

**AN APPROACH TO THE WTO MINISTERIAL DECLARATION ON
THE TRIPS AGREEMENT AND PUBLIC HEALTH**

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AN APPROACH TO THE WTO MINISTERIAL DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

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The public debate on access to medicines and TRIPS

One of the worldwide most uniform and strong social movement ever known took place with the public awakening to the correlation between medicines' prices and pandemics after developing countries had suffered through HIV/AIDS. The consequent national and international initiatives, together with the need to impulse a new round of multilateral trade negotiations which would be focused on development, made it politically "compulsory" for the WTO to voice a position on the alleged legal uncertainties on the trade related aspects of intellectual property rights and access to medicines' debate.

The most discussed causes for uncertainty during the whole process have been the flexibility margins provided by the TRIPS' provisions on exhaustion of rights (parallel imports), and patents' compulsory licenses and exceptions. In the last session of the Ministerial Conference in Doha, it was finally possible to reach an agreement among all WTO Members to sign an awaited and politically needed Declaration on TRIPS and Public Health, through which the WTO presumably aims to "reduce" the alleged legal uncertainties on the flexibility margins offered by the Agreement. In this sense, however, the most real uncertainty comes from the legal status of the Doha Declaration¹. In the view shared here, regardless its legally binding nature on Members, the Declaration constitute a supplementary means of interpretation under article 32 VCLT.

A critical assessment of the Ministerial Declaration on TRIPS and Public Health

This approach to the content of the Declaration will mostly reflect on its significance from the TRIPS legal perspective. However, its political contribution is self-revealed constantly. In this regard, references to the two prior drafts of a would-be Ministerial Declaration prepared by different groups of developing² and developed³ countries are enlightening. Essentially, developing countries intended for a recognition of the freedom to adopt measures on public health grounds, particularly on access to medicines, while developed countries pursued instead assurances that the rights and duties under the Agreement were not devaluated.

Although the majority of the debates on access to medicines have dwelled on pharmaceutical patents, the Declaration refers to the whole TRIPS Agreement. Nevertheless, the main assertions implicitly tackle patents in general and, following the TRIPS model, only the transitory rules mention pharmaceutical patents in particular.

A. The final text starts by recognizing **the gravity of public health problems** afflicting developing countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics (point 1); and the need for the **TRIPS to be part of the wider national and international action to address these problems** (point 2). The

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¹ S. Charnovitz, "The Legal Status of the Doha Declaration". *JIEL* 5 (1).

² African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Peru, Philippines, Sri Lanka, Thailand and Venezuela. IP/C/W/312 or WT/GC/W/450.

³ Australia, Canada, Czech Republic, Japan, New Zealand, Switzerland and United States of America. IP/C/313.

importance of intellectual property for the development of new medicines, and the concerns about their effects on prices are also recognized (point 3).

Though pandemics are specially mentioned, the Declaration's scope is wider, as developing countries intended, public health. To satisfy developed countries, the relevance of intellectual property rights to invent medicines, and therefore to counter and/or cure the sickness is recognized. Thus, the reference to intellectual property rights is implicitly limited to patents and trade secrets.

The obvious effects of intellectual property rights on medicines' prices are acknowledged to be a "recognized concern". Though there is no reference to possible reactions to this concern, prices may well justify the adoption of national measures in certain circumstances, particularly in the case of patents. This is nothing that could not be covered by TRIPS prescriptions themselves. Hence, the Declaration does not add any legally relevant clarification nor advances views on the usage of certain provisions, compulsory licenses in particular. However, this statement can be considered politically significant provided that price increases provoked by patents has been the main argument in the public debate on access to medicines.

B. Based on these premises, the Declaration reveals the agreement that TRIPS does not and should not prevent Members to take measures to protect public health; and that it can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. Therefore, Members have the right to use, to the full, the provisions in the Agreement which provide flexibility for this purpose (point 4).

The references to Members' right to protect public health and to promote medicines' access for all, deserve some attention. They are not two different rights; on the contrary, promotion of access to medicines constitutes a part of the Members' right to protect public health. The right's exercise is limited by public international law to situations in which the State has jurisdiction. Therefore, the reference to *all* when talking about access to medicines, which could have eventually included third States' population (especially when production capacity is scarce or non existent; *vid. supra*), can only be referred to nationals and those within national boundaries.

That the Agreement's rules providing flexibility can be used, and that it can be done "to the full" seem two obvious statements. What is important to remember is that the use to the full of prescriptions affording flexibility does not allow to infringe their conditions and/or limitations when they exist. Nor does it neglect the usually "exceptional character" of the prescriptions affording flexibility⁴; and exceptions are deemed to be interpreted restrictively. Therefore, without prejudice of the doubtless political relevance of this statement' inclusion in the Declaration, it does not provide further legal information than the already existing.

C. The "flexibility catalog" offered by the Agreement in this field (point 5) (without prejudice of its application to others) includes:

1. Each provision of the TRIPS shall be read in the light of the object and purpose of the Agreement as expressed, particularly, in its objectives and principles. This goes in **application of the customary rules of interpretation of public international law** (point 5 a).

⁴ Flexibility is often gained through exceptions to the ordinary regime, however, this is not always the case: i.e. international exhaustion of intellectual property rights.

This point merely reminds that public international rules on treaty interpretation apply also to the WTO, a fact that has been acknowledged by a number of WTO Panels⁵. In this regard, mentioning the objectives and principles of the Agreement has, beyond the legally evident implications, the political impact of reminding the goal of economic and social welfare for all, together with the right of Members to adopt the measures *necessary* to protect public health when implementing TRIPS Agreement.

2. Each Member has the **right to grant compulsory licenses** and the **freedom to determine the grounds** upon which such licenses are granted (point 5 b).

This aspect was expressly mentioned in the developing countries' draft. TRIPS article 31 evidently recognizes Members' right to issue compulsory licenses and to freely determine the reasons to issue those licenses. Regardless the reference to anti-competitive behavior and the so-called dependent patents, the article does not mention, even *ad exemplum*, the situations which may lead to the issuance of a compulsory license. It is foreseeable that the Members' freedom to determine the grounds for issuing compulsory licenses will come into the legal discussion when considering whether issuing a compulsory license constitutes the least possible interference with the intellectual property right at stake. GATT article XX jurisprudence on "necessity" comes to mind, but its "parallel" application regarding TRIPS would require further study.

3. Each Member has **the right to determine what constitutes a national emergency or other circumstances of extreme urgency**, it being understood that health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency (point 5 c).

This was proposed in developing countries draft and could not be opposed by developed countries. Here, as in the previous number, the legal issue is not so much about freely deciding when a health crisis exists, but whether the national measures adopted to cope with the situation should cause the least possible interference with the intellectual property rights at stake.

4. TRIPS Agreement **Members are free to establish their own regime on exhaustion of intellectual property rights** without challenge, subject to the MFN and national treatment provisions of articles 3 and 4 (point 5 d).

This point addresses the famous parallel imports' issue or, expressed in intellectual property right terms, the admissibility of these rights' international exhaustion. Developing countries' draft stated the admissibility of international exhaustion under TRIPS. Though it had been discussed by some developed countries, from the juridical point of view this was a very clear issue. Even the developed countries' draft could only recognize what was evident. However, they wanted to go one step further. Developed countries major concern in this regard is commercial deflation. Therefore, they intended to insert an "encouragement" reference for Members to take measures preventing that medicines provided for the poorest populations under discounted prices schemes or aid regimes be parallelly re-imported into developed markets for which they were not intended. This aspect, which is linked to international proposals of differential prices'

⁵ In *Reformulated Gasoline* (WT/DS2/R) and in *Alcoholic Beverages* (WT/DS,8, 10-11/AB./AB/R), the Appellate Body held that articles 31 and 32 of the Vienna Convention on the Law of the Treaties constituted customary rules of interpretation of Public International Law for purposes of the Dispute Settlement Understanding (DSU) article 3.2.

regimes for pharmaceuticals⁶, clearly exceeds TRIPS rules and reduces international transactions; hence it could by no means be included in the Declaration.

D. TRIPS article 66.2 commitment of developed countries to incentive technology transfer towards least developed countries is reaffirmed (point 7).

Developing countries' draft included all developing countries, but, following article 66.2, the Declaration just mentions least developed countries. Developed countries' draft did not refer to this aspect, focusing only on the need to technically assist developing countries for them to comply with their TRIPS obligations in article 67 terms. It is evident that technology transfer commitments of article 66.2 imply much more of an economic and/or development compromise than the mere technical assistance to apply TRIPS Agreement of article 67.

E. Simultaneously (point 7), Members agree on a new transitional application deadline for least developed countries on pharmaceutical products' patent and trade secrets protection. These Members will not be obliged to implement, apply or enforce rights in these fields until the first of January 2016. As a matter of course, it is understood that they maintain their right to apply for further extensions as provided in article 66.1.

Developing countries' draft aimed at equally extending the transition periods for both developing and least developed countries on product or processes relating to public health. Though the Declaration delays the application date for least developed countries only, the accorded deadline lasts far more than the five years period proposed by developing countries, and encompasses not only patents but also trade secrets. The proposal would have meant that, without prejudice of new extensions, the Agreement would have been applicable on 1st January 2011, and the Declaration has reached the same day in 2016. Developed countries' draft said nothing about extending application deadlines. It must be considered that TRIPS' article 66 establishes that this decision should be taken by TRIPS' Council following individual applications made by interested Members. The extension is the only real concession in favor of developing countries (least developed) in the whole Declaration. However, its interest and relevance does not exclusively rest on its content. It is politically significant that the extension has been agreed for least developed countries in general and that it has been incorporated in a Ministerial Declaration. Anyhow, the Declaration does not affect rules regarding mailbox protection and exclusive commercialization rights, that will be applicable during the new transition periods.

F. As to the problems created by the lack or insufficient production capacity in the pharmaceutical sector of a number of Members, the Declaration only recognizes that this could create difficulties in making effective use of compulsory licenses and instructs the TRIPS' Council to find an expeditious solution and report to the General Council before the end of 2002 (point 6).

⁶ This issue was discussed in the *Workshop on differential pricing and financing of essential drugs*. Hobsjor (Norway), 8-11 April, 2001, organized by the WIPO and WTO Secretariats, Norway's Foreign Relations Ministry and Health Global Council. As I see it, differential prices regimes should be framed within a special regime in favor of developing and least developed countries. C. Otero García-Castrillón; "Acceso a los medicamentos: las patentes y el Acuerdo sobre los derechos de propiedad intelectual relacionados con el comercio". Accepted for publication in *Boletín de Información Comercial Española*.

Developing countries' draft pointed that *a Member (A) may give effect to a compulsory license issued by another Member (B)*; who, at the mean time, could authorize the supplier within its territory to manufacture and export the product under the license predominantly for the supply of its domestic market. Although the draft does not provide more details, one can assume that this Member (B) would only authorize the local licensee-supplier to export once the other Member (A) has decided to "give effect within its territory" to the license and if the licensee manages to export without shortening the supply in the national market. In any case, the TRIPS' departure point in this discussion is that compulsory licenses are issued by national authorities responding to a situation within its jurisdiction, and aim essentially to satisfy national market' needs⁷. Therefore, a national authority can decide the issuance of a compulsory license within its territory, but not beyond. If only the affected country can issue a compulsory license with effects in its territory; it would have to "issue a new license", to the same holder if that is the case, in order to "give effect" to a foreign license.

From my perspective, TRIPS Agreement does not prevent a compulsory license be exploited through imports. Article 27 forbids discrimination between imported and local production. Since article 31 is subject to the non-discrimination rule⁸, the prohibition applies to patent rights' exploitation as much as to the exploitation of compulsory licenses. This is without prejudice that TRIPS can justify that, in certain cases, compulsory licenses may be conditioned to local manufacturing. It is true, however, that the text of the Declaration seems to imply Members' belief that compulsory licenses are exploited essentially, if not exclusively, through local manufacturing.

Developing countries' draft did also mention that under *article 30 exceptions* Members could authorize the production and export of medicines by persons others than the patent holders to address public health needs of importing countries. It is not surprising that the proposal does not receive any attention in the final Declaration. Moreover, it does not seem feasible that this option could ever be admitted. Article 30 is not meant to attend to the circumstances and needs of countries other than the exceptions' regulator. In addition, the simultaneous admission of both developing countries proposals (compulsory licenses and exceptions) for the same goal would have been absolutely impossible because article 31, which covers compulsory licenses, does only apply to uses not covered by article 30. Therefore, the Declaration instructs the TRIPS Council to find an expeditious solution to the problem, be it through compulsory licenses, exceptions or any other approach, and to inform the General Council before the end of 2002. Meanwhile, without prejudice of resorting to the issuance of compulsory licenses to be exploited through imports, the immediate effect of TRIPS' patent rules in these situations does not seem to be too relevant. Without minimizing the importance of the cases, Members lacking manufacturing capacity are mostly least developed countries and do not have to apply TRIPS' patent rules on pharmaceuticals until 2016⁹.

⁷ This is without disregarding the sanctioning of anticompetitive practices and the dependent patents dimensions; which anyway refer to effects on national market and on the use of other patent nationally.

⁸ Panel on Canada's protection of pharmaceutical patents; WT/DS114/R de 17th March 2000, at 170.

⁹ However, though it has not been mentioned in the Declaration, these countries would be required to comply with TRIPS' trademark rules from 1st January 2006; and the vast majority of medicines, even generics, are commercialized under a trademark. In this regard, any possible extensions of the transition periods should be decided by the TRIPS Council following article 66 prescriptions.

G. Contrary to Developing countries' intent¹⁰, the Ministerial Declaration does not mention **dispute settlement** under TRIPS Agreement. From the moment in which the Declaration recognizes the different freedoms, the fear of claims being presented before the Dispute Settlement Body (DSB) is drastically reduced. Developing countries could go without a reference to dispute settlement in the Declaration since claims regarding measures adopted to protect and promote public health is not so much an issue when the most disputed questions had been settled. This does not mean that eventual interpretative legal issues regarding the application of some "flexibility devices" cannot be foreseen.

Conclusions

Overall, the Ministerial Declaration on TRIPS and Health constitutes a WTO politically necessary action for the continuity and coherent implementation of the Organization's work on TRIPS within the absolute indispensable and rightly "presiding force" of the economic development concern. From the perspective of TRIPS legal content and its alleged uncertainties, one may conclude that, except for the application deadline for least developed countries on patents and trade secrets regarding pharmaceuticals, the Ministerial Declaration does not provide news or more clarity than it was already existing. As a matter of fact, from my perspective, many of its legal assertions are perfectly applicable to public interests others than health. Although at certain times some developed countries have supported interpretative arguments contrary, for example, to the admissibility of international exhaustion of intellectual property rights under TRIPS, their legal basis were weak enough not to have resisted a claim before the DSB. Nevertheless, there is no doubt that regarding the Agreement's interpretation, the Declaration's contribution rests on providing an almost¹¹ definitive certainty on a number of basic issues. Consequently it provides the relieve of knowing that, most likely, no complaints on these issues will be presented before the DSB. However, it is possible to foresee interpretative problems on other legal issues linked to the use of compulsory licenses of patents, which would not be limited to public health cases.

¹⁰ On one hand, they aimed at Members to exercise the utmost restraint in initiating and pursuing dispute settlement procedures on measures adopted or implemented to protect and promote public health, particularly by developing countries. On the other hand, the intention was that under no circumstance Members could base their complaints against measures adopted to protect or promote public health, particularly by developing countries, on GATT-94' article XXIII. 1 b. and c.

¹¹ The legal nature of the Declaration must be taken into account.