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A Critical Assessment of the Effectiveness of Existing Legal Measures Available to Reconcile the Public Interest in a Wide Range of Affordable and Accessible Medicines

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ABSTRACT

The concept of intellectual property (IP) was developed during the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works treaties of 1883 and 1886, respectively. The intention was to provide legal protection to novel intellectual creations, including industrial novelties and accomplishments of art. Industrial IP law entails patents for novel inventions and trademarks for branded products. Research and development, and advances in biotechnology and bioinformatics have resulted in massive advances in medicine. As a result, the synthesis of new drugs has taken a turn following the incorporation of patent law in these developments to protect the novel formulas and protocols involved. The culminating effect is a drug-market monopoly and exorbitant pricing of modern drugs rendering them inaccessible to developing countries and poor populations in developed countries. Importantly, the actual tragedy is surrounded by the inequality between high and low-income countries in acquisition of essential drugs to curb infectious and emerging diseases, particularly in sub-Sahara Africa and some parts of Asia. A global crisis in relation to health has emerged with escalating deaths occurring yearly for treatable or preventable diseases.

The rising costs of drugs and medicines, coupled with changing economic policies and trends in the global market has advocated the awareness on the role of patents in drug pricing. It is in this regard that the World Trade Organization (WTO) was developed to establish trade liberalization and standardization. More importantly, the reduction of trade barriers in the global market is coupled with patenting, and the definition of minimum standards of intellectual property explained in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, introduce a contest with respect to their influence on public health. This article seeks in-depth understanding of the existing legal measures influencing access and affordability to drugs and medicines. Moreover, this article will critically evaluate the effectiveness of these legal measures and postulate the establishment of equitability and equality in public health interests and the rights of patent-holding companies.

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I. ACCESS TO AFFORDABLE MEDICINES

Access to drugs is defined by the capacity to have continuous availability of drugs and medicines that are affordable in health care facilities and outlets that are within a one-hour's walk from the hospices of patients.[2] In developing countries, availability of drugs and medicines is low in the public sector and is congruently lower when compared with the private sector. When drugs are unavailable in the public health institutions, patients turn to private facilities, whose drugs are overpriced, or do without treatment completely.[3] Considering the availability of free or low-priced medicines in public health facilities, they are pivotal in easing access to drugs among the poor.[4] The availability of drugs reflected the percentage of medicine outlets that stocked a particular drug or medicine needed by a patient,[5] without accounting for alternative dosages of the drug.

The primary block to access of medicines in the public sector is attributed to the consequences of patent law.[6] Despite the use of patent law in the past, the development of the TRIPS Agreement introduced a new drug-pricing problem. In the agreement, it is a requisite of WTO members to protect the IP rights, which detail the requirement of permission for production, import, sale and use of patented products from the patent holder.[7] Such patented products include drugs and medicinal products, and, hence, a period of monopolisation in the initial production and introduction in the market commanded high initial pricing.[8] During this period, no low priced generic alternatives were available in the markets.

Low economic populations access these branded drugs from their personal finances or via their insurance. This legal requirement exacerbates the pricing inaccessibility in developing countries where both the economic and health status are low.[9] At the same time, there is a

[2]United Nations Development Group, *Indicators for Monitoring the Millennium Development Goals* (United Nations, New York, 2003) 89

[3] WHO, 'An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines' (UNITAID Discussion Paper, Geneva 2016) 10

[4] Aaron S. Kesselheim, 'Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines' 34 AJLM 127 (2008)

[5]United Nations Development Group, *Indicators for Monitoring the Millennium Development Goals* (United Nations, New York, 2003)

[6] Peter K. Yu, 'Access to Medicines, BRICS Alliances, and Collective Action' 34 Am.J.L.& Med. 345 (2008)

[7] Alexandra G. Watson, 'International Intellectual Property Rights: Do Trips' Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries' 32 B C Int'l & Comp L Rev 143 (2009); WTO, TRIPS**:** A More Detailed Overview of the TRIPS Agreement (WTO 2017) 1 (June ,30, 2019, 12:05pm),https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[8] UNSG, *The United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* (Vienna: United Nations 2016) 8

[9] Sharifah Rahma Sekalala, *Beyond Doha: Seeking Access to Essential Medicines for HIV/AIDS through the World Trade Organisation* (PhD, University of Warwick School of Law) 3 (July 2, 2019, 11:00am) ,http://siteresources.worldbank.org/INTRAD/Resources/SSekalala.pdf

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relatively higher need for drugs and medical technologies, where a majority are under patent law. Health insurance coverage is equally low, requiring poor patients to engage their personal finances to pay for branded costly drugs. In essence, with increased medical needs and poor economic capacity, access to branded drugs command an expanded state expenditure on public health facilities, calamitous outflows among populations, and increased morbidity and mortality attributable to deficiencies in access to drugs.[10]

II. LITIGATION ON MONOPOLISATION AND CONTROL OF PRICES

The *India - Mailbox (US)* dispute pertaining "patent protection for pharmaceutical and agricultural chemical products," is a primary example of TRIPS lawsuits in quest of market superiority.[11] The case surrounded illegalities attached to TRIPS Agreement Article 27 with infringements directed towards India's procedural failures in the IP protection of drugs and agricultural formulations and products. In the case, the US purported that the respondent (India) had inadequately implemented requirements stipulated under TRIPS Agreement Articles 70(8) and 70(9) for patent application preservation, and legislature on market exclusivity.[12] Specifically, the US pointed India's absence of a mailbox system for patent application receipt for human medicines and agrichemicals. The determination was that the basis of India filing system was inconsistent with art 70(8), and that India lacked legal mechanisms for issuing market exclusivity for products covered, and deemed to violate Article 70(9).[13] Moreover, following a TRIPS interpretation, there was a rejection of the use of the "legitimate expectations" standard that is embodied within the TRIPS principle of non-violation. The *Canada – Generic Pharmaceuticals* disputes is another example reflecting the European Community's dissatisfaction with patent law enacted in Canada.[14] The EC's submissions entailed a contravention of Canadian Patent Act and drug regulations against TRIPS by allowing mass production and stockpiling of patented drugs.[15] This case was in view of the production and use of generic drugs, with Canada arguing provisions of "limited exceptions" in their manufacture. Further, the EC allegations identified noncompliance with legislation enacted in Canada based on its TRIPS obligations considering the lack of complete patent

[10]Ibid 4

[11]*India – Mailbox (US) (India v United States)* (1996) Appellate Panel (WT/DS) No DS50; Frederick M. Abbott, 'TRIPS Dispute Settlement Decisions' (International Centre for Trade and Sustainable Development, Geneva, 2009) 1

[12] TRIPS Agreement art 70(8) and 70(9)

[13]Frederick M. Abbott, 'TRIPS Dispute Settlement Decisions' (International Centre for Trade and Sustainable Development, Geneva, 2009) 2

[14] *Canada – Generic Pharmaceuticals (Canada v European Union)* (2000) Appellate Panel (WT/DS) No DS114

[15] Frederick M. Abbott, 'TRIPS Dispute Settlement Decisions' (International Centre for Trade and Sustainable Development, Geneva, 2009) 5; Frederick M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade And The Protection Of Public Health' 99 Am J Int Law 317 (2005)

protection of drug novelties as explained in TRIPS Agreement Articles 27.1, 28 and 33. The Appellate Panel determinations identified its neutrality to technology.[16]

Considerations on competition law identify its inactivity in price control of drugs and medicines.[17] In the US, the federal court has exerted no competitive law on disproportionate pricing on medicines or other drugs. In other countries, there is a sporadic application of antitrust doctrines, particularly with respect to drug pricing.[18] In practice, exorbitant pricing of medicines by dominating pharmaceutical firms is self-threatening. High pricing elicits a high capacity to attract new competition, considering the prevailing market environment is guided by a legislative monopoly. In this case, regulatory interpolation is ineffective or not applicable.[19] As such, a legal definition testing determinants of levels to cogitate when a price is deemed "excessive" is impractical, and even if there were such a test, difficulties for long-term pricing regulation would arise.

In the recent past, resurgence in antitrust doctrines on excessive pricing has resulted in controlling pharmaceutical markets.[20] For instance, in the UK, several cases are under investigation and others are subject to appeals as some medicines have faced de-branding while the manufacture and sale of others are off-patent. Consider the *Flynn Pharma Limited and Another v Competition and Markets Authority (CMA) (Interim Relief)* case,[21] for example. The infraction of prohibitions stipulated under Article 102 of the Treaty on the Functioning of the European Union,[22] and in Competition Act 1998, s 18[23]resulted in a £84.2 million penalty on Pfizer for overpricing phenytoin sodium, and £5.2 million penalty on Flynn Pharma for its distribution.

Use of market exclusivity, as described in the Food, Drug and Cosmetics Act,[24] enhance monopoly of branded drugs. Essentially, exclusivity hampers generic entry by preventing Abbreviated New Drug Application submissions and approvals. For instance, AstraZeneca

[16]Frederick M. Abbott, 'TRIPS Dispute Settlement Decisions' (International Centre for Trade and Sustainable Development, Geneva, 2009) 3
[17]Frederick M. Abbott, 'TRIPS Dispute Settlement Decisions' (International Centre for Trade and Sustainable Development, Geneva, 2009) 2
[18]Stephen P. Marks, 'Access to Essential Medicines as a Component of the Right to Health' in Clapham A and Robinson M (eds.), *Realizing the Right to Health*, (Zurich, Switzerland: Rüfer & Rub 2009)
[19]Frederick M. Abbott, 'Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health' 6 UC Irvine Law Review 281 (2016)
[20]Duncan Mathews, 'WTO decision on implementation of Paragraph 6 of the Doha Declaration on the TRIPS agreement and public health: a solution to the access to essential medicines problem?' 7 JIEL 73 (2004)
[21]*Flynn Pharma Limited and Another v Competition and Markets Authority (CMA) (Interim Relief)* [2017] CAT 1274
[22] Treaty on the Functioning of the European Union (European Union Series) 25 March 1957, 2-107-6192
[23] Competition Act 1998, s 18
[24]Food, Drug and Cosmetics Act 1938 (US)

holds 18 patents over Bydureon, with two expiring in 2026. The terms of exclusivity of the above drug expires in September 2018 but provides other generic companies no right to produce generic alternatives until after 2026 or face a lawsuit.

III. INTELLECTUAL PROPERTY RIGHTS

The interaction between IP rights and patent protection is complex vis-à-vis national and international policies. While the dogma on IP rights has national implications, they have international influences that are depicted in the TRIPS Agreement, as well as in bilateral and multidimensional trade treaties.[25] National implications of IP rights entail impacts on drug pricing policies, competition law, and government procurement policies. IP rights command a major role in motivating innovativeness, research and development of novel pharmaceutical products in counties commanding high technological and financial aptitudes. Conversely, acquisition of a patent may result in minimal innovation and market control since the market geography is small, and the technological capacity is derisory.[26] Devoid of operative, distinctive, and affordable prices, patenting expose drugs to increased prices rendering inaccessibility to essential drugs to poor populations in developed countries, and developing countries in general. With respect to IP rights, the cost-benefit analysis of patents is country dependent with respect to ease of access to the scientific and technological infrastructure, while the flexibilities entailed in the TRIPS Agreement establishes apposite pricing balance on drugs and medicines in a particular country.[27]

Patents

Introduction of monopolisation, due to patenting of novel drugs and medicines, has enabled price escalation of medicines and their sale at artificially high prices. Patents have eliminated competition to minimal levels. Essentially, holding a patent protection on drug molecule commands a monopoly in manufacture, distribution and sale of the medicine for a two decade term. As a result, the patent holder exercises monopoly in entirety including defining the product pricing. In some cases, exclusivity of an additional 15 years may be awarded where the holder has not made sufficient returns to cover the research, development, and manufacture returns.

[25]WTO, TRIPS**:** A More Detailed Overview of the TRIPS Agreement (WTO 2017) 1 (July 5, 2019), https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[26] Ruth Levine, Jessica Pickett and Neelam Sekhri, 'Demand Forecasting For Essential Medical Technologies' 34 AJLM 245 (2008)

[27]S Musungu and C Oh, The Use Of Flexibilities In TRIPS By Developing Countries: Can They Promote Access To Medicines? (Commission On Intellectual Property Rights, Innovation And Public Health, Switzerland, 2005) 7

An important tool in determining the price of a particular drug is the type of patent or exclusion protection. A patent holder has a legal obligation of fixing the prices of all patented drugs. Patented and branded drugs demonstrate higher prices compared to their generic alternatives in an open economical niche.[28] Multinational corporations use patent protection as a tool to compete effectively with generic drug producers, which may result in monopolistic control of manufacture, distribution, marketing, sale and pricing of the purported medicines.

Irrespective of the dire public health need for low-income countries to augment their access to affordable, essential medicines, all aspects surrounding drug patenting and pricing crises present ever-increasing impediments to this realization. In actuality, these patenting obstacles are developed to compel developing countries to seek issuance of compulsory licences under the TRIPS Agreement, together with parallel imports, to purchase the drugs at the predetermined prices. Fundamentally, cases illustrating access to affordable essential drugs define disconcerting principles of TRIPS in its facilitation of anticompetitive actions. In addition, TRIPS has ideally promoted a business flow of drug products whose prices are only predisposed to monopolistic segmentations, thereby preventing a free-market pricing trade a counter to the WTO liberalization principle on trade.

Compulsory Licensing

The concept of compulsory licensing entails the provisions in TRIPS pursuant to granting a compulsory licence to manufacture, distribute and sell branded drug products without any interference from the patent holder.[29] Varied reasons are accorded the grounds for a compulsory licence grant, which depends on the legal framework of a particular country. The Paris Convention and TRIPS provide conditions and infrastructure for compulsory licensing without specifications of situations guaranteeing the grant of compulsory licence.[30] Compulsory licences form a legal foundation for a government granting local manufacturers (or another country) legal rights to manufacture or import patented drug products devoid of sanctions from the patent holder.[31] Regarding members of the WTO, defined conditions articulated under TRIPS Article 31 are binding and subject to satisfaction.[32] Such conditions

[28] WHO, Public Health, Innovation and Intellectual Property Rights (Commission On Intellectual Property Rights, Innovation And Public Health, Switzerland, 2006) 28

[29]Jakkrit Kuanpoth, 'Intellectual Property And Access To Essential Medicines: Options For Developing Countries' 2 J Generic Med 53 (2004)

[30]Jakkrit Kuanpoth, 'Intellectual Property And Access To Essential Medicines: Options For Developing Countries' 2 J Generic Med 56 (2004)

[31]Frederick M. Abbott and Van Puymbroeck RV, 'Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision' (World Bank Working Paper No. 61, Washington DC, World Bank, 2005) 7

[32] TRIPS Agreement art 31

include, but not limited to, the requirement of a WTO member seek authorization on individual merits of a patent to use from patent holder, and associated third parties from the patenting government. Article 31 also purports the requisite for requesting the authorization to manufacture branded drugs defining reasonable terms and conditions for commercial use. In addition, other country specific legislative conditions may affect the issuance of a compulsory licence. In consideration of TRIPS Article 31 and the stipulations of the Doha Declaration, paragraph 6, poor countries are disadvantaged by the compulsory licence in view of their manufacturing incapacity.[33] The Doha Declaration, paragraph 6, decision was developed in August 2003. The intent of the declaration is a patent waiver for developing countries with drug manufacturing incapacities and a high potential of public health emergencies rendering compulsory licensing important. Such countries turn to importation of the generic alternatives manufactured and sold under compulsory licences, which are cheaper, but importation quantities are hampered by the "predominantly for the supply of the domestic market" obligation in TRIPS Article 31(f).

Compulsory licences actuate waiver of the "predominant domestic supply" requirement that reflect an exporting country as indicated in the TRIPS Agreement. The waiver takes effect in the event that a country with a health crisis is an "eligible importing member," describing a country that is least developed.[34] The importer may also be any WTO member provided that it makes applications and notifications to the Council for TRIPS identifying its intent as an importer to engage the system. Before importing, an eligible importing member is obligated to make statements and notices to the Council for TRIPS defining the patented drugs name and quantities to import, as well as confirmatory statements pointing to its insufficiency in pharmaceutical production to manufacture the drug (exemptions are provided for least-developed countries of this clause). In addition, the notification from the eligible importing member must include ratification that the exporting country has provisions for a granted compulsory licence as demarcated in the TRIPS Article 31.

The compulsory licence requires the exporting country to make formalizations to the Council for TRIPS detailing its intent to provide a compulsory licence and the affiliated conditions describing the licensee, drugs names and quantities required, period for which the licence will be active, and a digital platform (preferably a website) that details specified licence facts and

[33]Richard P Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care' 3 J World Intellect Prop 889 (2000)

[34]Frederick M. Abbott and Van Puymbroeck RV, 'Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision' (World Bank Working Paper No. 61, Washington DC, World Bank, 2005) 10

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figures. A compulsory licence is required to meet particular conditions regarding the drugs being produced or imported, including exporting or production of particular quantities that satisfy the needs of the importing member, specific identification of such drugs through labelling and markings specific to the system as defined in the decision. Such identification entails packaging, shape and/or colour without affecting the price of the drugs. Lastly, the compulsory licence stipulates the role of the licensee in positing the digital platform, the quantities of drugs being exported, and the countries to which they are being exported, including the packaging and labelling of each product.

Beall and Kuhn established that there are many obstacles hindering the effectiveness of compulsory licences in promoting access to affordable, essential drugs.[35]As a result, many countries particularly seek compulsory licences for HIV/AIDS drugs and a few for other communicable diseases guided by possible pandemic potential, including anthrax and influenza drugs.[36]Access to affordable treatment of diseases with high impact, such as sepsis, malaria and multidrug resistant tubercle bacilli infections, is poor with little to no compulsory licences.[37] Issuance of compulsory licences may be impeded by local government legal reforms. For instance, Rwanda made formal notifications to the WTO on its intent to import TriAvir, an antiretroviral therapy for HIV, from Canada in 2007. Initially, the Canadian Patent Act had not integrated fixed dose combinations, leading to amendments. Politics on the amendments and requests for approval on the nine patents in the manufacture of the drug made compulsory licensing cumbersome and expensive. Following the events surrounding the Canada-Rwanda compulsory licence influencing the export waiver policy described in the Doha Declaration, paragraph 6, lack of pharmaceutical manufacturing infrastructure, poor health system capacity, legislative complications in issuance of compulsory licences, and political pressures against compulsory licences impacted negatively on drug access.[38]

IV. GENERIC DRUGS AND ACCESS TO MEDICINE

The manufacture of generic drugs under the Food, Drug and Cosmetic Act was meant to delimit price escalation in the drug market following monopolisation of branded products and hence enhance access.[39] The manufacture of generic drugs follows approvals of the Abbreviated New

[35]R Beall and R Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis' 9 PLoS Med 1 (2012)
[36]Kenneth C. Shadlen, 'The Political Economy of AIDS Treatment: Intellectual Property and the Transformation of Generic Supply' 51 International Studies Quarterly 559 (2007)
[37] R Beall and R Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis' 9 PLoS Med 3 (2012)
[38]C Stavropoulou and T Valletti, 'Compulsory Licensing and Access To Drugs' 16 Eur J Health Econ 83 (2015)
[39] Ellen F.M.'t Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation*

Drug Application (ANDA) by the Food and Drug Administration. These applications are submitted after the expiration of a patent term to allow new entries. Essentially, for ANDA approval to be successful, it is requisite for the generic product to meet the bioequivalence threshold of the branded medicine. The Drug Price Competition and Patent Term Restoration Act of 1984[40] require the similarity in quality in terms of active ingredients, pharmacodynamics, pharmacokinetics, and clinical use between the generic and branded drugs.

The Trade Related Aspects of Intellectual Property (TRIPS) Agreement

In the contemporary drug and medicine market, primary legal approaches for protecting IP rights include using patents, copyrights and trademarks. The agreements defined in TRIPS identify mechanisms of manufacture, distribution and sale of medicines. As a mechanism of pricing control, TRIPS Article 31 points to a mandatory requisite of a patent owner granting another manufacturer a compulsory licence to allow the second producer to manufacture the patented drugs or medicinal molecules devoid of patent infringement. This Article, does not define the limits of issuance of such compulsory licences. On the other hand, it presents technical procedural and substantive obligations. For instance, substantively, it is obligatory for the patent holder to be recompensed adequately for non-exclusive licences, while applications for licences will be considered on individual merit basis.

Procedurally, TRIPS Article 31 dictates the issuance of a voluntary licence to an applicant with the patent holder defining judicious terms and conditions of licence use. Notable is the fact that compulsory licences are subject to dissolution and can be revoked in events contravening the conditions defined in the grant. For instance, Article 31(f) determines the use of the licence purporting that the licence holder primarily supplies medicines to the local market of the WTO member, as defined in the grant. In this regard, if a country is capable of manufacturing medicines, the licence limits the production and supply to the country's consumption predominantly, with a non-predominant export of the product. Similarly, Article 31(f) obligates a WTO member to provide a compulsory licence to a country with low medicinal manufacturing ability to import them to meet its national medical needs.

Even with the implementation of the Doha Declaration, paragraph 6, describing trademark protection, forms a stumbling block to its effectiveness considering the illogical requirement of compensation of patent holders even when a country is not producing the medicines.[41]

and the application of the WTO Doha Declaration on TRIPS and Public Health (Diemen, AMB Publishers 2009)

[40]Drug Price Competition and Patent Term Restoration Act 1984 (US)

[41]Duncan Mathews, 'WTO decision on implementation of Paragraph 6 of the Doha Declaration on the TRIPS agreement and public health: a solution to the access to essential medicines problem?' 7 JIEL 73 (2004)

Secondly, difficulties in calculations relating to remuneration amounts are additional problems with the declaration. In this regard, implementation of Doha places poor countries in a worse health compromise making essential drugs extremely expensive and inaccessible than when the country had a local drug manufacturing capacity.[42] Moreover, there is a heightened risk of manufacturing generic medicines identifiable by shrinking financial benefits and diminishing health markets in relation to the exclusivity of selected markets.[43] Ineffectiveness in TRIPS to mitigate drug pricing and access to essential drugs is housed within increased risk of litigation or heightened pressure on poor countries through a lack of legal determinations explaining the importations of medicinal products. It is also housed in poor demarcations defining insufficiency in public health or drug manufacturing capacity.

V. EXISTING LEGAL MEASURES AND ACCESS TO MEDICINES

The above analysis identifies several legal approaches to motivate multinational corporations to increase access to affordable, essential medicines through pricing procedures. TRIPS is the basis influencing international law, while the Doha Declaration, paragraph 6, provides waivers in exportation of patented products as described. Patent protection of novel drug discoveries has been in force for a long time with developed countries exploiting monopolies associated with exorbitant drug pricing in open markets.[44] Compulsory licensing described in Article 31 of the TRIPS Agreement provides supplication permitting WTO member countries to export and import drugs and medicines with respect to their pharmaceutical manufacturing capacity and patent power.

Patent law submits provisions for compulsory licensing with the intent of easing access to affordable drugs, and is the grounds for manufacture or importation of patented drugs. For instance, in the event of extreme urgency and national emergencies, law demands implementation of compulsory licence to mitigate health-related insufficiencies and emergencies, particularly in consideration of inadequate accessibility to antiretroviral drugs for HIV/AIDS treatment, emergence of bird flu, haemorrhagic fever diseases (HFD), or severe acute respiratory syndrome (SARS). In such emergencies detailing epidemics, pandemics, and war, a country issues a national emergency notification to use the compulsory licence clause with the government allotting authorisation to exploit the patented drugs during the emergency

[42] Alexandra G. Watson, 'International Intellectual Property Rights: Do Trips' Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries'32 B C Int'l & Comp L Rev 143 (2009)
[43] Sharifah Rahma Sekalala, 'Third World Access to Essential Medicines and the WTO General Council Decision 2003' 21 KLJ 172 (2010)
[44] WHO, 'An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines' (UNITAID Discussion Paper, Geneva 2016) 11

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period. This patent usage is within the TRIPS terms and conditions under patent law, and the usage is as the state reasons appropriate.[45] Extreme urgency defines situations such as mitigation of the spread of HIV/AIDS, malaria, haemorrhagic fever virus, or TB, and a state may use, without notification for authorisation, a patented drug.

International law also permeates compulsory licences in cases where the patent holder exercises abuse of patent rights, patent inactivity or inadequate activity of the patent holder.[46] The precinct of modern patenting dictates the reciprocity gain between the patent holder and the granting country. Access to medicines is not only limited to developing countries, but also a patent holder is required to manufacture amounts and prescriptions sufficient to cater to health inadequacies in the granting state. Therefore, patent abuse is described as an insufficiency in manufacturing patented drugs, and excess pricing, which calls for issuance of compulsory licences to restrain the patent abuse.[47] Moreover, negation to offer a voluntary licence to a state under reasonable and equitable terms call for a compulsory licence if the licensee has followed described protocols for a specified period. In order to enhance ease of access to essential drugs, patent law advises developing countries to include compulsory licences in their state law since it would expedite the creation and expansion of industrial or commercial undertakings in the country, with significant easement of medicinal accessibility.

Patent holders may engage in anticompetitive comportment considering the monopolistic foundation created by the patent, including controlling inflated selling and purchasing prices, engaging in collusive bargains for skewed benefits. It is requisite of the patenting state to offer compulsory licences to curtail the high pricing practice outside of Articles 31(b) and 31(f) conditions.[48] As identified in TRIPS, the manufacture of patented medicines is meant to assuage public health needs. According to this government use legal implication, expressed in many states' patent law, the health needs of a government, as noted in TRIPS, are met via authorisation by the government to manufacture or import, distribute and supply them on non-commercial terms. This basic insinuation is that the patent holder makes sales devoid of profits or losses.

The submissions of Article 31(b) define the permission of a state to issue compulsory licences

[45]Jakkrit Kuanpoth, 'Give the Poor Patients a Chance: Enhancing Access to Essential Medicines through Compulsory Licensing' 6 J Gen Med 23 (2008)
[46] Jakkrit Kuanpoth, 'Intellectual Property And Access To Essential Medicines: Options For Developing Countries' 2 J Generic Med 56 (2004)
[47]Jakkrit Kuanpoth, 'Intellectual Property And Access To Essential Medicines: Options For Developing Countries' 2 J Generic Med 56 (2004)
[48]TRIPS Agreement arts 31(b) and 31(f)

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with no discussions with the patent holder.[49] Moreover, a government may issue a compulsory licence in consideration of a dependent patent, which is an advancement of technology and economic gain to the first patent. In all the above compulsory licence indications, the subject of easy access of essential medicine is paramount. Evidently, arguments brought forth under the TRIPS Agreement deem to actuate the object. Conversely, as Beall and Kuhn purport,[50] other forces impede the acquisition of compulsory licences, and hence, negatively influence the achievement of accessible medicinal objectives set under TRIPS. As a result, the existing legal framework under patent law and protection of drugs and medicines within the precinct of the TRIPS Agreement has botched public health protection and failed to accommodate the needs and interests of the public in developing countries or poor populations in developed countries.[51]

VI. INTERESTS OF THE PUBLIC VIS-À-VIS THE RIGHTS OF PATENT HOLDERS

The basic interest of the public is better health outcomes through increased accessibility of essential drugs, among other medical services and technologies. The use of TRIPS was meant to assure the global community had affordable medicines while meeting the financial needs of patent holders. Evidently, definitions set out in the TRIPS Agreement, especially the outcome of decisions made in paragraph 6 of the Doha Declaration, focused on public health interests by allowing compulsory licenses to WTO members that lack the capacity to manufacture pharmaceuticals.[52] Developing countries share diverse health needs and technological incapacities.[53] The fight of infectious diseases HIV/AID, malaria and TB is poor in these countries, while their prevalence is high. Even with the positives identifiable with compulsory licensing, the conditions set by the patenting countries, and political influences hamper successful transitions in the health sector.[54]

Legal complexities surrounding patent law, the fear of legal suits and high penalties of patent infringement deter poor countries from seeking compulsory licensing,[55] or manufacturing

[49]Jakkrit Kuanpoth, 'Intellectual Property And Access To Essential Medicines: Options For Developing Countries' 2 J Generic Med 57 (2004)
[50] R Beall and R Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis' 9 PLoS Med 4 (2012)
[51] James Love and Tim Hubbard, 'Prizes for Innovation of New Medicines and Vaccines' 18 Annals Health L 155 (2009)
[52]Holger Hestermeyer , '*Human Rights and the WTO: The Case of Patents and Access to Medicines* (International Trade Law and Regulation 2008) 3
[53]GrahamDutfield, 'Delivering Drugs to the Poor: Will the TRIPS Amendment Help?' 34 American Journal of Law & Medicine 107 (2008)
[54]Amitava Banerjee, Aidan Hollis and Thomas Pogge, 'The Health Impact Fund: Incentives for Improving Access to Medicines' 37S Lancet 166 (2010)
[55]Emily Ng and Jillian Clare Kohler, 'Finding Flaws: The Limitations of Compulsory Licensing for Improving Access to Medicines - An International Comparison' 16 Health LJ 143 (2008)

generic drugs.[56] Developing countries with manufacturing capacity of pharmaceuticals, including India, China and South Africa, among others are manufacturing generic drugs to counter the high prices of branded drugs. Execution of the Drug Price Competition and Patent Term Restoration Act favours the introduction of generic drugs as a backlog to the competition of branded counterparts.[57] Conversely, the issuance of market exclusivity hampers the entry of affected generics resulting in poor access to essential medicine. Delinking patenting from revenue for research and development, and incentives for novel drug discoveries facilitates a major index for reducing drug prices, but the lack of legal definitions of delinking is a major setback. [58]

VII. CONCLUSION

The culminating effect on the use of IP rights and patent law is price-discriminating monopolisation of the global open market for drugs and medicines. The introduction of the TRIPS Agreement was geared towards equitable acquisition of essential medicines. On the contrary, the interpretation of Article 31 and implementation of the Doha Declaration, paragraph 6, commands exorbitant prices of essential drugs leading to their inaccessibility. The manufacture of generic drugs following the expiry of a patent term, deemed to be the best practice to enhance drug accessibility, particularly in developing countries. A combination of patent and market exclusivity is a major throwback on generic drugs considering their power over new generic entrants. Therefore, there is a need to streamline preconditions to facilitate easy application and usability of compulsory licences to promote the manufacture and importation of essential drugs to curtail infectious diseases in developing countries. Delinking the high price of drugs from research and development and creating innovator incentives is another process that will promote access to affordable drugs. Legal framework detailing the delinking process is necessary. Lastly, industrial investment in developing countries to exploit cheaper labour and promote industrialization with modern medical and pharmaceutical technology deems an option towards a sustainable research, development, manufacture, and access to essential medicines.

[56]Graham Dutfield, 'Delivering Drugs to the Poor: Will the TRIPS Amendment Help?'34 American Journal of Law & Medicine 107 (2008)
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