journals.unizik.edu.ng/index-php/jcpl
ISSN: 2736-0342
NNAMDI AZIKIWE UNIVERSITY, AWKA
JOURNAL OF COMMERCIAL AND PROPERTY LAW

TRIPS Compliance and Biotechnology Patenting in Africa: Lessons from India

Aishatu Eleojo Adaji*

Abstract

This paper considers India's obligation under the TRIPS Agreement 1994 (as amended) in relation to biotechnology patents. Specifically, it examined how India has incorporated the TRIPS provisions into its patent law to provide insights for African countries on meeting their international obligations while considering their national interests in biotechnology research and innovation to address pertinent issues such as nutrition, food security and public healthcare. As in the past two decades, African countries have been amending their patent laws to bring them in conformity with the TRIPS Agreement 1994 (as amended), it is strongly recommended that they leverage the policy space under the TRIPS Agreement 1994 (as amended) like India to ensure nutrition, food security and public healthcare in the continent.

Keywords: biotechnology, TRIPS Agreement, India, Patent, Africa

1. Introduction

India's biotechnology sector has been experiencing significant growth over the years. Biotechnology is recognised as a sunrise sector in India and a key enabler driving the country's bio-economy.[1] In the past 8 years, India's bio-economy has grown 8 times from $10 billion to $80 billion, with the number of biotechnology start-ups increasing from 50 to 5300.[2] Currently, India is ranked 12th in the biotechnology sector worldwide, 3rd in the Asia Pacific region, and the world's largest vaccine manufacturer.[3] These biotechnological advances are being propelled primarily by the interventions of the Indian government through its various agencies, including its Department of Biotechnology (DBT).[4]

India, like most countries in the African continent, including Nigeria, is a signatory to the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994 (as amended), which mandates member countries to provide patent protection for all technological fields, including biotechnology. Therefore, this paper analyses how India has incorporated the TRIPS provisions into its patent law to provide insights for African countries on meeting their international obligations while considering their national or domestic interests in biotechnology to address pertinent issues such as nutrition, food security and public healthcare. The analysis is presented in two parts. First, India's legislative experience is analysed to understand India's current approach to biotechnology patents. Thereafter, the paper analyses the current provisions of India's Patent Act 1970 (as amended) in relation to biotechnological inventions, focusing on the affordability of healthcare and food and nutritional security.

* **Aishatu Eleojo Adaji,** PhD,LL. B (Hons), BL, LL.M., PhD, Faculty of Law, Osun State University, Osogbo, Nigeria. Phone Number: 08023496370/08064414854**.** Email Address:eleojo.adaji@uniosun.edu.ng / aishatudaji@gmail.com

[1] India's Department of Biotechnology, 'Annual Report 2022-23' 2 <https://dbtindia.gov.in/sites/default/files/Final%20Annual%20Report%20English%202022-23.pdf> accessed 10 May 2024.

[2] Ibid.

[3] Ibid.

[4] India's Department of Biotechnology, 'Introduction' <https://dbtindia.gov.in/about-us/introduction> accessed 10 May 2024.

2. India's Pre-TRIPS Legislative Experience

As in the case of Nigeria, Ghana, South Africa, Kenya and other African countries, India's intellectual property rights system, and the patent system in particular, was imposed during British colonial rule, and as such, the Indian patent system was initially driven by British-made laws, which introduced a strong patent regime. The first legislation in this regard was enacted in 1856, following which a series of legislative acts culminated in the Indian Patents and Designs Act 1911, replacing all previously existing Acts.

The 1911 Act, still in force when India gained independence in 1947, was subject to further amendments, establishing a stronger patent regime in India. Of this, critics are of the view that the Indian Patents and Designs Act of 1911 was configured mainly to cater for the mercantilist interests of the British Empire and the West in general, echoing the situation in Nigeria and many other colonies.[5] As a result, the patents were mostly secured by foreign nationals and were not worked in India, but were held primarily to secure a monopoly over the importation of finished goods as the prevailing patent regime granted patent not only for process but for products as well.[6] This stunted the development of indigenous industries and rendered India dependent on the industrialised West for basic necessities, including medicine, at unaffordable prices.[7] Specifically, it is stated that in India, 'critical drugs such as insulin or penicillin were priced well out of the reach of large sections of the population'.[8] Yet, it is believed that most of the finished products were produced from raw materials obtained cheaply from India and other colonies.[9]

Hence, following the attainment of independence from the colonialists, India sought to establish a patent regime more in tune with the country's technological and economic status as it looked to become self-reliant.[10] To achieve this objective, two different committees were set up. Reportedly, the first committee appointed in 1949, Justice Bakshi Tek Chand Committee, found that *inter alia* the prevailing patent regime in India provided 'inequitably strong intellectual property protections' to foreign nationals while severely inhibiting the development of India's local manufacturing sector.[11] Specifically, the Committee recommended that India's patent law should contain a clear provision that would ensure that 'food and medicine and surgical and curative devices are made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee'.[12]

Based on the recommendations of the first Committee, the Indian Patents and Designs Act, 1911 was amended twice, in 1950 and 1952.[13] Part of the amendments provides for the grant of

---

[5] HK Singh and AR Khanna, 'India's IPR Regime: Reconciling Affordable Access with Patent Protection' (Strategic Studies Programme, Indian Council for Research on International Economic Relations, 2015) 4 - 8 <http://icrier.org/pdf/India's_IPR_Regime.pdf> accessed 30 April 2024; See also US Racherla, 'Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry' In Liu KC and Racherla U (eds) *Innovation, Economic Development, and Intellectual Property in India and China*. ARCIALA Series on Intellectual Assets and Law in Asia. (Springer, Singapore, 2019) 276.

[6] HK Singh and AR Khanna (n5); US Racherla (n5).

[7] Ibid.

[8] HK Singh and AR Khanna (n5) 4.

[9] Ibid.

[10] This is opposed the situation obtainable in Nigeria and some other African countries where the inherited patent system has remained essentially the same.

[11] US Racherla (n5) 276-277; See also HK Singh and AR Khanna (n5) 5.

[12] US Racherla (n5) 276-277; DP Verma, 'Critical Review of Indian Legal Regime on Patent System to be Harmonious with TRIPS Agreement' (PhD. Thesis, Himachal Pradesh University, India 2009) 35.

[13] US Racherla (n5) 276-277; DP Verma (n12).

compulsory licensing over 'patents in respect of food and medicines, insecticide, germicide or fungicide and a process for producing substance or any invention relating to surgical or curative devices'.[14] But by most accounts, it was the detailed report of the second committee, Justice N. Rajagopala Ayyangar Committee appointed in 1957, that provided the necessary blueprint for the Indian Patent Act of 1970, which repealed and replaced the Patents and Designs Act, 1911 with specific regard to the patent.[15] Their observations and recommendations brought about major changes in the Indian patent regime, particularly with regard to inventions for food and medicine.

Accordingly, to serve the country's interest, patentability was confined to processes in certain respects, particularly where the product results from chemical processes or is 'intended for use, or capable of being used, as food or as medicine or drug'.[16] In addition, while the term of protection for every patented invention was limited to 14 years, that of process patents relating to food and medicine was reduced to 5 or 7 years, as the case may be.[17] Furthermore, detailed provisions for compulsory licensing and working of patents are set out with particular emphasis on food and medicine, given the experience of India and other developing countries regarding product patents.[18]

Specifically, although there were no explicit provisions on biotechnology, the above provisions tend to restrict the scope and duration of protection for biotechnology. This is especially true in the aspects of agricultural biotechnology and biopharmaceuticals, where only biotechnological processes may be patentable as opposed to the products derived therefrom. It is opined that the grant of patents on process claims that is used for the production of substances containing life forms was barely in practice until 2002 when the Calcutta High Court in *Dimminaco AG. v Controller of Patents, Designs and Trade Marks (Dimminaco)* established that patent is obtainable for a process whose end-product involves a living virus.[19] But in this case, the Court also pointed out that a patent had previously been granted by the Indian authority regarding the process for preparing a therapeutic substance used for the treatment of diarrhoea, with the end products consisting of live *Lactobacillus (L.)reuteri* cells.[20] Notwithstanding, it is believed that *Dimminaco* paved the way for biotechnology patents in India.[21] As a result, it is considered as important as the United States' case of *Diamond v. Chakrabarty*,[22] at least in the Indian context.

The Indian Patent Act of 1970, before subsequent amendments, is considered a model for other developing countries.[23] It took into consideration the country's developmental needs, as it sought to create a balance between India's national interests and ambition to build a self-reliant economy

---

[14] Intellectual Property India, 'History of Indian Patent System' <https://ipindia.gov.in/history-of-indian-patent-system.htm#:~:text=Brief%20about%20Indian%20Patent%20System,disclose%20secret%20of%20their%20inventions.> accessed 10 May 2024; DP Verma (n12) 35.

[15] Although the Indian Patents and Designs Act 1911 continued to apply to designs. See US Racherla (n5) 276-279; See also Intellectual Property India (n14); HK Singh and AR Khanna (n5) 5; DP Verma (n12) 35-37.

[16] Article 5 of the Indian Patent Act, 1970, provides for subject matters excluded from product patent protection.

[17] Article 53 (term of patent) of the Indian Patent Act, 1970.

[18] Articles 82-98 (setting out provisions for working of patents and compulsory licensing, among others); See also Articles 99-103 (providing for the use or acquisition of inventions by Government).

[19] (2002) IPLR.July 255, 269.

[20] *Lactobacillus reuteri* (*L. reuteri*) is a specie of bacteria.

[21] KK Singh, *Biotechnology and Intellectual Property Rights: Legal and Social Implications* (Springer, New Delhi, India 2015) 100.

[22] (1980) 447 U.S. 303.

[23] DP Dineshkumar, 'Impact of Product Patent Regime on Public Health Policy under Patents Law in India: A Critical Study' (PhD. Thesis, Gulbarga University, Kalaburagi, India, 2016) 39; DP Verma (n12) 53.

and indigenous industries on the one hand and the private interests of inventors on the other. This is especially true by excluding critical sectors such as medicine and agriculture from the product patent regime and granting shorter terms regarding the process patent. It was driven by the philosophy encapsulated in section 83 of the Act, which is to the effect that 'patents are granted to encourage inventions' and not 'merely to enable patentees to enjoy a monopoly for the importation of the patented article'.

Significantly, the Indian patent law was to counter the practice of foreign firms who obtain patents in India merely to monopolise importation. It is often argued that this approach to patents obtainable under the Indian Patents Act of 1970 played a significant role in India's economic and industrial development, with the pharmaceutical sector often used as an example.[24] Rejecting a strong intellectual property system, India rose to become the 'pharmacy of the world', providing drugs at reasonably affordable prices not only to Indians but the poor population of many other developing countries, including Nigeria and sub-Saharan Africa.[25]

However, with specific regard to the Indian pharmaceutical sector, some contributors suggest that while the generic drug industry was booming, there was stagnation in pharmaceutical research and the development of new drugs.[26] Supposing the assertion is true, it can nevertheless be argued that a product patent regime is not the solution, as exclusive rights can adversely impact access and further research and innovation.[27] Once a product patent is granted, others are prevented from developing the same product through another process, allowing patent holders to impose high monopolistic prices. Process patents, conversely, are more permissive, as substances with the same or similar composition can be manufactured without constituting infringement.

Particularly, the position of India before and after 1970 indicates that innovation can be better advanced under a far less stringent intellectual property system. Moreover, it is shown that, besides the low product prices obtainable under the process patent regime of India, 'it also became possible to produce many new pharmaceutical products in India much faster than what could have been otherwise', with the time lag ranging between four and six years only.[28] It is believed that during the process-patent regime, pharmaceutical companies in India accumulated extensive experience and trained their own technical personnel.[29] Specifically, in counter to the earlier assertion, there are suggestions that some local pharmaceutical companies further embarked on medicinal research and development to the extent that they could apply for drug patents in both the United States and the European Union.[30]

---

[24] US Racherla (n5) 280; DP Verma (n12) 37.

[25] S Basheer and P Agarwal, 'India's New IP Policy: A Bare Act' The Indian Journal of Law and Technology (2017) 13 1, 22; See also PK Yu, 'China's Innovative Turn and the Changing Pharmaceutical Landscape' University of the Pacific Law Review (2020) 51 593, 594. <https://ssrn.com/abstract=3437632> accessed on 30 April 2024.

[26] HK Singh and AR Khanna (n5) 5-6; US Racherla (n5) 276.

[27] AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents on Public Health and Food Security in Nigeria' Institute Journal of Administration & Law (2024) (forthcoming).

[28] J He, 'Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?'. In Liu KC and Racherla U (eds) *Innovation, Economic Development, and Intellectual Property in India and China*. ARCIALA Series on Intellectual Assets and Law in Asia. (Springer, Singapore 2019) 258.

[29] Ibid, 259.

[30] Ibid; See also DP Verma (n12) 54-55; JM Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' University of Pittsburgh Law Review (2007) 68(3) 491, 500 <https://ssrn.com/abstract=923538> accessed on 30 April 2024 (maintaining that beside the software and information technology sector, India is experiencing rise in research and innovation within the pharmaceutical and

Be that as it may, Joseph's argument about the growth of the Indian generic pharmaceutical industry is very instructive with regard to biotechnology research and development in Nigeria and other developing countries. He opined thus: '[w]hile the Patents Act, 1970 played a significant role in the emergence of a strong generic pharmaceutical industry in India, it was the innovation ecosystem created in India by the Government, public sector pharma industry and universities that actually helped innovations to happen in the field of pharmaceuticals'.[31]This assertion particularly underscores the public sector's role in a country's technological development. In other words, the Indian government issued policies suitable for research and innovation and took other concrete steps through its various agencies, directly engaging in the technological research and innovation process.

As a member of the World Trade Organisation, India has had to make a series of amendments (in 1999, 2002 and 2005) to the Patents Act of 1970 to meet the TRIPS obligations and thereby pave the way for stronger protection of biotechnological inventions.[32] Among other major changes, section 5 of the then Indian Patents Act, 1970, restricting protection process patents in certain regards, was repealed, with the product and process patent regime now provided for all forms of inventions in line with the minimum standards under Article 27 of the TRIPS Agreement, 1994 (as amended).[33] In addition, the term of protection is generally extended to 20 years, also to meet the minimum requirement of the TRIPs Agreement, 1994 (as amended).[34]

While India may have succumbed to international pressure, many lessons can be drawn from its legislative process regarding patents. First is India's historical adaptation of her patent law since independence. As evident from the legislative history discussed above, the government of India has been mindful of the nation's interests, its human rights obligations to the people and its emerging leadership role in promoting access to affordable drugs and various other technologies for developing countries and Africa in particular. In line with these socio-economic and technological goals, it has often taken deliberate steps to stimulate the indigenous industries by specifically formulating policies or enacting laws that prioritise the interest of indigenous innovators and manufacturers. This is exemplified more by India's process-patent-only policy, in contrast to patent regimes, such as Nigeria's, which had granted product patents before TRIPS.

The Indian government has shown some political will to adapt, modify and interpret international legal frameworks to its own advantage, as demonstrated in this paper. This is not to state that the recent changes, particularly in line with TRIPS, do not raise questions about India's obligation to offer stronger patent protection to biotechnological inventions against the commitments to public or domestic interests. Recognising the challenges ahead, India had tried to prepare the domestic industry by utilising the transition period provided under TRIPS.[35] In other words, India adopted

biotechnological fields contrary to the impression mostly from the West and the Multinational Companies that India is merely an imitator).

[31] RK Joseph, 'National IPR Policy of India and Innovation' Institute for Studies in Industrial Development Policy Brief (2016) 6 <https://www.researchgate.net/publication/305349240_National_IPR_Policy_of_India_and_Innovation> accessed 30 April 2024.

[32] For elaborate discussion on the individual amendments see, DP Dineshkumar (n23) 55-64; DP Verma (n12) 75-96.

[33]See section 2(1)(j) of the Indian Patent Act, 1970 (as amended).

[34] See section 53 of the Indian Patents Act 1970 (as amended).

[35] World Trade Organisation, 'Developing Countries' Transition Periods' <wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm> accessed 30 April 2024; See also, World Trade Organisation, 'Responding to Least Developed Countries' Special Needs in Intellectual Property' <wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm> accessed 30 April 2024.

a careful approach with the necessary amendments introduced in piecemeal. More significantly, recounts of the debates by the Indian legislature as regards the amendments show its understanding of the need to safeguard the interests of Indians, to say the least. While referring to the parliamentary debates on the Bill that culminated in the enactment of India's Patents (Amendment) Act of 2005, the Supreme Court of India in *Novartis AG v Union of India and Others* (*Novartis* case),[36] expressed the following views which are very instructive and reiterate the position taken above:

> *To anyone going through the debate on the Bill, Parliament would appear keenly alive to national interests, human rights considerations and the role of India as the producer and supplier of drugs to different parts of the world where impoverished humanity is critically in need of those drugs at cheap and affordable prices. Cutting across party lines, member after member from the Opposition benches highlighted the grave risk in creating private monopolies in an area like pharmaceuticals, the abuses to which product patents in pharmaceutical products were vulnerable, and the ploys used by big companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high. It was strongly argued that, while fulfilling its commitment under the TRIPS Agreement, the Government must not bring in a patent regime where all the gains achieved by the Indian pharmaceutical industry are dissipated and large sections of Indians and people in other parts of the world are left at the mercy of giant multinational pharmaceutical companies.*

Having enacted the relevant amendments, what is more important now is how India looks to fully take advantage of every flexibility and legislative space within the TRIPS Agreement, 1994 (as amended) to suit its domestic interests, particularly with regard to public health and food security. This would serve as a crucial lesson for Africa. India's approach to biotechnology patentability following the amendments to India's Patent Act of 1970 will now be considered.

3. Patentability of Biotechnological Inventions under India's 'TRIPS-Compliant' Patent Regime

With the amendment of the Indian Patent Act 1970, in accordance with the TRIPS Agreement, it is safe to argue that biotechnological inventions are generally patentable in India. Together with the decision in *Dimminaco*, it is believed that the patenting of biotechnology products and processes in India has legislative and judicial sanctions.[37] This is because, while the *Dimminaco* case was decided in relation to process patents, it also validates product patents for biotechnological inventions given that the said section 5 of the Indian Patent Act of 1970 before the amendments providing only for process patents with regards to chemical process and biotechnological process, in particular, had been deleted.[38]

As with patent laws in Africa, biotechnological inventions must pass the patentability standard tests of newness, inventiveness, and industrial applicability before being patented in India.[39]

---

[36] (2013) Civil Appeal Nos. 2706-2716, paragraph 79 (SC) <https://main.sci.gov.in/jonew/judis/40212.pdf> accessed 30 April 2024; (2013) All India Reporter (AIR) 1311; See also *Novartis AG v Union of India and Others* (2007) 4 MLJ 1153, 1297 (HC) (where the High Court of India had earlier taken a similar position).

[37] KK Singh (n22) 103.

[38] India's Patents (Amendment) Act 2005.

[39] Section 2(1)(j), (ac) and (ja) of the Indian Patent Act, 1970 (as amended); Section 1(1 – 3) of the Nigerian Patents and Designs Act 1970, Chapter P2, Laws of the Federation of Nigeria 2004; Section 3 of the Ghanaian Patents Act,

However, compared to the African patent laws, the Indian Patent Act of 1970 (as amended) is generally more detailed, providing safeguards in certain respects to align the patent system with India's national interests and ambition. Similar to the United Kingdom and other jurisdictions, the Indian Patent Office also publishes the 'Manual of Patent Office Practice and Procedure' to clarify the statutory provisions' application.[40] In all of these contexts, there are provisions of specific importance to patenting biotechnological inventions and innovations in India.

To begin with, section 3 of the Indian Patent Act, 1970 (as amended) provides an extensive list of non-patentable subject matters, which implicate the scope of biotechnology patents in India and are further elaborated upon by the Manual of Patent Office Practice and Procedure. As in most cases in Africa, some of the excluded subject matters bother on questions of public order or morality, discovery, plants and animals in whole or any part thereof other than microorganisms and essentially biological processes, among others.[41] By these, the discovery of any living thing occurring in nature, including microorganisms as opposed to genetically modified ones, seeds and plant varieties, methods for cloning humans and computer programs *per se*, among others, are not patentable subject matters under the Indian Patent Act, 1970 (as amended).[42]

Further leveraging TRIPS flexibilities, India makes provisions for additional exclusionary subject matters. One such exclusion of particular relevance to biotechnology patents is contained under subsection (d) of section 3 of the Indian Patent Act, 1970 (as amended), which deals on the evergreening of patents. Evergreening in the context of biotechnology is most common in medicines, particularly frustrating introduction and access to generic drugs while undermining further research and innovation.[43] Following the reintroduction of product patents, particularly in the pharmaceutical and biopharmaceutical sector, India saw the crucial need to curb this trend and safeguard public health.[44] To this end, section 3(d) of the Indian Patent Act, 1970 (as amended) considers as non-patentable:

> *the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any*

2003 (Act 657); Sections 22 – 25 of the Kenyan Industrial Property Act 2001 (No. 3); Section 25(1) of the South African Patents Act 1978 (Act No. 57 of 1978, as amended up to Patents Amendment Act 2005).

[40] The Office of the Controller General of Patents, Designs and Trademarks, 'Manual of Patent Office Practice and Procedure' (Version 3.0, 26th November, 2019). <https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf> accessed on 30 April 2024; The United Kingdom Manual of Patent Practice (MPOP) 2016 (as updated on 02 April 2024) <https://www.gov.uk/government/publications/patents-manual-of-patent-practice>accessed 30 April 2024; United Kingdom Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office, 2016. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/512614/Guidelines-for-Patent-Applications-Biotech.pdf> accessed 30 April 2024.

[41] Section 1(4 -5) Nigerian Patents and Designs Act 1970; Section 2 of the Ghanaian Patents Act, 2003); Section 26 of the Kenyan Industrial Property Act 2001; Section 25(2 – 4) of the South African Patents Act 1978.

[42] See the Indian Manual of Patent Office Practice and Procedure, 2011; Plant varieties are protected under the Indian Protection of Plant Varieties and Farmers' Rights Act of 2002; For discussions on the patentability of software in India, see B Dhar and RK Joseph, 'India's Information Technology Industry: A Tale of Two Halves' In Liu KC and Racherla U (eds), *Innovation, Economic Development, and Intellectual Property in India and China*. ARCIALA Series on Intellectual Assets and Law in Asia. (Springer, Singapore 2019).

[43] AE Adaji and RG Okplogidi (n27).

[44] SS Mondal and V Pingali, 'Competition and Intellectual Property Policies in the Indian Pharmaceutical Sector' Vikalpa (2017) 42(2) 61, 74. <https://doi.org/10.1177/0256090917704561> accessed 30 April 2024; LL Lee, 'Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India' Berkeley Tech. LJ (2008) 23 281, 285; JM Mueller (n29) 550-551.

> *new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*

But the above provision has been the subject of controversy between the developed countries, particularly United States and European Union on the one hand and India and various other developing countries 'like Argentina, Brazil, China, Indonesia, Malaysia, the Philippines, South Africa, and Thailand', some of them having adopted similar provisions modelled on section 3(d) of the India Patent Act, 1970 (as amended).[45] While its application is not confined to drugs, it is often the complaint of multinational pharmaceutical and biopharmaceutical companies that 'section 3(d) of the India Patents Act restricts patent eligible subject matter in a way that poses a major obstacle to innovators'.[46] Critics have further questioned its compatibility with TRIPS.[47]

However, it is maintained by some contributors and further underscored by the Indian Supreme Court decision in the *Novartis AG v. Union of India and Others*, that clause (d) of section 3 of the Indian Patents Act, 1970 (as amended) is TRIPS-compliant. It is argued that the TRIPS Agreement, 1994 (in Articles 1, 7, 8 and 27), together with the Doha Declaration (in paragraphs 4 to 6) have sufficient flexibility that countries could take advantage of so as to counteract the adverse impact of patent rights particularly with regards to public health.[48] An instance explained in this regard is with regard to Article 27 of the TRIPS Agreement, 1994 (as amended).[49] While it enunciates essential patent law concepts such as invention, novelty, inventiveness and industrial applicability, it leaves their definition and how they are to apply at the domestic level to the discretion of member states. Yet, the way these key concepts are defined can be of the utmost importance for both innovation and access to medicine. Put differently, countries in taking advantage of the TRIPS Flexibilities and the Doha Declaration can adapt the patent standards to suit national conditions by for instance regulating the grant of patents and setting up higher standards for patent protection as reflected in the Indian Patents Act, 1970 (as amended). Also, it is strongly argued that the clause is not a discriminatory measure against multinational (pharmaceutical) companies as some countries of the West would want the world to believe, especially as existing evidence points to the fact that most of the pharmaceutical patents in India are owned by foreign firms.[50]

---

[45] US Racherla (n5) 286; HK Singh and AR Khanna (n5) 12.

[46] The Office of the United States Trade Representative, '2018 Special 301 Report' (2018) 49. <https://ustr.gov/sites/default/files/files/Press/Reports/2018 Special 301.pdf> accessed 30 April 2024; The Office of the United States Trade Representative, '2019 Special 301 Report' (2019) 51. <https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf> accessed 30 April 2024. The Office of the United States Trade Representative continues to monitor the application of section 3(d) of the India Patent Act, 1970 (as amended). The Office of the United States Trade Representative, '2024 Special 301 Report' (2024) 54. <https://ustr.gov/sites/default/files/2024 Special 301 Report.pdf> accessed 13 May 2024.

[47] It was also a bone of contention in *Novartis AG v. Union of India and Others* (HC) (n36), with the appellant, a pharmaceutical company (Novartis AG), asserting that section 3(d) of the Indian Patent Act, 1970 (as amended) is not TRIPS-compliant.

[48] *Novartis AG v. Union of India and Others*, (HC) (n36) pp.1296 – 1297; See also the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) 2001. <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPS_e.htm> accessed on 30 April 2024; US Racherla (n5) 286-288; A Ristanić, 'Using Compulsory Licenses to Facilitate Access to Medicines: The Indian Experience' (Masters Dissertation, University in Lund, Sweden, 2016) 18-20; HK Singh and AR Khanna (n5) 12-16; LL Lee (n44) 309.

[49] A Ristanić (n48) 18; HK Singh and AR Khanna (n5) 9-10; LL Lee (n44) 309.

[50] See *Novartis AG v Union of India and Others* (HC) (n36) (where section 3(d) of the Indian Patents Act, 1970 (as amended) was challenged on the ground that it is discriminatory, but the court found that the provision does not discriminate); See also HK Singh and AR Khanna (n5) 15.

While turning down the appeal of Novartis AG in a case that indeed drew enormous interests from the international community, the Supreme Court of India *inter alia* held the view that the objective of the qualifying standards under section 3(d) of the Indian Patents Act 1970 (as amended), are meant to keep the door open 'for true and genuine inventions', while simultaneously checking attempts 'at repetitive patenting or extension of the patent term on spurious grounds'.[51] Significantly, contrary to the views by detractors that it precludes all forms of incremental innovations, the Supreme Court of India insists that section 3(d) of the Act does not bar patent protection for all incremental inventions.[52] In the same vein, Singh and Khanna pointed out that drugs with 'relatively minor variations over pre-existing compounds, yet upon successfully demonstrating enhanced efficacy over the base formulation, had been awarded patents in India'.[53] In addition, it is strongly suggested that the logic and motives behind section 3(d) of the Indian Patents Act 1970 (as amended), is no different from the approaches adopted by the United States and various other developed countries in assessing the patentability of derivatives or improvements to existing inventions and new uses of known substances in order to curb evergreening.[54]

In light of the above discussions, there is no gainsaying that the provision of section 3(d) of the Indian Patents Act 1970 (as amended), tested in the case of *Novartis AG v. Union of India and Others* significantly reflects how India strives to balance its international treaty obligations, particularly TRIPS, with its commitment to protect and promote the public interests, not only of Indians but many other needy people of the world particularly Africans. Again, the recount of the history of India's patent regime and legislative process by the Court in the *Novartis* case before reaching its decision, shows all three arms government are highly sensitive to the social and economic needs of Indians and as a result, they work harmoniously to achieve common goals including improved public health and food security.[55]

Another significant exception under section 3 of the Indian Patents Act, 1970 (as amended) bothers on traditional knowledge. Particularly, section 3(p) of the Indian Patents Act, 1970 (as amended), provides 'invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components' is not

[51] *Novartis AG v. Union of India and Ors.* (SC) (n36) paragraph 103.

[52] ibid, paragraph 190.

[53] HK Singh and AR Khanna (n5) 15-16.

[54] LL Lee (44) 286, 304-310 (arguing that 'because other countries have taken more indirect routes to achieve similar objectives, section 3(d) is not a radical departure from international practices'); HK Singh and AR Khanna (n5) 10-11 (noting that, in the case of the United States, the Manual of the Patent Office requires that the claimed invention must demonstrate 'unexpected results' over the known substance. This principle was applied in *Pfizer v Apotex* (2007) where the United States Court of Appeal for the Federal Circuit denied Pfizer's patent claim on the ground that it does not demonstrate 'unexpected superior results' over the base compound. They also argue that the requirement of 'enhanced efficacy' specified under section 3(d) of the Indian Patents Act 1970 (as amended) is a 'refinement (albeit a more restrictive one) of the 'inventive step' and 'industrial applicability' guidelines rather than a separate and additional requirement').

[55] It is well established that India has frequently come under attacks internationally because of section 3(d) of its Patents Act, 1970 (as amended). Curiously though, there have been recent legislative efforts in the United States to amend its patent law in this line through the draft No Combination Drug Patents Act of 2019. While it was subsequently withdrawn (due the successful lobby by private interests no doubt) it is instructive to note that within the draft law, it is stated that findings by the United States Congress reveals the increasing drug prices by far surpasses the spending on research and development in the pharmaceutical and biopharmaceutical industry. It was also pointed out that the evergreening of drug patents 'have created dense patent thickets that deter competition from generic versions of those drugs or biological products'. See section 3(4-5) of the United States Draft No Combination Drug Patents Act of 2019. <https://www.ipwatchdog.com/wp-content/uploads/2019/06/DRAFT-Patent-Bill2.pdf> accessed on 30 September 2020.

patentable. It is intended to curtail the misappropriation of India's biological resources and associated traditional knowledge exemplified by the various attempts of foreign firms to patent inventions which in effect are traditional knowledge highlighted in chapter three and four of this study.[56] In this regard, it is the practice of the Indian Patent Office to rely on the Indian Traditional Knowledge Digital Library (TKDL) and other resources in conducting investigation as to whether a patent claim falls within the purview of section 3(p) of the Indian Patents Act, 1970 (as amended).[57]

Established in 2001 by the Indian Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) in collaboration with the Indian Council of Scientific and Industrial Research (CSIR), the TKDL is a database that provides information on India's traditional knowledge. It is accessible not only by patent examiners at the Indian Patent Office but various other national and international patent offices including the European Patent Office and the United States Patent and Trademark Office.[58] In addition to existing legislative frameworks, the TKDL serves as a technical mechanism against the misappropriation of India's biological resources and associated traditional knowledge, and is increasingly considered a model to be emulated by countries rich in traditional knowledge most of whom are developing countries.[59] Besides its utilisation as prior art evidence regarding patentability, it is also considered as a mechanism that could serve to foster innovation, further research and development by simplifying access to relevant knowledge especially those that are associated with plants.[60] However, in this regard, there are concerns that access to the TKDL particularly by the private sector could again lead to misappropriation by multinational corporations.[61]

To further safeguard traditional knowledge, the said section 3(p) is reinforced by various other provisions inserted in the Indian Patents Act, 1970 (as amended). For instance, where a patent claim involves the use of biological material, section 10(4)(ii)(D) requires a disclosure of the source and geographical origin of the biological material.[62] In this regard, it is pertinent to note section 6 of the Indian Biological Diversity Act, 2002 (BDA) mandating prior approval from the Indian National Biodiversity Authority (NBA) before applying for patent if the biological material is specifically from India. However, where no prior approval has been obtained before the patent application, approval may be applied for and obtained before the sealing of the patent.

While there is no corresponding provision in the above regard under the Indian patent law, it is now an established practice at the Indian Patent Office that patent applicants submit proof of

---

[56] JM Mueller (n29) 562.

[57] See the Office of the Controller General of Patents, Designs and Trademarks. 'Manual of Patent Office Practice and Procedure', p.95.

[58] See'About TKDL'. <http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng> accessed on 30 September 2020; Council of Scientific & Industrial Research (CSIR). 'Traditional Knowledge Digital Library (TKDL)'. <https://www.csir.res.in/documents/tkdl> accessed on 30 September 2020.

[59] See World Intellectual Property Organisation. 'International Conference Concludes TKDL Can Prevent Misappropriation and Fuel Innovation'. Press Release (PR/2011/683, 2011). <https://www.wipo.int/pressroom/en/articles/2011/article_0009.html> 30 September 2020.

[60] For instance, see paragraph 2.20 of the Indian National Intellectual Property Rights Policy, 2016; World Intellectual Property Organisation. 'International Conference Concludes TKDL Can Prevent Misappropriation and Fuel Innovation'.

[61] See D K Abrol, 'Who will Gain from the National IPRs Policy?', 4.

[62]Unlike other national patent laws in Africa, section 30 of the South African Patents Act 1978 (as amended by the Patent Amendment Act of 2005) contains a similar provision regarding the use of the indigenous biological resource, genetic resource, or of the traditional knowledge.

approval from the Indian National Biodiversity Authority in the course of patent application where the claim pertains to biological material obtained from India.[63] As a result, there are suggestions that suitable amendments be made so as to harmonise the workings of Indian Patent Office and National Biodiversity Authority in such a manner as to expedite the procedures involved. In addition, pre- or post-grant opposition may be brought on the ground that the relevant claim or invention 'was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere'.[64]

There are other notable provisions relevant to biotechnology research and development under the Indian Patents Act, 1970 (as amended). Section 10(4)(ii) of the Indian Patents Act, 1970 (as amended) particularly provides for the depositing of biological material where the situation so demands. The Indian Patents Act, 1970 (as amended) further contains detailed provisions on compulsory licensing, through which India champions affordable access to medicine and other patented technologies for the people of India and those of other developing countries, particularly due to their low manufacturing capacity.[65] The provision gained prominence in 2012 following the *Natco Pharma v Bayer Corporation* (*Nexavar Compulsory License* case), where the Controller General of the Indian Patent Office granted, for the first time, a compulsory license under section 84 of the Indian Patents Act, 1970 (as amended).[66] This was granted with regard to a patented drug on the grounds that the patent holder *inter alia* failed to ensure affordability and availability to the public.[67] The decision was upheld by the Indian Intellectual Property Appellate Board (IPAB) in 2013 and then by the Supreme Court of India in 2014.[68] In analysing the *Nexavar Compulsory License* case, Sood specifically notes that the approach of the Indian Intellectual Property Appellate Board had been 'from a public health perspective in the context of the right to life under Article 21 of the Constitution of India….'[69] This further underscores the approach in the *Novartis* case.

4. Conclusion

The foregoing discussions reflect commendable efforts by the Indian government to further a people-driven patent system while meeting its international obligations regarding biotechnology patenting. India has always taken a hard stance against the application of intellectual property in both the agricultural and pharmaceutical sectors, given the implications on access and innovation. Since the entry into force of the TRIPS Agreement 1994 (as amended), there have been various legislative efforts by the Indian government to cushion the inherent defects of the globalised intellectual property standards by inserting recommendable clauses into the country's patent

[63] See the Office of the Controller General of Patents, Designs and Trademarks. 'Manual of Patent Office Practice and Procedure', 14.; M Lakshmikumaran, 'Implications of the Biological Diversity Act, 2002 on Seeking IP Registrations: Valuing Diversity'. (2016) 1(3) Biotechnology Industry Research Assistance Council (BIRC) i3 Newsletter 13.

[64] See section 25(2)(k) and 64(1)(q) of the Indian Patents Act, 1970 (as amended).

[65] See generally sections 82-94 of the Indian Patents Act, 1970 (as amended); Significantly, section 92A of the Indian Patents Act, 1970 (as amended), incorporates relevant aspects of the Doha Declaration which as discussed elsewhere in this study allows member countries to produce drugs under a compulsory licence for the purpose of exporting to countries facing public health problems but lacking manufacturing capacity in the pharmaceutical sector.

[66] US Racherla (n5) 289 – 291; HK Singh and AR Khanna (n5)16-18; A Singhai and M Singhai, 'A Study of Natco v. Bayer Case: Its Effect and Current Situation' MIT International Journal of Pharmaceutical Sciences (2016) 2(2) 21, 22; M Sood, 'Natco Pharm Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India' NUJS Law Review (2013) 6 99, 104 – 107.

[67] US Racherla (n5) 289 – 291; HK Singh and AR Khanna (n5)16-18; A Singhai and M Singhai (n62); M Sood (n62).

[68] US Racherla (n5) 289 – 291; HK Singh and AR Khanna (n5)16-18; A Singhai and M Singhai (n62); M Sood (n62).

[69] M Sood (n62) 104 – 105.

regime, as indicated in this paper. African countries must adopt a similar approach to biotechnology protection, leveraging the policy space in the TRIPS Agreement 1994 (as amended) to advance food security, nutrition and public health on the continent.