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Compulsory licensing: Procedural requirements under the TRIPS agreement

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Compulsory licenses of patents under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are often mistakenly viewed as a solution to problems relating to access to medicines in developing countries. Access requires a strong political commitment, a health system that contains multi-disciplined health professionals, and an adequate infrastructure to enable transportation of patients and equipment. The use of compulsory licenses should be a rare event considered only under extremely limited circumstances and not an instrument of industrial policy. If a government decides to issue a compulsory license, there are several technical and procedural requirements that must be satisfied under TRIPS. This paper explores those requirements and examines instances where courts have issued decisions relating to compulsory license requests or grants. It analyses the key provisions of TRIPS that are relevant to a government grant of a compulsory license without the authorization of the right holder. It also provides examples and analyses of previous grants of compulsory licenses that have been deficient in meeting on more more procedural requirements under TRIPS.

Keywords: Patent law, compulsory license, World Trade Organization (WTO), Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

1. Introduction

Intellectual property protection mitigates the scientific, regulatory, and economic risks of pharmaceutical innovation because inventors are afforded time to recoup investments in research and development (R&D). In addition, national intellectual property (IP) policies should be flexible enough to anticipate social and economic changes. This balance is reflected in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires WTO Members to provide a minimum level of IP protection, but leaves the precise manner of implementation to each WTO Member. Certain "flexibilities" relating to IP protection and enforcement are incorporated into TRIPS. For example, WTO Members may provide "more extensive protection" than required in TRIPS, as expressly indicated in TRIPS Article 1.1. This provision acknowledges that such protections may be beneficial to developing an enabling environment for innovation in particular markets. A WTO Member can also include certain limited exceptions to rights conferred by TRIPS, such as the limited exceptions to patent rights found in TRIPS Article 30. In addition, Article 31 of TRIPS provides that WTO Members may permit the use of a patented invention without the authorization of the

right-holder, under certain defined circumstances. Such unauthorized use is generally referred to as a "compulsory license."

Compulsory licenses of patents are sometimes mistakenly viewed as a solution to the problem of access to medicines in developing countries. However, while permissible under TRIPS in certain limited circumstances, compulsory licenses are only intended as an option of last resort in extraordinary circumstances. They are not a sustainable solution to access problems, which are generally not a result of patents or other intellectual property protection [1]. Achieving sustainable access is complex and requires different elements to work together. First and foremost, access requires strong political commitment, a health system that contains multi-disciplined health professionals, and adequate infrastructure to enable transportation of patients and equipment [2]. Routine use of compulsory licenses is not consistent with the intent of TRIPS, provides only short-term solutions that risk undermining long-term needs, and, rather than enhancing access, could instead discourage the introduction of new medicines. Frequent use of compulsory licenses weakens the global intellectual property framework and critically undermines the incentive system that underpins the ability of the private sector to undertake essential R&D, especially capital-intensive and high-risk pharmaceutical R&D. Compulsory licenses are also less effective than other mechanisms and access initiatives [3], as it can take much longer to manufacture and deliver treatments than to secure a voluntary license via direct negotiations with the patent holder, or to utilize tiered pricing initiatives. History has demonstrated that compulsory licenses are seldom used because other mechanisms facilitate medicines procurement in a more efficient and sustainable manner. In appropriate circumstances, voluntary licenses often provide more than a simple license to the patents and may include rights to underlying technologies, know how, and technical expertise. Another mechanism with demonstrated effectiveness is a non-assertion declaration of intellectual property rights. This option is similar to voluntary licensing, but instead of active involvement by an innovator company, an agreement is reached that intellectual property rights will not be asserted, provided that certain criteria, like product quality and geographical distribution, are met. Access to medicines in developing countries is also further enhanced by tiered-pricing policies and numerous product donation programs.

The use of compulsory licenses should be a rare event, considered only under extremely limited circumstances, rather than an instrument of industrial policy. Nonetheless, before a government decides to issue a compulsory license, there are several technical and procedural requirements under the TRIPS Agreement that must first be satisfied. This paper explores those requirements and examines instances where courts have issued decisions relating to compulsory license requests or grants. Section 2 analyzes the key provisions of TRIPS that are relevant to a government grant of a compulsory license without the authorization of the right holder. Section 3 provides examples and analyses of previous grants of compulsory licenses that have been deficient in meeting one or more procedural requirements under TRIPS.

2. TRIPS – Key provisions relating to compulsory licenses

The key provision relating to compulsory licenses in TRIPS is Article 31, entitled "Other Use Without Authorization of the Right Holder." However, this is not the only provision that is relevant for governments wishing to ensure that a compulsory license grant is legally and procedurally compliant with TRIPS. It is first important to look at the general requirements of Article 27, which are imposed on all WTO signatories.

Paragraph 1 of Article 27 TRIPS states:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. . . . [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and *whether products are imported or locally produced*.

The "non-discrimination" clause in Article 27.1 clarifies that a patented invention must be accorded similar rights and protections, regardless whether the manufacturer produces the patented invention locally or chooses to import the invention. Thus, if a government considers whether to authorize use of a patented invention without the consent of the patent holder, it cannot legally use as the basis for that authorization the fact that the patented product in question is imported. The non-discrimination provision of Article 27.1 recognizes that in any modernized industrial sector, it would be highly impractical to suggest that a company could or should build manufacturing plants in every country in which the company wishes to conduct business.

Article 30 of TRIPS further clarifies that WTO members may provide exceptions to the rights of the patent holder, but that such exceptions must meet three criteria: 1) the exception must be limited; 2) the exception must not unreasonably conflict with normal exploitation of the patent; and 3) the exception must not unreasonably prejudice the legitimate interests of the patent holder (while also taking into account the legitimate interests of third parties). It is within the bounds of this provision that many governments have created legislation to allow for exceptions such as prior user rights or exemptions to infringement for the purpose of compiling data to obtain regulatory approval (commonly referred to as "Bolar" exceptions).

The conditions of Article 30 were analyzed and interpreted in the decision of the WTO Dispute Settlement Body (DSB) in "*Canada – Patent Protection of Pharmaceutical Products*." In that matter, the European Union brought a complaint against Canada for provisions of its patent law that allowed for manufacturing and stockpiling of pharmaceutical products without the patent holder's consent [4]. The panel found that whether an exception is "limited" does not depend on the economic impact to the patent holder, but on the level of curtailment of the patent holder's rights. According to Article 28 of TRIPS, patent holders are entitled to five rights under the patent system – the right to prevent third parties from making, using, offering

for sale, selling, and importing the patented product. The DSB held that the number of rights curtailed is not the determining factor on whether the exception is limited; rather, the extent to which the rights are curtailed must be examined [5]. As a result, the DSB panel found that the "Bolar" exception, when limited to activities related to compiling data for regulatory approval, was a "limited exception" within the scope of Article 30, but that the provision in Canada's patent law that allowed "stockpiling" exceeded the meaning of "limited exception" under Article 30 [6].

While Article 30 allows for certain limited exceptions to the five rights provided by Article 28 that do not otherwise interfere with the normal exploitation of the patent, it is very narrow in focus. Other exceptions to patent rights, such as compulsory licenses, do not fall under Article 30. In contrast, Article 31 lists several conditions that must be met before a government-authorized use of a patent can occur without the authorization of the right holder. In fact, Article 31 includes a footnote, which further clarifies that the "other use" permitted under Article 31 refers specifically to exceptions other than those permitted under Article 30.

In 2001, during the Fourth Session of the WTO Ministerial Conference in Doha, Qatar, WTO Members adopted a declaration on the TRIPS Agreement and Public Health (the "Doha Declaration"). The text of the declaration reiterates Member States' recognition of the public health problems facing developing and least-developed countries (LDCs), but also states that the TRIPS Agreement should be "part of the wider national and international action to address these problems." [7] WTO Members agreed that the TRIPS Agreement allows for certain flexibilities, including:

> (5b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[1]
> (5c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

In order to address the concern that countries with insufficient manufacturing capacity would be unable to benefit from the compulsory licensing provisions of Article 31, Members adopted the decision on "Implementation of Paragraph 6 of the

[1] Notwithstanding the inclusion of this provision in the Doha Declaration, at least one WTO member specifically determined that granting a compulsory license for "refusal to license on reasonable commercial terms and conditions empties the substance out of the exclusive rights granted by a patent and protected by the TRIPs Agreement." *See* European Communities, "Report to the Trade Barriers Regulation Committee: Examination Procedure Concerning an Obstacle to Trade within the Meaning of Council Regulation (EC) No. 3286/94 Consisting of Measures Adopted by the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu Affecting Patent Protection in Respect of Recordable Compact Discs." (2008), available at http://trade.ec.europa.eu/doclib/docs/2008/january/tradoc_137632.pdf.

Doha Declaration on the TRIPS Agreement and Public Health" on August 30, 2003.[2]

The Decision creates certain exceptions to the requirements of Article 31. For example, the requirement under Article 31(f) that a compulsory license is to be granted predominantly for the domestic market is waived for a Member that exports pharmaceutical product under the August 30 Decision.[3] In addition, the requirement for adequate remuneration under Article 31(h) is waived for the LDC or other Member that notifies it will make use of the August 30 decision, as long as the exporting Member, which must grant a compulsory license for export, adequately remunerates the patent holder [8]. Remuneration by the exporting Member country to the patent holder is to be based on the economic value to the importing Member country.

3. Examples of legally-deficient compulsory license grants

Despite the reiteration in the Doha Declaration that WTO Members may grant compulsory licenses in the absence of a national emergency, such grants must still comply with the requirements of TRIPS – particularly Article 27 and Article 31. The following section provides examples of national laws or grants of compulsory licenses that have demonstrated a failure to comply with the legal requirements of TRIPS.

3.1. Article 27 – "Without Discrimination . . . Whether Products Are Imported or Locally Produced"

TRIPS Article 27 is explicit in requiring that the patent holder's right to obtain and enforce a patent must not be contingent on "whether products are imported or locally produced." As noted below, the "non-discrimination" protections of Article 27 are applicable even in the rare instance that an exception is granted under either Article 30 or Article 31.

[2]WT/L/540, August 30, 2003. In order to secure adoption of the Decision, a separate statement was delivered by the WTO General Council chair, Uruguayan ambassador Carlos Perez del Castillo (though it is commonly referred to as the "Menon Text," in reference to Ambassador Vanu Gopala Menon of Singapore, for his role in reaching an agreement that would provide assurance that the Decision would not lead to abuse or weakening of patent rights). The statement can be found at JOB(03)/177, and includes an attachment of "best practice" guidelines.

[3]WT/L/540 at para. 2. According to para. 6(i) of the Decision, if an importing Member is a developing or least-developed country and is also party to a regional trade agreement to which at least half of the members were LDCs at the time of the Decision, the Article 31(f) obligation is further waived to allow the importing Member to export the imported pharmaceutical product to other developing or least-developed countries that are also parties to the regional trade agreement.

India

On March 9, 2012, the Patent Controller General of India granted a compulsory license to Natco Pharmaceuticals Limited for the Bayer anticancer drug, sorafenib (Nexavar®). The decision was appealed to the Intellectual Property Appellate Board (IPAB), which upheld the decision on March 4, 2013. The IPAB decision was further appealed to the High Court of Bombay, which also upheld the compulsory license grant to Natco.

In its arguments to the High Court, the Indian government took the position that a patented product must be manufactured in India in order to satisfy the working requirement of India's patent law. The High Court took exception to this position, stating that "the contention of Union of India that 'worked in India' must in all cases mean only manufactured in India is not acceptable." [9] The High Court nonetheless held that whether importation could satisfy the 'worked in India' requirement would depend upon a sufficient showing by the patent holder as to why the product is not manufactured in India. According to the High Court, this is required by Section 83 of India's Patents (Amendment) Act, 2005, which states that patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article." The High Court reasoned that this provision of India's national law requires some effort on the part of the patent holder to manufacture the product in India.

In holding that India's national law would allow a finding that importation is insufficient to satisfy local working requirements, the High Court dismissed Bayer's contention that Article 27 of TRIPS prohibits any form of discrimination on the basis of whether a product is imported. The High Court stated, "[s]o far as reliance upon Article 27 of TRIPS by the petitioner is concerned, we find that it ignores the exceptions thereto provided in Articles 30 and 31 of TRIPS." [10] However, this is clearly in contravention of the WTO DSB panel's finding in *Canada – Patent Protection of Pharmaceutical Products*, which held that "in the rights available under national law, that is to say those resulting from the basic rights and any permissible exceptions to them, the forms of discrimination referred to in Article 27.1 should not be present."[4] Thus, there is no basis to argue that the exceptions to patent rights found in Articles 30 or 31 are not still subject to the non-discrimination prohibition found in Article 27.

[4]Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, at para. 7.91. Interestingly, in taking the position that the exceptions of Article 30 were not subject to Article 27, even Canada acknowledged that the same could not be said of Article 31. Canada conceded that Article 27.1 was meant to prohibit discrimination against products that, prior to TRIPS, were denied patent protection or that were automatically subject to compulsory licenses under national laws – products such as pharmaceuticals. *See para. 7.90.*

Brazil

Brazil's national patent law also includes a provision that permits the grant of a compulsory license on the basis of failure to manufacture the patented product locally. According to Article 68(1) of Brazil's Industrial Property Law No. 9279/1996, a compulsory license may be granted for "the non-exploitation of the subject matter of the patent in the territory of Brazil, by lack of manufacture or incomplete manufacture of the product or, furthermore, by lack of complete use of a patented process, except in the case of non-exploitation due to economic inviability, when importation will be admitted".[5]

On May 30, 2000, the United States sought consultations with Brazil via the WTO dispute settlement procedure, contesting Brazil's local working requirement as a violation of Articles 27 and 28 of TRIPS. The DSB established a panel on February 1, 2001; however, as a result of consultations between the US and Brazil, a settlement was reached. According to the notification of the settlement, the US acknowledged that the law as written had not been applied by Brazil, and Brazil agreed that in return for US withdrawal of its complaint to the WTO, the Brazilian government would hold talks with the US prior to issuing a compulsory license against a US company on the basis of Article 68 [11].

3.2. Article 31(a) – "Such Use Shall Be Considered on its Individual Merits"

According to Article 31(a), each grant of a compulsory license must be considered on its individual merits. The basis for this provision is to effectively prohibit governments from issuing "blanket" authorizations of compulsory licenses. Under a proper reading of Article 31(a), each product, and indeed, each patent covering such product, must be evaluated separately.

Indonesia

In 2012, the government of Indonesia issued Presidential Decree 76/2012, under which multiple pharmaceutical products were compulsorily licensed. The Presidential Decree failed to provide reasoning or justification regarding the need for, or merits of, each authorization. Under the Trade Policy Review Mechanism (TPRM) of the WTO, Indonesia's trade practices were reviewed on April 10 and 12, 2013, at which time Indonesia was questioned about its practice of granting multiple compulsory licenses in a single decree without individual analysis. In response, Indonesia noted that its Patent Law No. 14, 2001 included no provision either allowing or expressly

[5]The same provision remains in the patent law as amended in 2001 – Law no. 10.196/01, February 14, 2001.

prohibiting the grant of multiple compulsory licenses in a single decree. The government acknowledged that the Presidential Decree authorized compulsory licenses for six antiviral and antiretroviral drugs, "while TRIPs required that the authorization shall be considered on its individual merits," and further responded that it would examine the obligations of Article 31(a) in view of its existing patent law and current practices [12].

3.3. Article 31(b) – "Efforts to Obtain Authorization from the Right Holder"

Before a government can authorize non-voluntary use of a patented invention, the third party in question must be able to demonstrate that efforts were made to obtain a voluntary license on reasonable terms and conditions, and that such efforts were unsuccessful within a reasonable period of time. This requirement can be waived only in the event of a "national emergency" or other extremely urgent circumstance, or when the government authorizes public, non-commercial use of a patented invention. Even if a compulsory license is granted in the event of an emergency, the right holder must nonetheless be notified as soon as reasonably practicable. Similarly, government authorization of third-party use of a patented invention for the public good and for strictly non-commercial purposes also requires the right holder to be promptly informed.

India

Despite the holding by India's High Court in the Nexavar® case that Natco's efforts to obtain a voluntary license were sufficient to satisfy the requirement found in Section 84(6)(iv) of India's Patents Act, the communications between Bayer and Natco would appear to demonstrate otherwise [13]. Natco sent a single communication to the right holder in which it requested a license to produce sorafenib. However, in listing the basis for its request, Natco simply reiterated the provisions of Section 84(1) of India's Patents Act – the terms under which a compulsory license may be granted under Indian law, which are: (a) failure to satisfy the reasonable requirements of the public, (b) failure to provide the product at an affordable price, or (c) failure to manufacture locally. It is not clear from the High Court decision whether Natco actually proposed terms for a voluntary license. The right holder declined, but also invited Natco to respond with any further information that may be relevant to the request. More than six months after that single communication, Natco subsequently applied for a compulsory license. The High Court decision stated that the mere fact of Bayer's refusal was sufficient to show that any further efforts by Natco to seek a voluntary license would be unsuccessful. In support, the High Court merely cited to Section 84(6) of India's Patents Act, which states that a "'reasonable period' shall be construed as a period not ordinarily exceeding a period of six months."

Interestingly, and in contrast to the approach taken by the Controller General and the courts in the Nexavar® matter, in a subsequent case, India's Controller General of Patents denied an application by BDR Pharmaceuticals for a compulsory license on the Bristol Myers Squibb drug, dasatinib (Sprycel®) [14]. In response to a single communication from BDR, the right holder sought detailed answers to questions about BDR's ability to manufacture and supply the drug, issues of quality control, and other substantive matters relevant to the request. BDR did not respond or otherwise answer any of the questions raised by the patent holder. The Controller General found that BDR's failure to provide any response to these questions, followed only by an application for a compulsory license almost one year later, failed to satisfy the requirement that the applicant make efforts to obtain a voluntary license. The Controller General ruled that BDR's subsequent inaction for almost one year, during which it merely waited for the passage of time, was not sufficient to show that a "reasonable period" under Section 84(6) had elapsed [15].

The plain language of Article 31(b) is clear that authorization of a compulsory license must be preceded by the applicant's efforts to negotiate a voluntary license "on reasonable terms and conditions." The Controller General's decision regarding the corresponding language in India's Patents Act in the dasatinib matter provide strong evidence that the High Court's decision in the Nexavar® matter is inconsistent with the requirements of Article 31(b).

Indonesia

TRIPS Article 31(b) includes an exception to the requirement to seek a voluntary license from the patent holder in cases of a "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." However, as noted above, even if one of these specific circumstances is invoked, the patent holder must nonetheless be promptly notified.

In issuing Presidential Decree 76 of 2012, the government of Indonesia argued that the blanket grant of compulsory licenses was a "government use" meant to address an "emergency situation." Thus, it argued, the government could issue the decree without making efforts to ensure that a voluntary license was first sought, presumably invoking the waiver of this requirement in cases of "public non-commercial use." [16] However, even assuming this was a case of "extreme urgency" or "public non-commercial use," the government was nonetheless required to notify the right holder of such use.

3.4. Article 31(c) – "Scope and Duration of Such Use Shall Be Limited"

TRIPS Article 31(c) requires that the scope and duration of a compulsory license grant must be "limited to the purpose for which it was authorized." Thus, it is incumbent on the granting authority to ensure that such grant is limited in time to address

only the specific condition that prompted the grant. A compulsory license cannot be extended for purposes beyond the specific license grant under which it was authorized.

India

The compulsory license grant for sorafenib by the Patent Controller of India was for the "balance term" of the patent [17]. On appeal, the High Court noted that Section 84(1) of the Indian Patents Act authorizes the grant of a compulsory license if "the reasonable requirements of the public with respect to the patented invention have not been satisfied." The High Court continued, whether, under Section 84(7)(d), the reasonable requirements of the public are met must be based on working the patented invention "to an adequate extent." The Court noted that the test for determining what constitutes "adequate extent" would depend on the product for which a compulsory license is sought. For medicines, the High Court noted, "the adequate extent test has to be 100% i.e. to the fullest extent. Medicine has to be made available to every patient and this cannot be deprived/scarified at the altar of rights of patent holder" [18]. The court's decision suggests that at no time would a compulsory license for a medicine be subject to a review relating to the scope or duration of the license if "the requirement [sic] of all the patients are not being met by the patented drug." [18] Clearly, the non-discrimination principles of Article 27 would be completely vitiated if Article 31 were interpreted to permit a compulsory license grant on any medicine that was not reasonably available to the entire population of a member country. Thus, the reasoning by which India issued a compulsory license for the duration of the sorafenib patent term would necessarily be inconsistent with the Article 31(c) requirement that the scope and duration of a compulsory license be "limited to the purpose for which it was authorized."

Indonesia

Indonesia has granted compulsory licenses on three separate occasions – 2004, 2007, and 2012. On each occasion, the grant was for the full duration of the patent term [19]. Presumably, by arguing that the compulsory license grants were based on the need to secure medicines in the interest of public health, the government took the position that such a need would exist for the full term of each of the patents at issue. As in the case of the Indian compulsory license, the government of Indonesia gave no indication that the scope and duration of these compulsory licenses were limited in any meaningful way.

Ecuador

On October 23, 2009, Ecuador's President Rafael Correa signed Executive Order

118, which authorized a mechanism for government-issued compulsory licenses . The requirements under the Decree are textually consistent with the requirements of Andean Community Law and TRIPS Article 31. However, in practice, compulsory licenses have been authorized for a total of nine medicines thus far [20]. Furthermore, there is no evidence to suggest that the scope and duration of these compulsory license grants were limited [21]. TRIPS Article 31, and in particular Article 31(c), was designed specifically to prevent member states from exercising such extensive curtailment of the rights of patent holders.

3.5. Article 31(f) – "Predominantly for the Supply of the Domestic Market"

Because the intent of Article 31 is to provide a mechanism for governments to ensure supply of medicines for their own population, Article 31(f) makes clear that any grant of compulsory license must be authorized *predominantly* for the supply of the market in the Member that granted such license.

India

The Indian Patent Controller's 2012 order granted a compulsory license for sorafenib that restricted Natco Pharmaceuticals Limited to making, using, offering for sale, and selling the drug "within the Territory of India" [22]. This is consistent with TRIPS Article 31(f), as well as Section 90(vii) of India's Patents Act. Despite this explicit restriction, the patent holder was forced to seek an order to prevent the export of generic sorafenib by Natco. On March 26, 2014, the Delhi High Court issued an injunction prohibiting any exports of sorafenib [28]. However, the High Court acknowledged that Natco could petition the court for permission to export sorafenib for purposes of "experimentation and generation of clinical trial data and for submission to the Drug Controlling Authorities" [23]. There is no clear evidence to suggest that Natco planned to export its generic product for purposes other than experimentation or generation of clinical trial data. However, any attempt to export its product for sales in other markets could violate the provision of Article 31(f) if the exports were demonstrated to exceed the amounts supplied by Natco domestically. By requiring Natco to petition the Court before exporting product for clinical trials, the Delhi High Court instituted necessary safeguards to ensure no violation of Article 31(f).

3.6. Article 31(g) – "Authorization for Such Use Shall Be Liable... To Be Terminated If and When the Circumstances Which Led to It Cease to Exist and Are Unlikely to Recur"

According to TRIPS Article 31(g), a compulsory license may be terminated if the circumstances leading to the grant of such license no longer exist and are unlikely to recur. While the interests of the authorized licensee must be considered, upon request, the competent authority of any WTO Member granting a compulsory license must review the circumstances under which the grant was initially made.

Indonesia

As noted above, the government of Indonesia authorized compulsory licenses via Presidential Decree in 2004, 2007, and 2012. The government has indicated that a patentee may request revocation of such grant if the grounds that precipitated the compulsory license were no longer applicable, which would be consistent with Article 31(g). However, the government took the position that the Presidential Decrees were "government use" grants, which, under national law, did not include provisions for a patent holder to request revocation of the compulsory license [24]. Despite Indonesia's attempt to distinguish between so-called government use and compulsory licenses *per se*, the TRIPS Agreement draws no such distinction. In contrast, each of the provisions of Article 31 is a necessary legal requirement that must be complied with before any Member may grant a third party the right to use a patented invention. As clearly stated in the preamble to Article 31, Article 31 must be complied with when a patent is used without the authorization of the right holder, "including use by the government or third parties authorized by the government."

3.7. Article 31(i) – "Authorization of Such Use Shall Be Subject to Judicial Review or Other Independent Review by a Distinct Higher Authority"

It is to be expected that any decision by a government to undermine the rights granted through its own patent system must be taken with caution. Thus, TRIPS Article 31(i) requires the Member state to provide a mechanism for independent review of such decisions – a protective measure for the right holder. According to Article 31(i), the legal validity of any compulsory license must be subject to challenge via "judicial review or other independent review." Moreover, such review process must be conducted by a "distinct higher authority" in that WTO Member.

Indonesia

As noted above, Article 102 of Indonesia's Patent Law (Law 14, 2001) recognizes two distinct mechanisms for the use of a patent without authorization of the right holder – a compulsory license *per se* and so-called "government use." According to the government, issuance of a "government use" license or other use of a patent by the government may be authorized in the event of a public health emergency or for defense of the country. As such, the government has argued, such "government use" is "not for commercial purpose." As a result, the government provides a mechanism for independent judicial review for a compulsory license grant, but not in the event of an authorized "government use." [25] Under Indonesia's patent law, only the remuneration rate for such "government use" may be subject to an independent review process – a requirement that is separately found in TRIPS Article 31(j). However, as noted above, the Indonesian government's attempt to draw a distinction between a

"compulsory license" and "government use" is not supported by Article 31 of TRIPS. It is interesting to note that in the most recent WTO review of Indonesia's trade policies, the government acknowledged that its laws may need to be amended in view of TRIPS Article 31 [25].

4. Conclusion

Patent rights are granted by governments as a tool to encourage innovation and development. Strong intellectual property protection is essential to ensure that new and innovative medicines are developed and accessible to patients around the world. However, when the same government that grants patent rights subsequently authorizes those rights to be undermined, it is incumbent on the government to ensure that due process is followed, and that the action is proportionate to the need. Furthermore, the use of compulsory licenses must only occur under extremely limited circumstances so as to ensure that the mechanism is not overused or abused. Failure to do so risks eroding the incentives of the patent system, which may ultimately cause delay or denial of patients' access to innovative treatments. These policy considerations led to the agreement by WTO Members to include the legal and procedural requirements of Article 31. Regardless, the very government that first issued a patent must ultimately be accountable to ensure the rights granted by such patent are respected. A commitment to achieving sustainable access to medicines requires strong political and community commitment [26] and policy coherence [27] between Government agencies and health providers. It is crucial that governments to formulate a long-term strategy, rather than short-term, temporary solutions, which risk undermining a commitment to health innovation and access [28].

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[10] *Bayer*, at 47 (para. (D)(15)(b)).

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