹³⁹ UNCHR Res 33 (2001) UN Doc E/CN.4/ RES/2001/33, cl 1.

¹⁴⁰ *ibid* cl 3(a).

¹⁴¹ *ibid* cl 4(b).

¹⁴² UNCHR (Sub-Commission on the Promotion and Protection of Human Rights), 'Economic, Social and Cultural Rights: The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13.

¹⁴³ UNCHR (Sub-Commission on the Promotion and Protection of Human Rights) Res 21 (2001) UN Doc E/CN.4/SUB.2/RES/2001/21.

¹⁴⁴ *ibid* Preamble.

¹⁴⁵ Chapman (n 21) 14.

makes it far more explicit and exacting.¹⁴⁶ As already mentioned, a human rights approach further establishes a requirement for the state to protect its citizens from the negative effects of IP regimes.¹⁴⁷

E APPLICATION AND JUDICIAL INTERPRETATION OF HUMAN RIGHTS NORMS TO PROMOTE ACCESS TO MEDICINES

The relationship between the protection of IP and human rights norms has been examined in a growing body of literature, most of which focuses on the substantive overlaps, interfaces, and tension between the two areas of law.¹⁴⁸ Several landmark decisions by the judiciaries in different countries have raised popular awareness of the conflict between IP regimes and human rights norms. Although scholars have advanced theses suggesting that human rights trump IP protection, there still exist challenges inherent in the analysis of the intricate correlation between these two fields of law.¹⁴⁹

In fact, the conflict is complicated by the fact that the right to IP exists within the human rights frameworks.¹⁵⁰ The complex interface between these strands of treaties is an area that deserves our renewed attention, given that we have not seen many of these judicial interventions in Africa. To start with, on 1 February 2011, in its decision in *Novartis Pharma AG v Monte Verde SA*,¹⁵¹ the Federal Court of Appeals in Civil and Commercial Matters, Division III, an Argentinean court, rejected a heightened IP standard, in part with reference to human rights.

In this litigation, Novartis argued that Argentina must afford the company data exclusivity in order to fulfil its TRIPS obligations. In rejecting that argument, the court stated that ‘one cannot ignore that developing countries imitate medical products through reverse

¹⁴⁶ *ibid.*

¹⁴⁷ *ibid* 15.

¹⁴⁸ Laurence R Helfer, ‘Human Rights and Intellectual Property: Conflict or Coexistence?’ (2003) 5 *Minnesota Intellectual Property Review* 47, 48.

¹⁴⁹ Peter K Yu, ‘Intellectual Property and Human Rights in the Nonmultilateral Era’ (2011) 64 *Florida Law Review* 1045, 1047.

¹⁵⁰ Megan M Carpenter, ‘Intellectual property: A human (not corporate) right’ in David Keane and Yvonne McDermott (eds), *The Challenge of Human Rights: Past, Present and Future* (Edward Elgar 2012) 314.

¹⁵¹ *Novartis Pharma AG c/ Monte Verde SA s/ varios propiedad industrial e intelectual CFed*, Causa No 5.619/05, 1 February 2011 (Argentinian Federal Appeals Court).

engineering in order to cover the public health necessities; nor that the right to health—internationally recognised in treaties that carry constitutional weight—is rigorously tied to the right to life, without which the rest of the guarantees of the Constitution lose their purpose’.¹⁵² The court also noted that ‘the reasonability of an impugned legal regime is better understood when one reads it in light of international human rights obligations’.¹⁵³ Thus, the Argentinian court used human rights obligations to explain why the proposed IP standard was impermissible.¹⁵⁴

Secondly, in August 2011, the Superior Court of Justice of Brazil reversed a Federal court decision, which had found that ANVISA had violated Article 39(3) of TRIPS in granting registration to an unauthorised third party if they used the test results and data of the dossier sent by Lundbeck Brazil Ltda, the producer of Lexapro, a reference drug, to receive the registration for the drug.¹⁵⁵ The Supreme Court reasoned that its decision to reverse the Federal Court’s decision was ‘subject to the existence of a manifest public interest in order to avoid harm to public order, security, health or economy’.¹⁵⁶ The Superior Court of Justice’s decision was squarely within the Brazilian national public policy, enshrined in Law 9.787 of 1999, which provides the legal framework for access to generic medicines.¹⁵⁷

Finally, on 29 February 2012, the Supreme Administrative Court of Colombia, Civil Circuit Court 37 of Bogota, ruled that Abbott must respect Colombian price controls on its HIV medication Kaletra.¹⁵⁸ The lawsuit, filed by Colombian health organisations in September

¹⁵² Thomas Dreier and Marco Ganzhorn, ‘Intellectual property in decisions of national Constitutional Courts in Europe’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 219, 221.

¹⁵³ *ibid.*

¹⁵⁴ Brennan and others (n 50) 22.

¹⁵⁵ *Agência Nacional De Vigilância Sanitária – ANVISA v Lundbeck Brasil Ltda: Suspensão De Liminar E De Sentença*, No 1.425 - DF (2011/0184444-8), 17 August 2011 (Brazilian Superior Court of Justice). See also Felipe Fischmann, ‘Comments on the “Lexapro” Decision of the Brazilian Superior Court of Justice of 17th August 2011’ (2012) 43 *International Review of Intellectual Property and Competition Law* 217–222.

¹⁵⁶ Brennan and others (n 50) 221.

¹⁵⁷ Pamela Andanda, ‘Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health’ (2014) 44 *International Review of Intellectual Property and Competition Law* 140, 149.

¹⁵⁸ Tribunal Administrativo de Cundinamarca, Sala, Lab. Febrero 2012, Carlos Enrique Moreno Rubio, Expediente No 2009-00269-01 (Columbian Administrative Court of Cundinamarca).

2009, was a ‘Popular Action’, a mechanism under Article 88 of the 1991 Colombian Political Constitution (as amended) to protect collective rights, public safety and health, administrative morality, and other interests of a similar nature. This provision regulates actions arising out of harm caused to a large number of individuals.¹⁵⁹

Critically, the Supreme Court’s decision recognised that the right to health holds implications not only for the government’s system of distributing medications, but also for its manner of acquiring and paying for medications.¹⁶⁰ The court explained how the right to health necessarily touches on any law that affects the accessibility of medications: ‘One must take into account that the right to health has a compensatory character, and for this compensatory character to be effective, the right to health requires that budgetary and procedural aspects be made viable and balanced’.¹⁶¹

F THE COMPLEX INTERFACE BETWEEN INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES FROM THE AFRICAN COURTS PERSPECTIVE

1 Aventis Pharma SA and Others v Cipla Life Sciences and Others

In 2012, the Supreme Court of Appeal in South Africa handed down a contentious decision in the matter between *Aventis Pharma SA and Others v Cipla Life Sciences and Others*,¹⁶² with the Treatment Action Campaign (TAC) intervening as amicus curiae pursuant to ‘Docetaxel’.¹⁶³ While essentially a dispute as to whether a 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 instance, the right of access to health care services and medicines) in IP disputes.¹⁶⁴ The principle that the public

¹⁵⁹ Donald T Fox, Gustavo Gallón-Giraldo and Anne Stetson, ‘Lessons of the Columbian Constitutional Reform of 1991: Toward the Securing of Peace and Reconciliation?’ in Laurel E Miller and Louis Aucoin (eds), *Framing the State in Times of Transition: Case Studies in Constitution Making* (United States Institute of Peace 2010) 467, 477.

¹⁶⁰ Tribunal Administrativo de Cundinamarca (n 158) 53.

¹⁶¹ *ibid.*

¹⁶² *Aventis* (n 62).

¹⁶³ *ibid* [43].

¹⁶⁴ *Aventis* (n 62). See also Emmanuel Kolawole Oke, ‘South Africa: *Aventis Pharma SA & Ors v. Cipla Life Sciences*’ (2013) 44 *International Review of Intellectual Property and Competition Law* 245–247.

interest applies in IP disputes had already been established in a previous unsuccessful application for a compulsory licence.¹⁶⁵

The disputed patent in the ‘Docetaxel’ case related to a composition of unpatented products, which, when combined, facilitate the intravenous administration of docetaxel, a treatment for cancer.¹⁶⁶ The holder of the patent (Aventis Pharma SA) maintained that the generic manufacturer (Cipla Life Sciences) had infringed its patent by registering and commencing the manufacture and marketing of a cheaper version of the medicine.¹⁶⁷ Cipla countered that the patent is invalid on account of ambiguity and lack of novelty and inventive step, essential requirements for patentability under South African law.¹⁶⁸ A key complication is the fact that the South African patents office does not conduct substantive examinations as to the merits of each patent application, nor is there any opportunity for an interested party to oppose such applications. Thus, these court proceedings presented the first opportunity for any tribunal to consider the substantive merits of the docetaxel patent.

In its heads of argument, the TAC submitted that the Patents Act¹⁶⁹ must be construed ‘through the prism of the Constitution’ and in a way that appropriately balances the rights of a patentee against the constitutional rights of others, and that it ‘must be interpreted and applied to ensure the public interest in patent protection is in fact served and ensuring other rights are not unreasonably limited thereby’.¹⁷⁰ Section 39(2) of the South African Constitution indeed calls upon a court to ‘promote the spirit, purport and objects of the Bill of Rights’ when interpreting legislation. Thus, the TAC argued that the rights of the patent holder need to be balanced with those of persons requiring, but unable to afford, the relevant medication.¹⁷¹

¹⁶⁵ *Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* (449/96) [1998] ZASCA 74 (ZASCA).

¹⁶⁶ *Aventis* (n 62) [3], [10]–[12].

¹⁶⁷ *ibid* [3].

¹⁶⁸ Patents Act, 57 of 1978 (South Africa) s 25(1), (6), (10) (South Africa). See also *Ensign-Bickford (South Africa) (Pty) Ltd v AECI Explosives and Chemicals Ltd* (4/95) [1998] ZASCA 8 (ZASCA).

¹⁶⁹ Patent Act, 57 of 1978 (South Africa).

¹⁷⁰ *Aventis* (n 62) [44].

¹⁷¹ Yousuf A Vawda, ‘Patent Law in emerging economies: South Africa’ in Frederick M Abbott, Carlos M Correa and Peter Drahos (eds), *Emerging Markets and the World Patent Order* (Edward Elgar 2013) 291f.

Note that section 27(1)(a) of the South African Constitution provides for the right to have access to health care services. Universal access to health care services in that sense includes access to medications.¹⁷² In the case of *Minister of Health v New Clicks SA (Pty) Ltd*,¹⁷³ access to medications was qualified by the court to mean access to affordable medications.¹⁷⁴

Secondly, when considering the requirement of ‘balance of convenience’ in interdict proceedings which potentially threaten the right to access medicines, the party requesting the interdict must prove that its grant will not harm the public interest.¹⁷⁵ Thirdly, while the evidence to enable the court to assess whether the rights of cancer patients would be prejudiced is inadequate, on the basis of the available information on the record, the interdict-seeker failed to discharge its onus of proof.¹⁷⁶ And finally, the TAC argued that, in line with courts in the USA, the court must assess whether a satisfactory alternative remedy (such as damages) is available to the party seeking an interdict.¹⁷⁷

In its judgment, the Court accepted TAC’s argument that the broader public interest, and not merely those of the litigating parties, ought to be considered when determining the balance of convenience in interdict proceedings, citing US Supreme Court case law.¹⁷⁸ However, it concluded that the public interest would not be served by denying an interdict on the facts of this case, citing *eBay Inc v Mercexchange LLC*.¹⁷⁹

¹⁷² *Minister of Health and Others v Treatment Action Campaign and Others (No 1)* (CCT9/02) [2002] ZACC 16 (South African Constitutional Court (ZACC)).

¹⁷³ [2005] ZACC 14 (ZACC).

¹⁷⁴ *ibid* [514] (Ngcobo J), [706] (Moseneke J).

¹⁷⁵ *Aventis* (n 62) [46].

¹⁷⁶ *ibid* [59].

¹⁷⁷ *ibid* fn 35. See also Emmanuel Kolawale Oke, ‘Patent Rights, Access to Medicines, and Justiciability of the Right to Health in Kenya, South Africa and India’ in Alice Diver and Jacinta Miller (eds), *Justiciability of Human Rights Law in Domestic Jurisdictions* (Springer 2016) 91, 114.

¹⁷⁸ *Aventis* (n 62) [55] citing *Innogenetics, NV v Abbott Laboratories* 578 F Supp 2d 1079, 1105 (WD Wis 2007) (United States District Court for the Western District of Wisconsin), *Bard Peripheral Vascular, Inc v WL Gore & Assocs. Inc.* No 03-CV-0597 (United States District Court for Arizona, 24 August 2010); *Johnson & Johnson Vision Care, Inc v Ciba Vision Corporation* 712 F Supp 2d 1285 (MD Fla 2010) (United States District Court for the Middle District of Florida).

¹⁷⁹ 547 US 388 (2006).

The court noted that Cipla's opposition was based on commercial considerations, namely its need to establish a presence in the generics market.¹⁸⁰ Furthermore, it noted that there was no evidence before it that Aventis could not continue to meet the demand for the medicine, nor was Cipla able to demonstrate that its product offered either superior medicinal benefits or more than a marginal saving on the cost of its generic version of docetaxel in relation to Aventis's generic version (marketed as Docetere).¹⁸¹ And finally, it held that there would be no material disruption of medicine supply to patients should the interdict be granted.¹⁸² While the court made a concession to the consideration of the public interest when determining the balance of convenience, its judgment was not unexpected given the constraints imposed by the legislation and the mind-set of the judiciary.¹⁸³

This decision once again highlights the need for amending the South African patent laws to specify and properly apply the strict standards of novelty and inventive step required for the granting of a patent, and to prioritise the public interest in disputes concerning life-saving medicines.¹⁸⁴ The decision also highlights the power of patent right holders to frustrate generic competition,¹⁸⁵ and hence access to cheaper medicines, by introducing their own generic versions when such a threat is imminent.

Importantly, the South African government responded to the ruling and, in 2013, the Department of Trade and Industry of the Republic of South Africa released a Draft National Policy on Intellectual Property of South Africa.¹⁸⁶ This policy framework was gazetted in the Government Gazette, 4 September 2013.¹⁸⁷ This document deals with many aspects of IP,

¹⁸⁰ *Aventis* (n 62) [42].

¹⁸¹ *ibid* [57], [58].

¹⁸² *ibid* [58].

¹⁸³ *ibid* [61].

¹⁸⁴ Julia E Hill, 'Changes to intellectual property policy in South Africa: putting a stop to evergreening?' (2014) 24 *Expert Opinion on Therapeutic Patents* 839, 841 (comparing s 3(d) of the Indian Patent Act 1970).

¹⁸⁵ *ibid* 840.

¹⁸⁶ South African Department for Trade and Industry, 'Draft National Policy on Intellectual Property of South Africa' (2013) <ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf> accessed 16 August 2016.

¹⁸⁷ Vol 579, no 36816.

including public health matters and recommendations in relation to the possibility of public policy intervention that will protect people's health needs.¹⁸⁸

2 Kenya—a controversial patent decision: *Pfizer Inc v Cosmos Limited*

While a court in Kenya struck down an 'anti-counterfeiting' law as a violation of the right to health in the Kenyan constitution,¹⁸⁹ in 2008 the Kenyan Industrial Property Tribunal made a terrible declaration on the relationship between the right to health and IP rights in a dispute between a foreign multinational pharmaceutical company and a local pharmaceutical company in Kenya.¹⁹⁰

This followed an allegation under section 106 of the Kenyan Industrial Property Act 2001 by Pfizer that Cosmos had infringed its patent on a medicinal product known as 'azithromycin dihydrate' under the trademark 'Zithrox'.¹⁹¹ Cosmos, however, contended that the patent was not in force between 2003 and 2006 (when the alleged infringement occurred) due to the failure of Pfizer to pay the renewal fees on the patent.¹⁹² The tribunal, however, held that there was no evidence that the patent had lapsed or that it had been removed from the patent register at any time.¹⁹³

The patent in question was registered by the African Regional Intellectual Property Organisation (ARIPO), of which Kenya is a member, and Kenya was among the designated states for the patent. Section 81(3) of the Kenyan Industrial Property Act 2001 provides that 'a patent, in respect of which Kenya is a designated state, granted by ARIPO by virtue of the ARIPO Protocol shall have the same effect in Kenya as a patent granted under this Act'.¹⁹⁴

¹⁸⁸ South African Department for Trade and Industry (n 186) ch 2. For further analysis see Carolyn Ncube, 'The Draft National Intellectual Property Policy Proposals for Improving South Africa's Patent Registration System: A Review' (2014) 9 *Journal of Intellectual Property Law & Practice* 10, 830–834.

¹⁸⁹ *Patricia Asero Ochieng and Others v Attorney General*, Petition No 409 of 209, 20 April 2012 (Kenyan High Court (KHC)).

¹⁹⁰ *Pfizer* (n 63).

¹⁹¹ Pfizer's ARIPO Patent No AP44.

¹⁹² Oke (n 177) 113.

¹⁹³ *Pfizer* (n 63) 7.

¹⁹⁴ Emmanuel Kolawole Oke, 'Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes' (2013) 15 *Health and Human Rights* 97, 101.

The default mechanism is that failure to pay the maintenance fee of a granted patent on time renders the patented invention duly vacated or abandoned.¹⁹⁵ In fact, the ARIPO's Regulations for Implementing the Harare Protocol¹⁹⁶ are explicitly clear on this. Rule 21(4) dubbed 'Payment of Annual Maintenance Fees' provides that: 'If an annual maintenance fee is not paid in accordance with this Rule, the application shall be deemed to have been withdrawn or the patent shall lapse'. Reinstatement is possible,¹⁹⁷ but only when the evidence logically supports an unintentional delay.¹⁹⁸ Within this logic, the respondent contended that the patent had expired due to non-payment or late payment of renewal fees and relied on the case of *Sanitam Services (EA) Ltd v Rentokil (K) Ltd and Another*.¹⁹⁹

Cosmos raised an alternative defence that it was entitled to import, manufacture, sell, and export the patented product without the authority of Pfizer by virtue of section 58(2) of the Industrial Property Act, which allows parallel importation.²⁰⁰ Section 58(2) provides that 'the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya'. Cosmos presented evidence to the tribunal establishing that the medicines containing the patented product were available in Kenya, having been imported from India, Bangladesh and China.²⁰¹

¹⁹⁵ Industrial Property Act 2001 (Kenya) ss 39, 40.

¹⁹⁶ African Regional Intellectual Property Organisation (ARIPO), 'Regulations for Implementing the Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (ARIPO)' (entered into force 25 April 1984, last amended 17 November 2015).

¹⁹⁷ ARIPO, 'Administrative Instructions under the Regulations for Implementing the Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (ARIPO)' (25 April 1984), instruction no 13(1); In *The Matter of Patent Grant No AP 773* entitled "Foot Operated Sanitary/Litter Bin" (ARIPO Board of Appeal, 30 August 2007). Note that under the Convention on the Grant of European Patents (adopted 5 October 1973, entered into force 7 October 1977, revised 29 November 2000) 1065 UNTS 199 (European Patent Convention (EPC)) requests for re-establishment of rights in respect of any of the periods specified in art 87(1) and in art 11(2)(a)(4) must, however, be filed within two months of expiry of that period.

¹⁹⁸ 35 USC § 41(c)(1) (1952) (United States); 37 CFR 1.378 (United States) (1984). See also *Ex parte BW Industries Ltd* (United Kingdom Intellectual Property Office, 22 January 2013).

¹⁹⁹ Civil Suit 597 of 2007, 20 February 2008 (KHC).

²⁰⁰ *Oke* (n 177) 113.

²⁰¹ *Pfizer* (n 63) [3], [4].

In other words, the patent rights of Pfizer, with respect to those products which were readily available in Kenya had been exhausted.²⁰² Cosmos was trying to rely on the principle of international exhaustion of patent rights as reflected in section 58(2), and though this principle might not give Cosmos the right to manufacture the patented product, it would entitle Cosmos to import those patented products from India, Bangladesh, and China and to resell them in Kenya.²⁰³

However, in a rather curious and confusing manner, the tribunal conflated parallel importation with compulsory licences and voluntary licences. According to the tribunal,

parallel importation... is applicable for instance where the government has allowed a third party to exploit the patent, and that party imports the product from other countries where it is legitimately put on the market... This could also be with the authority of the patent holder by way of a contractual or voluntary license.²⁰⁴

The tribunal could not envision a situation where a third party could engage in the parallel importation of a patented product without the authorisation of the patentee or the government and its definition of parallel importation clearly contradicts what is contained in section 58(2).²⁰⁵ Section 58(2) does not require a person or a company to obtain government authorisation or a compulsory/voluntary licence before engaging in parallel importation.²⁰⁶

Cosmos equally argued that the patented product was used for the treatment of opportunistic infections in HIV/AIDS patients and that the WHO listed the product as an essential medicine for the treatment of genital chlamydia trachomatis and trachoma.²⁰⁷ By raising this argument, Cosmos highlighted a tension between the enforcement of Pfizer's patent

²⁰² Oke (n 177) 103.

²⁰³ Ragnish Kumar Rai and Srinath Jagannathan, 'Parallel imports and unparallel laws: an examination of the exhaustion doctrine through the lens of pharmaceutical products' (2012) 21 *Information & Communications Technology Law* 1, 53–89; Keith E Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries' (Final Report to the World Intellectual Property Organisation, 2001) <http://193.5.93.81/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf> accessed 17 February 2017.

²⁰⁴ *Pfizer* (n 63) 13.

²⁰⁵ Oke (n 177) 102.

²⁰⁶ Linda Makutsa Opati, 'Intellectual Property Rights In Health – Impact On Access To Drugs' in Moni Wekesa and Ben Sihanya (eds), *Intellectual Property Rights in Kenya* (Konrad Adenauer Stiftung and SportsLink Limited 2009) 13, 27.

²⁰⁷ *Pfizer* (n 63) 16.

rights on the one hand and the need to facilitate access to this essential medicine for Kenyan patients on the other.²⁰⁸

The resolution of this tension therefore required a proper appreciation of the fact that patent rights are instrumental rights that should serve the needs and interests of fundamental rights such as access to affordable medicines. If the tension had been approached from this dimension, it would have enabled the tribunal to interpret the patent law with the objective of ensuring that it did not impede access to medicines.²⁰⁹ However, in this particular case, the Kenyan tribunal took the view that the product was not a first-line treatment for HIV/AIDS patients and that even if this were the case, it would not entitle the respondents to exploit the patent without authorisation.²¹⁰

The tribunal thus failed to appreciate the essential distinction between the instrumental nature of patent rights and the fundamental nature of access to essential medicines.²¹¹ It can be argued that the tribunal failed to appreciate this essential distinction because Article 43(1)(a), which made the right to health justiciable in Kenya, was introduced into the Kenyan Constitution only in 2010—two years after the tribunal's judgment.

As noted above, section 58(2) was introduced in order to facilitate the importation of medicines for the treatment of HIV/AIDS and opportunistic ailments. However, even without invoking the constitutional right to health, a court that is mindful of the fundamental importance of securing access to medicines would have examined the rationale behind the inclusion of Section 58(2) in the Kenyan patent law in accordance with the objective of ensuring that the enforcement of a patent right does not defeat the aims of the drafters of the patent law.²¹²

A classic example of a case where the court recognised this essential distinction, even in the absence of a constitutional right to health, is the English case of *Roussel-Uclaf v GD Searle & Co Ltd (No 1)*²¹³ In that case, the claimants (who held a licence under a patent to exclusively

²⁰⁸ Oke (n 177) 102.

²⁰⁹ *ibid.*

²¹⁰ *Pfizer* (n 63) 17.

²¹¹ Oke (n 177) 102.

²¹² *ibid.*

²¹³ [1977] FSR 125 (England and Wales High Court (EWHC)).

sell certain drugs) sought to restrain the defendants from selling one of those drugs in the United Kingdom (UK). However, the court refused to grant an injunction restraining the defendants from selling the drug because it was a unique, life-saving drug with no precise equivalent in the market, and the claimants were not yet selling the drug in the UK.

Thus, the English court was clearly concerned about preserving access to this life-saving drug for patients in the UK.²¹⁴ A court that is mindful of the fundamental importance of securing access to medicines will never permit the enforcement of patent rights in a manner that impedes access to medicines. In the *Pfizer* case, the approach adopted by the Kenyan tribunal essentially elevated the rights of patentees above the right to health of patients in need of essential medicines. The tribunal lost sight of the fundamental importance of securing access to essential medicines while it was adjudicating the patent dispute between the parties.²¹⁵

These cases are illustrations of a quiet revolution, but one that has far-reaching and unpredictable consequences for IP regimes, and which is now affecting the social structures of societies both at the world and national level and will affect them even more in future. In fact, these cases reinforce the notion that capacity building in the judicial arena in the interpretation of IP regimes consistent with public interests as underlined by human rights norms, even though significant for public health protection, is still lacking.

G THE FRAMEWORK OF INTERNATIONAL TECHNICAL ASSISTANCE ON INTELLECTUAL PROPERTY

It must be noted that when TRIPS entered into force in 1995, many developing countries already had significant IP laws and administrative systems in place, but had to revise their national regimes accordingly.²¹⁶ But to implement the full set of TRIPS standards presented a significant challenge for most developing countries, as it involved substantial development of their laws and administrative systems. Developing countries were concerned, when implementing TRIPS standards, to ensure that their IP systems operated in a balanced and

²¹⁴ Oke (n 177) 102.

²¹⁵ *ibid.*

²¹⁶ UNCTAD and ICTSD (n 118) 483.

effective way as a tool of public policy. Achieving this objective can call upon a wide array of technical, legal and policy expertise.²¹⁷

As already mentioned, an extended period was provided for developing and LDC members to implement TRIPS²¹⁸ and facilitate this implementation, and developed countries agreed to provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and LDC members.²¹⁹ This technical cooperation has continued through to the present, and these initiatives have sought to build sustainable capacity by concentrating on strengthening the policy and analytical skills within these countries.

Therefore, based on Article 4 of the Agreement between WIPO and the WTO,²²⁰ the former would provide varying degrees of capacity building—predominantly relating to institutional, technical, and human resources-based aspects—to developing countries with regard to the TRIPS Agreement. In line with this obligation, the IP system, including its legal, institutional, and human resources aspects, should meet national policy objectives and should be effective, affordable, and easily accessible to all stakeholders.²²¹ The policy objectives for WIPO's technical assistance programmes are set out in the Medium Term Plan for WIPO Program Activities - Vision and Strategic Direction of WIPO.²²²

The guiding principle of this plan is that every country should be encouraged to develop an IP culture appropriate to its needs, including a national IP strategy, the most suitable national infrastructure, and the fostering of a nationwide perception of IP as a powerful tool for economic, social, and cultural development.²²³ Governments are free to identify their capacity needs and request programmes from a wide range of areas including how to use the TRIPS

²¹⁷ TN Srinivasan, 'Doha Round of Multilateral Negotiations and Development' (2005) Stanford Centre for International Development Working Paper No 252, 6
<scid.stanford.edu/sites/default/files/publications/252wp_0.pdf> accessed 27 November 2016.

²¹⁸ TRIPS (n 1) art 65(2), (4); WTO (Council for TRIPS) (n 37).

²¹⁹ TRIPS (n 1) art 67.

²²⁰ WIPO and WTO Agreement (n 34).

²²¹ *ibid* [10(c)].

²²² WIPO (Assemblies of the Member States of WIPO), 'A Medium Term Strategic Plan for WIPO, 2010 – 2015' (20 August 2010) WIPO Doc A/48/3.

²²³ 'WIPO and WTO Agreement' (n 34) [10(b)].

flexibilities in their countries. Importantly, the use of flexibilities is also addressed in a number of recommendations contained in WIPO's DA.²²⁴

According to WIPO's policy framework for technical assistance, national IP systems in developing countries should maintain a balance between the interests of the holders of IPRs and those of the public at large.²²⁵ As the UN agency responsible for IP, WIPO's overall objective is the promotion of effective protection and use of IPRs throughout the world through cooperation with, and among, its member states and other stakeholders within the framework of the UN Millennium Development Goals (MDGs).²²⁶ With the aim of building on the MDGs, which were agreed in 2000 at the United Nations Sustainable Development Summit, on 25 September 2015 world leaders adopted the 2030 Agenda for Sustainable Development, and this includes capacity building.²²⁷

According to WIPO documentation, this objective is to be achieved by creating an enabling environment and infrastructure conducive to an enhanced understanding of the contribution of IP to economic, social, and cultural development,²²⁸ and, in particular, by assisting developing countries in building their capacity for greater access to, and use of, the IP system.²²⁹ This includes, for example, the provision of legislative advice to member states

²²⁴ Cluster B: 17 & 22. According to the WIPO CDIP Report, the term 'flexibilities' means that there are different options through which TRIPS obligations can be transposed into national law, so that national interests are accommodated and TRIPS provisions and principles are also complied with. This definition would effectively delimit the scope of the concept through the following elements: It highlights the idea of using various options as a means of implementation. It refers to the legislative process of implementation, reflecting the view that the first step needed in order to take advantage of a given flexibility consists of incorporating that flexibility into national law. It refers to the reason for flexibilities, which is to accommodate national interest. It reflects that a given flexibility needs to be compatible with the provisions and principles of the TRIPS Agreement: see, 'Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels' (Geneva, Committee on Development and Intellectual Property, fifth-session, CDIP/5/4, 1 March 2010) [34] <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629> accessed 10 April 2017.

²²⁵ 'WIPO and WTO Agreement' (n 34) [10(d)].

²²⁶ The MDGs were adopted by UNGA Res 55/2 (18 September 2000) UN Doc A/RES/55/2. See also WIPO (CDIP), 'The Measurement of the Millennium Development Goals in other United Nations Agencies and the Contribution of WIPO to the MDGs' (21 November 2013) WIPO Doc CDIP/12/8.

²²⁷ Sustainable Development Goals (n 38).

²²⁸ WIPO (CDIP), 'WIPO and the Post-2015 Development Agenda' (9 October 2015) WIPO Doc CDIP/16/8.

²²⁹ FIVS, 'WIPO Liaison Group' (2010) <fivs.org/wm/committees/wipo.htm> accessed 1 July 2016; WIPO (CDIP), 'Mapping of WIPO Activities Related to the Sustainable Development Goals (SDGs) Implementation' (25 February 2016) WIPO Doc CDIP/17/8.

in line with countries' development needs and priorities, making use of the flexibilities available under the international IP system.²³⁰

Following the request of the Committee on Development and Intellectual Property, WIPO prepared a preliminary study on patent related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels.²³¹ The study presents a non-exhaustive number of flexibilities in the patent area, accompanied by a conceptual development for each, as well as annexes and tables reflecting corresponding legal provisions and practices in a substantial number of countries. The report shows a diverse approach to the implementation of the TRIPS flexibilities in national laws.

Specifically, it highlights the importance of compulsory licensing as an instrument of government policy to provide access to affordable medicines for public health protection. Notwithstanding this, African LDCs have not made better use of the key flexibility of not complying with the TRIPS Agreement at all except for Articles 3 and 4 of TRIPS, which formulate key principles such as national treatment and the most-favoured nation clause.²³² An independent report has found critical shortcomings in the technical assistance activities under WIPO.²³³

H THE DOCTRINE OF INTERNATIONAL COOPERATION AND ITS RELEVANCE TO CAPACITY BUILDING FOR DEVELOPING COUNTRIES

While the concept of international cooperation is not a recent norm, the need for it as an impetus for development is a recent innovation. A great deal of it takes place under bilateral agreements.²³⁴ The concept has received adequate consideration in the international relations scholarship, which delves much into its theoretical foundation. At the heart of many of the most

²³⁰ WIPO (CDIP) (n 17).

²³¹ 'Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels' (n 224).

²³² Gail E Evans, 'TRIPS and the Sufficiency of the Free Trade Principles' (1999) 2 *The Journal of World Intellectual Property* 707, 714.

²³³ Carolyn Deere Birkbeck and Santiago Roca (n 42) ii, 90, 92, 93.

²³⁴ UNGA (High-level Committee on the Review of Technical Cooperation among Developing Countries), 'Review of Progress made in Implementing the Buenos Aires Plan of Action and the Decisions of the High-level Committee and Implementation of the Recommendations of the South Commission' (7 April 1995) UN Doc TCDC/9/2 [20].

significant theoretical debates lies the importance of international cooperation as a tool for building capacity. Significantly, Robert Keohane's 'After Hegemony',²³⁵ Ernst Haas' 'Beyond the Nation-State',²³⁶ and Thomas Franck's 'The Power of Legitimacy Among Nations',²³⁷ have all made contributions reinforcing the importance of cooperation at the international level. Together, these works represent three decades of functional scholarship on core questions regarding the continuing relevance of international cooperation, although from different theoretical positions.²³⁸ The importance of cooperation among developing countries in general, and of technical cooperation in particular, has been recognised in a series of declarations, resolutions, and decisions of the UN.²³⁹

Notably, the theoretical trend upon which international cooperation is built follows either the North-South or South-South model.²⁴⁰ While there exist conceptual underpinnings that support the two, in practice the favoured option is that of the conventional North-South model. More importantly, in 1978, recognising that technical cooperation among developing countries is a critical means for fostering national and collective self-reliance, delegations from 138 countries adopted the Buenos Aires Plan of Action for Promoting and Implementing Technical Cooperation among developing countries.²⁴¹ This resulted in the establishment of the UN's Unit for South-South Cooperation in 1978.²⁴²

²³⁵ Robert O Keohane, *After Hegemony: Cooperation and Discord in the World Political Economy* (Princeton University Press 1984).

²³⁶ Ernst B Haas, *Beyond the Nation-state: Functionalism and International Organisation* (Stanford University Press 1964).

²³⁷ Thomas M Franck, *The Power of Legitimacy Among Nations* (OUP 1990).

²³⁸ For further analysis of these theories see Anne L Herbert, 'Cooperation in International Relations: A Comparison of Keohane, Haas and Franck' (1996) 14 *Berkeley Journal of International Law* 222–238.

²³⁹ See, eg, UNGA Res 32/183 (19 December 1977) UN Doc A/RES/32/183; UNGA Res 33/134 (19 December 1978) UN Doc A/RES/33/134; UNGA Res 46/159 (19 December 1991) UN Doc A/RES/46/159; UNGA Res 49/96 (19 December 1994) UN Doc A/RES/49/96; UNGA Res 50/119 (20 December 1995) UN Doc A/RES/50/119; UNGA Res 52/205 (18 December 1997) UN Doc A/RES/52/205.

²⁴⁰ Piera Tortora, 'Common Ground between South-South and North-South Co-Operation Principles' (Issues Brief, OECD 2011) 1 <www.oecd.org/dac/stats/49245423.pdf> accessed 1 July 2016.

²⁴¹ United Nations Conference on Technical Co-operation among Developing Countries, 'Buenos Aires Plan of Action for Promoting and Implementing Technical Co-operation among Developing Countries' (United Nations 1978) endorsed by UNGA Res 33/134 (19 December 1978) UN Doc A/RES/33/134.

²⁴² See, United Nations Office for South-South Cooperation <ssc.undp.org/content/ssc.html> accessed 14 July 2016.

Under the same principle, the UN upgraded this institution to the High-level Committee on South-South Cooperation, as a multilateral support body to promote South–South collaboration within its agencies.²⁴³ Notwithstanding its doctrinal sense, support from the international community, and advocates’ argument for developing countries to resort to the South-South model, African policymakers engage in traditional North-South cooperation to a substantial degree. In other words, African policymakers may in theory support the South-South model, but in practice this is neglected. This trend confounds logic. This paucity exists because when it comes to institutional and human capacity, the notion of development follows the model known in developed countries.

This practice is inconsistent with the position recognised by the UN’s Office of the Special Adviser on Africa, which reaffirmed the importance of these partnerships for enhancing and consolidating the growth of the continent.²⁴⁴ The Office, therefore, encourages and promotes the convening of forums on South-South and triangular cooperation with a view to enabling African countries to benefit from the sharing of experiences, technical assistance as well as cooperation on the part of other developing and emerging countries.²⁴⁵

I BUILDING INSTITUTIONAL, TECHNICAL, AND HUMAN RESOURCED-BASED ASPECTS CAPACITY OF THE JUDICIARY

There is no doubt that human rights norms can be interpreted to promote access to affordable medicines for public health protection. However, in order to determine the proper normative relationship between IP law and the right to health, one must understand how they relate to one another. In other words, one must determine the appropriate structure of a human rights argument context that addresses unreasonable IP protection. This conceptual view is important, as courts of law in several countries have demonstrated sensitivity to promoting the interest of the public health in their judgements and pronouncements.²⁴⁶ Therefore, the judiciary remains

²⁴³ UNGA Res 35/202 (16 December 1980) UN Doc A/RES/35/202.

²⁴⁴ The Office of the Special Adviser on Africa (OSAA) was officially established on 1 May 2003 by the Secretary-General (UN Doc ST/SGB/2003/6), in line with UNGA Res 57/7 (4 November 2002) UN Doc A/RES/57/7.

²⁴⁵ Office of the Special Adviser on Africa, ‘North-South, South-South and Triangular Cooperation’ <www.un.org/en/africa/osaa/partnerships/south.shtml> accessed 1 July 2016.

²⁴⁶ Norheim and Wilson (n 48). See also *Ochieng* (n 189); *Dickson Tapela and Others v Attorney General and Others*, High Court Civil Case No MAHGB-000057-14, 22 August 2014 (High Court of Botswana (BHC))

an important organ of government that could provide an interpretation as to how aggressive IP law-making undermines or produces violations of the right to health.

With this, the logical deduction often advanced by some scholars is that an efficient judiciary remains a major component of access to medicines. However, this cannot be achieved, as the capacity of judges to come up with appropriate remedies requires professional competence and creativity, access to relevant knowledge, and command of the necessary legal remedies. There is no doubt that in Africa, the judiciary as an institution is still new and generally in a phase of initial experimentation. Therefore, given the evolving nature of the issue of inadequate access to medicines, a problem framed within human rights norms, the need for institutional training of judges has long been felt.

With income improving and populations growing, and as countries implement their IP obligation under TRIPS, Africa will soon be the hotbed for IP-related litigations. The issues of trade law that are likely to come before courts in a dynamic IP sector will pose a major technical challenge for judges in these countries. That is, if the judges lack the capacity to understand the intricate interface between IP and human rights and the need to circumvent IP protection, which TRIPS envisages as private rights, in favour of the overriding interest of the protection of the public, which is a major principle of the patent regime under TRIPS by virtue of Article 8, access to medicines cannot be realised.

There is, therefore, a need to sensitise judges through a combination of introducing the normative framework, experience sharing with counterparts in jurisdictions with similar challenges, and exposure to IP matters that conflict with human rights. It is only with this approach that the judiciary can be positioned as a crucial institution in promoting access to medicines through the development, interpretation, and enforcement of applicable human rights norms.

Importantly, with a view to enhancing its technical assistance mandate for IP matters, WIPO, in 2015, specifically launched a thematic project proposal aimed at targeting the

(securing access to HIV treatment for prisoners), affd Court of Appeal Civil Case No CACGB-096-14, 26 August 2015 (Court of Appeal of Botswana (BCA)).

capacity building of the judiciary directly.²⁴⁷ However, there are concerns as to whether these training programmes are meant to encourage the judicial officials of developing countries and LDCs to enforce IP rights without considering the development concerns or public interest issues.²⁴⁸

J JURISPRUDENCE APPLICABLE TO THE PROTECTION OF PUBLIC INTERESTS WITHIN THE INDIAN PATENT LAW

At the heart of the Indian patent regime lie several provisions aimed at protecting the interest of the public. For instance, section 84(1) of the Indian Patent Act²⁴⁹ hints that the granted patent must satisfy the reasonable requirements of the public, including a requirement that the patent must be reasonably affordable to the public. This is a legal requirement on the part of patentees. Thus, the public interest norm—a principle on which the grant of patent rights sits—implies that patents granted must not impede the protection of the public interest, but rather should act as an instrument to promote the reasonable legitimate expectations of the public.²⁵⁰

Notably, according to the logical view of the Indian Patent Act, patents are granted not in the commercial interest of patentees but rather the fundamental welfare of the public. Additionally, section 83(d) of the Indian Patent Act provides that: ‘patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interests especially in sectors of vital importance for socio-economic and technological development of India’. Therefore, consistent with the goal of public interest protection, the relevant provision of the Indian Patent Act provides that ‘patents granted do not in any way prohibit Central Government in taking measures to protect public health’.²⁵¹

²⁴⁷ WIPO (CDIP), ‘Cooperation on Intellectual Property Rights Education and Professional Training with Judicial Training Institutes in Developing and Least Developed Countries’ (8 September 2015) WIPO Doc CDIP/16/7, annex (addressing WIPO’s Development Agenda Recommendations 3, 10, and 45).

²⁴⁸ KM Gopakumar, ‘WIPO: Proposal for Training of Judiciary Raises Concerns’ (*Third World Network*, 13 April 2016) <www.twn.my/title2/intellectual_property/info.service/2016/ip160403.htm> accessed 16 August 2016.

²⁴⁹ Patents Act, 1970 (India).

²⁵⁰ Bryan Mercurio and Mitali Tyagi, ‘Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements’ (2010) 19 *Minnesota Journal of International Law* 275, 281.

²⁵¹ Patents Act, 1970 (India) s 83(e).

The judiciary remains an important institution that is playing a critical role in shaping the scope of protection and public interest safeguards contained in the Indian Patents Act, despite many of the flexibilities in its patent regime being relatively new to Indian patent law. There have already been a number of decisions that have the potential to foster a unique line of Indian jurisprudence that could inject fundamental public health considerations into how patent law should be interpreted.

K THE ROLE OF THE JUDICIARY IN THE PROTECTION OF PUBLIC INTERESTS WITHIN THE INDIAN PATENT REGIME

Since the initial High Court judgement in the *Novartis* case issued in 2007,²⁵² there have been a number of developments that help illustrate the critical role that the Indian judiciary is playing in promoting the public interest in the patent system pursuant to the TRIPS provisions. To start with, a decision by the Indian Patent Office in response to a pre-grant opposition filed by the Indian Network for People Living with HIV/AIDS (INP+) rejected the patent application of Boehringer Ingelheim (BI) relating to a paediatric formulation of nevirapine, a critical first-line AIDS medicine, as inconsistent with the reasonable requirements of the public.²⁵³

In considering the patent opposition, the patent office cited the Madras High Court's judgment in the *Novartis* case, and agreed with the opponents that it needed to 'give a strict interpretation of patentability criteria, as a decision... thereof shall affect the fate of people suffering from HIV/AIDS for want of essential medicine'.²⁵⁴ Applying these strict criteria, the patent office concluded that BI's application, which covered a pharmaceutical composition of a specific crystal form of nevirapine along with a variety of common inactive pharmaceutical ingredients, could not be considered an invention under Indian law under both sections 3(d) and 3(e), the latter excluding 'mere admixtures' from patentability.²⁵⁵

²⁵² *Novartis AG and Another v Union of India and Others*, WP (C) 24759 and 24760 of 2006, HC Mad, 6 August 2007 (High Court of Madras, India (IHCM)).

²⁵³ *Boehringer Ingelheim Pharmaceuticals, Inc v Indian Network for People Living with HIV/AIDS*, 11 June 2008 (Indian Patent Office, Delhi)
<static1.1.sqspcdn.com/static/f/129694/5244519/1262645549853/Boehringer+Ingelheim+-+Nevipramine+Hemihydrate.pdf?token=qYvJH%2F9yRtoYR7vYjOdg3vemGXc%3D> accessed 28 November 2016.

²⁵⁴ *ibid* 3.

²⁵⁵ *ibid* 13, 14.

Additionally, in patent infringement cases, some courts have refused to automatically hand out injunctive relief that prohibits the commercialisation of a patented product. Such injunctive relief can be sought as a remedy by multinational pharmaceutical companies against generic producers. The Indian courts have argued, as have the US courts since the *eBay Inc v MercExchange LLC* Supreme Court decision,²⁵⁶ that they must weigh up the public interest in choosing the appropriate remedy, as the familiar principle of equity suggests that the public interest may not be served by an injunction.

The Indian courts have argued that the public interest includes the potential risk of denying patients access to life-saving medicines. As noted above, the provisions of the Indian Patent Act provide a lot of room for interpretation and each time the judiciary plays the role of final arbitrator on disputes related to the interpretation of law and facts, the public interest is considered.²⁵⁷ In the last five years, the courts have examined three important issues with regard to patent law. As mentioned earlier, the Madras High Court dismissed the petition of Novartis, which challenged the constitutional validity of section 3(d) of the Patents Act.

In another case, the Single Bench²⁵⁸ and Division Bench²⁵⁹ dismissed a petition by Hoffmann-La Roche, seeking a preliminary injunction against a generic manufacturing company to prevent it from producing the anticancer drug erlotinib. While dismissing the preliminary injunction, the Single Bench noted that:

[T]he court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a lifesaving drug, the balance has to be tilted in favour of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public would be deprived of the defendant's product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable.²⁶⁰

²⁵⁶ *eBay Inc* (n 179).

²⁵⁷ KM Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' (2010) 3 Law and Development Review 326, 357.

²⁵⁸ *F Hoffmann-La Roche Ltd and Another v Cipla Limited* 148 (2008) DLT 598 (Delhi High Court, India (IHCD)).

²⁵⁹ *F Hoffmann-La Roche and Another v Cipla Limited*, FA (OS) 188 of 2008, HC Del, 24 April 2009 (IHCD).

²⁶⁰ *Hoffmann-La Roche* (n 258) [86].

The Division Bench of the Delhi High Court, while dismissing the appeal against the order of the Single Bench, found that the petitioner, Hoffmann-La Roche, agreed with the Single Bench judge on the question of public interest while issuing the injunction. The Division Bench held that:

[T]he question of general public access in our country to life saving drugs assumes great significance and the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for. This Court finds no ground to differ with the reasoning or the conclusions arrived at by the learned Single Judge on this aspect.²⁶¹

The Division Bench also found that the petitioner had suppressed material facts and failed to disclose the complete invention. Therefore the court dismissed the petition with cost and ordered to pay the defendant Rs. 500,000 (approximately USD7,500).²⁶² Both the *Hoffmann-La Roche* judgement and the INP+ decisions explicitly placed the need to promote access to medicines as background considerations within the primary legal framework of the patent law. The *Hoffmann-La Roche* decision stated:

[U]ndoubtedly, India entered into the TRIPS regime, and amended her laws to fulfil her international obligations, yet the court has to proceed and apply the laws of this country, which oblige it to weigh all relevant factors. In this background the Court cannot be unmindful of the right of the general public to access lifesaving drugs which are available and for which such access would be denied if the injunction were granted.²⁶³

The third important case decided by the Delhi High Court concerned Bayer's writ petition seeking court intervention to prevent the Drug Controller General of India (DCGI) from issuing a manufacturing licence to generic companies for patented medicine.²⁶⁴ This was an attempt to establish a 'patent linkage' in India through court orders to prevent the issuance of manufacturing licences for patented medicines. This would have turned the DCGI into a *de facto* enforcing authority for patented medicines. Such a linkage between patent and drug registration would have undermined the TRIPS flexibilities, such as early working (Bolar provision),²⁶⁵ parallel importation, and compulsory licences. While dismissing the writ petition

²⁶¹ *Hoffmann-La Roche* (n 259) [85].

²⁶² *ibid* [87].

²⁶³ *Hoffmann-La Roche* (n 258) [85].

²⁶⁴ *Bayer Corp and Others v Union of India and Others*, WP (C) 7833 of 2008, HC Del, 18 August 2009 (IHCD). See also Gopakumar (n 257) 358.

²⁶⁵ Patent Act (RSC, 1985, c P-4) (Canada), s 55.2(1). This 'regulatory review provision' was the subject of a WTO dispute in WTO, *Canada – Patent Protection of Pharmaceutical Products—Report of the Dispute*

with costs of Rs. 600,000 (approximately USD9,000) to be paid to the respondents, the court remarked that:

[T]his court is constrained to observe that the present litigation was what may be characterized as a speculative foray; an attempt to “tweak” public policies through court mandated regimes. The petitioner doubtless is possessed of vast resources and can engage in such pursuits. Yet, often, these attempts, even unsuccessful in the ultimate analysis, achieve short-term goals of keeping out competitors, through interim orders. That short term objective has been achieved, and the petitioner has successfully stalled an independent examination of Cipla’s application.²⁶⁶

Significantly, in 2009, the Division Bench of the Delhi High Court affirmed the decision of the Single Bench.²⁶⁷

In the *Natco v Bayer*²⁶⁸ case, Bayer made several attempts to oppose the granting of a compulsory licence. Not satisfied with the IPAB decision, Bayer subsequently moved to the High Court in Bombay, India, seeking relief by way of a writ petition, which sought to challenge the decision by the IPAB on the grounds that it was arbitrary, which was dismissed.²⁶⁹ Not satisfied with the High Court’s decision, Bayer appealed to the Indian Supreme Court with a special leave petition. Bayer submitted that the Bombay High Court, in its judgment, had made unsustainable findings on several questions of law and fact.²⁷⁰ Bayer contended, for instance, that while considering whether the patentee under section 84(1) of the Indian Patent Act had met the reasonable requirements of the public, the Bombay High Court had erred in its interpretation of the law. Bayer further claimed that compulsory licensing was a violation of its patent rights consistent with Article 27(1) of TRIPS.²⁷¹ Refusing to accept the submission, the bench, comprising Justice Ranjan Gogoi and Justice Rohinton Nariman, on 12 December 2014 dismissed the Special Leave Petition.²⁷² The Court, on 12 December 2014,

Panel (17 March 2000) WT/DS/114/R. Note that the Panel confirmed the consistency of the ‘Bolar Exception’ with TRIPS at [7.105].

²⁶⁶ *Bayer Corp* (IHCD) (n 264) [53].

²⁶⁷ *Bayer Corp and Another v Union of India*, LPA 443 of 2009, HC Del, 9 February 2010 (IHCD).

²⁶⁸ *Bayer Corp* (ICP) (n 54).

²⁶⁹ *Bayer Corp* (BHC) (n 59).

²⁷⁰ *Bayer Corp* (ISC) (n 60).

²⁷¹ *ibid.*

²⁷² *ibid.*

made the following order: ‘In the facts of the present case, we are not inclined to interfere. The Special Leave Petition is dismissed, keeping all questions of law open’.²⁷³

India is the perfect demonstration of the fact that the TRIPS Agreement leaves developing countries far more flexibility in the area of medicine than is generally recognised. The creative interpretation and extensive implementation of flexibilities has helped India to reach a good balance between a harmonised IP and public health protection.²⁷⁴ Given the *Novartis* case in particular and several other judicial decisions mentioned above, Africa should be able to approach India for South-South judicial cooperation with a view to training judges in the protection of public health in IP-related matters. Central to this recommendation is the fact that the Indian judiciary has, through successive decisions, understood that the reasonable requirement of the public pursuant to patent law is subject to human rights considerations for the promotion of access to medicines.

L SOUTH–SOUTH COOPERATION WITH INDIA FOR THE TRAINING OF JUDGES: A POLICY OPTION FOR AFRICAN COUNTRIES

One central question is whether India is ready to provide technical assistance to African countries and, if so, on what terms. It must be noted that African and Asian countries have a long-standing operational framework for cooperation on the Bandung principles, which sets out a comprehensive conceptual structure of technical cooperation among developing countries.²⁷⁵ Specifically, India and Africa have a long history of partnership,²⁷⁶ even if this is not effective. In Africa and India, domestic expectations and democratic structures have evolved to a point where both sides need partners willing to work with them towards the fulfilment of their development requirements. The solidarity and complementarity between India and Africa reflect the new aspirations of their people. Driven by the time-tested principles of mutual benefit, understanding, and equality, the heightened pace of engagement marks the emergence of new dynamics in South-South cooperation.

²⁷³ *Bayer Corp* (ISC) (n 60).

²⁷⁴ Sidonie Descheemaeker, ‘India, Pharmacy of the Developing World IP, Trade and the Access to Medicine’ (2012–13) 49 *Jura Falconis* 543, 564.

²⁷⁵ Asian-African Conference of Bandung, ‘Final Communiqué’ (24 April 1955) <franke.uchicago.edu/Final_Communique_Bandung_1955.pdf> accessed 1 July 2016.

²⁷⁶ Ian Taylor, ‘India’s Economic Diplomacy in Africa’ in Ajay Kumar Dubey and Aparajita Biswas (eds), *India and Africa’s Partnership: A Vision for a New Future* (Springer 2016) 99, 102.

In recognition of the growing importance of Indian-African ties and prospects for much closer development cooperation, it was decided to convene regular India-Africa Forum Summits (IAFS).²⁷⁷ These Summits have laid the foundation of a new architecture for a structured interaction and cooperation between India and Africa.²⁷⁸ One of the strongest focuses of the current Indian partnership with Africa is the empowerment of people through capacity building and human resources development, which is specifically highlighted under the Indian-Africa Framework of Cooperation.²⁷⁹

It is worth noting that India's cooperation with Africa has had a positive impact in Africa.²⁸⁰ Importantly, India currently provides the world with one-fifth of its generics, of which about half are sent abroad to other developing countries, and Africa is a major beneficiary.²⁸¹ India has a key role in Africa's development process and lays particular emphasis on capacity building in different African countries. India recognises Africa's need for human resources development in overcoming the gap in development.

In the multilateral sphere, India has been a very active proponent of, and willing participant in, programmes such as the Special Commonwealth Assistance for Africa

²⁷⁷ The first of these summits was held from 4–8 April 2008 in New Delhi, India. The second summit was held in Addis Ababa, Ethiopia, in 2011, and the third was again held in New Delhi, India.

²⁷⁸ Ruchika Singh Malyan and Lokesh Jindal, 'Capacity Building in Education Sector: An Exploratory Study on Indian and African Relations' (2014) 157 *Procedia - Social and Behavioral Sciences* 296, 301.

²⁷⁹ India-Africa Forum Summit, 'Delhi Declaration 2015' (29 October 2015) [vii], [viii]. <mea.gov.in/Uploads/PublicationDocs/25980_declaration.pdf> accessed 16 August 2016.

²⁸⁰ UNCTAD, *Economic Development in Africa Report 2010: South-South Cooperation: Africa and the New Forms of Development Partnership* (United Nations 2010) 17 (mentioning trade and investment, technical assistance, and infrastructure finance through loans).

²⁸¹ Campaign for Access to Essential Medicines, 'Examples of the Importance of India as the "Pharmacy of the World"' <www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_PharmacyForDevelopingWorld_India_ENG_2007.pdf> accessed 14 August 2016, stating that 80 per cent of ARVs MSF uses are purchased in India and distributed in treatment projects in over 30 countries. Approx. 50 per cent of the essential medicines that UNICEF distributes in developing countries comes from India. 75–80 per cent of all medicines distributed by the International Dispensary Association (IDA) to developing countries are manufactured in India. Globally, 70 per cent of the treatment for patients in 87 developing countries, purchased by UNICEF, IDA, the Global Fund (GFATM), and the Clinton Foundation since July 2005 has come from Indian suppliers. PEPFAR, the US President's AIDS initiative also purchases ARVs from India for distribution in developing countries, thus resulting in cost-savings of up to 90 per cent. 89 per cent of the generic ARVs approved by the US Food and Drug Administration for PEPFAR are from India.

Programme.²⁸² India is a full member of the Africa Capacity Building Foundation (ACBF).²⁸³ ACBF was established by African Governments and their Development Partners to help build sustainable human and institutional capacity for good governance and economic development management. To date, the Foundation has empowered governments, parliaments, civic society, the private sector, and higher education institutions in more than 45 countries and 6 regional economic communities. ACBF supports capacity development through investment, technical support, knowledge generation, and sharing across Africa. India became the first Asian country to become a full member of the ACBF and pledged USD1 million towards the foundation's sustainable development.²⁸⁴

Stating India's commitment to Africa's capacity building in his special address during the inaugural session of the two-day 11th CII-EXIM Bank Conclave on India Africa Project Partnership organised in New Delhi, General (Rtd) VK Singh, the Indian Minister of State for External Affairs, said that India's economic resurgence will have a continued positive bearing on Africa's development initiatives. He said that 'capacity building is an important element of cooperation between India and Africa and this engagement is required to forge development with the continent'.²⁸⁵ He further reiterated that:

[W]e feel that capacity building will always remain as a very important element of our cooperation. Our approach of development has always been because we believe that when you partner for development you must build capacities and capabilities in that country and it should not be extracted in your engagement.²⁸⁶

Consequently, India has augmented its development package pursuant to capacity building for Africa. India's support for the New Partnership for Africa's development initiative since its inception in 2001 is another step that is indicative of its efforts to assist Africa in

²⁸² Malyan and Jindal (n 278) 299.

²⁸³ *ibid* 300.

²⁸⁴ Sanusha Naidu, 'Upping the ante in Africa: India's increasing footprint across the continent' in Emma Mawdsley and Gerard McCann (eds), *India in Africa: Changing Geographies of Power* (Pambuzuka Press 2011) 48, 60.

²⁸⁵ PTI, 'Capacity building vital for India-Africa cooperation: VK Singh' (*The Economic Times*, 14 March 2016) <articles.economictimes.indiatimes.com/2016-03-14/news/71509489_1_vk-singh-india-africa-india-africa-summit> accessed 15 August 2016.

²⁸⁶ *ibid*.

achieving its development goals.²⁸⁷ Human capacity and institutional building initiatives, including those relating to the judiciary and the health and pharmaceutical sectors, were formally identified as a joint priority.²⁸⁸ More specifically, India pledged to provide Africa with extensive programmes, capacity building, training and skills development, the setting up of training institutes, and the provision of scholarships for Africans to study at Indian institutions of higher learning.²⁸⁹

For historical reasons, the legal systems of India may be different from countries in Africa. Within this conceptual view, the most fundamental question is whether, given the lack of cooperation in the judicial arena and the difference in the structural underpinnings pursuant to their legal traditions, capacity building in the judiciary can be effective. Nevertheless, these concerns do not arise because several developed countries with different legal traditions continue to give various forms of technical assistance to African countries. A classic example is the Swiss-Ghana Intellectual Property Project.²⁹⁰

Remarkably, India has some good institutes, under its central government control within the Ministry of Commerce and Industry,²⁹¹ which are engaged in conducting training programmes relating to IPRs and could be used to train Africans, as nothing of this kind exists anywhere in Africa. More importantly, under the 2016 Indian IP policy, the country stresses the need to enhance international and bilateral cooperation and coordinate with Indian Missions

²⁸⁷ Ajay Debey, 'Looking West 3: Africa' in David Scott (eds), *Handbook of India's International Relations* (Routledge 2011) 189, 195.

²⁸⁸ James Thuo Gathii, *African Regional Trade Agreements as Legal Regimes* (CUP 2011) 416.

²⁸⁹ Nivedita Ray, 'Third India-Africa Forum Summit: Priorities, Proposals and Prospects' (Issue Brief, Indian Council of World Affairs, 16 November 2015) 5, 6
<www.icwa.in/pdfs/IB/2014/ThirdIndiaAfricforumsummitIB16112015.pdf> accessed 16 August 2016.
See also Navdeep Suri, 'India and Africa: Contemporary Perspective' in Atish Sinha and Madhup Mohta (eds), *Indian Foreign Policy: Challenges and Opportunities* (Academic Foundation 2007) 507, 515, stating 1 billion worth of assistance including training.

²⁹⁰ Swiss Federal Institute of Intellectual Property, 'Swiss-Ghana IP Project, Phase II (SGIP II)' <www.ige.ch/fileadmin/user_upload/Juristische_Infos/e/factsheet_ghana.pdf> accessed 20 August 2016.

²⁹¹ The Rajiv Gandhi National Institute of Intellectual Property Management <www.ipindia.nic.in/rgniipm.htm> accessed 28 November 2016; National Judicial Academy India <<http://www.nja.nic.in/>> accessed 19 August 2016.

abroad to follow IP developments and advice on IP-related matters.²⁹² The policy further states that continued efforts should be made towards the promotion of technical cooperation with IP offices in other countries in areas such as capacity building and human resource development.²⁹³ Having committed to providing African countries with human and institutional capacity building initiatives, African countries are free to request that India tailors this technical assistance to the training of judges in IP matters.

M CONCLUSION

As seen above, by virtue of the dispensation given to LDC members of the WTO by the TRIPS Council, they generally have the right not to enforce patents on pharmaceutical products. Notwithstanding this, LDCs in Africa have notably failed to implement the flexibilities inherent in the TRIPS Agreement to promote their public health interests. This is largely due to the fact that several capacity issues ranging from institutional to resource-based inadequacies exist. Admittedly, today, development cooperation is populated by more actors, and is delivered through several modalities.²⁹⁴ In fact, the diversified development cooperation landscape offers developing countries a wider array of options from which to choose, with large potential benefits to their development processes.

Throughout this analysis, it has been shown that international cooperation could help developing countries, and in particular LDCs in Africa, to gain capacity either through the North-South or South-South model.²⁹⁵ However, as they currently choose the path of the North-South model, the capacity building initiatives that exist today have not translated into actual capacity, or capacity has not improved substantially. Unfortunately, even with substantive common ground among developing countries, which calls for stronger collaboration, the principles of South-South cooperation have so far received little attention, although there is no

²⁹² Indian Department of Industrial Policy & Promotion, 'National Intellectual Property Rights Policy' (12 May 2016) [4.15] <https://www.vtpckarnataka.gov.in/wp-content/uploads/2016/05/National_IPR_Policy_12.05.2016.pdf> accessed 19 August 2016.

²⁹³ *ibid* [4.11].

²⁹⁴ 'Pharmaceutical Production and Related Technology Transfer: Landscape Report' (World Health Organisation, 2011) 35 <http://www.who.int/phi/publications/Local_production_and_access_to_medicines.pdf> accessed 10 April 2017.

²⁹⁵ UNGA, 'Report of the World Summit on Sustainable Development: Johannesburg, South Africa, 26 August – 4 September 2002' (2002) UN Doc A/CONF.199/20, [90(d)], [90(e)].

doubt that the South-South model could be a logical platform for African countries to build capacity.

What we learn immediately from this vacuum is that there is a lack of dynamism in thinking, and this has tended to render the South-South model redundant. Thus, African countries generally lack innovative momentum or motivation to pursue the South-South model in their governance arrangements for promoting cooperation with other like-minded countries. This exists partly because the trend known to many policymakers is that of the North-South model, which is often linked to comparatively rich and powerful states. Nevertheless, it appears that developed countries have commonly failed to inform developing countries as to their right to implement the TRIPS safeguard measures to obtain essential medicines, which remains a component of the right to health.

Significantly, this is not to suggest that developing countries should ignore completely the North-South model, however, in thinking about policy direction a key distinction is whether South-South model may not provide them with a practical policy experience necessary for the implementation of compulsory licensing to obtain essential medicines. For instance, the experience of Brazil, India, and Thailand provide an illustrative example of this point, except that in the context of Africa the situation is more complex given several internal capacity constraints, including unviable local industries and small market size.²⁹⁶ Moreover, there are certain general categories of legal tradition that differentiate the legal systems of Africa from that of India. Still, the judiciary, as seen in the case of India, remains a significant institution that could play an active role in the interpretation of TRIPS provisions consistent with human rights norms to promote access to medicines. However, there is no doubt that the African judiciary simply lacks the capacity in IP matters.²⁹⁷ It is on this basis that the author concludes that it is time to test a new model in capacity building based on South-South judicial cooperation with India.

This contention is premised on the understanding that judicial cooperation with India may offer African countries a logical platform for them to build capacity to promote a health

²⁹⁶ Dirceu B Greco and Mariangela Simão, 'Brazilian Policy of Universal Access to AIDS Treatment: Sustainability Challenges and Perspectives' (2007) 21(Suppl 4) AIDS 37, 41.

²⁹⁷ See text to n 61.

sensitive interpretation of IP regimes consistent with human rights instruments as the Indian judiciary has done consistently. A more advanced form of cooperation that could be used is mutual technical assistance. This draws conceptually on the principle of mutual recognition based on the mutual trust that already exists between African countries and India. Within this essence, African countries could reach out to India in order to set up specific structures to facilitate mutual assistance and support cooperation between the two.

As WTO members, developed countries have an obligation to provide technical and financial assistance under Article 67 of TRIPS in meeting the obligation underlined in Article 66(2) of the Agreement.²⁹⁸ This is a legal duty, which is also codified by the DA under WIPO. Usually, technical assistance under WIPO's mandate reflects a measure that appears to be a central component of the organisation's deliberations, which demonstrates the potential sensitivity and importance of domestic IP regulatory policymaking. The TRIPS Agreement, in its Preamble and in Article 66(2), recognises the special needs of developing countries, LDC members in particular, in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enhance innovation and the technology infrastructure to promote domestic socio-economic welfare.

In order to facilitate the implementation of the Agreement, Article 67 of TRIPS stipulates that:

[D]eveloped country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

It is clear from this provision that developed countries have an affirmative legal duty, subject to request and on mutually agreed terms and conditions, to provide technical and financial cooperation in favour of developing and LDC members. While the language of TRIPS suggests that technical capacity building is a condition for TRIPS to achieve its intended purpose of contributing to the promotion of technological innovation, the transfer and

²⁹⁸ WTO, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' WT/L/540, 2 September 2003 [6(ii)&7]
<http://www.who.int/medicines/areas/policy/WT_L_540_e.pdf?ua=1> accessed 17 February 2017.

dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and a balance of rights and obligations, it follows that capacity building remains demand driven.

Therefore, in this particular case, Africa should be the principal actor in the process, and as a matter of legal logic, developed countries will not generally object to any requests that are made regarding the building of national initiatives on capacity consistent with the objectives of the WIPO DA for IP matters. This conclusion is relevant, as the guiding principles established by the Doha Declaration pursuant to the TRIPS flexibilities and also reaffirmed in the 2001 Doha Ministerial Declaration recognised the importance of technical assistance and capacity building for developing countries and LDCs.

AUTHOR NOTES

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