Compulsory Licenses after Doha Declaration on the TRIPS Agreement and Public Health

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I. Introduction

THE MINISTERIAL Conference of the World Trade Organization (WTO) adopted the "Declaration on the TRIPS Agreement and Public Health"[1] – hereinafter the Doha Declaration- on November 14, 2001.

The Doha Declaration was conceived in an extremely complex global scenario where some developing and least developed countries having significant sectors of their populations infected with HIV/AIDS, malaria, tuberculosis or other epidemics, proposed or implemented policies to reduce the cost of patented medicines to treat these diseases, such as compulsory licensing or the application of the international exhaustion regime.

These policies were adverse to the interests of the patent holders, which provoked conflicts and tension at both bilateral and multilateral levels.

In this state of affairs, the Doha Declaration constituted a milestone in the TRIPS Agreement history for two reasons: first, because it ensures balance between the right of the Members to implement policies intended to safeguard public health and patent rights; second, because the Doha Declaration sets forth a clear preventive standard of the whole TRIPS Agreement, as well as some other specific rules of that Agreement, such as compulsory licenses and exhaustion of intellectual property rights.

In fact, the Declaration acknowledges the importance of intellectual property for the development of new drugs[2] but it also recognizes the concerns about the effects of intellectual property rights on prices.

The Ministers pointed out, *"TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our*

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1. WTO, Ministerial Conference, Fourth Session, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2.
2. *Doha Declaration*, para. 3.

commitment to the TRIPS Agreement, we affirm that the Agreement 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"[3].

The Members are to implement the minimum standards laid down in the TRIPS Agreement, but the Doha Declaration recognizes that they may use, to the full, the flexibilities in the Agreement.

II. Interpretation of the TRIPS Agreement under the Doha Declaration

Legal status of the Doha Declaration

The legal status of the Doha Declaration is controversial since some believe that it is a mere "declaration" of the Ministerial Conference and not a "decision" and thus, a simple political declaration with no legal authority[4] that does not amend the obligations under the TRIPS Agreement.

Even when this position is right in that the Doha Declaration is not a "Decision" from the formal point of view and regardless of the formal mechanisms of the WTO to adopt "decisions", the Doha Declaration is, at least, an "agreement" among the WTO Members.

Article 31 of the Vienna Convention on the Law of Treaties sets forth that treaties should 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"*.

Paragraph 3 (a) of Article 31 of this Convention provides that *"shall be taken into account, together with the context:... any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions"*.

The International Law Commission has pointed out that "an agreement as to the interpretation of a provision reached after the conclusion of the treaty represents an authentic interpretation by the parties which must be read into the treaty for purposes of its interpretation"[5].

In short, even if the Doha Declaration is not a "decision", it contains an "agreement" among the Members as to how the TRIPS Agreement should be interpreted in general and how some rules in particular should be

3. *Doha Declaration*, para. 4.
4. See, Gathii, James Thuo, "The Legal Status of the Doha Declaration on TRIPS and Public Health under The Vienna Convention on the Law of Treaties", 15 *Harv JL & Tech* 315 (Spring 2002); see also, Reichman, Jerome H. and Hasenzahl, Catherine, *Non-voluntary Licensing of Patented Inventions: Historial Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States* 14 (UNCTAD/ICTS, Capacity Building Project on IPRs, September 2002).
5. *Corfu Channel* (Merits), 1949 *IE* 4, 25 (Apr. 9); *Certain Expenses of the United Nations* (Art. 17, para. 2 of the Charter), 1962 *ICJ 151*, 157, 160-61, 172-75; *Territorial Dispute (Libyan Arab Jamahiriya/Chad)*, 1994 *ICJ* 6, 21-22 (Feb. 3) at 34-37.

interpreted. The panels, the Appellate Body and the Council for TRIPS, among others, should apply the guidelines set in the "agreement" that includes the Doha Declaration.

Rules for the interpretation of the TRIPS Agreement

The Doha Declaration determines, in general, that in applying "the customary rules of interpretation of public international law, each provision of the 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"[6].

In this item, the Declaration emphasizes on the importance of objectives and principles of the TRIPS Agreement to interpret the scope of its provisions; the person who makes the interpretation must first resort to the objectives and principles, on an equal footing with the other "rules of interpretation of public international law". This reverses the order of the practice followed by the Dispute Settlement Body (DSB), of resorting, in the first place, to a word for word analysis and then, in a second stage, and always provided no satisfactory result is obtained, to the context analysis.

In this way, any of the provisions of the TRIPS Agreement should be construed by specially taking into account the objectives[7] and principles[8] of the Agreement, as described in Articles 7 and 8, respectively.

In a communication recently submitted to the Council for TRIPS[9], the European Community and their Member States further express that *"it should be borne in mind that the principles of the Doha Declaration can also be carried through to issues other than compulsory licensing or parallel imports, such as exceptions to exclusive rights or other policy options"*.

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6. *Doha Declaration*, para. 5 (a).
7. Art. 7, TRIPS Agreement: "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".
8. Art. 8, TRIPS Agreement: "1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".
9. Communication by The European Communities and their Member States, *The Implementation of the Doha Declaration on the Trips Agreement and Public Health*, IP/C/W402, footnote 3.

Compulsory licenses and patent rights exhaustion

As anticipated, the Doha Declaration contains paragraphs that deal with the interpretation of the obligations and rights of the Members as to the grant of compulsory licenses and the exhaustion of rights.

As concerns the compulsory licenses, the Doha Declaration confirms that the TRIPS Agreement gives the Members full freedom to grant compulsory licenses and determine the grounds upon which such licenses are granted, irrespective of the fact that the terms and conditions in Article 31 of the TRIPS Agreement that govern the grant of such licenses[10], should always be observed.

In this line of thoughts, the Doha Declaration expresses that the TRIPS Agreement does not limit the right of the Members 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 epidemic[11] can represent a "national emergency".

The scope of diseases that may cause a public health crisis is illustrative and not restrictive, the Member being able to grant compulsory licenses to face any public health crisis caused by other diseases not included in paragraphs 1 and 5(c) of the Doha Declaration.

The Doha Declaration also puts an end to the debate about whether the TRIPS Agreement is compatible with an international exhaustion regime of intellectual property rights.

Subparagraph 5(d) sets forth that the effect of the provisions in the TRIPS Agreement is to set each Member free to establish the most appropriate regime for exhaustion –whether national, regional or international- leaving this issue out of the WTO dispute settlement procedure[12].

In short, the Ministerial Conference, through the Doha Declaration, provides an actual interpretation of some of the provisions in the TRIPS Agreement –such as compulsory licenses and exhaustion of rights – and establishes a clear mandate for the Council for TRIPS, the Appellate Body and the future panels, on how to interpret the TRIPS Agreement, applying the "customary rules of interpretation of public international law", but specially in the light of "its objectives and principles".

III. Paragraph 6 of the Doha Declaration

Notwithstanding the interpretation made in the Doha Declaration of the TRIPS Agreement that ratifies that the Members shall keep full powers

10. *Doha Declaration*, para. 5 (b).
11. *Ibid.*
12. *Doha Declaration*, para. 5 (d).

to struggle against the diseases described in paragraph 1 and grants –when necessary- compulsory licenses to reduce the costs of treatments, the truth is that many Members have insufficient or no manufacturing capacities in the pharmaceutical sector, which could hinder or directly prevent the effective use of compulsory licenses because the Members would not have anyone to grant to the compulsory license.

The Ministers acknowledge this situation in paragraph 6 of the Doha Declaration and point out 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"*[13].

Therefore, the Ministerial Conference instructed the Council for TRIPS *"to find an expeditious solution to this problem and to report to the General Council before the end of 2002"*[14].

Additionally, in paragraph 7 of the Doha Declaration, the Ministerial Conference agreed to extend until January 1, 2016 the transition period for the least-developed Members to grant patents for pharmaceutical products and to grant protection to undisclosed information related to these products[15], without prejudice to the right to seek other extensions as established in Article 66 (1) of the TRIPS Agreement[16].

IV. Discussion of the problem identified in paragraph 6 of the Doha Declaration in the Council for TRIPS

In compliance with the mandate included in paragraph 6 of the Doha Declaration, the Council for TRIPS considered during the year 2002[17] the different proposals[18] of expeditious "solution" submitted by the Members

13. *Ibid*, para. 6.
14. *Ibid*, para. 6.
15. *Doha Declaration*, para. 7.
16. The Council for TRIPS, through the Decision adopted on June 27, 2002, implemented the extension adopted at the Ministerial Conference in para. 7 of the Doha Declaration, see, IP/C/25.
17. During 2002, the Council for TRIPS held four formal meetings: March 5-7 2002, June 25-27, September 17-19 and November 25-27 and 29, 2002. On December 20 it reconvened the last meeting held. See, *Annual Report (2002) of the Council for Trips*, IP/C/27, of December 27, 2002, para. 1.
18. For the March meeting, papers were provided by the European Communities and their Member States (IP/C/W/339) and the United States (IP/C/W/340). For the June meeting, proposals were submitted by the African Group (IP/C/W/351), the European Communities and their member States (IP/C/W/352), the United Arab Emirates (IP/C/W/354), Bolivia, Brazil, Cuba, China, the Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela (IP/C/W/355), and the United States (IP/C/W/358). For the September meeting, the Council received a non-paper from Switzerland (JOB(02)/109). Prior to the November meeting, non-papers were submitted by South Africa (JOB(02)/156) and the European Communities and their member States (JOB(02)/157).

to the problem identified in paragraph 6.

The mechanisms proposed may be classified into four big groups[19]:

(1) an authoritative interpretation of Article 30 of TRIPS, that recognizes the right of Members to allow the production, without the consent of the patent holder, in order to address public health needs in another country;[20]

(2) an amendment of Article 31 to circumvent the requirements of Article 31 (f), to overcome the possible restrictions on exporting products manufactured and/or sold under a compulsory license;[21]

(3) a dispute settlement moratorium with regard to non-compliance with Article 31 (f); and

(4) a waiver of obligations with respect to Article 31 (f).

On December 16, 2002 the Chairman of the Council for TRIPS, Ambassador Eduardo Pérez Motta, submitted a recommendation draft[22] to the General Council with a proposal of the solution to the problem identified in paragraph 6 of the Doha Declaration; hereinafter, Pérez Motta's draft.

At the last 2002 meeting of the Council for TRIPS –December 20- all WTO Members other than USA consented to Pérez Motta's draft after intensive consultations; this represented a hindrance to its approval and delivery to the General Council.

US representative before the Council for TRIPS informed at such meeting that the United States "was willing to join the consensus on all parts of the draft, except the one on the scope of diseases"[23]

Once the term granted to the Council for TRIPS at the Doha Ministerial Conference, for it to find a solution to the problem identified in paragraph 6 expired, the Council for TRIPS held two other meetings during 2003 at which Pérez Motta's draft could not be approved either for the reasons expressed *supra*, or some Members filed two new submissions related to this matter[24].

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19. See, Haag, Thomas A., "TRIPS since Doha: How far will the WTO go toward modifying the terms for compulsory licensing?", *J Pat & Trademark Off Soc'y* 945 at 953-954 (December, 2002); Sun, Haochen, "A wider access to patented drugs under the TRIPS Agreement", *BU Int'l LJ* 101 at 115-116 (Spring 2003).
20. See, Sun, Haochen, *id.*, at 121.
21. *Id.*, at 116.
22. Document JOB(02)/217. The draft job is attached hereto.
23. WTO, Council for TRIPS, *Minutes of meeting held in the Centre William Rappard* on 25-27 and 29 November, and 20 December 2002, IP/C/M38, para. 34.
24. To date, the Council for TRIPS held two meetings during 2003: February 18 and 19, and June 4 and 5. The following communications were submitted for the February meeting: United States: document IP/C/W/396/Corr.1; European Communities and their Member States: JOB(03)/9); and Japan: JOB(03)/19). For the June

After the June discussions, the Chair of the Council for TRIPS *"expressed its intention to remain in close contact with delegations with a view to resuming consultations as soon as developments showed signs of renewed consultations being useful. He urged delegations to continue to dialogue with each other so that a solution could be found based on the 16 December 2002 text. He hoped that a solution could be found before the Cancun Ministerial Conference and preferably in time for the next General Council meeting scheduled for 24 July 2003"*[25].

However, by the time this paper was completed, no consensus had been reached regarding the outstanding Pérez Motta's draft issues and there is no certainty that consensus will ever be reached before the Fifth Ministerial Conference to be held in Cancún, México.

V. Pérez Motta's draft

Pérez Motta's draft proposes a "solution" to the problem identified in paragraph 6 of the Doha Declaration: to import patented pharmaceutical products –or product manufactured through a patented process - in the Member affected by circumstances of extreme urgency ("importing Member") and to grant a compulsory license so that the holder of the patent cannot exercise the *ius excluendi* as regards the import of such products; and, on the other hand, to grant a compulsory license to a WTO Member that has manufacturing capacities in the pharmaceutical sector ("exporting Member") so that a third party may produce the pharmaceutical products and export them to the "importing Member".

However, this proposal, which seems to be of easy implementation, should solve two limitations arising from Article 31 of the TRIPS Agreement that establishes that compulsory licenses *"... shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use"* (paragraph f) and that *"the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization"* (paragraph h).

To overcome these difficulties, the draft addresses four simultaneous courses of action:

(1) A waiver from the obligations set out in Article 31(f) and (h) of the TRIPS Agreement by the Members that make use of the "solution" proposed in the draft "Decision", and the Council for TRIPS shall review annually the functioning thereof and shall annually report on

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meeting, two new communications were submitted: "African, Caribbean and Pacific Group of States", document IP/C/W/401; and the European Communities and their Member States, document IP/C/W/402. See, *Update to the Annual Report (2002) of the Council for TRIPS*, IP/C/27/Add.1, of July 2, 2003, para. 1.

25. *Ibid*, para. 7.

its operation to the General Council[26];

(2) The commitment that no Member shall *"challenge any measure taken in conformity with the provisions of waivers"*[27].

(3) The conditions, safeguards and mechanisms that should be complied with by the Members to grant compulsory licenses under the "waiver"[28]; and

(4) An amendment to Article 31 of the TRIPS Agreement that includes the principles of the proposal. Until such amendment becomes effective in each Member, the "solution" proposed in the "Decision" –including the waivers granted in it- should continue to be in full force and effect. To implement such amendment, the Council for TRIPS should initiate work by the end of 2003 with a view to its adoption within six months.[29]

Pharmaceutical products included in Pérez Motta's draft and eligible Members

The "solution" proposed in the draft may be applied to *"any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration"*[30].

Particularly, the scope of diseases and thus the products that fall within the ambit of the proposed system was the subject matter of the debate held by the Council for TRIPS and which caused the United States to be against the draft, thus hindering its approval since, from their point of view, the scope of the diseases listed in the draft Decision had to be limited.

As regards the Members that can use the system proposed in the draft, both "least-developed country Members" as well as any other WTO Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, shall be eligible[31].

Twenty-three Members are not eligible for the system as "importing

26. Pérez Motta's Draft, para. 8. Therefore, the provisions of Art. IX, para. 4 of the WTO Agreement are complied with, which determines as to the waivers for periods of more than one (1) year, that the Ministerial Conference/General Council is to review it not later than one year after it was granted, and thereafter annually until the waiver terminates. See, Council for TRIPS, para. 6 of the *Doha Declaration on the TRIPS Agreement and Public Health: Information on Waivers*, IP/C/W/387, (June 22, 2002), para. 22).
27. *Ibid*, para. 10.
28. *Ibid*, paras. 1 - 5.
29. *Ibid*, para. 11.
30. *Ibid*, para. 1.(a).
31. *Ibid*, para. 1 (b).

Members"[32], but an interpretation *contrarius sensus* would allow us to assert that all Members –including the twenty-three ones on the list- may grant a compulsory license under the proposed system to export pharmaceutical products to an "importing Member" manufactured under a compulsory license because, in defining the term "exporting Member" in paragraph (1) (c), no Member was excluded from such category.

In the January 2003 communication from the United States stated that, to them, the products manufactured under a compulsory license might not be addressed to economies "classified by the World Bank as 'High Income Economies'[33]. Therefore, developing countries with high or medium incomes would be excluded –according to the US proposal– from paragraph 6 of the Doha Declaration.

The Pérez Motta's draft establishes that the Member that uses the system as an importer shall make a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that the Member may notify at any time that it will use the system in whole or in a limited way in case of a: (i) national emergency; (ii) other circumstances of extreme urgency; or (iii) public non-commercial use.

Waiver from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement

Paragraph 2 of the draft provides for a waiver from the obligations set out in paragraph (f) of Article 31 of the TRIPS Agreement to allocate the goods produced under a compulsory license mainly to the local market. In this way, the licensee in the "exporting Member" shall be able to allocate its production to the "importing Member".

To that end, the terms set out below in this paragraph should be complied with:

First, the "importing Member" should make a notification to the Council for TRIPS stating the names and the expected quantities of the pharmaceutical product needed.[34] Then, it should confirm that the "importing Member", other than a least developed country, *"has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product in question"*[35]. Likewise, where the pharmaceutical product is patented

32. Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden Switzerland, the United Kingdom and the United States of America.
33. Communication from the United States, *Moratorium to Address Needs of Developing and Least-Developed Members With No Or Insufficient Manufacturing Capacities in The Pharmaceutical Sector*, IP/C/W396 (January 14, 2003), para. 1.
34. Pérez Motta's draft, subpara. 2.(a) (i).
35. *Ibid*, para. 2.(a) (ii).

in the territory of the "importing Member", it has to confirm that it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the draft[36].

Second, the compulsory license issued by the "exporting Member", shall contain the following conditions:

(a) Only the amount necessary to meet the needs of the "importing Member" may be manufactured and the entirety of the production shall be exported to "importing Member" [37];

(b) Before shipment begins, the "licensee" of the "exporting Member" shall post on a website the quantities being supplied, the destination thereof and the distinguishing features of the product. [38]

Third, the "exporting Member" shall notify the Council for TRIPS of the grant of the compulsory license, including the conditions attached to it, the name of "licensee", its address, the product for which the license has been granted, the quantities for which it has been granted, the duration of the compulsory license and the address of the website where the information, identification and destination of the manufactured product were posted.[39]

On the other hand, paragraph 6 of the draft sets out that, with a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products and where a developing or least-developed country is a party to a regional trade agreement,[40] and at least half of the current membership which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31 (f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licensee in that Member to be exported to the markets of other developing or least-developed country parties to the regional trade agreement that share the health problem in question[41].

Patent holder remuneration

Paragraph 3 of the draft sets out the remuneration to be paid to the patent holder for the grant of the compulsory license, thus confirming the

36. *Ibid*, para. 2.(a) (iii).
37. *Ibid*, para. 2.(b) (i).
38. *Ibid*, para. 2.(b) (iii).
39. *Ibid*, para. 2.(c).
40. In accordance with the meaning of Art. XXIV of the GATT 1994 and the Decision of 28 November 1989 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903).
41. It is expressly made clear in this para. that *"it is understood that this will not prejudice the territorial nature of the patent rights in question"*.

provisions of Article 31 (h) of the TRIPS Agreement that sets forth that a remuneration is to be paid in accordance with the draft.

The draft proposes two hypotheses about this issue: 1) that the compulsory license has been granted solely in the "exporting Member"; and 2) that the compulsory license has been granted in the "exporting Member" as well as in the "importing Member".

In the first hypothesis, remuneration should be paid in the "exporting Member" taking into account the economic value to the "importing Member" of the use, thus excluding the value in the "exporting Member" market.

The second hypothesis deals with a waiver for the "importing Member" and remuneration should not be paid in that Member if it has already been paid in the "exporting Member".

The second hypothesis is based on the assumption that the patent holder in both Members –importing and exporting- is the same person, but fails to instruct how to proceed in case the patent holders in both Members are different persons. In this case, we believe that the issue should be solved by applying the principle implied in paragraph 3 of the draft, that is to avoid paying a double remuneration to the patent holder.

Safeguards

The products manufactured under a compulsory license granted in accordance with the system proposed in Pérez Motta's draft should be clearly distinguished and shall be clearly identified as having been produced under such system.

Likewise, the products *should be distinguished through special packaging and/ or special colouring/shaping of the products themselves*", provided that such distinction is feasible and does not have a significant impact on prices[42].

In the same way, paragraph 4 provides that to ensure that the products imported under the system set out in the draft are used for public health purposes underlying their importation, the "importing Member" shall take reasonable measures within its means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into its territories under the system.

If the "importing Member" is a developing country or a least-developed country and experiences difficulty in implementing such safeguards, a developed country Member, on request of the "importing Member" and on mutually agreed terms and conditions, may provide technical and financial cooperation in order to facilitate its implementation.

42. *Ibid*, para. 2.(b) (ii).

Likewise, paragraph 5 lays down the obligation of all Members to ensure the availability of the legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.

VI. Conclusions

The Doha Declaration constitutes a true interpretation of the TRIPS Agreement; the Ministerial Conference clearly ascertains that it should be interpreted by applying the customary rules of interpretation of public international law and that each one of its provisions should be read in the light of its objectives and principles.

In applying this interpretation criterion, the Ministerial Conference affirmed that the Members have full powers under the TRIPS Agreement to (i) establish such regime for the exhaustion of rights as they may deem appropriate; (ii) grant compulsory licenses and determine the grounds upon which same are granted; (iii) that a "public health crises" –including those caused by HIV/AIDS, tuberculosis, malaria and other epidemics- can represent a "national emergency" or "other circumstances of extreme urgency" that justify the grant of a compulsory license.

The Ministerial Conference recognized in paragraph 6 of the Doha Declaration that there are some Members that, in case of "public health crises", cannot make effective use of the compulsory licenses under the TRIPS Agreement for they have insufficient or no manufacturing capacities in the pharmaceutical sector; thus it instructed the Council for TRIPS to propose the General Council an "expeditious solution" to that problem.

Failure to reach a consensus about the "scope of diseases" and to determine the Members that were eligible for the system as "importing Members", prevented the Council for TRIPS form approving Perez Motta's draft and reporting the General Council an "expeditious solution" to the problem identified in paragraph 6.

Notwithstanding the above and the contents of the minutes of the meetings held by the Council for TRIPS, the Members would have allegedly consented to the rest of Pérez Motta's draft –not yet formalized though - which proposes as a solution to the problem identified in paragraph 6, to authorize another Member to grant a compulsory license and export patented pharmaceutical products or products manufactured through a patented process to the Member affected by the "public health crises".

The draft provides for the adequate measures to ensure that the grant of compulsory licenses affects the rights of patent holders to the smallest extent possible; in this way, it confirms that a remuneration is to be paid to the patent holder for the use of the invention and sets the grounds under which such remuneration should be determined. Likewise, safeguards are

proposed to prevent the products manufactured under compulsory licenses from being diverted to other markets, to the detriment of the patent holder.

To that end, two courses of action are proposed: amend Article 31 of the TRIPS Agreement in the short and in the medium term with a view to including the principles of the solution proposed; as a provisional but immediately effective measure, a waiver so that the exporting Member can export pharmaceutical products to the importing Member without infringing the rules.

In this way, the Doha Declaration, through the interpretation of the TRIPS Agreement, and Pérez Motta's draft –if approved- shed light on and develop new terms and conditions under which the Members may grant compulsory licenses to address public health crises.