

# Jus Corpus Law Journal

Open Access Law Journal – Copyright © 2022 – ISSN 2582-7820 Editor-in-Chief – Prof. (Dr.) Rhishikesh Dave; Publisher – Ayush Pandey

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# TRIPS Agreement: India's Position over the years

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Received 24 January 2022; Accepted 09 February 2022; Published 12 February 2022

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The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement completed 25 years in 2020. The agreement was a result of the need to provide due protection to Intellectual Properties and facilitate trading between countries at the same time. TRIPS has been a controversial affair even before the agreement was finalised in 1995. Since the implementation of the agreement, the issue of pharmaceutical patents and compulsory licensing have come up time and again in the discourses around public health, access to medicines, generic medicines, and human rights. The most recent controversy remains around the COVID-19 pandemic and the availability of vaccines, medicines, and medical equipment necessary to manage the infection. India, along with South Africa, presented a proposal to the WTO in 2020, demanding waiving off certain provisions of the TRIPS agreement for accessing vaccines and drugs needed to treat COVID. Developed countries have cried foul on such demands. This paper looks at India's position with regards to the TRIPS agreement over the years

**Keywords:** intellectual property, compulsory licensing, patents.

#### INTRODUCTION

The World Trade Organisation (WTO) became functional on 1st January 1995. It is a successor of the General Agreement on Tariffs and Trade (GATT). It was the result of the Uruguay round of negotiations that happened over seven and a half years. The main objective of the

WTO has been to facilitate multilateral trade in goods as well as services. As described WTO itself, WTO's focus remains on barrier-free trade and open borders, following the principle of most-favored-nation by all the member countries, non-discrimination between and among the members, and transparency in all its activities.<sup>1</sup>

#### WHAT ARE TRIPS?

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement became effective on January 1, 1995.<sup>2</sup> It was also the result of the 1986-1994 Uruguay round of negotiations.<sup>3</sup> The WTO describes it as the "most comprehensive multilateral agreement on intellectual property". The nature of the TRIPS agreements is in the form of a treaty of the WTO and it is binding on its signatories. The agreement is administered by the TRIPS Council which is composed of all WTO members. The TRIPS Council reports to the WTO General Council. The agreement seeks to bring together the aspects of Intellectual Property (IP) and trade in an increasingly globalised world. It legalises the need for the protection of IPR. The TRIPS agreement, over the years, has helped determine benchmarks to several provisions under the scope of IPR. It manages the aspects of multilateral trading and IPR protection, minimum standards of protection under IPR, enforcement of TRIPS provisions within the member countries' territories, dispute settlement on IPR, and any specialised arrangements for the implementation of TRIPS. TRIPS, like WTO, emphasises the 'non-discrimination' aspect using the Most-Favored-Nation (MFN) status or treatment to all member states.<sup>5</sup> The agreement describes its main features as being minimum protection standards to be fixed by the member countries on their IP, the enforcement of the agreement which deals with domestic procedures as well as remedies, and the dispute settlement provision available within the ambit of the

<sup>&</sup>lt;sup>1</sup> 'Overview' (WTO) < <a href="https://www.wto.org/english/thewto-e/whatis-e/wto-dg-stat-e.htm">https://www.wto.org/english/thewto-e/whatis-e/wto-dg-stat-e.htm</a> accessed 20 January 2022

<sup>&</sup>lt;sup>2</sup>'Overview: The TRIPS Agreement' (WTO)

<sup>&</sup>lt;a href="https://www.wto.org/english/tratop\_e/trips\_e/intel2\_e.htm#patents">https://www.wto.org/english/tratop\_e/trips\_e/intel2\_e.htm#patents</a>> accessed 19 January 2022

<sup>&</sup>lt;sup>3</sup> 'Intellectual Property: Protection and Enforcement' (WTO)

<sup>&</sup>lt;a href="https://www.wto.org/english/thewto\_e/whatis\_e/tif\_e/agrm7\_e.htm">https://www.wto.org/english/thewto\_e/whatis\_e/tif\_e/agrm7\_e.htm</a> accessed 19 January, 2022

<sup>&</sup>lt;sup>4</sup> 'Frequently asked questions about TRIPS (Trade-related aspects of intellectual property rights) in the WTO: What is the role of the TRIPS Council?' (WTO)

<sup>&</sup>lt;a href="https://www.wto.org/english/tratop\_e/trips\_e/tripfq\_e.htm#TripsCouncil">https://www.wto.org/english/tratop\_e/trips\_e/tripfq\_e.htm#TripsCouncil</a> accessed 19 January 2022

<sup>&</sup>lt;sup>5</sup> Overview: The TRIPS Agreement (n 2)

WTO's dispute settlement mechanism. The Preamble to the agreement also seeks to establish a "mutually supportive relationship" between WTO and World Intellectual Property Organisation (WIPO).<sup>6</sup> The agreement also requires member countries to adhere to WIPO's Paris Convention on industrial property, and the Berne Convention on copyright in their most recent versions. The agreement is also described as the "Berne and Paris-plus" agreement. The agreement uses certain provisions from the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty) and the International Convention for the Protection of Performers, Producers of Phonograms, and Broadcasting Organizations (Rome Convention).

#### WHAT IPS ARE PROTECTED UNDER TRIPS?

Section 1 through 7 of Part II of the TRIPS agreement covers each IP in detail. The IPs that are included are (1) Copyright and Related Rights, (2) Trademarks, (3) Geographical Indications, (4) Industrial Designs, (5) Patents, (6) Layout-Designs of Integrated Circuits, (7) Protection of Undisclosed Information. TRIPS requires its members to prescribe to minimum standards of protection for the IPs in their respective countries.

### **INDIA'S IPR REGIME**

After independence, the first major law related to IPR in India was the Copyright Act of 1957. Later, the Patents Act, 1970<sup>7</sup> repealed and replaced the British-era Indian Patents and Designs Act, 1911. The Patents Act, 1970<sup>8</sup> has undergone a few amendments over the years. India has several extensive laws covering different types of IPs separately:

- **Patents:** Governed by the Patents Act, 19709; supported with the Patents Rules, 2003.
- **Trade Marks:** The Trade Marks Act, 1999<sup>10</sup> came into effect in 2003.
- **Copyright:** The Copyright Act, 1957<sup>11</sup>; supported with the Copyright Rules, 1958.
- **Industrial Designs:** The Designs Act, 2000<sup>12</sup>; supported with the Designs Rules, 2001.

<sup>&</sup>lt;sup>6</sup> World Intellectual Property Organization, 1967

<sup>&</sup>lt;sup>7</sup> Patents Act, 1970

<sup>8</sup> Ibid

<sup>9</sup> Ibid

<sup>&</sup>lt;sup>10</sup> Trade Marks Act, 1999

<sup>&</sup>lt;sup>11</sup> Copyright Act, 1957

- **Geographical Indications:** Geographical Indications of Goods (Registration and Protection) Act, 1999<sup>13</sup> which came into effect in 2003.
- Integrated Circuit: Semiconductor Integrated Circuits Layout Design Act, 2000<sup>14</sup>.
- Plant Varieties: The Protection of Plant and Varieties and Farmers Rights Act, 2001<sup>15</sup>.
- **Biological Diversity:** The Biological Diversity Act, 2002<sup>16</sup> in compliance with the Convention on Biological Diversity.
- Confidential Information and Trade Secrets are not covered separately under any specific statute.

The Intellectual Property Appellate Board was set up in 1958 in New Delhi, India as a quasi-judicial body to adjudicate disputes concerning copyright registration and assignment, grant of licenses, unpublished Indian works, etc. The Controller General of Patents, Designs, Trademarks, and Geographical Indications acts as India's patent office and works under the aegis of the Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India.

#### INDIA AND TRIPS AGREEMENT: COMPLIANCE AND CLASHES

# • India's journey towards TRIPS compliance

India, being a member of the WTO, and thus, a signatory to the TRIPS agreement, was bound to comply with standards set up by the agreement within a certain time frame set up for developing countries. India has introduced several changes to its IPR regime over the years to become a TRIPS compliant nation. The Patent Act, 1970<sup>17</sup> was amended thrice to conform to the standards of the agreement. The term for patent protection was also extended to be 20 years. The Copyright Act, of 1957<sup>18</sup> was amended to add computer programs and compilations of data owing to the rapid digitization that the world was undergoing at the time. The Indian

<sup>&</sup>lt;sup>12</sup> Designs Act, 2000

<sup>&</sup>lt;sup>13</sup> Geographical Indications of Goods (Registration and Protection) Act, 1999

<sup>&</sup>lt;sup>14</sup> Semiconductor Integrated Circuits Layout Design Act, 2000

<sup>&</sup>lt;sup>15</sup> Protection of Plant and Varieties and Farmers Rights Act, 2001

<sup>&</sup>lt;sup>16</sup> Biological Diversity Act, 2002

<sup>&</sup>lt;sup>17</sup> Patents Act, 1970

<sup>&</sup>lt;sup>18</sup> Designs Act, 2000

Trade and Merchandise Marks Act, 1958 was replaced with the Trade Marks Act, 1999<sup>19</sup> to give recognition to distinguishing marks, service marks, abolition of compulsory licensing of trademarks, etc.

## • Major clashes concerning TRIPS

**Novartis AG v Union of India**<sup>20</sup> - The case is a landmark case concerned with the evergreening of patents. The international pharma company Novartis International filed an application with the Chennai Patent Office for patenting of its anti-cancer drug "Glivec". The application got rejected by the office for failing to satisfy the aspect of novelty and non-obviousness and finding it non-patentable under Section 3(d) of the Patent Act, 1970<sup>21</sup>. Novartis subsequently went to the Madras High Court in 2006 challenging Section 3(d) of the Patent Act, 1970 for not being compliant with the TRIPS agreement. The case was eventually transferred to IPAB and further to the Supreme Court where the SC pronounced its landmark judgement. The SC observed that the pharma companies use ever-greening of patents as a tool for monetary gains whereas life-saving drugs are needed by the general public at affordable prices. Novartis' application for a patent was thus rejected by the SC.

**Protection of traditional knowledge -** Dr. Suman Sahai points out that "TRIPS hinders the protection of traditional knowledge and does not provide for fair and equitable sharing of benefits stemming from the utilisation of genetic resources."<sup>22</sup> The issue of bio-piracy arises because TRIPS does not require divulging the source of biological materials that are being patented. She believes that TRIPS would be detrimental to the conservation, preservation, and sustainable use of biodiversity. The cases of neem and turmeric come to mind where the United States Patent and Trademarks Office (USPTO) had granted patents on these items

<sup>&</sup>lt;sup>19</sup> Copyright Act, 1957

<sup>&</sup>lt;sup>20</sup> Novartis AG v Union of India [2013] 6 SCC 1

<sup>&</sup>lt;sup>21</sup> Patents Act, 1970, s 3(d)

<sup>&</sup>lt;sup>22</sup> Subramanya Sirish Tamvada, 'TRIPS and Human Rights: The Case of India' (2010) 2 (1) JGLR

<sup>&</sup>lt;a href="https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1020&context=stusch\_lawrev">stusch\_lawrev</a> accessed 22 January 2022

which have long been known for their medicinal usages. The case of basmati being patented by USPTO was also challenged.<sup>23</sup>

Compulsory Licensing - The legal basis for compulsory licenses can be found under the Patents Act, 1970 read with Indian Patent Rules, 2003. Section 84(1) of the Act reads " At any time after the expiration of three years from the date of the 1[grant] of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely: —

- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- (b) that the patented invention is not available to the public at a reasonably affordable price, or
- (c) that the patented invention is not worked in the territory of India."24

The decision allowed Natco Pharma to produce the generic version of Bayer Corporation's life-saving drug used for treating liver and kidney cancer called Nexavar. The issue brought into limelight arguments on the inconsistencies between Section 84(1)(c)<sup>25</sup> of the Patents Act with the TRIPS. This argument has been consistently brought up by countries like the US, Japan, EU against India.<sup>26</sup>

#### TRIPS AND COVID-19: INDIA'S CALL FOR WAIVER

In October 2020, India and South Africa had submitted a draft proposal to WTO suggesting a waiver on enforcement, implementation, and application of certain provisions of the TRIPS agreement considering the situation created by the COVID-19 pandemic. Although a much-needed step that was ushered in by many with open arms, experts suggest it is too little being

<sup>&</sup>lt;sup>23</sup> Ibid

<sup>&</sup>lt;sup>24</sup> Patents Act, 1970, s. 84(1)

<sup>&</sup>lt;sup>25</sup> Patents Act, 1970, s. 84(1) (c)

<sup>&</sup>lt;sup>26</sup> B N Pandey & Prabhat Kumar Saha, 'Natco-Bayer Verdict: Decoding Local Working Requirement' (2016) 51 (20) Economic and Political Weekly <a href="https://www.epw.in/journal/2016/20/notes/natco-bayer-verdict.html#:~:text=Bayer%20has%20lost%20its%20case,remains%2C%20in%20general%2C%20unsettled">https://www.epw.in/journal/2016/20/notes/natco-bayer-verdict.html#:~:text=Bayer%20has%20lost%20its%20case,remains%2C%20in%20general%2C%20unsettled</a> accessed 22 January 2022

done by a country like India where public health facilities have been stretched thin. Latha Jishnu's article titled "Who is really afraid of the TRIPS agreement?" asks a pertinent question on India's lack of action on using in-built flexibilities provided in the TRIPS agreement to meet public health requirements, especially during a worldwide pandemic. Countries like the USA, UK, Norway, Canada, and EU have also strongly objected to India and South Africa's demand for the waiver of IPR on Covid-19 vaccines putting up the same argument of countries having in-built flexibilities under TRIPS.

The Doha Ministerial 2001 reiterated the very same matter in its Declaration on the TRIPS agreement and public health (Adopted on 14 November 2001). The 4th para of the agreement specifically states "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health" and further that "we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose". On the other hand, pharma companies have always maintained the position that having stringent mechanisms in place for protecting their IP is crucial for innovation as the pharmaceutical industry is a research and development-based industry. Incentives in the form of patents act as encouragement to the company itself, increasing its chances of finding much-needed capital from investors. The temporary monopoly created by patents also helps such companies outperform their competitors. In the case of COVID vaccines, pharmaceutical companies have blamed the lack of infrastructure and manufacturing facilities in developing and underdeveloped countries as well as stockpiling of vaccines by wealthier nations as the main contention in the availability of vaccines.

Article 31 of the TRIPS agreement deals with the 'compulsory licensing' of a patent. Compulsory licensing allows the government to use or produce a patented invention without the consent of the patent holder. The issue of compulsory licensing has flared up during the discussions of the production and distribution of COVID-19 vaccines as vaccines began to enter the market in the early months of 2021. Experts have pointed out that IPR waiver would

<sup>&</sup>lt;sup>27</sup> Latha Jishnu, 'Who is really afraid of the TRIPS agreement?' (Down to Earth, 09 October 2020)

<sup>&</sup>lt;a href="https://www.downtoearth.org.in/blog/economy/who-is-really-afraid-of-the-trips-agreement--73746">https://www.downtoearth.org.in/blog/economy/who-is-really-afraid-of-the-trips-agreement--73746</a> accessed 22 January 2022

be unlikely to create any difference in terms of augmenting the supply of vaccines and have criticised India's stand of not pushing for compulsory licensing strongly enough<sup>28</sup>. India, after granting its first and only license to Natco Pharma in 2013, has not given any further licenses.

#### **CONCLUSION**

India has had to make numerous changes to its IPR regime to make itself compliant with the TRIPS agreement provisions. The issue of patenting and compulsory licensing has remained the most controversial. Over the years, developed countries have criticised India for contravening the provisions of the TRIPS agreement time and again whereas, environment activists and health activists have criticised the government for not doing enough justice to the country's public who needs cheaper access to medicines, which was desperately required during crises like the COVID-19 pandemic. When this paper is being written, an informal WTO mini-ministerial meeting organised by Switzerland is going on, and India along with South Africa, supported by 100 other developing countries are pushing for the IPR waiver<sup>29</sup>, which, according to experts, won't amount to much anyway, due to lacking infrastructure in the country and insufficient capacities. The final stance of the WTO on this issue remains to be seen.

<sup>&</sup>lt;sup>28</sup> Nilanjan Banik & Debashis Chakraborty, 'An Indian Perspective: COVID-19 and IPR Waiver' (2021) 56 (35) Economic and Political Weekly <a href="https://www.epw.in/journal/2021/35/commentary/covid-19-and-ipr-waiver.html">https://www.epw.in/journal/2021/35/commentary/covid-19-and-ipr-waiver.html</a> accessed 22 January 2022

<sup>&</sup>lt;sup>29</sup> 'TRIPS waiver, developing nations' policy space key, India tells WTO' (*The Economic Times*, 22 January 2022) <a href="https://economictimes.indiatimes.com/news/india/trips-waiver-developing-nations-policy-space-key-india-tells-wto/articleshow/89051764.cms">tells-wto/articleshow/89051764.cms</a> accessed 22 January 2022