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Exclusive study on operation of 31 bis of trips-with special reference to public health

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***Abstract*---**World wars brought economic depression resulting in the need to regulate the trade relationship among the international community. Such a need to regulate trade relationships among world states compelled them to sign the General Agreement on Tariffs and Trade (GATT) agreement. The initial stages of GATT did not have provisions to protect Intellectual Property Rights. There were international conventions to address the issues concerning Trade aspects of intellectual property. The international conventions were like the Paris convention for protecting an invention, Berne for Copyright, Madrid for Trademarks etc... Several rounds of GATT gave birth to the World Trade Organization in 1995. The World Trade Organization (WTO) planned to bring unification of Intellectual Property Laws and enacted a new multilateral agreement on Trade-related aspects of Intellectual Property Rights (TRIPS). TRIPS are multifaceted agreements where many aspects of IPR are discussed. Article 31 bis of TRIPs agreement concerning public health will be critically analysed in this paper. Article 31 Bis was the result of the Doha declaration that deeply discussed the issue of Article 31 F and its gap in serving the countries that lack the manufacturing capacity to address their issues of accessibility and affordability to pharmaceutical products. This paper would articulate whether Article 31 Bis came to address the issue of Article 31 F potentially meeting the gaps. To better grasp the situation on working of Article 31 bis, the evolution of Article 31 bis, its content and practice, and answer to any barriers in the application and its viable solutions would be discussed. Hence, this paper identifies the deficiency of Article 31 bis in addressing public health issues with suggestions to best work the

provisions of Article 31 bis to benefit people and patients of all sections of the society without disparity.

***Keywords*---**TRIPS, Article 31 Bis, Pharmaceutical Product.

Introduction

Life seems to exist due to the phenomenon of peaceful co-existence. Despite disparities among people, peaceful co-existence remains the best choice of all. Amidst the realistic philosopher's view, an individual is selfish and are a warmonger for one's existence, today's multipolar world tends to adapt measures for peaceful co-existence. One such measure is the World Trade Organization (WTO). WTO was not the result of a single day harvest. WTO was the result of several rounds of GATT after facing the economic depression resulting from two devastating world wars. The international community was of consensus that the only way to avoid the third world war was regulating and strengthening International Trade. International trade has resulted in interdependency resulting in a war-free world though tensions tend to exist between states.[1] WTO addressed the multiple trade aspect issues through multilateral agreements and one such agreement is TRIPS. TRIPS addressed the issues regarding all varieties of Intellectual Property Rights (IPR). Before the advent of TRIPS, there were separate international conventions for addressing different kinds of Intellectual Property like the Paris convention for protecting an invention, Berne for Copyright and Madrid for Trademarks etc. TRIPS brought unification of Intellectual Property Laws under one roof. TRIPS also addressed many unaddressed areas and compelled the world countries either to sign the agreement to comply with certain conditions or insisted them to come up with their sui generis laws for protection within their territory.[2]

This paper would ponder on the issues of public health concerning TRIPS. TRIPS in the segment of patent provide conditions of patenting a novel invention. TRIPs insist on protecting novel products as well as the process of invention. Apart from above mentioned special provisions TRIPs categorizes non-patentable subject matter in an invention. TRIPs apart from the unification of Intellectual Property laws insist on issuing compulsory licensing for those patented inventions that are not worked for a certain period and which remains non-accessible and non-affordable to the public.[3] Compulsory licensing is also provided in the situation of national emergency and extreme urgency where the nation initiates the process of issuing licenses to interested persons who can best work the invention for the betterment of society. TRIPs in provisions of Article 31 (f) provides compulsory licensing, has emphasized the need to produce medicine to meet the requirement of its citizens and did not utter a word of exporting the medicine for those poor countries that lack manufacturing capacities. [4] This was addressed through Doha declaration 2001 and a special provision of Article 31 Bis was introduced through the amendment of 2017. [5] This paper tries to analyse the working of Article 31 Bis by discussing its evolution, content, practice and barriers in its application. Besides that, it would also throw light upon deficiencies of Article 31 Bis in addressing the issues of public health; with suggestions to best work the

provisions of Article 31 Bis to benefit people and patients of all sections of the society without disparity.

Evolution of article 31 BIS

The 1995 Uruguay rounds resulted in the evolution of the World Trade Organization (WTO) and TRIPS. TRIPS is a multilateral agreement that protects copyright, trademarks, geographical indication, industrial designs, patents, layout designs of integrated circuits and undisclosed information (including trade secrets and test data). The Agreement also includes enforcement obligations, border measures and criminal procedures about criminal activities. [6] The source of the TRIPS provision has been from Paris, Berne and other Intellectual property related conventions. This agreement has dispute settlement understanding that addresses the issues between states concerning Intellectual Property. The idea of a Dispute settlement board is the one that was available in the General Agreement on Trade and Tariffs. Hence TRIPs could be considered a mixture of all negotiations. The somewhat unlikely pairing of TRIPS being a part of the WTO, its IPR provisions being rooted in the Paris and Berne Conventions, and its main dispute-settlement mean, the DSU, being rooted in the GATT has led some commentators to suggest the agreement is, “like a cuckoo’s egg, laid and hatched in the nest of another species.” [7] That is, the Agreement (i.e., the egg) is focused on IPRs, but has been “laid and hatched “in the “nest,” or context, of trade and trade-related proceedings.

Though TRIPS has provisions and forums to address the issues relating to Intellectual Property TRIPS has been always considered to show favouritism towards developed nations. Developing nations always suffered compulsion in compelling to comply with IP laws in consonance with TRIPS. The economic conditions of developing and least developed nations were very poor. The transition periods given for both were not enough to adapt TRIPs provision in their national laws. Especially adapting product patenting increased the prices of medicine making it very difficult to access the medicines in the least developed and developing nations.[8] Product patenting nullified the scope of producing generic versions of drugs which were possible before compliance with the TRIPs agreement. India had developed a great hub for generic medicines that used the technology developed from reverse engineering process patented drugs. India which was also famously known as Pharmacy of the world as it exported the drugs to least developed countries was in trouble by adopting product patenting as insisted by the TRIPs agreement. On one hand, the generic drug industry was largely impacted by product patenting thereby curbing the chance to reverse engineer developed nations that have spoken about the positive side of TRIPs.[9] Developed nations say that by stronger protection given by the TRIPs agreement developing nations would become the safest place for industries to establish and produce the products that would naturally lead to the transfer of technologies by enhancing economic development. So, there is always an argument whether TRIPS has been a boon or a bane for the poorest and developing nations, especially about pharmaceutical companies.

Articles from 27 to 34 of TRIPS protect Patents. The most controversial provision of the patent in TRIPs relating to public health is Article 31. To set right the

issues in Article 31, para6 of Doha declaration evolved. Para 6 of the Doha declaration paved the way for the inclusion of Article 31 bis.[10] This part of the paper would in brief discuss the evolution of Article 31 bis. To understand the prominence of article 31 bis, it is necessary to understand the significance of compulsory licensing. However, it is necessary to analyse how and why compulsory licensing is issued under Article 31 of TRIPs. There are two provisions of Article 31 such as Article 31 (f) and Article 31 (h) which have necessitated the inclusion of Article 31 bis. [11] Article 31(f) restricts the scope of utilizing compulsory licensing in a member's domestic market, while Article 31(h) specifies that, “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.” Before discussing the impact of Article 31(f) and Article 31(h) it is vital to discuss the impact of product patents after the TRIPS agreement. The major impact of mandating the inclusion of product patenting especially including pharmaceutical products as patentable subject matter largely affected those countries which produced generic medicines using reverse engineering techniques and supplying medicines for domestic purposes and exported them to the other countries lacking manufacturing countries. The reason behind their grief was they refused product patenting of pharmaceutical products before TRIPS. India was one such country that got affected by signing the TRIPs agreement. Though Article 31 has come up with provisions of issuing compulsory licensing by the government, Article 31 f and Article 31 h stood up as a hurdle in applying the same. The countries which facilitated exporting generic medicines to countries that lacked manufacturing capacity were left helpless after becoming members of TRIPs. Countries applying for compulsory licensing faced challenges of determining an appropriate remuneration to be given while considering the economic significance proved to be challenging. Precisely the main goal of enshrining compulsory licensing was to facilitate the availability and accessibility of essential medicines however goals of article 31 and its content were in contrast. [12]

TRIPs Articles 31 (f) and 31 (h) contradict Article 7, which states that technology should be transferred to the mutual benefit of consumers and producers of technical knowledge and in a way that promotes economic and social wellbeing by balancing rights and obligations. Similarly, the provisions of Article 31 affected the provisions of Article 8 that state members may advocate for the public good in areas that would enhance their socio-economic and technological advancement. As a result, to resolve the problems produced by Article 31 and bridge the gap between the issues in health policy and intellectual property rights, the ministerial conference in 2001 adopted the Doha Declaration (paragraph 6). The "gravity of public health" and access to vital medicines was the focus of this declaration. The Doha Declaration provided a temporary waiver for Articles 31 f and 31 h, allowing countries without manufacturing capacity to access essential medicines without infringing on the creator's rights, and preventing resource-poor nations from having to pay developed countries for pharmaceutical items. The idea of the Doha declaration was to make the temporary waiver a permanent one as present in Paragraph 6. Regardless, the WTO general council took 12 years to enact the protocol into an article of the TRIPs agreement, based on decisions made on December 6, 2005.[13] Article 31 bis followed Article 31 of TRIPs agreements however deadlines for the acceptance by member countries have been extended several times.

Several countries have amended their domestic legislation to implement the 2003 waiver and 2005 decision by the WTO's intellectual property agreement. Several countries have updated the legislation and notified the same with WTO TRIPs council. However, few other WTO members who have implemented have not yet been notified in TRIPs. Countries like Canada, India, Jordan, Switzerland, China, Albania, Hong Kong, Cuba, Norway, Oman, Botswana, New Zealand, Croatia, Republic of Korea, European Communities, Kazakhstan, Russian Federation, Philippines, Singapore, Chinese Taipei and Japan have notified their amendments regarding the proposal to issue compulsory licensing to import or export the pharmaceutical products under certain exceptional circumstances to uphold the public health and facilitate access to medicines. Proposal for amending TRIPs to facilitate compulsory licensing made many countries anticipate that these actions would lead nations to claim compulsory licences for pharmaceutical products with the greatest regularity. There were handfuls of potential compulsory licensing episodes in member countries. However, there was a doubt that many compulsory licensing occurred due to given political pressure.

The mandate of implementing compulsory licensing provisos agreed in Uruguay rounds by developing nations caused major concerns concerning the epidemic in Africa. The WTO's IP rights compelled public officials to address long-term trade implications.Developing countries feared retaliation from pharmaceutical companies and trade partners in high-income countries if compulsory licensing was implemented. Hence WTO signatories of African countries called for a re-evaluation of the policy to comprehend "how far their right to use the Compulsory Licensing" would be respected. [14]In response to the passage of the "Medicines and Related Substances Control Amendment Act, 1997," the Pharmaceutical Manufacturers Association South Africa, alongside forty multinational corporations, filed a lawsuit against the government in 1998. This Act was drafted to afford and access drugs by their citizens. Pharma association of South Africa contended that its Act was against the provisions of TRIPs and the South African Constitution. At this point, the Indian pharmaceutical company Cipla came into the picture and offered to supply South Africa with low-cost generic ARV drugs.[15] South Africa was not the only country to face this situation however similar concern was faced by many other nations. Hence the series of negotiations focusing on compulsory licensing instigated WTO to re-evaluate the provisions of TRIPs relating to compulsory licensing in the Doha declaration.

In midst of hassles happening in South Africa relating to compulsory licensing, the patent dispute in Brazil was taking its recourse. Brazil amended its domestic legislation to comply with TRIPs in 1996.9279 law was legislated in Brazil to protect pharmaceutical patent and compulsory licensing provisions. International patent holders were required to manufacture drugs in Brazil for a minimum of three years under Article 68(5) of the 9279 legislations. If the patent holders are unable to meet the public's needs, they can arrange with local manufacturers to start manufacturing the medications. [16] The USA was against Article 68(5) of 9279 law. U.S.A filed a case against Brazil in WTO's Dispute Settlement Board on this issue in 2001. However, the pressure from the international community made the U.S.A withdraw the case against Brazil from DSB. Following it Brazil started to invoke compulsory licensing provisions explicitly and confidently. Brazil's

threat to issue compulsory licensing made the pharmaceutical companies like Merck and Roche provide a significant discount on the cost of the drugs. [17]

Simultaneously, the anthrax attack caused the media to raise hype. Even though there were several other drugs available on the market that could cure anthrax, media advertisements for "Cipro", a Bayer-patented antibiotic that could be effective in curing anthrax; officials worried about a shortage. Canadian authorities suspected that there could be the possibility of anthrax crossing the borders. However, as a precaution, the Canadian Government issued compulsory licensing and Ciproflaxin was quickly stocked upon.[18] Canada was the first richest country to issue compulsory licensing. Subsequently, too, tackle the situation in the USA Senator Charles Schumer, a Democrat of New York prompted the Department of Health and Human Services (HHS), to follow Canada's footsteps by issuing compulsory licensing. [19] Tommy Thompson, the then-secretary of the HHS, was subsequently brought into question about the probability of following Canada's lead. On the other hand, Thompson claimed that he had the authority to grant a compulsory licence. Whereas on the contrary, George W. Bush (American President) established flexibility through executive order 13323, which allowed the Secretary of HHS to issue compulsory licenses during public health emergencies incorporating national defence. Confused with US compulsory licensing policy Thompson proceeded with price negotiation with Bayer for Cipro. The negotiation with Bayer made them donate drugs to the USA. Some said Bayer was generous in giving drugs at a discounted price was to evade the issuance of compulsory licensing. Though no compulsory licensing was ever issued by the USA, it revised the compulsory licensing policy in the face of a public health emergency. This instance and response of the USA to the anthrax situation "effectively destroyed any credibility left in the US argument that compulsory licensing for pharmaceuticals was an undesirable option to address the public health crisis." With these circumstances, WTO members convened the Doha declaration in 2001 to address the public health crisis in circumstances of national emergency and urgency. [20]

The main point of contention was to argue for a broader definition of what situations should justify the use of compulsory licencing. In the case of issuing compulsory licensing based on the circumstance, the diseases could be divided into three categories. "Category I" would involve infectious and acute disease where the disease has the potential to spread and kill rapidly, "Category II" involves infectious chronic disease where it is transmissible; it takes many years for a disease to progress into a life-threatening affliction.[21] Finally, "Category III" involves non-infectious chronic illnesses like heart disease and cancer where situation, is a lesser level of immediacy is required. In analysing, TRIPs provisions for compulsory licensing, the Wording "Public health emergencies to respond immediately without delay. However, except in dealing with the issuance of compulsory licensing for "Category I" disease the other scenarios seeking compulsory licensing for "Category II and III" diseases, the time taken to negotiate is more as there is no high level of immediacy as in "Category I" disease.[22] Another point of disagreement was whether compulsory licencing could be used to import or export goods. Because TRIPs agreement clearly states that compulsory licensing could be issued for domestic purposes only. Hence this put many countries in danger that had no or insufficient means to produce lifesaving

or essential drugs. Therefore, the intention to revise the TRIPs policy was agreed upon in Doha. The concerns raised in TRIPs policy was revised and officially expressed in Doha Declaration 2003 by appreciating the negotiating power of developing nations. Apart from appreciating negotiating power Doha declaration has facilitated some nations to use allowance of generic importation under compulsory licensing's and to develop a legal and practical way to purchase from the patent holder for high-tech medications at a low price, providing the country with a significant bargaining edge. [23]

After revising the policy of TRIPs there was a raise in issuing compulsory licensing. In 2004, Malaysia became the first country to use the compulsory license (CL) policy to import ARVs from India.[24] In the same year, Mozambique and Zambia took advantage of the legislation allowing domestic producers to produce generic medicines of branded pharmaceuticals. Abbott's plans to create generic medicines of the branded medication "Kaletra" at domestic; prompted Brazil to threaten Abbott with a CL. Abbott was concerned about this and eventually agreed to a significant price drop in return for becoming Brazil's main provider of medicine. As there was no high level of compliance for least developed countries, they issued compulsory licensing.[25] Indonesia, Thailand, and Brazil issued more compulsory ARV licences for ARVs between 2006 and 2007. India too issued compulsory licensing in 2012. The following paragraphs will provide case studies of various countries that had the chance to issue compulsory licensing and places where compulsory licensing was issued to overcome the impact of the patents.

Korea had to overcome numerous obstacles in the process of obtaining compulsory licencing for medications for a rare form of cancer (Gastrointestinal Stromal Tumours and Chronic Myeloid Leukaemia). Glivec was the medicine prescribed for patients with CLM. Novartis the Swiss pharmaceutical company owned the patent for Glivec. Korea gave CLM an orphan drug status. Orphan diseases are those diseases that affect fewer than 200,000 people and in the case of CLM, there were only 5000 patients.[26] Usually, the producers of the orphan drugs were given a special set of benefits for their producers. Korea gave priority to Novartis in the drug approval application process before it would be approved by the Korean Food and Drug Administration (KFDA). Around 91 patients were administered with Glivec during the pre-market window. Hence this proved beyond reasonable doubt that Glivec was the suitable medicine to treat CLM. Everything was fine till Novartis fixed the price for Glivec. Novartis charged 21 US dollars per capsule of Glivec. However, treatment would cost 25 to 37 % of their income on average. Novartis filed a request to have the medicine covered by the national health insurance programme. Glivec was added to the insurance coverage by the Korean Health Insurance Review Agency (HIRA). Due to Glivec's high cost, HIRA stated that only 70% of the entire cost of the treatment would be covered by the insurer. Further pursuance of Novartis for raising the limits under insurance coverage made HIRA increase the price per capsule to 14 US dollars. As it did not match Novartis's claim, Novartis was dissatisfied. In midst of it, the CLM patients demanded to reduce the cost of Glivec or even persuaded the Korean government to issue compulsory licensing. Novartis submitted that the price was standard worldwide and it could not make any price changes. Novartis was sympathetic to the CLM patient's demands and made a move to donate the

drugs. Novartis proposed donating 30% of the total medicine supply required in Korea or providing a 30% rebate to low-income patients. In this situation, KFDA recommended drugs only for patients with acute illness. This caused concern among patients who were in the early stage of illness and denied treatment. Korean Ministry of Health and Welfare fixed Glivec's price at 14.90US dollars. Exasperated Novartis threatened to stop supplying Korea with Glivec in case of non-acceptance to its price of 21 US dollars. Refuse to compromise by both Korea and Novartis forced some hospitals to suspend Glivec being prescribed to CLM patients who were afraid of being held liable for the remaining costs that were not covered by the national insurance plan. This made Novartis supply patients with Glivec free of charge and promised to do so until the situation was normal.[27] This tug of war between Korea and Novartis resulted in few patients being denied access to Glivec; even though the patients are ready to pay the remainder of the drug's cost that is not covered by national insurance.[28] CLM patients even tried to have a meeting with Novartis which was intervened by Korean policy officials. Hence the present situation is that Glivec is being sold at full price and health insurance covers only the partial cost of the treatment and Novartis continues to supply the drug-free of cost for patients with the low-income groups. The case study of Korea shows that political implication was the reason behind Novartis's action. Korean government was only ready to lower the cost of medicine and convince the patients concerning access to the medicines; however Korean government never attempted to use compulsory licensing as a negotiating tool with Novartis in a significant way. In this case, the threat to issue CL by Korea would have done more wonders rather than reducing the cost or usage of Glivec.[29]

India while trying to accommodate the TRIPs provision of the patenting product was trying on the other hand to protect its generic industry. During the transition and adopting TRIPs provision to cover product patent; India used mailbox provision to receive product patent applications till 2004. They had plans to review the application, meanwhile allowing the patent applicant to apply for exclusive marketing rights which would limit generic producers from marketing their versions of branded products in the country. Sorafenib is a cancer drug created by Bayer Corporation for liver, renal and thyroid cancer therapy. Bayer successfully got a patent for Sorafenib in India in 2008. The price of this drug is too high, approximately 2.80 lakhs for a one-month medication. In 2010 M/s Cipla an Indian generic drug manufacturer, reverse engineered sorafenib and marketed their drug in the name of "Soranib" but in the description, they mentioned it as sorafenib tablets 200mg. Hence, Bayer filed an infringement case against Cipla under Section 48 of the Patent Act and stated that Cipla's drug is 'spurious' under Section 2 of the Drug and Cosmetic Act. Drug Controller General of India (DCGI) denied Bayer's claim that the marketing of patented products does not come under the Drug and Cosmetic Act. The DCGI's award of a drug regulatory licence to Cipla on the basis that its medicine is safe and effective does not equate to the petitioners' patented product being "made, used, offered for sale, sold, or imported". [30]

In the Natco Vs Bayer case, Natco applied for a Voluntary license to produce a generic version of Nexavar, as per Section 84(1) of the Indian Patent Act, 1970 (as amended in 2005), citing the reason as non-affordability of drugs by the public

due to its high price.[31] Bayer refused Natco's voluntary licence. Natco then filed a compulsory licence application with the Controller of Patents to produce and market a generic version of Nexavar. Natco claimed they could give the drug required in one month for less than 9,000 rupees. Natco's offer was much cheaper than Bayer's price. Bayer sold the same drug at Rs.2,80,000. Bayer sold only 593 boxes of medicine whereas the requirement was much higher. Hence to satisfy the requirements of the public Natco was awarded compulsory licensing by the Controller of Patents in2012.[32]

The launch of Exclusive marketing rights (EMR) via mailbox provision in India attracted Novartis to apply for the same. In 2003 EMR was awarded for Novartis to sell Glivec in the Indian market. However, EMR was issued to Novartis and allowed Novartis even to seek rulings prohibiting the commercialization of generic versions of Glivec by several generic manufacturers, claiming that there was growing recognition for the drugs. This allowed Novartis to produce the same and allowed in the Indian market enthusiastically. Novartis was very generous in giving drugs for free. Some experts were sceptical about Novartis' donation levels in India. It was seemed to be a marketing strategy. Novartis besides being granted with process patent expected that it would be issued with a product patent too. Just the opposite happened for Novartis's expectation. In January 2005 when the Controller of Patent started to evaluate the Mailbox applications; it simply rejected the application of Novartis and refused to issue a product patent providing reasons for the same.[33] The denial was based on the fact that the innovation was merely a minor modification of a well-known substance; as a result, the innovation did not vary significantly that much from the source and lacked the necessary level of innovation to support a patent. Novartis was furious and filed an appeal.[34] However, the then health minister warned Novartis for filing an appeal and asked to withdraw the same; in case of denial to withdraw an appeal by Novartis, he said India hadn't used its compulsory licensing yet and shouldn't be pushed towards using the same. However, the Madras High court upheld the denial of the product patent for Glivec. Hence, India has been criticised for being averse to small-scale advances that would be widely accepted in other countries.. The decision clearly showed that India is trying to abide by the standards of WTO at the same time trying to protect its generic drug industry.[35]

Philippines CL dispute over hypertension drugs called "Norvasc" the pharmaceutical goliath Pfizer, owned the patent. The dispute arose when Norvasc's patent was about to expire. The Philippine patent law encouraged parallel importing of drugs that were to expire soon.[36] Hence Philippine International Trading Corp (PITC) owned by state started with the process to the procedure for obtaining generic Norvasc from Pakistan and India over a year before Norvasc patent expiration. PITC submitted the samples with the Philippine Bureau of Food and Drug (BFDA) to approve for importing generic versions of Norvasc. However, this caused concern for Pfizer and encouraged it to file a lawsuit against both BFDA and PITC for patent infringement. Pfizer has expressed concern about the safety and quality of pharmaceuticals being imported. However, CP tech attorney Judit Rius Sanjuan anticipated that Pfizer's intent to delay parallel import would be to benefit from monopoly even after the expiration of its monopoly.[37] The Philippines Government assured Pfizer that parallel importing would not happen until the patent expires. However, Pfizer was steady

in its stand and continued to show importance in its lawsuit. At this point, NGOs criticised the act of Pfizer and demanded the government to issue compulsory licensing.[38] Instead of issuing CL; The PITC worked to have the Pfizer patent revoked, claiming that the medicine was not truly unique and was simply a variation on previous innovations. If this was to be accepted, then it would be held that the patent issued would be held void from the start and this would lead to cancelling of the patent before a month of its expiration. However, this threat to cancel the patent was more precarious. However, the narrow window of opportunity for Philippine officials to consider CLs was shortened by the possibility of rescinding the patent entirely.[39]

Thailand's situation regarding issuance compulsory licensing was very active from 2006 to 2010. Many CLs was issued by Thailand during this short period. Thai health Minister Mongkolna Songhla issued CL for Drugs like Kaletra and Efvarienz, which are used for ARV's and cardiovascular diseases respectively.[40] This facilitated for price cut using negotiations to acquire Glivec for free by issuing a compulsory licensing threat. Apart from the above CLs, there were many compulsory licensing issued. However, Chaiya Sasomsab who replaced Mongkolna Songhla threatened to rescind the second batch of CLs. Chaiya Sasomsab was criticised for his threat to rescind CL and stopped the same from doing it.[41] The reason behind a greater number of compulsory licensing issued by Thailand A military coup happened in 2006, according to the government. To gain the support of the public and establish Coup's governing authority Pro-poor policies that resulted due to the economic crisis of 1997 were addressed. Thailand's plan for national welfare and public protection from financial catastrophes helped recoup Thailand from its economic crisis.[42] The election agenda for health care reforms paved way for the ruling parties' success in 2001.[43] Coup chose to make global or universal health care coverage a primary campaign focus. This gave the Minister of Health the authority to issue CL to acquire public support and legitimacy by taking on pharmaceutical behemoths. Hence the phenomenon behind issuing many CL was Poverty, Health, and WTO TRIPs Flexibilities. The Thai Ministry of Public Health (MoPH) was fed up with price reductions with pharmaceutical companies that had dragged on for several years. However, the Disease control Senior Advisor in the Thai MoPH in an interview expressed that "people advised us those negotiations with pharmaceutical industries are pointless unless you start announcing your intention to pursue compulsory licencing. Then they begin to converse with you." Hence TRIPs flexibility has been used successfully and positive by Thailand.[44]
The above case studies show how compulsory licensing has been used as a threat in negotiating prices as well as applied the same success for the benefit of the public. The following part would deliberate the usage of compulsory licensing procedure by analysing content and practice of the TRIPs flexibilities 31 bis.

Content and practice of article 31 BIS

Article 31 Bis has five paragraphs, Appendix and annexes which will be discussed in this part. The first paragraph of Article 31 bis (1) focuses to alleviate the issues raised by Article 31 (f) and criticize the inability of countries that can produce but who were unable to distribute pharmaceuticals under a compulsory license to developing and least developed nations due to restrictions of issuing compulsory

licensing only to produce and distribute to satisfy the domestic market needs. The content in the first paragraph of Article 31 bis acts as a permanent waiver to Article 31 (f).
Paragraph 2 of Article 31 bis a permanent waiver for TRIPs agreement's Article 31(h). This paragraph erodes the complications of the least developed country from paying twice to the patent holder. In short, it curbs the double remuneration to the patent owner. The third paragraph of article 31 bis is concerned with controlling the economies of scale concerning regional agreements that involve developing and least developed countries. The fourth paragraph puts forth a non-violation provision that states that member nations cannot challenge any measures taken under Article 31 bis under Article XXIII of the GATT. The main objective of paragraph four is that eligible members on request can receive benefits from contracting parties based on sympathetic consideration of their representations or proposals. Finally, Para 5 of article 31 bis emphasizes in maintaining of all existing flexibilities under TRIPs, stating that, This Agreement's Article and Annex is without any prejudice to the general rights, responsibilities, and stretchability that members have rights under the terms of this agreement except the provisions mentioned in Article 31 (h) and Article 31 (f).

Even after drafting an article conducive to the least developed or developing country to access pharmaceutical products through Article 31 bis the major concern was regarding diversion of pharmaceutical products to wrong markets. Hence to assure the purpose of Article 31 bis is achieved, Article 31 bis has come up with an annexe and appendix that defines the terms for applying Article 31 bis and avoiding pharmaceutical products being diverted to the wrong markets. Article 31 bis ask the eligible members to comply with several details regarding the product's name and the expected volume of products needed. Apart from that, the suitable eligible country making the request must demonstrate that it lacks manufacturing capacity in the pharmaceutical field to produce the essential drugs. The notification should also state whether the pharmaceutical product is patented in the country in question. Hence Annex para 2 (a) of Article 31 bis perfectly accesses the manufacturing capacities in the pharmaceutical industry of a member country that applies for the need of pharmaceutical products. This results in two scenarios one where LDCs are regarded to be lacking in manufacturing capacity hence, they need not demonstrate insufficient manufacturing capacities. In the second scenario, other eligible countries that apply for access to pharmaceutical products have to prove beyond reasonable doubt that it has insufficient manufacturing capacities, or the country does not have manufacturing capacity that is sufficient to meet the current or immediate requirements of people's need. The requirement to be complied with for applying for a waiver is mentioned in paragraph 2(b) of the annexe of Article 31 bis.[45] This mentions what must be done by an exporting member while applying for a waiver. First is they should export only to the limit of meeting the requirement of the importing member. The product produced under the license should be capable of distinction by labelling or marking differently to bring the pharmaceutical products that are produced under this framework. Unique packaging, colouration and product shaping are all examples of labelling. The main thing is that distinction in the product should not impact the price of the product and make it infeasible to acquire the same. The details of the pharmaceutical product so produced and requirement of importing members should be conspicuously

displayed on the website of WTO or its website of the exporting country. In addition to protecting the patent owner's national rights, this provision protects the international rights of the patent holder. This way of distinction in labelling and displaying the requirements and production helps to prevent spill-over of the licensed products and even at times intentional re-exportation of the products. This shows how the content of Article 31 bis has been structured logically to overcome all the defects on its way to waiving Article 31(f) and Article 31(h). Despite these many positive aspects, Article 31 bis lack the explanation concerning dosage sharing in patients receiving the therapeutic drugs. This section tries to balance the public as well as the patentee's interests. Even though it requires both importing and exporting members to follow certain rules, it does not set a limit on the number of pharmaceutical products that can be imported. Still, Article 31 bis have not shed light upon the framework about the administrative burden of importing countries and challenges with applying Article 31 bis framework to all types of pharmaceuticals outside of chemical-based formulations.[46]

Article 31 bis can be seen as a gifted provision however practice and application of the same cannot be at ease. Since its inception only once has it been used. The first nation to seek application of Article 31 bis was Rwanda. The process for procuring pharmaceutical products started in 2007. Rwanda notified its intention to import around 2, 60, 000 packs of Triavir for treating HIV/AIDs over two years. Rwanda also mentioned in its notification that a tablet it was seeking was produced in Canada by Apotex. Apotex filed the compulsory licensing with Canada in 2007. The license was approved in 2007 and it complied with Canada's Access to medicines regime that was enacted based on the Doha Declaration (Paragraph 6) into Canadian national laws. Despite adhering to the provisions of Article 31 bis and its annexe as mentioned in paragraph 2 it took three years for Canada to supply through shipment the requisite drugs to Rwanda. The first shipment on request was received under the framework. However, the second shipment of the products was not scheduled until 2009. Due to lengthy procedures, the procurement of drugs has seen many turbulent paths. In 2010 members of TRIPs were very much eager to hear the experience of Rwanda and Canada in using Article 31 bis framework. Canada stated that their duty to ship twice the medicine was an achievement and they have complied with Article 31 bis provision. Rwanda applauded the effort taken by Canada in delivering the products very efficiently, effectively and timely without delay.[47] Though member nations accepted that Article 31 bis worked without any issue and it would be more useful in working it in need of national emergencies. However, Indonesia rightly said that time lost in waiting for the deliveries of drugs could almost certainly wipe out the possibility of using this in particular circumstances of national emergencies. Indonesia also highlighted that in case of emergency raised after the issue compulsory licensing could not be addressed immediately as in notification the requisite is mentioned in the notification.[48] Then in such a case the process for procuring medicines during an emergent situation Rwanda would have to start the process from the beginning. Though Article 31 bis was a boon by overcoming the issues of Article 31(f) and Article 31 (h) it was certainly not a complete panacea for immediate requirements. The upcoming part would discuss the areas where Article 31 bis have to be reworked and shortcomings in its application could be overcome.

Barriers in application and viable solutions

Though Article 31 bis is a favour to LDCs and countries without a manufacturing base. it has a few shortcomings. This part would identify and try to suggest some ideas to overcome the same. There are three shortcomings for this Article 31 bis. First, it ignores the administrative burden imposed on the importing country who is often a resource-strapped member. Second, although the framework may apply to chemically based formulation medications, emerging therapeutics such as biologics, cellular and gene-based therapies present unique issues that were not considered in the writing of Article 31 bis and its associated components. The third and final shortcoming is that it fails to consider data exclusivity agreements included in other international agreements, and as a result, it provides no mechanism for reconciling TRIPs rules with contradictory terms in other accords.

The system of Article 31 bis has been considered to be deficient due to the administrative burden that has to be faced by least developed and developing nations due to their low socio-economic status. In the case of least developed nations, they need not file any proof of their manufacturing inability however in the case of nations who apply for compulsory licensing should prove their lack of manufacturing capacity or they have to show that their production is not sufficient to satisfy the requirements of the people. Hence this fall as a burden on an already potentially strapped for resources member just to avail the benefit of compulsory licensing. Although the procedures in Article 31 bis are to safeguard the interest of patentees getting affected by spillover, the procedures delay the access to medicines. Compulsory licensing is being issued for many reasons and one among those is national emergency and urgency. These are the situations that would require countries to ensure that their people get access to medications without any delay. The least developed nations are affected by diminished direct investment due to their lack of production capabilities. Hence patent owners consider these countries to be potentially hostile to patents and businesses. This may impose trade-related sanctions by governments of exporting countries or there can be chances of retaliation or revenge for what exporting members would have thought to lose by being forced to comply with compulsory licensing framework. Hence WTO should act as a watchdog in the system of Article 31 bis and compulsory licensing framework. To avoid the burden falling on the importing country, it is necessary to make sure that licenses are appropriately tailored to place more emphasis on an actual public health need and to educate the public about the suffering that was prevented by those who benefited from the pharmaceutical products offered as part of the compulsory licensing.

The second foremost chief challenge that disturbs the framework of Article 31 bis is pharmaceutical products related to biological products. Treatment of disease includes chemical-based formulations as well as novel therapeutics in development, such as biologics, cell-based and gene-based therapies. Annexe of Article 31 bis mentions the distinction between patented pharmaceutical products from that of pharmaceutical products issued with a compulsory license. The distinction can be made in the case of pills, however not in the case of biological treatments, which cannot be straightforwardly labelled according to the Annex's labelling requirements. It is very difficult to impose any meaningful physical identifier on a treatment that, to the naked eye, is a liquid in a vial, or that has

been isolated from cell culture. Even if it is going to be affixed the type of distinction can be easily tampered with by scratching it off, covering the same, removing or altering in any other way to tamper the labelling. Compared to chemical compositions the biologic composition is very difficult to distinguish. Since prices of biologics are comparatively higher than the normal pills of chemical-based drugs there are more chances of spillover by generating market disruption in nations. Second, pharmaceutical products derived from biological sources such as vaccinations, antibody-based therapies, blood products, gene-based therapies and cell-based treatments are made up of complicated combinations of diverse components that are significantly more complicated than a basic chemical composition. Third, biologics deals with viruses and sometimes cells extracted from a patient, reprogrammed, and re-administered to the patient and used in the treatment of various types of diseases. Hence these biologics are susceptible to various types of contamination and often require refrigeration or special storage conditions. Despite massive efforts to implement a global logistics network for the shipment and storage of vaccines and biologics, preservation during production, transit; the administration has become a major concern for some developing nations and least developed nations that lack the resources and assistance to appropriately store such kinds of pharmaceuticals. Hence this increases the cost of the biologics which makes it non-affordable, non-commercial use by the general public in case of national catastrophe by least developed and developing countries.[49]

Certain articles of TRIPs stand as a barrier while using Article 31 bis, and there is no viable solution to overcome the same. For example, article 39(3) protects information that has not been disclosed. Article 39(3) states that members are obligated to safeguard "undisclosed test or other data" necessary for the commercialization of a medicinal product "unfair commercial use." When many members require a drug to be approved before it can be used or marketed in their country, the content of Article 39(3) of TRIPs becomes a problem. This compels those countries to approve the drugs in the territory for them to be used or marketed in their country. This Article 39(3) is included in the TRIPS Agreement to prevent “unfair commercial use”.[50] Especially in case of national emergency when it is required by many members and when an importing country is facing the hurdle of importing drugs by following the administrative procedure prescribed under Article 31 Bis, approving the marketing of pharmaceutical products adds a burden to the importing country. Provisions on data exclusivity stand as a barrier for emerging and least emerged countries. As these countries are resource-poor, responding to such regulatory tests in such a period of national emergencies would certainly be like a struggle that can emerge between protecting innovation and ensuring adequate access to medicines. For example, according to Article 15 of the CAFTA (Central American Free Trade Agreement), regulatory test data can be kept for five years. Hence in this case for five years approval of a pharmaceutical product to protect safety and efficacy would restrict any other member country for at least five years.[51]

The main argument is that Article 31 bis have not been used more frequently because compulsory licensing under the framework is just one way of many to access medicines. Hence it is argued that infrequent use of the framework cannot be held as a reason for lack of interest in the program or lack of success. The full

utilization of this article by including new varieties of the plan by including suggestions to use resources like Medicines Patent Pool and to prepare pricing models to facilitate access to medicines in the least developed nations and developing nations. Hence instead of finding the disadvantage on TRIPs Article 31 bis, now it is essential to find feasible solutions for better working of Article 31 bis.[52] Solutions for better working of Article 31 bis would be to encourage the importance of regional agreements and thereby complement the requirements of least emerged and emerging nations. Along with the above solution waiving off the data exclusivity requirement under very stringent conditions in article 31 bis, compulsory licensing agreements would pave the way in better working of Article 31 bis. The first solution will be to emphasize the importance of regional trade agreements that would help the countries to avail medicines, using agreements between countries in a similar crisis or that may lack the ability to do on their own. Regional agreements would facilitate a country-to-country approach. However, this would make regional agreement play a crucial part in reducing the administrative burden and social costs. The second solution would be to instigate least developed and developing countries to show zeal in developing their scientific infrastructure to become more self-reliant by attracting outside investment from both private and public sources. Developing scientific infrastructure would facilitate the country doing so to accrue many benefits like creating job potentials and focusing on education, ability, or training among their population. The third solution is to waive off the data exclusivity requirement under very stringent conditions in an Article 31 bis compulsory licensing agreement. Hence these could be a few ways to overcome the shortcomings of Article 31 bis. However, these solutions are not enough to fix the issues created by Article 31 bis.[53]

Conclusion

The most significant thing to be noted in implementing Article 31 Bis of TRIPs is a shortcoming in practising the theory. Although it provides waiving of patent and issuance of compulsory licensing the procedures to adopt the same cause its application to be very difficult and delayed. Along with time delay, it also costs heavy those countries that are poor with no or insufficient manufacturing capacity. This paper has tried identifying barriers after analysing the evolution of TRIPS and coming up with a few solutions. The major problem in implementing the solution is that there is a difference between the country's economic status. Because there can be countries that have not even met the problem than any other country that imports medicine favours. Given the situation is different varies from country to country. Hence one size will not fit all. Hence Article 31 bis should be allowed to be tailored to suit the needs of every country that is ready to import and that is applied to export. International relationships are always subject to change, hence new frameworks can be provided to overcome shortcomings of Article 31 bis to balance the interest of patentee and public health.

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