FEMINISTS FOR A PEOPLE'S VACCINE

Issue Paper #3

AN EVALUATION OF TRIPS FLEXIBILITIES

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An Evaluation of TRIPS Flexibilities

For many years, the fight for access to medicines has been pushing for reforms to the intellectual property (IP) and patent protection system enshrined in the WTO TRIPS agreement. The inclusion of intellectual property under the realm of trade has created many legal barriers to equitable access for public health. It is becoming increasingly clear that COVID-19 vaccines will not be distributed equitably, as a result of these barriers imposed by the TRIPS Agreement.

Key Issues

1 Patents and other IP protections enshrined in the WTO TRIPS agreement that grant biotechnology and pharmaceutical companies market monopoly have been abused for years. There are many instances in the past wherein such IP protection has withheld essential medicines from vulnerable populations, causing them to suffer.

2 The COVID-19 pandemic is in danger of disintegrating into a similar mess of patent infringement lawsuits that will prevent vulnerable populations from accessing the new vaccines quickly and at affordable costs.

3 A close evaluation of the current TRIPS agreement with its Flexibilities, and the Doha Declaration on TRIPS and Public Health reveal a restrictive, cumbersome and inefficient system that clearly works at the behest of a few powerful Northern governments.

4 Urgent action is needed to reform the current system that incentivizes and rewards Big Pharma for price gouging instead of creating global public goods and to suspend its operation when needed, such as in a pandemic situation.

Introduction

The control over knowledge and technology has for long been a barrier to access to medicines and treatment. The system of protection of intellectual property has granted various instruments of ownership to innovators and manufacturers in the form of patents, copyrights, trademarks and industrial design. While intended to encourage innovation and technology development, these have in fact constrained access to critical products including medicines, vaccines, medical devices and diagnostic tools, by allowing monopolistic price setting and limiting production. Trade secret claims have also restricted the dissemination of technological know-how, adding to patent barriers. The 1995 Agreement on Trade-Related Intellectual Property Rights (TRIPS) administered by the WTO compels Member states to enact and enforce IP laws according to standards that favour multinational corporations. Such globalization of intellectual property combined with high demand for medical products in less developed nations have exacerbated the problem of timely and equitable access to medicines.

This paper focuses on patents. The TRIPS Agreement requires a patent exclusivity term of 20 years. In addition, there are many ways patent durations can be extended by making minor changes to a product[1]. As a result, a product can be kept out of reach of competitors for much longer than 20 years. Though IP laws are meant to reward innovation in theory, they end up granting market monopoly. If the same happens with potential COVID-19 vaccines, there can be a shortage in supply of the drug leading to impeded access and costly delays[2]. This is already happening.

1- Prabhala, A., & 't Hoen, E. (2020, April 15). We'll find a treatment for coronavirus – but drug companies will decide who gets it. Retrieved October 4, 2020, from https://www.theguardian.com/commentisfree/2020/apr/15/coronavirus-treatment-drug-companies

2- Prabhala, A., & 't Hoen, E. (2020, April 15). We'll find a treatment for coronavirus – but drug companies will decide who gets it. Retrieved October 4, 2020, from https://www.theguardian.com/commentisfree/2020/apr/15/coronavirus-treatment-drug-companies

An example of how patents impede access to medicine can be seen through the medical drug Remdesivir. This drug was used to treat Ebola and was developed by the pharmaceutical company Gilead Sciences. Current patents applied to Remdesivir are valid until 2038. In 2020 during the first wave of the pandemic, Remdesivir was used as a treatment for COVID-19 which prompted Gilead to apply for something called "Orphan drug" status, in order to extend their patent duration. This drug status provides companies incentives to conduct research into medical drugs for rare diseases, that would otherwise be "unprofitable". On the contrary, COVID-19 is certainly not a rare disease, invalidating Gilead's intentions to obtain exclusive control over a crucial drug. The company later withdrew its application following widespread public outcry.[3]

However, the TRIPS Agreement does contain several exceptions and limitations to patents and other intellectual property claims. These are called "flexibilities" including the freedom for each WTO Member to decide on the criteria or standards for that is patentable, and the right to issue compulsory license.

Thus, a possible solution to patent barriers is to invoke compulsory licensing. As stipulated in the WTO TRIPS Agreement, this measure is where a government allows another party to manufacture or import a patented product without the consent of the patent holder, or the government uses the patented product itself. This is an integral part of the patent system, allowing other competitors to manufacture or import the product, and is not an infringement of patent rights. This flexibility was gaining traction around the world when COVID-19 reached a pandemic level. Chile and Ecuador passed parliamentary resolutions that would support compulsory licenses. Canada and Germany "amended their patent laws" to ensure a quick approval of compulsory licenses, while Australia introduced measures to improve government use of patents and designs.[4]

3- Prabhala, A., & 't Hoen, E. (2020, April 15). We'll find a treatment for coronavirus – but drug companies will decide who gets it. Retrieved October 4, 2020, from https://www.theguardian.com/commentisfree/2020/apr/15/coronavirus-treatment-drug-companies

4- For more information se https://www/keionline.org/coronavirus

In 2020 Israel issued a compulsory license for local manufacture of lopinavir/ritonavir (an ARV that they are using for COVID-19)[5] while Hungary issued a CL for Remdesivir with one day's notice to the patent holder[6]. Russia issued its first compulsory license for local manufacture of Remdesivir in January 2021[7] and Gilead Sciences has filed a court case to challenge the action triggering public outcry and government censure, with most lawyers saying that the company has no chance of succeeding[8].

While these measures are certainly a step in the right direction, they are not effective on a large- scale manner – each country must enact these TRIPS flexibilities into its national laws but most have not maximized the use of those flexibilities. Secondly, these are slow processes and takes time to implement. Thirdly, experience shows that each time a developing country issues a compulsory license there has been tremendous pressure from the pharmaceutical industry, often backed by the US government. Furthermore, simply granting a compulsory license does not provide a country with the technology and resources to manufacture. Pooling of resources and the actual access to technology is necessary to enable mass production. Furthermore, trade secrets (another type of IP) block off a chunk of the technology know-how and are not subject to compulsory licensing.

6- https://www.keionline.org/35558

7- Russian government issues its first health-related compulsory license (2021, January 13). Retrieved April 30 from https://makemedicinesaffordable.org/russian-government-issues-its-first-ever-compulsory-license-for-covid-19-treatment/

8- Gilead Sciences challenges compulsory licensing of its anti-COVID-19 drug in Russia. (2021, April 27). Retrieved on May 2 from https://www.thepharmaletter.com/article/gliead-sciences-to-challenge-compulsory-licensing-of-its-anti-covid-19-drug-in-russia

The Doha Declaration on TRIPS and Public Health

Many wealthy, developed nations claimed that the TRIPS Agreement did not present a detrimental barrier to achieving "public health objectives"[9]. The European Commission insisted there was no clash between IPR and public health goals. Rather, the two were "mutually supportive"[10] of one another. The purpose of TRIPS is to "create a level playing field for IPR[11], which would encourage trade and economic growth. Protection of intellectual property would create incentives for the research and development of "effective medicines", without which "public health policies would be hampered"[12].

The reality is that TRIPS did nothing more than push forward the "corporate agenda" of giant pharmaceutical companies. It plays along the interests of highly industrialized countries- namely the US, Japan, the European Union- that are home to these pharmaceutical corporations. As a result, the access to medicines for many vulnerable populations has been jeopardized. Countries that are comparably poorer to the developed world are at the mercy of "major trading nations"[13]. This is especially proven through the attempted use of TRIPS flexibilities. While such allowances exist, developing countries are still hesitant to use them because in the past, they have faced challenges, "politically and legally"[14], by pharmaceutical companies and from the governments of developed nations. For example, in 2000, no less than 39 drug companies attempted to take the South African government to court in order to challenge the governments' use of laws enabling TRIPS flexibilities.[15]

9- Correa, C. M. (2002). IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH Carlos M. Correa University of Buenos Aires June (pp. 7-46, Tech.). World Health Organization.

10- Correa, C. M. (2002). IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH Carlos M. Correa University of Buenos Aires June (pp. 7-46, Tech.). World Health Organization.

11- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

12- Correa, C. M. (2002). IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH Carlos M. Correa University of Buenos Aires June (pp. 7-46, Tech.). World Health Organization.

13- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

14- The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation (pp. 2-10, Issue brief No. 7). (2011). South Centre.

15- For the full text of the Doha Declaration see https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Thus in 2001 developing countries took this up at the WTO where they raised questions on the TRIPS Agreement and the inability to exercise their right "to formulate their own health policies" and to protect the same. After intense negotiations they succeeded in obtaining the Declaration on the TRIPS Agreement and Public Health, adopted on November 14th, 2001 at the WTO Ministerial meeting in Doha, Qatar[16]. Better known as the Doha Declaration, it affirms that the TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, access to medicines for all". It also reaffirmed "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility" for public health purposes. (Paragraph 4)

> 1. The Declaration recognizes the TRIPS flexibilities, and on the right to grant compulsory licenses, Members have "the freedom to determine the grounds upon which such licenses are granted" and this naturally includes public health in many national laws. Some of the other grounds for compulsory licensing as found in various national laws include abusive exercise of patent rights, non-working of the product or process that is patented.
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> The general rule is that a compulsory license is given only after attempts to obtain a voluntary license on reasonable commercial terms from the patent holder has failed. However, such prior negotiations are not required in the case of a "national emergency" or "circumstances of extreme urgency" or a "public non-commercial use" (commonly known as "government use") – Article 31(b) of the TRIPS Agreement. The Doha Declaration makes it clear that what constitutes a national emergency or circumstances of extreme urgency is up to each WTO Member to decide, and can include public health crises such as HIV/AIDS, tuberculosis, malaria and other epidemics. It is important to note that compulsory licensing can be used in "normal times" for public health needs as well.

16 The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation (pp. 2-10, Issue brief No. 7). (2011). South Centre.

2. The Doha Declaration covers all intellectual property "within the scope of the TRIPS Agreement". It is not just about patents, and for access to medicines. It would include trade secrets over manufacturing know-how and clinical test data related to a vaccine or treatment drug. The Declaration also clarifies that the TRIPS agreement flexibilities apply to any public health problem and epidemic.

Significance and Implications of the Doha Declaration on Public Health

The contribution of the Doha Declaration in reaffirming that IP must serve public health is unquestionable, especially in light of the COVID-19 pandemic.

The new element for public health under the Doha Declaration was paragraph 6 to overcome the shortcomings of Article 31(f) of the TRIPS Agreement. Article 31(f) states that a compulsory license can only be used to manufacture medicines "predominantly" for the domestic market thereby limiting exports to countries that lack manufacturing capacity. Paragraph 6 recognizes that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement". Accordingly, the ministers through the Doha Declaration "instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002".

This solution enables the issuing of a compulsory license for domestic needs as well as for the purpose of exporting generic medicines to countries that lack manufacturing capacity. However it took 11 years to become reality – first there were difficult negotiations to be had and the amendment was adopted in December 6, 2005 introducing a new Article 31bis. It was only on January 23, 2015 that it entered into force after the requisite number of WTO Members adopted it legally

Under Article 31*bis*, a country in need of a particular pharmaceutical product, and without the manufacturing capabilities to produce it, is able to

import the drug under a compulsory license from a producing country without violating provisions found elsewhere in the Agreement. Although the framework was expected to be widely used, it has been used only once, and the reasons include the administrative burden that falls on the importing country and recent developments in pharmaceuticals and clinical therapeutics that presents challenges[17].

Calls to simplify the Article 3bis have been made over the years and COVID-19 has certainly emphasized the difficulties in using the framework.

Lastly, the Doha Declaration extended the transition period of least developed countries to introduce patent protection for pharmaceutical innovations until 1st January 2016. In 2015 this transition period was further extended until 1st January 2033.

Successful Applications of TRIPS Flexibilities

One success of the Doha Declaration is that it provided a large degree of certainty and confidence to developing countries and this led to the issuance of at least 74 instances of compulsory licensing on accounts of public health interests. A study examining the price reductions of 24 such events reveals that the compulsory licenses resulted in price reduction and promoted access to medicines[18]. These have never been brought by developed countries as a dispute to the WTO settlement body as countries were exercising their rights under the TRIPS agreement. Flexibilities have been used in spite of the "commercial and political pressure" developing countries face as a deterrent[19].

The threat to use compulsory licensing can also yield results. For example, the Brazilian government successfully obtained several lower-cost

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17- Vincent, N. (2021). TRIP-ing Up: The Failure of TRIPS Article 31bis. Retrieved on May 2 from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3778945

18- Urias, E. and Ramani, S.V. (2020). Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. Retrieve dMay 2 from https://link.springer.com/article/10.1057/s42214-020-00068-4

19- The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation (pp. 2-10, Issue brief No. 7). (2011). South Centre.

antiretroviral drugs for HIV from big pharmaceutical companies when it threatened Abbott, Merck, and Roche with compulsory licensing in order to procure the ARV at a cheaper price. The discounted drugs allowed the Brazilian government to treat more than 100,000 people for free: 46% (Abbott in 2005), 37% (Roche in 2003), 40% (Roche in 2001)[20]. While this was successfully executed, we must note that repeated threat of a compulsory license without actually using it may not be a sustainable long term price reduction strategy, and this may not even work at all for smaller poorer developing countries. In the case of Brazil, the government held 16 meetings of "exhaustive negotiation" with Merck from 2003 onwards, but failed to get an affordable price and so in 2007 a compulsory license to manufacture efavirenz (an ARV) was finally issued.[21]

Thailand authorized manufacturing of generic versions of efavirenz from 2006 until 2011, and to import generic versions of the same from India until its domestic manufacturing capacity was ready. Merck, one of the on-brand manufacturers of efavirenz, admitted this "was in compliance with TRIPS"[22], but hit back with claims that the Thai government did not "engage in sufficient consultation to allow negotiation" for a cheaper-priced drug. The United States government stepped and questioned the "validity of the license"[23] issued by Thailand. They went on to pressure the Thai government to withdraw their license and "negotiate with Merck". The Thai government paid no heed and pushed through two more compulsory licenses in 2007 for Kaletra (for HIV) and Plavix (for coronary illness), each patented by Abbott and Sanofi-Aventis respectively. While the Thai government was successful, it is important to note the alarmed response the United States had to their actions. This shows the immense amount of pressure on countries to forgo using TRIPS flexibilities, lest they incur the wrath of wealthy nations[24].

20- Khor, M. (2009). Patents, Compulsory Licenses and Access to Medicines: Some Recent Experiences. (Publication)
21- Canisio Binsfeld, P. (2012). The use of compulsory license as patent related flexibility – the Brazilian Experience in Health (powerpoint presentation at the Seminar for Certain Latin-American and Caribbean Countries on the Implementation of Several Patent Related Flexibilities, February 6 to 8, 2012), retrieved from https://www.wipo.int on May 1, 2021.
22- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).
23- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).
24- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

In 2017 Malaysia issued a government use compulsory license to import sofosbuvir for national free treatment of hepatitis C. The cost for 12 weeks of treatment that cures early-stage hepatitis C went from about USD100,000 (for 2 patented drugs) to USD300 (for 2 generic drugs). After 2 years of negotiations with Gilead Sciences, the patent holder, the last known price for 12 weeks was about USD12,000 for sofosbuvir alone. Industry pressure accompanied by efforts by the USTR and US Embassy in Malaysia dogged the government even though the compulsory license was only for 2 years.

Thus, the pressure continues when TRIPS flexibilities are used and has intensified in recent years, led by Big Pharma and the biotechnology industry, especially with the support of the US Trade Representative Office[25]. Historically, the US is known for its notorious undermining of the use of compulsory licenses especially through use of its "Special 301" Report. This is an annual review of the global state of intellectual property rights protection and enforcement, conducted by the Office of the United States Trade Representative (USTR) since 1989 under a domestic law, the Trade Act of 1974. This Report "reflects the Administration's resolve to encourage and maintain effective IPR protection and enforcement worldwide". Although this is a unilateral domestic law and measure, and therefore not in line with the WTO that was set up to prevent unilateral trade actions and sanctions, the US has consistently used its Special 301 report to intimidate developing, and also other developed, countries that use their TRIPS flexibilities for public health purposes.[26]

Failures and limitations of TRIPS Flexibilities

A holistic evaluation must also consider the issues with implementing the TRIPS flexibilities shored up by the Doha Declaration. Most of the national legislation of developing countries have not incorporated the full extent of the flexibilities, and the actual use of the flexibilities has also not been maximized.

25- Knowledge Ecology International compilation of US Trade Representative Special 301 Report 1998 to 2020: https://www.keionline.org/ustr/special301

26- See compilation of Special 301 Reports 1989 to 2020 with highlights on submissions related to use of TRIPS flexibilities for public health and access to medicines. Knowledge Ecology International https://www.keionline.org/ustr/special301

There is still a lack of access to medicine. For much of the world's population. A few main problems arise for public health.

First, developing and least developed countries face issues with implementing TRIPS flexibilities. This is due to a combination of continuing lack of full understanding of the TRIPS flexibilities and the constant often inappropriate "technical assistance" and "capacity building and training" provided by the patent/intellectual property offices of developed countries especially the US, EU and Japan as well as the World Intellectual Property Organization.

Second, there is danger of TRIPS flexibilities being undermined by regional and bilateral trade agreements that uphold TRIPS and also allow "TRIPS Plus" provisions, which result in many countries being disadvantaged by the "world trading system as a whole"[27].

Third, the TRIPS Agreement's Article 31bis framework involves cumbersome procedural requirements and therefore is not an effective solution for countries with limited or no manufacturing capacity.

Lastly, the TRIPS Agreement stipulated for the transfer of technology and building up manufacturing capacity for LDCs. This has not been fulfilled by developed countries[28].

Issues with Article 31bis

This system has caused confusion and reluctance to use it. Rwanda is the only country that has used it to import low-cost ARV's from the Canadian generics company Apotex and treat 21,000 HIV/AIDS patients[29]. It took almost 27 months to simply meet the complex requirements of what is known as the

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27- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

28- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

29- The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation (pp. 2-10, Issue brief No. 7). (2011). South Centre.

"paragraph 6 system"[30] that was the interim system before WTO Members adopted the legal amendment of the TRIPS Agreement to include the system in Article 31*bis*. What was intended to be a solution and a more expedited solution for developing countries and LDCs turned out to be the very opposite. This is a consequence of the fact that a greater burden is placed on importing countries making use of the system, than on countries who can issue a compulsory license for domestic manufacturing.

The amendment itself is 'overly cumbersome to use'. According to Medecins San Frontieres (MSF), the large burden on drug procurement would end up discouraging generic production. For example, if a compulsory license were issued for the ARV cocktail consisting of three separate drugs, a separate application would have to be filed for each drug[31]. This causes considerable delays.

In addition, when a country intends to import under a compulsory license, they must determine the amount of drugs to import with great precision beforehand[32]. Ordering too little would require the importing country to issue a license all over again and start the process from scratch. If a surplus is ordered, then exporting the excess to another country in need is not permitted. Furthermore, the patent holder can undermine the system at any time by deciding to offer the medicine at lower cost or for free. This would frustrate the meticulous effort put in by nations to issue compulsory licenses under the system.

Political pressure

Since the entry into force of the TRIPS Agreement in 1995, WTO members have been required to grant exclusive rights to patent holders to "produce and sell protected drugs"[33]. As a result, generic industries in many

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30- The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation (pp. 2-10, Issue brief No. 7). (2011). South Centre.

31- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

32- The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation (pp. 2-10, Issue brief No. 7). (2011). South Centre.

33 Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

developing countries have withered. This is problematic because many countries depend on generic companies for lower-cost drugs. Being forced to give exclusive rights to the patent holder in compliance with TRIPS has reduced competition in the pharmaceutical market. This leads to high prices and reduced sources of affordable medicines. Countries with insufficient manufacturing capacity in the pharmaceutical sector will have no choice but to import expensive patented versions of drugs[34].

At the same time, developed countries continue to pressurize developing countries against the use of TRIPS flexibilities. Further, developed countries ratcheted up the norms and standards for the protection and enforcement of IP standards and limited the flexibilities through the Free Trade Agreements and Bilateral Investment Treaties. Many countries are forced to forgo flexibilities despite the Doha Declaration to promote access to medicines in favor of trade agreements and economic partnerships. These agreements also place restrictions on data exclusivity, which enable patent owners to withhold important information, and delay the entry of generic competition in the market. For example, the US-Australia Free-Trade Agreement provides a 5-year protection period on "undisclosed pharmaceutical test data"[35].

Countries that implemented the TRIPS Flexibilities, especially use of compulsory license, such as Thailand, Malaysia, India and Colombia faced political pressure for using TRIPS flexibilities. Consequently, there is extreme reluctance amongst the South to use TRIPS flexibilities to their fullest. In an extremely globalized economy, the pressure of "maintaining one's standing as a trading partner"[36] is often (though misguided) paramount over ensuring access to medicines. Many developing countries depend on trade to promote the growth of their economies through export markets in industrialized countries. Therefore, they are reliant on their powerful trading partners and fear jeopardizing these partnerships. As a result, building a strong public health system that ensures access to medicines has taken a backseat to trade and economic growth.

34- Correa, C. M. (2002). IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH Carlos M. Correa University of Buenos Aires June (pp. 7-46, Tech.). World Health Organization.

35- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

36- Bradford Kerry, V., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: What are the remaining steps for protecting access to medicines? (Publication).

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