Amendment to TRIPs Agreement: consensus or dissension?

by

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1. Introduction

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement)\(^1\) is one of the core trade agreements established by the World Trade Organization (WTO). There has never been an amendment to the TRIPs Agreement since its inception on 1 January 1995. On 6 December 2005 the Members of the WTO agreed to adopt a proposed amendment to Article 31 of the TRIPs Agreement (TRIPs Amendment Decision).\(^2\) The TRIPs Amendment Decision includes a protocol amending the TRIPs Agreement, an annex to the protocol amending the TRIPs Agreement, an annex to the TRIPs Agreement and an appendix to the annex to the TRIPs Agreement.\(^3\) The TRIPs Amendment Decision provides a framework for taking measures aimed at protecting public health. This paper seeks to analyse the impact of the TRIPs Amendment Decision on access to patented medicines. The focus will be on Members with insufficient or no manufacturing capacities in the pharmaceutical sector in southern and eastern Africa.

2. Background

TRIPs Agreement calls upon the Members to enact legislation that would protect patents within their jurisdiction.\(^4\) Article 31 of TRIPs Agreement provides a list of provisions that shall be respected whenever the law of a Member allows use of the subject matter of a patent without the authorisation of the right holder. This is commonly referred to as compulsory licensing.

Although Article 31 applies to patents generally, its application to pharmaceutical products has been a cause for divisive debate and concern. Members with insufficient or no manufacturing capacity in the pharmaceutical sector have championed a more intense debate over Article 31(f). Article 31(f) provides that, normally, any compulsory licences granted in a supplying Member ‘shall be authorised predominantly for the supply of the domestic market of the Member’ granting the compulsory licence. This sub-Article was seen as reducing the ability of

\(^{1}\) 33 I.L.M. 81 (1994).
\(^{2}\) Decision on ‘Amendment of the TRIPs Agreement’, WTO document WT/L/641.
\(^{3}\) Ibid.
\(^{4}\) Article 41(1) of TRIPs Agreement states that ‘Members shall ensure that enforcement procedures as specified in this part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered under this agreement, including expeditious remedies to prevent infringements and remedies which constitute a further deterrent to further infringements....’ (33 I.L.M. 81 (1994)).
Members that had limited or no manufacturing capacity in the pharmaceutical sector to import pharmaceutical products from Members that had that capacity through compulsory licences.

This difficulty posed by Article 31(f) was recognised in paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health (Doha Declaration on TRIPs and Public Health) on 14 November 2001, where Ministers expressly:

recognize[d] 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.

Paragraph 6 of the Doha Declaration on TRIPs and Public Health included the instruction from the Ministerial Conference to the Council for TRIPs (TRIPs Council) to ‘find an expeditious solution to this problem and to report to the General Council before the end of 2002’. The TRIPs Council arrived at, and adopted, a decision on the Implementation of Paragraph 6 of the Doha Declaration on TRIPs and Public Health on 30 August 2003 (the ‘August Decision’).

Paragraph 2 of the August Decision waived, subject to certain terms, the requirements of Article 31(f). The waiver was with respect to the grant by a Member of a compulsory licence ‘to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)’.

Paragraph 11 of the August Decision called upon the TRIPs Council to initiate work on the preparation of an amendment to the TRIPs Agreement to replace the provisions of the August Decision. The TRIPs Council submitted its proposal for a decision on an amendment to the TRIPs Agreement to the General Council on 6 December 2005, which was accepted by the General Council that same day as the TRIPs Amendment Decision.

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5 Doha Declaration on the TRIPs Agreement and Public Health, WTO Document WT/MIN(01) DEC/2.
6 Ibid.
7 Decision on ‘Implementation of Paragraph 6 of the DOHA Declaration on the TRIPs Agreement and Public Health’, WTO document WT/L/540.
8 For a detailed discussion on the August Decision, see Avafia, 2005.
10 Decision on ‘Amendment of the TRIPs Agreement,’ WTO document WT/L/641.
3. **The substantive aspects of the TRIPs Amendment Decision**

The substantive aspects of the TRIPs Amendment Decision are contained in Article 31bis contained in the Annex to the Protocol amending the TRIPs Agreement.11 Article 31bis reads:

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of 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) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the

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11 Ibid.
regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPs Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

For purposes of this paper, paragraph 1 of Article 31bis shall be referred to as the ‘first tier waiver’ and paragraph 3 of Article 31bis shall be referred to as the ‘second tier waiver’, described in further detail below.

3.1 First tier waiver: paragraph 1 of Article 31bis

The first tier waiver waives, in certain circumstances, the Article 31(f) requirement that production under compulsory licence should be predominantly for the domestic market of the Member granting the compulsory licence. The terms for the grant of compulsory licences to the extent necessary to produce and export pharmaceutical products to eligible importing Members will be discussed in the next sections.

3.1.1. Duties of the eligible importing Member

An ‘eligible importing Member’ is defined in paragraph 1(b) of the Annex to the TRIPs Agreement as:

any least-developed country Member, and any other Member that has made a notification to the Council for TRIPs of its intention to use the system set out in Article 31bis and this Annex (‘system’) as an importer ....
Paragraph 2(a) of the Annex to the TRIPs Agreement sets out some of the contents of the notice to the Council. The notice must specify the names and quantities of the product(s) needed. Secondly, it must confirm a grant or intention to grant a compulsory licence where the product is patented in the territory of the eligible importing Member. Lastly, all non-LDC Members must also confirm that they have insufficient or no manufacturing capacity for the product(s) in question.

LDC Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. Other eligible importing Members may establish insufficient or no manufacturing capacities by showing that they have no manufacturing capacity in the pharmaceutical sector; or that their capacity, to the exclusion of the patent owner, is currently insufficient for the purposes of meeting its needs.

Further, importing Members are required to take reasonable measures proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the product(s) imported under the system. A developing country Member or LDC Member may request technical and financial cooperation from a developed country Member to facilitate implementation of this provision.

3.1.2. Duties of the exporting Member

An ‘exporting Member’ is a Member ‘using the system to produce pharmaceutical products for, and export them to, an eligible importing Member’. According to paragraphs 2(b) and (c) of the Annex to the TRIPs Agreement an exporting Member is required to issue a compulsory licence with the following conditions:

a) The allowable quantity must be commensurate with the needs of the eligible importing Member(s);

b) The entire production shall be exported to the eligible importing Member(s);

c) The product(s) must bear distinctive features to clearly identify them as being produced under the system;

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12 See the Appendix to the Annex to the TRIPs Agreement, WTO document WT/L/641.
13 Ibid.
14 See Paragraph 3 of the Annex to the TRIPs Agreement, WTO document WT/L/641.
15 Ibid.
16 Paragraph 1(c) of the Annex to the TRIPs Agreement, WTO document WT/L/641.
d) Prior to the shipment, the licensee has to post on a website the quantities being supplied to each destination and their distinguishing features. Licensees may use their own website or, with the assistance of the WTO secretariat, the page on the WTO website dedicated to the system; and
e) The exporting Member has to notify the Council the grant of the licence, the conditions attached to it, duration, name and address of the licensee among other things.

3.2 Second tier waiver: Paragraph 3 of Article 31bis

The second tier waiver is meant to harness economies of scale for purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.17 It applies where a developing or LDC Member is a party to a regional trade agreement18 (RTA) with at least half of its current membership being countries presently on the United Nations list of LDCs.19 Such a Member can export pharmaceutical products produced or imported under a compulsory licence in that Member to the markets of those other developing or LDC parties to the RTA that share the health problem in question.20

There are four main RTAs in southern and eastern Africa: Southern Africa Customs Union (SACU), Southern Africa Development Community (SADC), East African Community (EAC) and Common Market for Eastern and Southern Africa (COMESA).21 A look at the United Nations’ List of LDCs shows the following results

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17 Paragraph 3 of Article 31bis states 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: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of 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) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.’

18 According to paragraph 3 of Article 31bis, the RTA must be within the meaning of Article XXIV of the GATT 1994 (that is both Customs Union and Free Trade Areas) and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903).

19 For more details of United Nations’ List of LDCs, see United Nations, 2006.

20 See par. 3 of Article 31bis.

21 SACU is made up of Botswana, Lesotho, Namibia, South Africa and Swaziland; SADC countries comprise Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe; the EAC has three Members, that is, Kenya, Uganda and Tanzania; and COMESA
when applied to these RTAs. Members of SACU and EAC do not qualify for the second tier waiver since at least half of their members are not on the United Nations List of LDCs. SADC Member states barely qualify – with exactly half of the 14 Members being on the United Nations’ List of LDCs. As such, any slight change in membership can remove its preferential status under the second tier waiver. Lastly, COMESA has comfortably more than half of its Members on the United Nations’ List of LDCs.

Distinctive features of the second tier waiver are:

a) It allows re-exportation of pharmaceutical products imported under the system. By way of example, South Africa, as a Member of SADC, can issue a compulsory licence for the production and exportation of medicines to another SADC Member, for example, Lesotho. In turn Lesotho can re-export some of the medicines to yet another SADC Member, Swaziland. Notably, the allowance on re-exportation tends to suggest that a country can import over and above its domestic requirements.

b) Its utility is limited to developing and LDC Members within a qualifying RTA. In the example (above), if South Africa becomes a developed Member country, the developing and LDC Members of SADC will not be able to benefit from South Africa’s manufacturing capacity for generic medicines. The second tier waiver requires that both the exporting and importing Members have either developing or LDC Member status. This is in contrast to the first tier waiver where virtually any Member, subject to capacity requirements and unilateral undertakings, can import and export to any other Member. However, the first and second tier waivers are mutually inclusive in that a beneficiary of one is not barred from utilising the other.

Suffice that the issue of multiple memberships to several RTAs and the application of the second tier waiver can only be analysed on a case by case basis. For instance, Swaziland qualifies for the second tier waiver as a Member of SADC as well as COMESA. In the example given above in (a), Swaziland

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22 See note 19 above.
may further re-export some of the medicines to Burundi by virtue of their common membership to COMESA although Burundi is not a Member of SADC.

c) There is no specific reference to notification requirements to the TRIPs Council as in the first tier waiver. Understandably, the second tier waiver is meant to offer flexibilities over and above the first tier waiver. Suffice that the explanatory footnote to paragraph 2(a) of the annex to the TRIPs Agreement envisages joint notifications under the second tier as well.

4. Advantages and disadvantages of the TRIPs Amendment Decision

The major advantage of the August Decision and the TRIPs Amendment Decision is that now an exporting Member can grant a compulsory licence that is predominantly for the supply of an export market. This flexibility ensures access to pharmaceutical products in Members that have limited or no manufacturing capacity in the pharmaceutical sector. For those Members, this device would seem vital in the quest for access to medicines for present and future health calamities.

That said, there has never been a compulsory licence issued under the August Decision. Nonetheless, it has been argued that the success of the August Decision should not be exclusively judged by the frequency of use since the fact that the system is in place could have positive secondary effects. Certainly, the August Decision and the TRIPs Amendment Decision, even without being used, create a threat of compulsory licensing that may be a useful tool in the bargaining process with patent holders. As noted from the trend that ensued after the August Decision, there was a considerable drop in the prices of both brand name and generic pharmaceutical products. While the thrust of the waiver is the granting of compulsory licences, this secondary effect arguably has been an advantage for many developing and LDC Members.

A major disadvantage is that the grounds in domestic laws for the granting of compulsory licenses are not exhaustively laid out in the TRIPs Agreement and TRIPs Amendment Decision. The TRIPs Agreement and TRIPs Amendment Decision set

23 See Paragraph 1 of Article 31bis as read with Paragraph 2 of the Annex to the TRIPs Agreement.
24 It states that ‘Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of the eligible importing Members using the system that are parties to them, with the agreement of those parties.’
25 For a detailed discussion on the reasons for non-use of the August Decision, see Avafia, 2005.
26 Palmedo, 2005.
27 See Avafia, 2005.
out minimum standards. Compulsory licensing has to comply with the TRIPs Agreement, TRIPs Amendment Decision and the relevant domestic laws of the importing or exporting Member. Members can lawfully implement domestic laws that are more onerous than those of the TRIPs Agreement and TRIPs Amendment Decision provided that they meet their minimum standards.

A Member can unilaterally limit its own use of the TRIPs Amendment Decision as an importing Member. Notably, some Members have stated that they will not use the system as importing Members, and others have limited the use to no more than situations of national emergency or other circumstances of extreme urgency. Paradoxically, few Members, as of June 2006, had changed their domestic laws so as to grant compulsory licences for export markets.

Ultimately, the use of the system depends on the passing of domestic laws that enable the grant of compulsory licences in the Member states that have manufacturing capacity. This aspect of the system makes Members in eastern and southern Africa, where very few Members have manufacturing capacity, vulnerable. As such, the conduct of WTO Members with sufficient manufacturing capacities in the pharmaceutical sector is crucial to the effective use of the TRIPs Amendment Decision.

5. Acceptance of the Amendment Decision

The Amendment Decision is open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference. Governments’ positive appraisal of the TRIPs Amendment Decision has been unequivocal. They have argued that: first, it will help to further reduce the price of pharmaceutical products; second, it will help developing countries devastated by HIV/Aids and other public health crises; and third, it is an important step in making drugs available in poor countries.

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28 See Articles 31 and 31bis of the TRIPs Agreement and TRIPs Amendment Decision respectively.
29 These are Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States. See paragraph 1(b) of the Annex to the TRIPs Agreement, WTO document WT/L/641.
30 The Members are the European Communities, Canada, China, India, Norway and Korea. See Anderson and Wager, 2006.
31 See the Protocol Amending the TRIPs Agreement.
33 Ibid.
In contrast, non-governmental organisations have been sceptical towards the TRIPs Amendment Decision. It is argued that: first, it does not allow procurement of medicines through international tendering; second, it is replacing a system that has failed to prove it can increase access to medicines; and lastly, it has been rendered complicated and ineffective by conditions attached to its use (the process is long and resource-intensive).\(^{34}\)

Unfortunately, the Amendment Decision may have the effect of depreciating the debate on TRIPs and Public Health by bringing it into a false comfort zone. It must be noted that waiver of the August Decision was a temporary measure whereas the TRIPs Amendment Decision will bring into effect a permanent system.\(^{35}\)

6. Conclusion

In conclusion, there has been no significant change to the waiver of the August Decision in respect to the first tier waiver. Suffice that the amendment will be permanent whereas the waiver was temporary. There is need for WTO Members to enact laws that take into account the needs of both exporting and importing Members under the system. Further, the ‘second tier waiver’ will enhance flexibility in the use of the TRIPs Agreement for developing or least-developed country WTO Members that are parties to qualifying RTAs. As such, RTAs must work towards synchronisation of their regulatory framework.

\(^{34}\) Ibid.

\(^{35}\) Anderson and Wager, 2006. See note 30 above.
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