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Occasional Paper 14

The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements

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The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements[1]

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Individuals operating in the real world of medicines regulation, procurement and distribution cannot be expected to sort out these incredibly complicated rules.

On November 14, 2001, WTO Ministers meeting in Doha adopted the Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration"). In the Doha Declaration, Ministers stated:

> "4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our 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.
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> In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
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> 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
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> (a) 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.
> (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
> (c) 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.
> (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

Subsequent to adoption of the Doha Declaration, WTO Members spent close to two years in negotiations that culminated on August 30, 2003, in the Decision on Implementation of Paragraph 6. That Decision is intended to permit Members with insufficient or no manufacturing in the pharmaceutical sector to make effective use of compulsory licensing.

Yet efforts have been underway to undermine the flexibilities that were so strongly recognized and endorsed at Doha, and more recently by the World Health Assembly.[2] Specifically, reference is made to the negotiation of bilateral and regional "free trade agreements" that include as one of their major elements provisions contradictory to the letter and spirit of the Doha Declaration.

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[1] An earlier version of this paper was discussed informally at a Quaker House seminar in March 2003.

[2] WHO, Fifty-Sixth World Health Assembly, Agenda item 14.9, WHA56.27, 28 May 2003, urging members to "consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)".

1. The Contradictory Trend in Public Health Negotiations

The Report of the WTO Secretariat in connection with the seventh Trade Policy Review of the United States called attention to the proliferation of preferential trading arrangements negotiated and concluded by that Member, reflecting on certain risks associated with those agreements:

> "The expanding U.S. preferential network could serve to draw its partners more closely into the multilateral trading system, the acknowledged 'first-best'; however, care should be taken that negotiating and administrative resources are not distracted away from the multilateral system, *that vested interests are not created that complicate multilateral negotiations*, and that trade and regulatory structures attendant on preferential agreements do not hinder trade."[3] [italics added]

Of course, free trade agreements are not unilateral undertakings. Each such agreement by definition includes more than one Member, and each Member that participates in the negotiation and conclusion of such an agreement does so on the basis of sovereign autonomy. Yet one must be cognizant of the balance of interests present in these negotiations.

Most WTO Members are not significant producers of pharmaceutical products, relying on imports for supply to their public health systems. FTA negotiations involve the creation of market-access opportunities for export-oriented industries. Only a few developing countries are in a position to expand export opportunities in the pharmaceutical sector, or are in a position of protecting a substantial domestic pharmaceutical sector. Because domestic industry is not affected, substantial restrictions in FTAs on access to pharmaceutical products may be accepted within highly complex provisions with respect to patents and regulatory approval without close examination by public health officials. Developing Members face difficulties in multi-sectoral negotiating processes, where they are asked to accept obligations in the public health sector in exchange for concessions in areas such as market access for agricultural products, on which their economies may substantially rely. With few exceptions, negotiations on FTAs have been conducted in a non-transparent way. The public is afforded access to texts only after they are concluded. There is a strong presumption against subsequent modification during the process in which ratifications are approved.

2. Recent Developments

As noted in the Secretariat's Trade Policy Review Report on the United States, that Member has negotiated a substantial number of free trade agreements (FTAs).[4] The United States' has recently concluded FTAs with Jordan, Singapore, Chile, Central America, Australia and Morocco, not all of which are yet in force. There is a considerable list of FTAs contemplated or under negotiation by and with the United States.[5]

The recently concluded Central American Free Trade Agreement (CAFTA) illustrates the treatment of pharmaceutical products embodied in these agreements, recognizing that there are variations among the agreements.[6]

CAFTA Chapter 15 acknowledges the rights and obligations of the parties under the TRIPS Agreement, stating at Article 15.1:

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[3] Report by the WTO Secretariat, Trade Policy Review, United States, WT/TPR/S/126, 17 December 2003, at pg. viii, para. 8.
[4] It also grants unilateral but "conditioned" preferences
[5] *See* Report, Trade Policy Review, United States, *id*., at pgs. 20-27.
[6] Available at http://www.ustr.gov. The CAFTA was the most recent for which a text was publicly available as of February 29, 2004, when this paper was initially prepared. The more recent agreements with Australia and Morocco are discussed *infra*.

> "7. Nothing in this Chapter shall be construed to derogate from the obligations and rights of one Party with respect to the other by virtue of the TRIPS Agreement or multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization and to which they are party."

Indeed, this provision might initially appear intended to preserve the flexibilities accorded to the parties under the TRIPS Agreement and the Doha Declaration. Yet, various other provisions in the Chapter very directly constrain the rights a WTO Member has under the TRIPS Agreement to implement it "within [its] own legal system and practice" (TRIPS Agreement, art. 1.1). That is, provisions are introduced that impose obligations on the parties that will effectively preclude the exercise of flexibilities. Note also that the subsequently concluded United States – Australia and United States – Morocco FTAs do not include comparable non-derogation provisions.[7]

Article 15.9(3) restates Article 30 (Exceptions to Rights Conferred) of the TRIPS Agreement, and Article 15.9(5) interprets Article 30, stating:

> "5. Consistent with paragraph 3, if a Party permits a third party to use of the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if a Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party."

Subparagraph 5 appears in some sense to reflect the discretion of Members approved by the dispute settlement Panel in *Canada – Patent Protection of Pharmaceutical Products*.[8] Consider, however, that it provides that marketing approval may only be effective "once the patent expires". Under the TRIPS Agreement "patent expiration" is not the sole mechanism for authorized use of an invention without the consent of the patent holder, including authorizations granted under compulsory license. Subparagraph 5 would not appear to contemplate approval of a medicine for export under the Decision on Implementation of Paragraph 6. In addition, findings of non-infringement or invalidity of a patent should permit exercise of marketing rights following regulatory approval. Such rights are recognized under the U.S. regulatory review "Bolar" exception.[9] Also, the subparagraph 5

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[7] But see the draft exchange of side letters to the U.S.-Morocco FTA, discussed *infra*.

[8] Report of the Panel, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, 17 Mar. 2000.

[9] For a complete explanation of the U.S. regulatory approval system, *see* U.S. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The relevant portion of U.S. Food and Drug Administration (FDA) regulations provides:

> " (2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include--
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> (A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)--
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> (i) that such patent information has not been filed,
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> (ii) that such patent has expired,
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> (iii) of the date on which such patent will expire, or
>
> (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted;" (21 USC §355(b)).

interpretation of Article 30 of the TRIPS Agreement must be read in contemplation of the limitations set forth in Article 15.10.

Article 15.9 further provides:

> "6. Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays."

The foregoing provision is not specifically directed to pharmaceutical inventions. It does, however, effectively establish a new standard for review of patent applications not included in the TRIPS Agreement. That is, there is in the CAFTA a maximum five-year patent review, after which the term of patents must be extended.

The provisions that most seriously intrude on the flexibilities in the TRIPS Agreement, as confirmed by the Doha Declaration, are embodied in Article 15.10. This Article provides:

> **"Article 15.10: Measures Related to Certain Regulated Products**
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> 1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.[14]
>
> (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in another territory or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party to the person who received authorization in the other territory. In order to receive protection under this subparagraph (b), a Party may require that the person providing the information in the other territory seek approval in the Party within 5 years after obtaining marketing approval in the other territory.
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> [footnote] 14: Where a Party, on the date of its implementation of the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural chemical products not involving new chemical entities from unfair commercial use which conferred a period of protection shorter than that specified in paragraph 1, that Party may retain such system notwithstanding the obligations of paragraph 1.
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> (c) For purposes of this Article, a new product is one that does not contain a chemical entity that has been previously approved in the Party.
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> (d) For the purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and each Party shall not consider information accessible within the public domain as undisclosed data. Notwithstanding

> the foregoing, if any undisclosed information concerning safety and efficacy submitted to a government entity, or an entity acting on behalf of the government, for purposes of obtaining marketing approval is disclosed by such entity, each Party is required to protect such information from unfair commercial use in the manner set forth in this Article.
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> 2. With respect to any pharmaceutical product that is subject to a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
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> 3. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory, that Party:
>
> (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and
>
> (b) if the Party permits a third person to request marketing approval of a product during the term of a patent identified as claiming the product or its approved use, it shall provide that the patent owner be informed of such request and the identity of any such other person."

The use of regulatory data is addressed in Article 39.3 of the TRIPS Agreement, which provides:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

3. Additional obligations under CAFTA

The number of obligations additional to those imposed on WTO Members that are parties to CAFTA is *very substantial.*

a) Data protection and market exclusivity

Article 15.10(1)(a) translates the requirement to protect certain regulatory submissions against unfair commercial use into a strict five year prohibition against granting marketing approval to a third party (i.e., generic producer) based on originator-submitted data or marketing approval granted to the originator. The United States and certain other developed country Members had argued for a five-year data exclusivity period during the Uruguay Round, but this was not accepted. It is now introduced in the CAFTA. Note that Article 15.10(1)(a) contains no reference to "unfair commercial use", which is the principal condition for assessing whether an act should be permitted or prohibited under Article 39.3 of the TRIPS Agreement. Thus, for example, *if a Member wishes to register a generic medicine for public non-commercial use in clinics, it is forbidden by this restriction.*

Article 15.10(1)(b) takes this additional obligation substantially further. *A third party (i.e. generic producer) may not for five years rely on data submitted in connection with obtaining marketing approval in "another territory".* A generic producer in Honduras, for example, may not obtain marketing approval for a bioequivalent medicine by relying on the fact it has been registered in the United States (or Switzerland, for that matter), for a period of five years from the date marketing approval of the medicine is granted to the originator in Honduras. Not only that, the originator need not request

marketing approval in Honduras for five years after marketing approval in another territory (e.g., the United States), so the originator may in effect preclude the entry of generics in Honduras for ten years following marketing approval in the other territory. This is because a prospective third party (generic) applicant for marketing approval will know that the originator has only to request marketing approval within the five-year window for its application to be rejected, or its supply contracts to be made unlawful.

Nowhere in the TRIPS Agreement is there a requirement that a Member refrain from granting marketing approval to a generic producer based on submission of regulatory data by the originator in another Member. This is an additional restriction of great importance. Honduras, for example, is prevented from approving a generic medicine on grounds that a bioequivalent medicine was approved in the United States, without having received or reviewed any confidential regulatory data whatsoever from the originator.

A key point to note about the fixed term prohibitions on marketing approval in 15:10(1)(a) & (b)is that *these prohibitions are distinct from patents*. They prevent marketing approval of drugs that are off-patent (*e.g.*, in either or both the United States and Honduras). *A restriction on marketing approval becomes another form of monopoly, here granted in ways the TRIPS Agreement does not require.*[10]

Article 15:10(1)(c) extends the scope of regulatory data coverage from "new chemical entities", as stated in Article 39.3 of the TRIPS Agreement, to any "new product" defined as "one that does not contain a chemical entity that has been previously approved in the Party." This is a significant technical modification. Under the new rule, a CAFTA Party does not look to whether an originator previously submitted data with respect to an innovative product in determining whether a generic equivalent may be approved.[11] Instead, the determination is made based on whether a prior

[10] Article 15.10(1)(d) is not well drafted. Its intent seems to be prevention of unfair use of data that is disclosed by a government to protect the public.

[11] Pharmaceutical products for which regulatory approval are sought typically are *not* "new chemical entities". The 2002 research report by the National Institute for Health Care Management (Research and Educational Foundation) (NIHCM) on innovation in the U.S. pharmaceutical sector relied on by the U.S. Federal Trade Commission in its report on patents and competition (*see* U.S. FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, October 2003, at Chapter 3, Part II) describes the classification system used by the U.S. Food and Drug Administration:

> "The FDA classifies all NDAs on two dimensions: by chemical type and therapeutic potential. One measure of innovation is the newness of the compound forming the drug's active ingredient. The agency designates drugs relying on compounds that have never before been approved for the U.S. market as new molecular entities (NMEs). The FDA also approves many new medicines whose active ingredients are already available in a marketed product. In most cases, the manufacturer has altered the original medicine to produce a drug with different features, such as a new dosage form or route of administration. The FDA classifies these drugs according to the type of change made to the original product, and this report refers collectively to all such products as "incrementally modified drugs" (IMDs). Finally, the FDA approves a few NDAs for drugs whose active ingredients are available in identical marketed products, usually to allow a new manufacturer to make the drug. This report refers to these as 'other drugs.'" NIHCM Foundation, Changing Patterns of Pharmaceutical Innovation (2002), at 2.

The NIHCM report observes:

> "In the 12-year period from 1989 to 2000, the FDA approved 1,035 new drug applications. Of these, 361 or 35% were for NMEs, or drugs containing new active ingredients. During this time, the FDA approved 674 medicines (65% of the total) containing active ingredients that were already available in marketed products. Of these, 558 drugs differed from the marketed product in dosage form, route of administration, or were combined with another active ingredient. These incrementally modified drugs, which can receive three years of market exclusivity under the

registration was for a chemical entity "not … previously approved". This means that the first registrant of a medicine in a CAFTA Party may obtain protection for a chemical entity that is quite old and well known, provided that it was not previously registered in that CAFTA Party. This may substantially impede the introduction of generic equivalents.

b) The intersection of data protection and patents

Yet perhaps the most problematic provision from a TRIPS flexibility standpoint is Article 15:10(3)(a) which provides that a third party (generic) producer, relying on "evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory", must be prevented from obtaining marketing approval such as will allow that third party to market the product "during the term of that patent, unless by consent or acquiescence of the patent owner". This provision effectively extends the term of data protection to the full term of a patent, rather than five years (as above), and is clearly not required by the TRIPS Agreement. Marketing exclusivity could be up to twenty years or more, depending on the remainder of the patent term.

In the first place, this rule burdens the medicines regulatory authority with establishing a process to assure that approval does not allow marketing during the patent term. This requires a procedure to determine the validity of patents. Medicines regulatory authorities typically do not have the capacity to make such determinations and so must either (a) take the patent holders' declarations of validity at face value and/or (b) make provision for allowing the patents to be challenged in court. A complex process that combines these features is used in the United States. It is very well known and documented by U.S. government authorities that this type of process is subject to "gaming" and abuse by patent holders. The United States has been at some great pains to bring these practices under a semblance of control.[12] Given that the U.S. legal and regulatory system has experienced great difficulties with (a) relying on the patent holders and (b) the delays attendant to court proceedings, it is a matter of serious doubt whether developing country medicines approval authorities will be able to effectively assess claims by patent holders to block the marketing of generics.

Most importantly, if approval cannot be granted for marketing during the term of the patent without the consent or acquiescence of the patent owner, this appears to effectively preclude the possibility of government use or compulsory licensing. Even if a license on the patent is granted to a generic producer/importer, the patent owner will be able to prevent marketing of the equivalent medicine (because it will not consent or acquiesce to marketing). The generic product cannot be put on the market on regulatory grounds, regardless of the grant of the license with respect to the patent.

Assume for the sake of argument that by virtue of Article 15.1(7) regarding "no derogation of rights", Article 15.9(5) relating to a regulatory review exception for patents was understood to not interfere with the right to grant compulsory licenses under Article 31, TRIPS Agreement, and the Decision on Implementation of Paragraph 6 of the Doha Declaration. What happens when the compulsory licensee must obtain marketing approval for the medicine? Does the licensee have a right to obtain approval for marketing during the term of the patent by virtue of Article 39.3 of the TRIPS Agreement which only obligates a Member to protect against "unfair commercial use" of regulatory data? Does Article 15.10(3) derogate from the rights of parties to the CAFTA to make effective use of compulsory licensing, such that a CAFTA party can invoke Article 15.1(7)? Or, does

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Hatch-Waxman Act, accounted for 54% of all approvals. The remaining 116 other drugs (11% of approvals) were identical to products already available on the U.S. market." NIHCM, at 3.

[12] *See* FTC report, note 9, *supra*.

Article 15.10(3) effectively bar use of Article 31 of the TRIPS Agreement and the Decision on Implementation of Paragraph 6?[13]

The net effect of Article 15.10 of the CAFTA is to create a web of restrictions and uncertainties that will have a powerful chilling effect on (a) the introduction of third party (generic) medicines that are not under patent in the CAFTA countries, and which are now subject to strict marketing approval conditions and (b) the effective use of compulsory licensing because of a mechanism for blocking regulatory approvals for marketing during the term of a patent.

c) Non-violation causes of action

In an earlier Occasional Paper the potential negative ramifications for developing countries of extending non-violation nullification or impairment causes of action to the TRIPS Agreement was discussed, including the potential implications for the field of public health.[14] Although the question whether such causes of action may be initiated at the WTO remains under active consideration in the TRIPS Council, the issue has been resolved in favor of allowing such actions under the intellectual property chapter of the CAFTA.[15]

d) Australia and Morocco

The draft United States – Australia Free Trade Agreement includes provisions regarding pharmaceutical products similar to those in the CAFTA and the subsequent draft United States – Morocco Free Trade Agreement. This Occasional Paper addresses concerns regarding access to medicines in developing countries, and will not analyze specific provisions of the U.S. - Australia FTA. The government of Australia was part of the small group of like-minded WTO Members working with the United States to limit the scope of the Doha Declaration in the negotiations leading up to its adoption, and it is not surprising that the Australian government would choose subsequently to surrender its flexibilities under the TRIPS Agreement in bilateral negotiations with the United States.

The draft United States – Morocco FTA adds several new restrictions on TRIPS flexibilities with respect to the pharmaceutical sector beyond those found in the CAFTA, including provision for the "evergreening" of marketing exclusivity.

(i) From non-derogation to rewriting Doha

Chapter 15 (IPRs) of the U.S – Morocco FTA does not include a provision similar to that of the CAFTA by which the parties agree that it does not derogate from their rights and obligations under the TRIPS Agreement. As legally problematic as such a non-derogation provision may be in the context of an express relinquishment of rights, it has at least some potential utility from a dispute settlement standpoint.[16] The United States and Morocco have attempted to ameliorate express derogation from rights under the TRIPS Agreement by means of a draft exchange of side letters, with operative language as follows:

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[13] And, as noted earlier, the subsequent U.S. – Australia and U.S. – Morocco FTAs do not include a comparable non-derogation provision.

[14] Frederick M. Abbott, *Non-Violation Nullification or Impairment Causes of Action under the TRIPS Agreement and the Cancun Ministerial Conference: A Warning and Reminder*, QUNO Occasional Paper 11, July 2003.

[15] Article 20.15(2) and Annex 20.2, CAFTA. *See for a detailed discussion* South Centre/CIEL Quarterly IP Update: First Quarter 2004, at 1-5.

[16] The author stresses here that it is counterproductive to become immersed in technical legal discussions of the role of non-derogation clauses in circumstances such as those presented here. The question is not whether and how lawyers can debate the fine points of interpretation under public international law, but what are the underlying medicines policies of the respective governments.

> "In connection with the signing on this date of the United States – Morocco Free Trade Agreement ("the Agreement"), I have the honor to confirm the following understanding shared by our two Governments, in relation to Chapter 15 (Intellectual Property Rights):
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> The implementation of the provisions of Chapter 15 of the Agreement does not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all. This will concern, in particular, cases such as HIV/AIDS, tuberculosis, malaria and other epidemics as well as circumstances of extreme urgency or national emergency.
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> "In the event the provisions of Chapter 15 violate an amendment that has entered into force with respect to the Parties of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) (the TRIPS Agreement), the Parties agree to immediate cooperative consultations in order to adapt Chapter 15 of the Agreement as appropriate in light of the amendment to the TRIPS Agreement."

It is not clear how this exchange of letters is expected to apply to the conflicts inherent in the text of Chapter 15 (IPRs). A host of interpretative issues are raised. Moreover, it incorporates limits not found in the Doha Declaration and which were specifically rejected during negotiations on the Decision on Implementation of Paragraph 6 (such as (i) an apparent restriction on the scope of diseases and (ii) a limitation to situations of emergency). Thus, while abjuring any intention to affect public health, the parties are rewriting the TRIPS Agreement, the Doha Declaration and the Decision on Implementation of Paragraph 6.

(ii) Overriding TRIPS exceptions

In Article 15.9(2) the Parties relinquish their rights under Article 27.3(b) of the TRIPS Agreement to exclude plants and animals from patentability. The Parties also "confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals". Thus, the Parties, *inter alia*, have relinquished flexibility to determine whether "second medical indications" for known compounds are patentable.

In Article 15.9(4), the Parties abandon their right under Article 6 of the TRIPS Agreement and express confirmation in Paragraph 5(d) of the Doha Declaration to determine their own policies with respect to exhaustion of rights, agreeing in respect to patents to prevent parallel importation.[17]

(iii) Data protection and market exclusivity revisited

Article 15.10: Measures Related to Certain Regulated Products of the U.S. – Morocco FTA is different than the comparable provision in the CAFTA.

Article 15.10(1) consolidates the general five-year marketing exclusivity rule of CAFTA as it applies to regulatory submissions of data concerning safety and efficacy, and evidence of prior approval within third territories, as well as incorporating the CAFTA definition of a "new product".[18] At this

[17] Per footnote 9 to this provision, the relinquishment may be limited to cases "where the patent owner has placed restrictions on import by contract or other means."

[18] U.S. – Morocco, Article 15:10:

> "1. If a Party requires, as a condition of approving the marketing of a new pharmaceutical and agricultural chemical product, *a)* the submission of safety and efficacy data, or *b)* evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third parties not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the

point, the U.S. – Morocco FTA has covered the ground covered by CAFTA Article 15.10(1). However, the U.S. – Morocco FTA adds a new clause directed to approvals based on "new clinical information" submitted for approval purposes in the Party or in another territory. It adds a three year marketing exclusivity for this approval.

> "15.10(2) If a Party requires the submission of a) new clinical information which is essential to the approval of a pharmaceutical product (other than information related to bioequivalency) or b) evidence of prior approval of the product in another territory that requires such new information , such Party shall not permit third parties not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. Protection is limited to new clinical information, the origination of which involves considerable effort.[12]
>
> Footnote 12: It is noted that, at present, neither Party permits third parties not having the consent of the person providing such new information to market a product on the basis of such new information submitted in another territory or evidence of prior approval of the product in another territory. In addition, when a product is subject to a system of marketing approval pursuant to paragraph 2 and is also subject to a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 2 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in Article 10.2."

Article 15.10(2) does not refer to a "new pharmaceutical product" (which has been defined as one not previously approved). It appears to expressly provide for the "evergreening" of marketing exclusivity by providing for additional three-year exclusivity periods that might, for example, cover previously unapproved uses of approved products based on "new clinical information". This is yet another potential obstacle to the introduction of generics. Originators of "new clinical information" will attempt to block approval of generics beyond the initial five-year marketing exclusivity period by asserting overlap with newly approved uses. Legal claims regarding such asserted overlaps are difficult to evaluate, create uncertainty, and will lead to more regulatory delay.

Article 15.4 of the U.S. - Morocco FTA includes a provision comparable to that of CAFTA in precluding approvals of medicines such as would permit marketing during the term of the patent. Again, this may prevent the effective use of compulsory licensing.

While the draft exchange of side letters may be intended to ameliorate some of the results outlined above, the letters raise a set of interpretation and implementation questions. How will the side letters be implemented in national law, and how will they be cognizable by courts? Why have the Parties elected to restrict the Doha Declaration and the Decision on Paragraph 6 in the terms of the letters? How will the letters affect the express limitation on parallel importation?

But to focus on the interpretative questions raised by the side letters may be to divert attention from the more fundamental issues. Why has Morocco agreed, and why has the United States asked

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> date of approval in the Party. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party.11
>
> Footnote 11: It is noted that, at present, neither Party permits third parties not having the consent of the person providing such information to market a product on the basis of such information submitted in another territory or evidence of prior approval of the product in another territory. In addition, when a product is subject to a system of marketing approval pursuant to paragraph 1 and is also subject to a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in Article 10.1."

It does not include the optional five-year limitation period for submitting an application following foreign approval.

Morocco to agree, to limit access to medicines in ways not required by the TRIPS Agreement? Do Morocco's citizens already have adequate access to medicines at affordable prices such that adding restrictions and raising prices will not have an adverse impact on public health? And, of course, this is not to single out Morocco as it is only the most recent link in this chain being drawn around and limiting access to generic medicines.

4. Contravening the Letter and Spirit of the Doha Declaration

In the Doha Declaration WTO Members committed themselves to implementing and interpreting the TRIPS Agreement to allow full use of its flexibilities, and to promote access to medicines for all. In the Doha Declaration there was an express acknowledgment of the right of Members to grant compulsory licenses on grounds determined by them.

The provisions relating to patents and regulatory approvals with respect to medicines in recently concluded FTAs such as the CAFTA and U.S. – Morocco FTA are intended to restrict the flexibilities inherent in the TRIPS Agreement, Doha Declaration and Decision on Implementation of Paragraph 6. They are designed to prevent registration and marketing approval of generic versions of medicines that are not under patent by establishing data exclusivity rules far beyond anything contemplated by Article 39.3 of the TRIPS Agreement. They appear designed to negate the effective use of compulsory licensing by blocking the marketing of third party medicines during the term of patents. This is contrary to the letter and spirit of Paragraph 4 of the Doha Declaration, "that the [TRIPS] 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."

The provisions of the CAFTA and U.S. – Morocco FTA relating to patents and pharmaceutical regulation are not accessible to laypersons. They are confusing to specialists in the field of intellectual property law and medicines regulation. Public international lawyers are needed to work out the complex hierarchical relationships among the conflicting provisions. From a practical standpoint, the overall effect of these provisions will be to establish potentially impenetrable obstacles to the supply of low priced medicines. *Individuals operating in the real world of medicines regulation, procurement and distribution cannot be expected to sort out these incredibly complicated rules.* This point cannot be stressed too strongly. This is not a happy occasion for lawyers to spend countless hours traveling to meetings to discuss the role of non-derogation clauses in international agreements, or the relationship between the WTO Agreement, GATT Article XXIV, TRIPS Article 4(d) and free trade agreements. Theses rules affect the lives and health of people – children, women and men.