

ANTI-DIVERSION MEASURES UNDER THE TRIPS PROTOCOL ON PUBLIC HEALTH – A COMMENTARY

The Agreement on Trade Related Aspects of Intellectual Property (“TRIPS”) is the legal instrument which sets common standards for World Trade Organization (“WTO”) members regarding, *inter alia*, the use of patents. Article 31 of TRIPS provides for Government use of a patent without the rights holder’s authorisation (*ie*, under a “compulsory licence”). It was recently amended to allow the export of patented pharmaceutical products under compulsory licence subject to certain safeguards. This article explains the rationale behind the amendment and examines the nuances of one such safeguard – that of anti-diversion measures. It suggests possible interpretations of the text in question and proposes approaches which WTO members may consider when implementing such measures.

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I. Background to Art 31bis of the TRIPS Agreement

1 Under Art 31(f) of the TRIPS Agreement, WTO members may use (or allow the use of) patents without authorisation of the rights’ holders. Such arrangement is commonly known as “compulsory licensing”. While Art 31(f) covers all kinds of patents, this provision is especially useful when a member needs to procure supplies of patented pharmaceutical products, especially in health crises.

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II. Limits of Art 31(f) – A legal and health problem

2 However, Art 31(f) provides that products made under compulsory licensing must be “predominantly for the supply of the domestic market of the Member”. In other words, a member can authorise the production of a required product, but the amount they can export is very limited as a “predominant” portion of what is produced must be consumed domestically. Therefore, members who are willing and able to export substantial quantities of patented pharmaceutical products are legally constrained from doing so by Art 31(f).¹

3 From the viewpoint of members who have insufficient or no manufacturing capacity for pharmaceutical products, they are unable to utilise Art 31(f) to help them access important patented drugs to resolve health problems because of the legal constraint described above.

III. The solution – Art 31*bis* of TRIPS

4 TRIPS was formally amended for the first time on 6 December 2005 to address this problem, and is currently pending acceptance by the WTO membership. As at December 2007, only 14 members or 9.3% of membership² have accepted this amendment. The Protocol amending Art 31 of TRIPS (the “Protocol” or “Art 31*bis*”) essentially “waives”, or exempts members from the above-mentioned limitation in Art 31(f) so as to allow the export of patented pharmaceutical products manufactured under compulsory licence, subject to certain conditions. These include, *inter alia*, notifications to the TRIPS Council of the import of such products, and measures to prevent wrongful re-export and import of such products (which is the subject of this paper). These measures are meant to ensure that Art 31*bis* is used strictly to deal with public health needs and not for commercial purposes.

5 Art 31*bis* thus delicately balances the existing rights of patent owners of pharmaceutical products under Art 31 of TRIPS, with the need to address the lack of access to such products – a key cause of public health concerns in developing countries.

1 This problem is recognised via para 6 of the Declaration of the TRIPS Agreement and Public Health, adopted at Doha on 14 November 2001.

2 Pursuant to para 4 of the Protocol, 67% of membership must accept the Protocol for it to take effect. See <http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> (accessed 14 January 2008) for the latest list of acceptances.

IV. Anti-diversion measures under Art 31bis

6 As the Protocol sets up a system to allow just the *export of patented pharmaceutical products* to meet the *public health needs of importing countries*, it was imperative that safeguards were incorporated to ensure that the Protocol would not be abused. One of these safeguards deals with ensuring that pharmaceutical products manufactured under the Protocol reach the member that actually requested for it.

7 The Chairman's Statement accompanying the Protocol of 6 December 2005³ sets out the spirit of this safeguard. It states that to fulfil the purpose of the amendment:⁴

[A]ll reasonable measures should be taken to prevent such diversion [of products supplied under the Protocol] in accordance with the relevant paragraphs of the amendment.

8 This article identifies, and comments on pertinent issues arising in the "relevant paragraphs" of the Protocol pertaining to anti-diversion measures.

9 There are two categories of anti-diversion measures, which may be summarised from the Protocol as follows:

(a) members *importing* pharmaceutical products ("PP") under the Protocol must put in place "*reasonable measures*", within their means and proportionate to their administrative capacities as well as the risk of trade diversion, to prevent their re-exportation⁵; and

(b) *all members* (regardless of whether they use the system under the TRIPS Protocol⁶) must put in place "*effective legal means*" to ensure that such PP made under compulsory licence elsewhere and not meant for their domestic markets do not get diverted into these markets⁷. [emphasis added]

10 The issues under each category will be examined separately.

3 The complete Chairman's Statement can be found at <http://www.wto.org/english/news_e/news05_e/trips_319_e.htm> (accessed 11 September 2007).

4 See the fourth paragraph of the Chairman's Statement. The relevant paragraphs would be paras 2–4 of Art 31bis, Annex to TRIPS.

5 See para 3 of Art 31bis, Annex to TRIPS.

6 This is the case because unlike para 3 of Art 31bis, Annex to TRIPS, there is no reference to the capacity of a member, either as importer or exporter.

7 See para 4 of Art 31bis, Annex to TRIPS.

V. For importing members – “Reasonable measures” to prevent re-export

A. What are “reasonable measures”? – A search for guidance

11 It is important for members to understand the exact nature of “reasonable” measures, in order to formulate and implement appropriate actions to prevent the re-export of PP.

12 However, there does not appear to be any specific guidance on the definition of “reasonable measures” or “reasonable” from the jurisprudence of WTO dispute settlement records.

13 In the writer’s opinion, references that are similar to “reasonable” in contract or tort in common law jurisdictions would not be instructive either, although some principles may be drawn from tort law.⁸

14 The word “reasonable” is certainly not defined in the Protocol. However, the 4th paragraph of the Chairman’s Statement, in outlining the importance of taking “reasonable” anti-diversion measures, alludes to “specific labelling or marking” (one of the conditions for exporting PP) as one such possible measure.⁹ A possible interpretation is that the Chairman was saying that special packaging/colouring/shaping of PP, being a possible anti-diversion measure, should not impact the price of PP.

15 In the next breath, the Statement continues with the topic of anti-diversion by referring to:¹⁰

8 For instance, ss 6 and 7 of the Unfair Contract Terms Act (UK) allow the exclusion or restriction of liability, subject to “reasonableness”, guidelines of which are contained in the Second Schedule. However, these guidelines speak of “customer/vendor relationships”. Tort cases speak of the “reasonable man” in determining the “standard of care”. This standard is “... objective. It does not take into account the particular idiosyncrasies or weaknesses of the defendant ... but ... there is a subjective element in that it is left to the individual judge to decide what is reasonable or what could have been foreseen”: Michael A Jones, *Textbook on Torts* (Oxford University Press, 8th Ed, 2005) at p 192.

9 The relevant portion reads:

In this regard, the provisions of para 2(b)(ii) of the Annex to the TRIPS Agreement in the amendment apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

10 These guidelines essentially refer to various means of differentiating PP from other similar products.

[P]rocedures to prevent diversion of products that are, for example, provided through donor programmes. 'Best practices' guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes.

16 Like "specific labelling or marking", such best practices guidelines are essentially measures taken by *exporters/producers of PP* to ensure there is no wrongful diversion of the same. It is worthy to note that the Chairman did not prescribe any specific action, practices or standards by importers of PP to prevent the re-export of PP.

B. "Reasonable measures" – A possible approach

17 Taking the above in totality, "reasonable measures" is arguably not a term of art and does not impose an ultimate, legal standard on members. While a court may consider the reasonableness of a certain measure objectively from the viewpoint of an average man, there is also an element of subjectivity involved as to what such measure entails, especially since it must be compared against what "means" and "administrative capacities" an individual member country has.

18 It seems that this provision was drafted with developing and least developed countries (*ie*, those who are likely to use the system under the Protocol to import PP) in mind. These are countries which may not have sophisticated legal or border control systems in place to monitor and enforce illicit re-export of PP.

19 It can thus be argued that while such measures may take the form of legislation, alternatives can also include the following:

- (a) administrative orders to health or border control authorities to detect/stop any attempted re-export of the PP (which would be easily recognisable by their distinct packaging/colouring/shaping) in question; or
- (b) self-help measures enabling the aggrieved parties (patent holders or the government importing the PP) to take action in a civil court for breach of contract against the actual importer/distributor in failing to prevent the re-export of the PP. Such measures shift much of the burden to prevent re-export to the actual importer/distributor, as they would be bound by a term(s) in the contract with the government (or party authorised by it) importing the PP prohibiting such re-export under any circumstances.

20 Ultimately, it appears that importing members are allowed to make their own judgment on what measures are "reasonable" in their context, and that a variety of options are available.

C. Different “reasonable measures” depending on whether the PP is patented or not?

21 The possible general approach in adopting “reasonable measures” described above needs to be considered against the fact that the PP being imported by a member may or may not be patented in therein.

22 Depending on the existing (importing) legislation of a member, or such legislation which it may enact to implement the Protocol, patented PP may have the added protection of legislation. For example, a member country’s Patents Act may contain a prohibition against re-exportation of PP, with the right for aggrieved parties to take the actual importer/distributor to task in court if the prohibition is breached. Further, some members may wish to enact criminal penalties against a breach of such prohibition.

23 However, given the territorial nature of patents, legislative protection would not be available to non-patented PP. Members would thus have to rely solely on administrative or self-help measures (as described above) to prevent the re-export of such PP.

24 It is thus quite clear that members thus need not enact special legislation to prevent the re-export of non-patented PP. Efforts on the legislative front should instead be targeted at introducing new laws or enhancing existing ones to prevent the re-export of patented PP.

VI. Suggested approach for a member seeking to formulate “reasonable measures” to prevent imported PP from being diverted

25 Having outlined an approach to take *vis-à-vis* “reasonable measures” and considering the same against whether a PP is patented or not, those seeking to formulate and implement such measures may consider the following:

(a) The measures implemented should be what it considers “reasonable” to prevent the re-export of PP in its context. Existing legislative measures and the member country’s contract laws and border control capabilities should be taken into account.

(b) The measures must be capable of being practically operationalised, given the administrative resources of the member country. In this regard, the size of the member and capabilities of health and border agencies must be considered. For example, a question to be asked is whether the member’s border agency has the existing manpower, legislative authority

and training to inspect PP and stop it from being illegally re-exported?

(c) The measures must be commensurate to the risk of re-exportation in the member country.

(d) Proposed measures (administrative or otherwise) should be considered for both patented and non-patented PP.

(e) Legislative provisions/recourse may be provided against re-export of PP patented in the member country.

26 Members should also remember the overarching principle – for the enforcement of IP (intellectual property) rights under TRIPS, they are not required to shift more enforcement resources to IP, nor ramp up enforcement measures.¹¹

VII. For all members – “Effective legal means” to prevent import and sale

27 Paragraph 4 of Art 31*bis* of the Annex to TRIPS obliges *all* members to prevent PP produced under compulsory licence in, say, member X for member Y, from being imported to/sold in their territories (apart from Y), using “means already required to be available under this Agreement”.¹²

A. Why and what are “effective legal means”?

28 There are two possibilities why anti-diversion measures to prevent the wrongful import of PP must be “effective”, as opposed to simply “reasonable” measures to prevent the re-export of PP from importing members:

(a) Wrongful import of PP is a more likely scenario than re-export, and thus a different standard was incorporated to prevent such a scenario.

(b) While it is the responsibility of all to prevent the wrongful import of PP, the standard incorporated focuses on the capabilities and resources of exporting members, who are likely to be developed countries.

29 The reasons for the different standards applied to the two categories of anti-diversion measures are not entirely apparent, but it nevertheless is important to understand the exact nature of “effective

11 This is reflected in Art 41(5) of TRIPS.

12 See para 4 of Art 31*bis* of the Annex to TRIPS.

legal measures”, in order to formulate and implement appropriate actions to prevent the wrongful import of PP.

30 This phrase appears to be of a higher legal standard than the phrase “reasonable measures”. The word “effective”, in its ordinary dictionary meaning, conveys to one that such means should be objectively enforceable, and *successfully prevent* the import and sale of PP in the relevant member.

31 It arguably implies that a member country must institute all necessary *laws* (as opposed to simply administrative measures) to give affected parties the right to prevent patented PP produced under compulsory licence elsewhere for one member from being diverted to another member. One must be able to *enforce* such laws. It is difficult to interpret the words “effective legal means” in any other way.

B. What are the “means already required to be available under this Agreement”?

32 This must surely refer to all *IP rights* under TRIPS, for “Agreement” is referred to in various key provisions of TRIPS.¹³ As TRIPS does not extend protection to non-patented products, and does not prescribe compulsory border measures for patent matters, it may be concluded that members are only obliged to utilise *TRIPS-compliant patent laws* to prevent the wrongful import/sale of PP patented in their territories.

C. When and what sort of “effective legal means” must be deployed?

33 Therefore, depending on whether or not a PP is patented in the member country concerned, “effective legal means” may not be required in every instance.

34 If a PP is patented in a member country, that member must ensure “effective” patent laws enabling affected parties to take action/pursue remedies against the unauthorised import and sale of such products.

35 However, if a PP is not patented in the member country, there is absolutely no obligation to prevent them from being wrongfully imported/diverted using IP or other laws (*eg*, customs or health laws).

13 For example, “Agreement” is used at the outset in Arts 1 and 2.

D. A possible lacuna?

36 Thus, there appears to be a *lacuna*, or gap, in the Protocol. If a PP is not patented in a member country, it could be wrongfully diverted into that member country without repercussions because it falls outside the scope of protection that is “required to be available under (the TRIPS) Agreement”. There would be no legal recourse for the rights holder, the exporting or importing member.

37 One thing is clear, there is no need to pass any law to prevent the wrongful import of PP that is not patented in a member, and who is not meant to receive such PP. However, given the spirit of the Protocol, members may need to weigh the risk of such wrongful diversion occurring and institute some *administrative* measures to prevent the same if necessary.

VIII. Suggested approach for all members formulating “effective legal means”

38 With a clearer understanding of the scope of “effective legal means”, those seeking to formulate and implement such means may consider the following:

(a) Practical and enforceable legislative measures (*eg*, under patents legislation) must be instituted to prevent the unauthorised import/sale of PP patented in the member country. Each member must determine objectively (taking into account all relevant circumstances) what sort of legislative measures are practically enforceable.

(b) In respect of PP not patented in the member country, the risk of import/sale of the same should be weighed. Administrative mechanisms to prevent such import/sale may be considered only if such risk is high, taking into account the resources/capacities of such member country.

39 The principle in Art 41(5) of TRIPS (mentioned above) should also be followed here.

IX. Conclusion

40 In implementing each of the two anti-diversion measures prescribed under the Protocol, members should:

(a) Consider whether a PP is patented or not. If a PP is not patented in a member country, the PP has no protection in that

member, and it is not obliged to consider “effective legal means” to prevent import/sale of the same in its territory.

(b) Bear in mind that the Protocol does not appear to oblige members to bear additional administrative burdens, beef up enforcement resources or make major legislative changes to implement such measures.

41 The current level of accession to Art 31*bis* is low. It is hoped that Art 31*bis* would come into force as soon as possible, in order that the system under the Protocol ensuring proper access of medicines to those who need it most would be made permanent. As it stands, the low level of accession to the Protocol has led the TRIPS Council meeting in October 2007 to extend the time for acceptance of the Protocol by another two years to December 2009.¹⁴ Meanwhile, members of the WTO who require much needed pharmaceutical products for which they have no or insufficient manufacturing capacity will have to utilise the *temporary* waiver of Art 31(f) created by a decision of the WTO General Council on 30 August 2003.¹⁵

42 Some quarters believe the low level of accession is due to perceived complicated procedures which will need to be initiated in order to use Art 31*bis*. It is hoped that this commentary will shed light on how the Protocol is to be implemented, give guidance to members who are considering acceding to the Protocol, and help them speed up their national process of accession.

14 As reported in IP Watch, 23 October 2007. See <<http://www.ip-watch.org/weblog/index.php?p=798>> (accessed 29 October 2007).

15 For more details of the actual text of this decision, please refer to <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> (accessed 16 November 2007).