



TRIPS and Public Health: The case of Compulsory Licensing for Public Health Purpose

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CLs for Public Health: Patents Act 1970

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- Two basic provisions: Section 84 and Section 92 (Section 92 A being third one for exports)*
- ✓ *Under Section 84 of Patents Act, at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of Compulsory License on any of the following grounds:-*
 - ✓ *(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.*
 - ✓ *Section 84 is more like a dispute inter-partes. Decision taken by Controller General after hearing both the parties.*

CLs for Public Health: Patents Act 1970

 **Under Section 92 of the Patents Act**, there is a special provision for **Compulsory Licences** on notification by Central Government. If the Central Government is satisfied, in respect of any patent in force **in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use**

- ✓ Government also has powers under **Section 92(3)** of the Patents Act to issue a Compulsory License (without going through the process of an application for a voluntary license and without serving a notice on the patentee as laid down in Section 87 of the Patents Act), in cases of national emergency, extreme urgency and public non-commercial use.
- ✓ The procedure laid down in Section 87 can be waived by the Controller of Patents in the above cases including public health crises relating to Acquired Immuno Deficiency Syndrome, Human immunodeficiency Virus, tuberculosis, malaria or other epidemics.
- ✓ Determination under Section 92: Subjective in nature.

CLs for Public Health: TRIPS Provisions



- ✓ *The TRIPS Agreement does not specifically define CL. Article 31 provides for ‘Other Use without authorization of the right holder’. Article 31 imposes procedural and substantive requirements relating to the grant of compulsory Licenses that WTO Members must respect*
- ✓ *TRIPS Article 31(b) requires a third party to seek a license on reasonable commercial terms over a reasonable period of time before a Compulsory License can be sought or granted. Article 31(b) is an important safeguard – it serves to ensure that a refusal to accept commercially impractical or illogical licensing offers cannot trigger the grant of a Compulsory License.*
- ✓ *Article 31(b) further provides that the conditions as laid down in Article 31(b) can be waived, only in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.*

CLs for Public Health: TRIPS Provisions

- ✓ *The TRIPS Agreement does not define the terms ‘national emergency’ or ‘other circumstances of extreme urgency’ or in ‘cases of public non-commercial use’ and does not list the reasons that might be used to justify CL.*
- ✓ *While the terms ‘national emergency’, ‘other circumstances of extreme urgency’ ‘public non-commercial use’ and ‘public health crises’ are not defined, the Doha Declaration and the August 30, 2003 TRIPS Council Decision does provide **the genesis and context of inclusion of the terms***
- ✓ *The preparatory work of the Doha Declaration and the circumstances of its conclusion, particularly the implementation of Para 6 as captured in the TRIPS Council Decision of August 30, 2003 can be referred to in order to confirm the meaning of the terms found in Paras 1 and 5 (c) of the Doha Declaration*

CLs for Public Health: TRIPS Provisions



- To interpret the meaning of an undefined term, the WTO Appellate Body and Dispute Settlement Panels have applied the first paragraph of Article 31 of the Vienna Convention on the Law of Treaties (Vienna Article 31), which provides: A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. Where necessary to determine the ordinary meaning of a particular word, panels and the Appellate Body have often relied on dictionary definitions.*
- ✓ *Article 32 of the Vienna Convention allows for supplementary means of interpretation in limited circumstances and reads as follows: “Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.”*

CLs for Public Health: TRIPS Provisions



- Thus, the negotiating history of the Doha Declaration and the August 30 Decision becomes relevant for purposes of interpreting the provisions of Section 92.*
- ✓ *While it was understood that flexibilities such as CL are written into the TRIPS Agreement, some governments were unsure of how these flexibilities would be interpreted, and how far their right to use them would be respected.*
 - ✓ *The African Group (all the African members of the WTO) was among the members pushing for clarification.*
 - ✓ *This led to the adoption of the main Doha Ministerial Declaration of November 14, 2001 which stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.*

CLs for Public Health: Doha Declaration

 In order to provide further clarity to the TRIPS flexibilities, the Ministers adopted a separate declaration on TRIPS and Public Health (Doha Declaration).

- ✓ **Para 1 states:** “We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”.
- ✓ **Para 2 states:** “We stress the need for the WTO Agreement on Trade Related Aspects of Intellectual Property Right (TRIPS Agreement) to be part of the wider national and international action to address these problems.”
- ✓ **Para 3 states:** “We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effect on prices.”

CLs for Public Health: TRIPS Provisions

- ✓ **Para 5 states:** “Accordingly and in the light of paragraph 4 above, while maintaining our commitment in the TRIPS Agreement, we recognize that these flexibilities include:
- ✓ *In applying the customary rules of interpretation of public international law, each provision of TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*
- ✓ *Each member has the right to grant compulsory Licenses and the freedom to determine the grounds upon which such Licenses are granted.*
- ✓ **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.**

CLs for Public Health: Doha Declaration



- ✓ *The Doha Declaration certainly confirms that countries are free to determine the grounds for granting CL in order to protect public health and promote access to medicines for all.*
- ✓ *Further, it clarifies the right of countries to determine what constitutes a national emergency or other circumstances of extreme urgency*
- .
- ✓ *However, it is important to bear in mind that Para 3 of the Doha Declaration also reconfirms that intellectual property protection is necessary for development of new medicines.*
- ✓ *Further, while using the flexibilities within TRIPS, countries cannot ignore that the additional flexibilities found in paras 4, 5 and 6 of the Doha Declaration which were designed to address the public health problems recognized in Paragraph 1 of the Doha Declaration on TRIPS and Public Health, which says that WTO ministers “recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”*

CLs for Public Health: TRIPS Provisions

- ✓ *The logical and only conclusion from the above is that while public health crises can represent situations of national emergency or other circumstances of extreme urgency, the public crises must be those relating to HIV/AIDS, TB, malaria and other epidemics of equal gravity and proportion.*
- ✓ *The term “epidemic” in this context assumes great importance as it connotes the quantum of the seriousness of disease burden in order to make a “public health crises” serious enough to be addressed by issuance of a compulsory license. In other words, mere existence of a disease burden will not be enough. The disease burden must be of a magnitude of an epidemic*



CLs for Public Health: Issues; Concerns and Questions In the Indian Context

Price as a trigger for CLs:

- ✓ *The element of 'pricing' sets a very troubling precedent for using patents to protect innovative products in India, particularly innovative pharmaceutical products.*
- ✓ *Under the "reasonable pricing" requirement, any price set above what the average Indian consumer can afford to pay will not be found to not be "reasonable."*
- ✓ *However, because a substantial portion of the Indian population cannot afford to pay any commercially viable price for a pharmaceutical product, this means that any commercially viable price set by the patent owner will be considered excessive.*

CLs for Public Health: Issues; Concerns and Questions In the Indian Context

Existence of emergent/deserving circumstances:

- ✓ *When does a situation of “National Emergency”; Extreme Urgency etc exist: Subjective interpretation.*
- ✓ *Determining the right situation in respect of a disease and candidate as CL target*
- ✓ *Ensuring that the emergent circumstances are actually mitigated by issuance of CLs*
- ✓ *Ensuring CLs provisions are not used in disguised manner for commercial aspirations of a third party.*



Thank You