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Paragraph 3 recognizes the importance of intellectual property protection ‘for the development of new medicines’. The Doha Declaration recognizes that the high prices of medicines as a result of patent protection are part of the severe problems facing developing and least-developed countries and is a ‘concern’ that needs to be dealt with. The consensus achieved on the impact of patent protection on drug prices may be considered one of the major political achievements of the developing countries in the Declaration.<sup>180</sup>

### **3.2.3 Public health measures**

The fourth paragraph states in clear terms that “the Agreement does not and should not prevent Members from taking measures to protect public health”. The wording of the first part of paragraph 4 that the TRIPS Agreement “does not and should not prevent Members’ rights to take measures ‘to protect public health” is arguably the most controversial mainly because of the opposing interest between developed and developing Members and therefore reflects a delicate compromise between Members.<sup>181</sup>

### **3.2.4 Flexibility in the TRIPS Agreement**

The last part of paragraph 4 echoes one of the major concerns raised by developing countries in the process leading to the Doha Ministerial, mainly the opposition when implementing the flexibilities. The importance of this paragraph is found in the fact that the Declaration was adopted for this very purpose-to clarify the flexibilities. The confirmation that the TRIPS Agreement has left room for maneuvering at the national level has crucial political and legal implication, in that pressures to impede the use of available flexibilities run counter to the spirit and

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<sup>180</sup> Correa (fn 2) 7.

<sup>181</sup> Correa (fn 2) 9.

purpose of the Agreement.<sup>182</sup> In legal terms, such confirmation means that in matters before panels issues of public health shall be taken into consideration.<sup>183</sup>

### **3.2.5 Interpretation**

The chapeau of paragraph 5 balances the interests of IP owners, on the one hand, and users, on the other, in that while it recognizes the importance of patents in promoting innovation, the effect of patents on prices is also acknowledged. This paragraph reinforces the availability of the flexibilities to Members pursuing pro-health goals. The Declaration goes beyond merely confirming the relevance of article 7 and 8 but it also provides an understanding about the purpose of the TRIPS Agreement in relation to public health issues, which should guide any future decisions by panels and Appellate Body dealing with such issues.<sup>184</sup>

### **3.2.6 Compulsory licences**

Developing countries had singled out compulsory licensing as the most crucial tool when addressing public policy issues particularly in ensuring the availability of alternative sources for the supply of medicines at lower prices as a result of increased competition.<sup>185</sup> Compulsory licensing is important as it increases competition as a result of which prices of drugs are reduced.<sup>186</sup> Subparagraph 5 (b) although it does not add anything substantive to provisions relating to compulsory licensing it is in this paragraph that the term “compulsory licence” is explicitly mentioned. It must be noted that although article 31 refers to some of the possible grounds for issuing compulsory licences, this list is not exclusive.<sup>187</sup>

### **3.2.7 Emergency**

Sub-paragraph 5(c) affirms Members’ right to determine “what constitutes national emergency or other circumstances of extreme urgency”. Such determination in

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<sup>182</sup> Correa (fn 2) 13.

<sup>183</sup> Correa (fn 2) 14.

<sup>184</sup> Correa (fn 2) 14.

<sup>185</sup> Correa (fn 2) 15.

<sup>186</sup> Sekalala, “Beyond Doha: Seeking access to essential medicines for HIV/ AIDS through the World Trade Organization” (2008) 9.

<sup>187</sup> Discussed at length at 36.

making use of the Agreement's flexibilities or the adoption of other measures permitted under article 8(1) of the Agreement.<sup>188</sup>

Paragraph 5 (c ) clarifies that “public health crises” can represent “a national emergency or other circumstances of extreme urgency”, thereby allowing for the granting of compulsory licences when provided under national law and pursuant to TRIPS article 31(b), without the obligation for prior negotiation with the patent holder.<sup>189</sup> The mention of “HIV/AIDS, tuberculosis, malaria and other epidemics is indicative of the fact that an “emergency” may be not only a short-term problem, but a long lasting situation, as is the case with epidemics given as examples.<sup>190</sup> Lastly it clarifies that if a Member disputes the qualification of a particular state of affairs by another Member as being a “national emergency or other circumstances of extreme urgency”, the burden of proving the non-existence of such a state of affairs rests with the complaining Member.<sup>191</sup>

### **3.2.8 Parallel importation**

Paragraph 5(c) also reiterates the provisions of article 6 regarding the doctrine of exhaustion and provides that Members have the flexibility of establishing any regime of their choice. The issue of parallel importation was one of the issues that the pharmaceutical industry had challenged, and as such developing countries were very interested in ensuring that it was also re-affirmed.<sup>192</sup>

### **3.2.9 Members lacking sufficient manufacturing capacity**

Paragraph 6 of the Declaration recognizes the problems that Members with insufficient manufacturing capacity may encounter when effectively implementing the issuance of compulsory licences. To remedy this problem Members instructed

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<sup>188</sup> Correa(fn 2) 16.

<sup>189</sup> Correa (fn 2) 16.

<sup>190</sup> Correa (fn 2) 17.

<sup>191</sup> Correa (fn 2 ) 17.

<sup>192</sup> Correa (fn 2) 17.

It was one of the grounds upon which the pharmaceutical industry challenged South Africa's Medicines Act discussed in the previous chapter.

the Council for TRIPS to “find an expeditious solution to this problem and to report to the General Council before the end of 2002”.<sup>193</sup>

Article 31(f) requires that manufacture of a product in terms of a compulsory licence must be predominantly for the supply of the licensee’s domestic market,<sup>194</sup> unless the licence was issued to rectify anti-competitive practices.<sup>195</sup> The primary problem that paragraph 6 seeks to address is that of lack of capacity to manufacture drugs prevalent among developing countries and LDCs. The limitation in sub-article 31(f) effectively prevented the granting of compulsory licences to supply the foreign markets.

### **3.3 Legal Status of the Declaration**

It is important to determine the legal status of declarations in the WTO set-up so as to understand what effect it will have on Members. The Vienna Convention on the Law of Treaties instructs that a treaty should be interpreted in good faith making use of the ordinary meaning of its terms in the context and light of the treaty’s object and purpose.<sup>196</sup>

There is no consensus regarding the status of the Declaration, with some academics suggesting that it does not have legal value as it does not constitute an authoritative interpretation in terms of article IX(2) of the Marrakesh Agreement.<sup>197</sup> Many are of the view that the plain meaning of “We agree” used in the Declaration should be an indication that it is a binding agreement.<sup>198</sup>

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<sup>193</sup> This deadline was missed as the solution was only adopted in 2003-the 30 August 2003 Decision.

<sup>194</sup> Article 31 stipulates that “where the law of a member allows for use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”.

<sup>195</sup> Article 31(k) provides, inter alia, that “Members are not obliged to apply the conditions set forth in sub-paragraph (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive”.

<sup>196</sup> Article 31(1) of the Vienna Convention on the Law of Treaties of 1969 (herein after the Vienna Convention).

<sup>197</sup>Hestermeyer (53) 279.

### **3.3.1 The Declaration as a subsequent agreement under article 31(3) (a) of the Vienna Convention**

The Vienna Convention requires tribunals to take into account any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions when interpreting a treaty.<sup>199</sup> The Ministerial Conference which adopted the Declaration has the authority to take on decisions on all matters under any of the Multilateral Agreements.<sup>200</sup>

The fact that the legitimate institutions of the WTO were involved in the Declaration's drafting and final adoption gives it the character of a subsequent agreement.<sup>201</sup> It has been suggested that subsequent agreements are also a reflection of the parties' intent and can be employed in interpreting the actual terms of the treaty.<sup>202</sup>

### **3.3.2 The Declaration as evidence of subsequent practice establishing the understanding regarding the interpretation of the TRIPS Agreement**

The general rule of interpretation in the Vienna Convention requires that "subsequent practice" be taken into account together with the context when interpreting the provisions of any treaty.<sup>203</sup>

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Art IX (2) of the Marrakesh Agreement establishing the World Trade Organization provides that "the Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements."

<sup>198</sup> Hestermeyer (fn 53) 280.

<sup>199</sup> Article 31(3) (a) stipulates that 'there 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'.

<sup>200</sup> Article IV (1) of the Marrakesh Agreement establishing the World Trade Organization stipulates that "there shall be a Ministerial Conference composed of the representatives of all the Members...which shall have the authority to take decisions on all matters under any of the Multilateral Trade Agreements".

<sup>201</sup> Gathii (fn 95) 301.

<sup>202</sup> Gathii (fn 95) 300.

<sup>203</sup> Article 31 (3) (b) provides that "there shall be taken into account together with the context any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation.

Consensus or common understanding between Members of the WTO, manifested by their conduct, can, therefore, provide important guidelines on the interpretation and implementation of the words of the TRIPS Agreement.<sup>204</sup>

In *Japan Taxes on Alcoholic Beverages* wherein the Appellate Body, although reversing the panel's finding that adopted GATT and WTO panel reports constitute subsequent practice under article 31(3) (b), found however that such reports create "legitimate expectation" which should be taken into account where they are relevant to a dispute.<sup>205</sup> In yet another dispute in *United States- Import Prohibition of Certain Shrimp and Shrimp Products* the Appellate Body made use of the 1996 Singapore Ministerial Declaration for purposes of interpretation.<sup>206</sup> It has been suggested that this signifies the readiness to refer to Declarations.<sup>207</sup>

### **3.4 The 30 August Decision**

Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find "an expeditious solution" to the problem confronting WTO Members without pharmaceutical manufacturing capabilities.<sup>208</sup> The Council for TRIPS was also required to "report to the General Council before the end of 2002", which deadline was missed. Almost two years after the adoption of the Doha Declaration, on 30 August 2003, the WTO's General Council adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.<sup>209</sup>

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<sup>204</sup> Gathii, (fn 95) 310.

Other decisions and policies adopted by Members may amount to subsequent practice under the TRIPS Agreement. For instance, the US withdrew its complaints against the governments of Brazil and South Africa (discussed in Chapter 2).

<sup>205</sup> WT/DS8/AB/R, it should be noted however that WTO panel or appellate body reports are only binding upon the parties with respect to resolving the dispute between the parties concerned.

<sup>206</sup> WT/DS58/AB/R.

<sup>207</sup> Gervais (36) 398.

<sup>208</sup> Paragraph 6 stipulates thus "we recognize that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

<sup>209</sup> WT/L/540 Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003)

It is important to note that the aim of the Decision was not to address the issue whether or not countries can issue compulsory licences, as compulsory licences have been a feature of the international patent practically since its inception.<sup>210</sup> Rather, the issue addressed by the Decision is the extent to which drugs could be made available to countries lacking manufacturing capacity.<sup>211</sup>

The Decision not only waived the article 31(f) requirement but article 31(h) as well which ordinarily requires that adequate remuneration be paid to the patentee.<sup>212</sup> Aside from these waivers of these all the other pre-conditions in article 31 continue to apply to licenses granted under the Decision.

#### **3.4.1 The article 31(f) hurdle**

The Decision seeks to alleviate the problems posed by article 31(f) which confront countries devoid of pharmaceutical manufacturing capacity. Article 31(f) stipulates that licenses should be granted “predominantly for the supply of the domestic market” of the Member issuing the licenses. Thus under this provision a country with manufacturing capacity in the pharmaceutical sector can grant a compulsory licence for its local production and supply all its internal needs but can only sanction the export of a “non predominant” part of the production.<sup>213</sup>

As such some countries cannot effectively grant licences when these countries themselves lack production capacity in the pharmaceutical sector, and also where the drug is patented in potential exporting countries and exports from these

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<sup>210</sup> Reichman and Hasenzahi, “Non-voluntary licensing of patented inventions: Historical perspectives, legal framework under TRIPS and an overview of the practice in Canada and the USA” 10 (2003) *UNCTAD-ICTSD Issue Paper No. 5*.

<sup>211</sup> Abbott(fn 51) 326.

<sup>212</sup> Article 31 (h) further stipulates that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”

<sup>213</sup> However article 31(k) stipulates that the provisions in article 31(f) shall not apply where the compulsory license is authorized to remedy anti competitive practices.

countries under compulsory licenses.<sup>214</sup> Thus article 31(f) not only restricts would be importers but potential exporters as well.

Article 31(f) by restricting the availability of export drugs manufactured under compulsory licence, limits countries without manufacturing capabilities under licence in the availability of generics. The requirement that production must be predominantly for domestic consumption restrains the flexibility of Members to authorize for export under compulsory licence and thereby take advantage of economies of scale.<sup>215</sup>

Article 31(f) creates a hurdle in the demand and supply of generic drugs in that if a developing Member lacks manufacturing capacity for a particular drug and there is no Member to supply it by export under licence, there may be no affordable drug available.<sup>216</sup>

### **3.5 The new compulsory licence**

The 30 August Decision creates a new type of a compulsory licence whereby pharmaceutical products can be manufactured entirely for export. It is meant to alleviate the problems of those countries without manufacturing capacity in the pharmaceutical sector.

#### **3.5.1 Product scope**

Paragraph defines what a “pharmaceutical products” is, to which the Decision shall apply.<sup>217</sup> The reference to the Doha Declaration means that the scope is not limited to particular products.

#### **3.5.2 Eligibility of Members**

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<sup>214</sup> Abbott (fn 51) 320.

<sup>215</sup> Abbott (fn 55) 17.

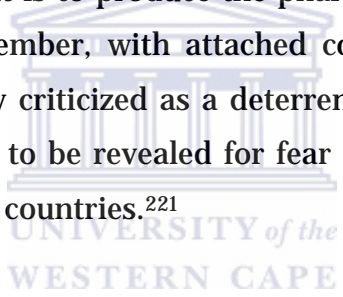
<sup>216</sup> Abbott (fn 55) 18.

<sup>217</sup> Paragraph 1 defines a pharmaceutical product as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health as recognized in paragraph 1 of the Declaration.”

An “eligible importing Member” is defined to mean “any least developed Member and any other Member that has made a sufficient notification to the Council for TRIPS to use the system as an importer” either in a whole a limited manner.<sup>218</sup> The Decision stipulates that it is understood among Members that this notification does not need to be approved by a WTO body in order to use the system. An exporting is defined as a Member using the system to produce pharmaceutical products for export to an eligible importing Member. An Annex to the Decision provides for the assessment as to whether an eligible importing Member has sufficient manufacturing capacity.<sup>219</sup>

### **3.5.3 Article 31(f) waiver**

Paragraph 2(a) waives the requirement in article 31(f) on an exporting Member if the compulsory granted by it is to produce the pharmaceutical product for export to an eligible importing Member, with attached conditions.<sup>220</sup> This notification procedure has been severely criticized as a deterrent on potential importers who may not want their identity to be revealed for fear of being subjected to political pressure from industrialized countries.<sup>221</sup>



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<sup>218</sup> Examples of a limited manner are: in cases of national emergency or other circumstances of emergency or in cases of public non-commercial use.

Some Members indicated that they will not use the system as importers while others stated that if they use the system it will only be in situations of national emergency or other circumstances of extreme emergency.

<sup>219</sup> The Annex stipulates that least-developed country Members are deemed to have insufficient manufacturing capacity in the pharmaceutical sector. For other eligible Members insufficient or no manufacturing capacity may be established in two ways. Firstly the Member has established that it has no manufacturing capacity in the pharmaceutical sector. Secondly where the Member has some manufacturing capacity in this sector it examines this capacity and finds that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient to meet its needs. However the Annex further provides that once such capacity has since become sufficient to satisfy the Member needs, the system shall no longer apply. Therefore Members are at liberty in determining whether or not they have manufacturing capacity.

<sup>220</sup> The conditions are that the eligible importing Member has made notification to the TRIPS Council, which notification specifies the names and expected quantities of the products needed, confirms that the eligible Member in question (other than a least developed country) has established its insufficient or no manufacturing capacities as laid out in the Annex, and confirms that where a product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with article 31 of the TRIPS Agreement as well as the Decision.

<sup>221</sup>Hoen, “The Global politics of pharmaceutical monopoly power: drug patents, access, innovation and the application of the WTO Declaration on TRIPS AND Public Health” (2009) 37. Available online at <http://www.msfacecess.org/main/access-patents/the-global-politics-of-pharmaceutical-monopoly-power-by-ellen-t-hoen/> (accessed on 10/03/09).

Paragraph 2(b) lays out the contents of the compulsory licence to be issued by the exporting Member. The licence must stipulate that only the amount of the product requested by the eligible importing Member shall be manufactured and that the entirety of this production shall be exported to the importing Member. Products destined for export shall be clearly identified as being for that purpose.<sup>222</sup> This information regarding the transaction must be published on a publicly accessible website.<sup>223</sup>

#### **3.5.4 Article 31 (h) waiver**

Paragraph 3 waives the article 31(h) requiring payment of adequate remuneration to the patent holder. In terms of this paragraph the remuneration is paid in the exporting Member, while the relevant “economic value” of the product for determining the amount to be paid is the value of the use to the importing country.<sup>224</sup> This waiver applies to both situations where an importing Member had to grant a compulsory licence owing to the existence of a patent and where there is no patent.<sup>225</sup>

Potential importers are also required, by paragraph 4, to take reasonable measures proportional to their means and the level of risk to prevent diversion of the imported products.<sup>226</sup> Paragraph requires Members to put into place effective legal mechanisms (already provided in the TRIPS Agreement) to curb the importation into their territories products manufactured under the system in order to avoid trade diversion.

#### **3.5.5 Regional grouping flexibility**

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<sup>222</sup> Such identification can be through special packaging, colouring and shaping provided that such distinction is feasible and does not have a significant price effect.

<sup>223</sup> The WTO in its website has dedicated a page specifically for notifications and pertinent concerning the usage of the Decision

<sup>224</sup> Hestermeyer (fn 53) 269.

<sup>225</sup> Hestermeyer (fn 53) 269.

<sup>226</sup> Paragraph 3 also provides that in the event that “an eligible importing Member is a developing or least developed Member and experiences in implementing this provision , developed Members shall render, upon request and mutually agreed terms and conditions, technical and financial to facilitate implementation”.

Paragraph 6 contains a waiver of article 31(f) for LDCs and developing countries in regional trade configurations, allowing re-exportation of the products without additional export licensing, with a view to harnessing economies of scale for the purposes enhancing purchasing and facilitating the local production of pharmaceutical products.<sup>227</sup> This waiver is said to have been particularly for African regional groupings to make easy the use of compulsory licences.<sup>228</sup>

### **3.5.6 Technology transfer and annual review**

Paragraph 7 recognizes the need for technology transfer and capacity building for countries lacking or with insufficient capacity and to that end encourages exporting Members to use the Decision such that this objective is realised.

Paragraph 8 requires that the TRIPS Council undertakes an annual review of the Decision and present an annual report to the General Council to ensure the Decisions effective operation pursuant to article IX (4) of the Marrakesh Agreement Establishing the WTO.<sup>229</sup>

### **3.6 The legal status of the Decision**

A waiver does not involve any change in the substantive treaty obligations; it is only a temporary suspension of the treaty's provisions.<sup>230</sup> A WTO waiver means

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<sup>227</sup> Paragraph 6 provides that “where a developing or least developed country is a member to a regional group where at least half of the group’s membership comprises of those countries listed as LDCs by the United Nations, the article 31(f) requirement shall be waived to the extent necessary to enable a pharmaceutical produced or imported under a compulsory licence in that Member to be exported to the market of those other developing countries and LDCs parties to the regional configuration that share the health problem in question”.

<sup>228</sup> Hestermeyer (fn 53 ) 268.

<sup>229</sup> Article IX(4) requires that “a decision by the Ministerial Conference granting a waiver shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver and the date on which the waiver shall terminate. Any waiver granted for a period of more than one year shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates. In each review the Ministerial Conference shall examine whether the exceptional circumstances justifying the waiver still exist and whether the terms and conditions attached to the waiver have been met. The Ministerial Conference, on the basis of the annual review, may extend, modify or terminate the waiver”.

<sup>230</sup> Correa, “Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health” (2004) 5 *World Health Organisation*

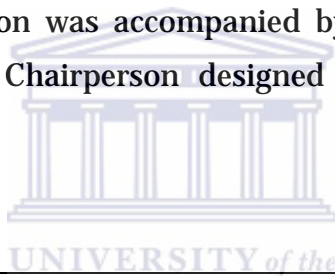
that a Member shall not challenge any measures taken by another Member provided that the measures are in conformity with the provisions of the waiver.<sup>231</sup>

The use of the other flexibilities envisaged by the TRIPS Agreement is also not affected by the Decision.<sup>232</sup> The Decision as well as the waivers on article 31(f) and (h) shall terminate for each Member on the date upon which the Agreement's amendment takes effect upon that Member. To that end the TRIPS Council had been tasked to initiate work on the preparation for such an amendment.<sup>233</sup>

Article 57 of the Vienna Convention also deals with the issue of waivers by providing that a waiver may be suspended in conformity with the treaty's provisions or by consent of all parties.<sup>234</sup>

### 3.7 The Chairperson's Statement

The adoption of the Decision was accompanied by a complementary statement from the General Council Chairperson designed to allay fears held by other



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*Essential Drugs and Medicines Policy* Available online at <http://apps.who.int/medicinedocs/en/d/Js6159e/2.html#Js6159e.2> (accessed on 11/04/09).

<sup>231</sup> Paragraph 10 of the Decision provides that “Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of article XXIII of the GATT 1994. Subparagraphs 1(b) and (c) require that “If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of either the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement or the existence of any such situation, the contracting party may with a view to the satisfactory adjustment of the matter, make written representations or proposals to the other contracting party or parties which it considers to be concerned.” This means that Members may not make use of the “nullification and impairment” provisions laid of in article XXIII of the GATT in order to challenge actions taken in conformity with the 30 August Decision.

<sup>232</sup> Paragraph 9 of the Decision stipulates thus “this Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of article 31(f) of the TRIPS Agreement.”

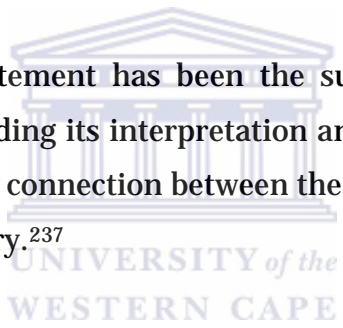
<sup>233</sup> Paragraph 11 provides that the “Decision , including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member”

<sup>234</sup> Article 57 stipulates that “the operation of a treaty in regard to all the parties or to a particular party may be suspended in conformity with the provisions of the treaty or at any time by the consent of all the parties after consultation with the other contracting states.”

Members as to the possible abuse of the Decision and the undermining patent protection.<sup>235</sup>

In the Statement the Chairperson made it clear that although it was limited to the Paragraph 6 Decision, it represented key shared understandings among Members regarding the Decision to be taken and the manner of interpreting and implementing it. The Statement also encouraged Members to implement it in good faith to protect public health and not to be used to achieve industrial or commercial gains. Attached to the Statement was a compilation of “best practices” guidelines containing illustrations on procedures that could possibly be used to prevent diversion of products manufactured and exported under the Decision and to that end the Chairperson encouraged Members to draw upon these guidelines.

The legal status of the Statement has been the subject of debate with various questions being asked regarding its interpretation and status.<sup>236</sup> To that end it has been suggested that the only connection between the Statement and the Decision is the Decision’s drafting history.<sup>237</sup>



### **3.8 Criticism levelled against the Decision**

Members welcomed the Decision with enthusiasm. Brazil, India and South Africa conceded that it would contribute in making medications more accessible to Members lacking manufacturing capacity while the representative of the Africa Group, Morocco applauding it as (a historic moment).<sup>238</sup> Even the WTO’s leadership applauded it as evidence that “the organization can handle humanitarian as well as trade concerns”.<sup>239</sup>

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<sup>235</sup> The General Council Chairperson’s Statement. Available online at [http://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm) (accessed on 11.04/09).

<sup>236</sup> Gervais (fn 36) 400.

<sup>237</sup> Hestermeyer (fn 53) 285.

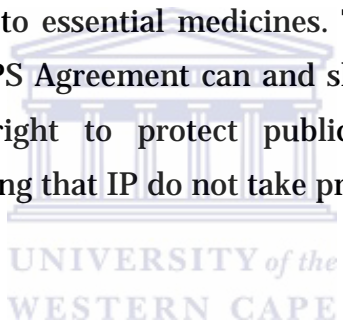
<sup>238</sup> Hestermeyer (fn 53) 271.

<sup>239</sup> Decision removes final patent obstacle to drug imports. Available online at [http://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm) (accessed 11/04/09)

In some quarters the argument was that system would not be workable owing to its intricate legal and institutional requirements would render it ineffective, while others argued that time would put it to the test and urged all stakeholders to make concerted efforts to make it work.<sup>240</sup>

The Decision has been termed a “procedural morass” in that it is elaborate, involves the procedural complexity of double licensing under article 31 with the result that it shrinks the market, increases the cost and is therefore neither a simple nor a sufficient solution.<sup>241</sup> It has also been referred to as “a textbook example of a WTO compromise with little practical use”.<sup>242</sup>

With regard to the Declaration, it re-affirmed the flexibility that Members have in addressing issues of access to essential medicines. The fundamental tenet of the Declaration is that the TRIPS Agreement can and should be interpreted in a way supportive of Members’ right to protect public health. Therefore it is a commendable step in ensuring that IP do not take precedence over Members’ right to protect public health.



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<sup>240</sup> Hestermeyer (fn 53) 271.

<sup>241</sup> Baker, “Arthritic flexibilities for accessing medicines: Analysis of WTO action regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health” (2004) *Indian International and Comparative Law Review* 15.

<sup>242</sup> Hoen (fn 221) 38.

## CHAPTER 4

### HAS DOHA DELIVERED ON ITS MANDATE OF ACCESS TO ESSENTIAL MEDICINES TO THE DEVELOPING WORLD?

The preceding chapter has discussed both the Doha Declaration as well as the 30 August Decision. The defects sighted in the Decision mainly had to do with the complex administrative procedure involved in making use of the Decision. The present chapter seeks to address the main question on whether the Doha Declaration has in fact translated into access to essential medicines for all, with emphasis on both developing countries and LDCs.

This chapter focuses on the amendments to Canada's Patents Act which incorporated the 30 August Decision. Canada is the first WTO Member to enact the provisions of the article 31(f) waiver into its domestic legislation in order to allow "eligible Members" to import generic versions of patented drugs.<sup>243</sup> The amendment has also only been used once by Rwanda. The aim of discussing Canada's Patents Act is to prove whether or not the 30 August Decision is indeed defective.

Although the Decision has only been used once, it has been argued in some quarters that the accomplishments of the Decision should not be solely judged based on the incidence of its use because the mere fact that the mechanism is in place has affirmative secondary effects.<sup>244</sup> Indeed it has been argued that its existence, which

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<sup>243</sup> Other countries which have incorporated the Decision include China- State Intellectual Property Office Order N. 37 (effective as of 1 January 2006) Norway-Policy rules on issuing compulsory licences pursuant to WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, under section 57(1) of the United Kingdom Act on Patents of 1995.

India-Section 49 of the Patents Amendment Bill No. 92 of 2003.

European Union Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

<sup>244</sup> Palmedo, "How reporters covered the 6 December 2005 WTO deal that amended the TRIPS Agreement on the topic of export of generic medicines manufactured under a compulsory licence". Available online at <http://www.cptech.org/ip/wto/p6/wtoreporting-table.html> (accessed on 14/03/09).

poses the threat of compulsory licences, gives developing countries some leverage when negotiating for licences.<sup>245</sup>

Case studies of other countries such as Brazil, India, Malawi and Thailand are also considered and a determination is made as whether these flexibilities actually improved access to essential medicines where used. The reactions that the use of these flexibilities drew from the pharmaceutical industry and other WTO Members are considered as well in a bid to establish whether the pre-Doha attitudes are still at play.

#### **4.1 Canada-the first country to implement the Decision**

In September 2003 Canada became the first country to publicly declare its intention to implement and incorporate the 30 August Decision into its domestic law. Bill C-9 is commonly referred to as the Jean Chrétien Pledge to Africa (JCPA)<sup>246</sup>. The JCPA authorizes the granting of “for export only” compulsory licences to Canadian generic pharmaceutical companies to supply countries lacking pharmaceutical manufacturing capacity with lower cost versions of pharmaceutical products patented in Canada.

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##### **4.1.2 The initial draft**

On 6 November 2003, after intense lobbying the federal government of Canada introduced a draft bill (Bill C-9) in the House of Commons, just a day prior to the closing of the parliamentary session.<sup>247</sup>The Bill received Royal Assent in May 2004 and exactly one year later, in May 2005 the amendments to the Canada’s Patent Act came into force.<sup>248</sup>

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<sup>245</sup> Mmeta, “Amendment to TRIPS Agreement: consensus or dissension?” (2006) *Tralac Trade brief* (No. 5 )8.

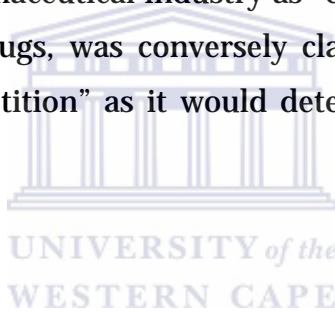
<sup>246</sup> The Jean Chrétien Pledge to Africa named after Canada’s Liberal Prime Minister during whose tenure the bill was first introduced in November 2003 (in full An Act to amend the Patent Act and the Food and Drugs Act). Bill C-9 which was introduced in the House of Commons on 12 February to amend Canada’s Patent Act and the Food and Drugs Act. The JCPA has come to be commonly known by the Canadian government as the Canadian Access to Medicines Regime (CAMR).

<sup>247</sup> Elliot, “Pledges and pitfalls: Canada’s legislation on compulsory licensing of pharmaceuticals for export” (2006) 1 *International Journal of Intellectual Property Management* 96.

<sup>248</sup> Patent Act, R.S.C, 1985, c. P-4.

Although the objectives of Bill C-9 gained widespread exhortation from the public, non-governmental organizations and the pharmaceutical industry, a number of civil society bodies had highlighted flaws within the proposed amendment that could ultimately weaken these objectives.<sup>249</sup> These concerns were “the right of first refusal”, the duration of the compulsory licence, the exclusion of NGOs from directly procuring drugs directly from the generic manufacturers, the limited list of drugs eligible for manufacture and export, the eligibility criteria for would-be importers as well as the regulatory review that would be brought about by amendments to the Food and Drugs Act.<sup>250</sup>

The “right to first refusal” was criticized as making Bill C-9 a TRIPS -plus law in that actually amounted to a “third right of refusal”.<sup>251</sup> This provision which had been described by the pharmaceutical industry as “equal opportunity to supply” to the country needing the drugs, was conversely classified by NGOs as an “early opportunity to block competition” as it would deter generic manufacturers from using it.<sup>252</sup>



#### **4.1.3 The final Act**

Facing pressure from activists the government of Canada removed the “right to first refusal” thereby avoiding setting a negative “TRIPS-plus” precedent for the

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<sup>249</sup> These concerns were highlighted in a letter dated 26 March 2004 addressed to the Standing Committee on Industry, Science and Technology. Available at <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1046> (accessed on 13/04/09).

<sup>250</sup> See fn 249.

<sup>251</sup> Canadian HIV/AIDS Legal Network, “Global access to medicines: will Canada meet the challenge?” A submission to the Standing Committee on Industry, Science and Technology regarding Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act, Canadian HIV/AIDS Legal Network, (26 February 2004) 14. Available online at <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=693> (accessed on 10/04/09).

<sup>252</sup> Canadian HIV/AIDS Legal Network, “Global access to medicines: will Canada meet the challenge?”, A supplementary submission to the Standing Committee on Industry, Science and Technology regarding Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act, Canadian HIV/AIDS Legal Network, (8 March 2004). Available online at <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=695> (accessed on 10/04/09).

Thus not only undermining countries’ ability to effectively make use of compulsory licensing, but also contradicted the letter and spirit of the Doha Declaration.

implementation of the August 30 Decision.<sup>253</sup> NGOs welcomed this decision and called upon the Government and Committee to resolve other outstanding issues before finally passing the bill into law.<sup>254</sup>

Soon after the coming into force of the Amendment, Stephen Lewis, then UN Special Envoy on HIV-AIDS in Africa applauded its enactment and urged Canada's government to take full advantage of it.<sup>255</sup> Conversely it was disparaged by the originator pharmaceutical industry.<sup>256</sup>

The Food and Drugs Act was also amended to apply to the products manufactured for export under CAMR's provisions. Section 37 provides that its requirements do not apply to any drug or device that is not manufactured for consumption in Canada, provided the package is marked as being for "export" and a certificate has been issued stating that the package together with the contents thereof is not in breach of any known requirement of the law of the importing country.<sup>257</sup>

Regardless of this long-standing practice, the Food and Drugs Act was amended to ensure that its regulations become applicable to pharmaceuticals that are produced for export pursuant to the WTO's 30 August Decision. On 1 June 2005 the

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<sup>253</sup> Elliot (fn 247) 44.

<sup>254</sup> Canadian HIV/AIDS Legal Network, MSF Canada, Canadian Council for International Cooperation, and Oxfam Canada, Media Release: Latest amendments to Canada Patent Act a good start, but still need work" Available on line at [www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag) (accessed on 10/04/09).

<sup>255</sup> Abbott, "Introductory note to World Trade Organization Canada first notice to manufacture generic drug for export" (2007) 46 *International Legal Materials* 1127. Available online at <http://www.frederickabbott.com/uploads/Abbott- ILM Note as Published.pdf> (accessed on 12/04/09).

<sup>256</sup> Abbott (fn 255) 1127.

Harvey Bale, the Director-General of the International Federation of Pharmaceutical Manufacturers Association (IFPMA) was quoted as publicly saying that the initiative by the Canadian government would be "a negative black eye" for Canada that would in all likelihood affect the investment climate.

<sup>257</sup> Section 37(1) of the Food and Drugs Act (R.S.,1985, C, F-27) provides that the Act "does not apply to any packaged food, drug, cosmetic or device not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "export" or "exportation" and the certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or about to be consigned. Section 37 (2) which is the amendment stipulates that despite the provisions in subsection (1) the Act shall apply "in respect of a drug or device to be manufactured for the purpose of being exported in accordance with the General Council Decision, as though it were drug or device to be manufactured and sold for consumption in Canada, unless the regulations provide otherwise."

accompanying regulations entered into force upon publication in the Canada Gazette.<sup>258</sup>

In light of the fact that the 30 August Decision itself is burdensome it is only to be expected that the Patent Act provisions should be unwieldy.<sup>259</sup> The Act contains 19 sections and above 100 clauses and sub-clauses. To understand this piece of legislation is quite a task as it requires legal training and support.<sup>260</sup>

The amendment to Canada's Patents Act which came into force in May 2005 incorporated the provisions of Bill c-9 by introducing new sections, namely sections 21.01 to 21.17 after the existing section 21. This would allow the granting of compulsory licences to Canadian pharmaceutical companies allowing them to manufacture within Canada, specified, patented pharmaceutical products for export to certain developing and least developed countries.

The amendment contains four clauses, the first clause adds a new heading "Use of patents for international humanitarian purposes to address public health problems", under which the additions to sections 21.01 -21.17 fall. Section 21.01 succinctly identifies the primary purpose of the new sections as being "to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least- developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".

Section 21.02 deals with definition of terms including the terms "patented product" and "pharmaceutical product", these with resonate the definitions in the 30 August Decision. Section 21.03 establishes four Schedules to the Act and provides for their amendment by Cabinet. Schedule 1 lists the patented products that could be used

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<sup>258</sup> These regulations were in three sets namely : Use of patented products for international humanitarian purposes regulations, S.O.R./2005- 143 ; Food and Drug Regulations (1402 drugs for developing countries), S.O.R./ 2005- 142; Medical devices regulations (developing countries), S.O.R./ 2005- 142

<sup>259</sup> The deficiencies of the 30 August Decision have been highlighted in Chapter 3.

<sup>260</sup> "Neither expeditious, nor a solution: the WTO august 30<sup>th</sup> decision is unworkable"- An illustration through Canada's Jean Chrétien pledge to Africa (prepared for the XVI International AIDS Conference, Toronto, August 2006 Available on-line at [www.accessmed-msf.org/documents/wtoaugustreport.pdf](http://www.accessmed-msf.org/documents/wtoaugustreport.pdf) (accessed on 13/04.08).

to address public health problems under the Act. The list currently includes products on the WHO's list of essential medicines that are currently under patent in Canada.<sup>261</sup>

Section 21.04 provides for the prescribed form for compulsory licence applications to the Commissioner of Patents.<sup>262</sup> Section 21.05 authorizes the Commissioner to grant a compulsory licence provided all conditions have been satisfied. Section 21.06 deals with the format of the compulsory licence. Disclosure of prescribed information on a website is dealt with in section 21.07. Section 21.08 specifies that the licensee must pay a royalty to the patentee in the amount of two percent of the value of products exported under the compulsory licence. The duration of the compulsory licence shall be two years as stipulated in section 21.09.

Sections 21.10-11 provide that use shall be non-exclusive and non-transferable; the patentee can continue to use the patent for commercial purposes during the term of the compulsory licence. The non-transferability shall be subject to article 31(e) of the TRIPS Agreement.<sup>263</sup> Section 21.12 deals with renewals<sup>264</sup>, while sections 21.13-14 provides for the licence's termination.<sup>265</sup>

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<sup>261</sup> Schedules 2 to 4 list countries that would be eligible importers under the Act. Schedule 2 being LDCs regardless of the WTO membership status. Schedule 3 lists those WTO Members, mainly developing countries that have not notified the TRIPS Council that they will not use the scheme as importers. The 4<sup>th</sup> Schedule lists those WTO Members that have indicated they will use the system to import patented medicines only in public health emergency. Also in the 4<sup>th</sup> Schedule are developing countries that are not Members of the WTO but are on the Organisation of Economic Co-Operation and Development (OECD)'s list of eligible for official development assistance. Section 21.03(2) precludes the addition to Schedule 3 of any WTO Member country if that country has notified the TRIPS Council that it will import only in situations of emergency. Available on line at [http://www.camr-rcam.gc.ca/countr-pays/elig-admis/countr-pays\\_e.html](http://www.camr-rcam.gc.ca/countr-pays/elig-admis/countr-pays_e.html) accessed on 15/04/09

<sup>262</sup> Section 21.04 stipulates that such applications must be brought to the attention of the patentee. The generics maker and the patentee must then negotiate a voluntary licence and if at the expiry of 30 days no agreement has been reached regarding the possibility of a voluntary licence the Commissioner is obliged to grant a compulsory licence to the generics maker.

<sup>263</sup> Article 31(e) provides that the use of patents under compulsory licensing shall be non-assignable "except with that part of the enterprise or goodwill which enjoys such use".

<sup>264</sup> This section requires that a licensee's application for renewal to the Commissioner of Patents must certify that the quantity intended to have been exported was not exported before the licence's expiration

<sup>265</sup> Section 21.12 stipulates that termination shall occur at the earliest of either the expiration of the two years, or on the day in which the Commissioner of Patents notifies the licensee that Minister of Health no longer believes that the product satisfies the requirements of the Food and Drugs Act and

Section 21.15 provides that the Commissioner of Patents must notify each patentee in writing of the granting of a compulsory license. The Advisory Committee which shall advise on products to be listed in Schedule 1 is provided for in section 21.16. Ministerial review is dealt with in the last section 21.17 which stipulates that the Minister of Industry shall be required to review section 21.01-16 and their applications three years after coming into force and report to the Parliament.

#### **4.4 Critique of Canada's Patent Act**

The provisions of the Patent Act deserve a close analysis in order to determine how it has implemented the provisions of the WTO's Decision of 30 August. Despite its commendable humanitarian goals it has been criticized for its lack of expediency in ensuring that medicines get to the intended beneficiaries, namely developing countries and LDCs.<sup>266</sup>

These deficiencies that have been cited by academics and those concerned with issues of access to medicines is be discussed below.

##### **4.4.1 Limited list of products**

Schedule 1 has also been a bone of contention as it specifies which pharmaceutical products would qualify for manufacture and exportation under the drug access scheme, and it has been suggested that this a double standard on developing countries lacking pharmaceutical manufacturing capacity.<sup>267</sup> Currently the Schedule contains 56 pharmaceutical products that can be manufactured by a

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its regulations, or on the day on which the last product provided under the compulsory licence is exported, or sixty days after the product or importing country is removed from the Schedule.

<sup>266</sup> Cohen-Kohler, 'Canada's implementation of the Paragraph 6 Decision, is it sustainable public policy?' (2007) 3 *Globalization and Health* 1. Available online at

<http://www.globalizationandhealth.com/content/pdf/1744-8603-3-12.pdf> (accessed on 21/04/09)

<sup>267</sup>(fn 252) 12.

generic maker for export.<sup>268</sup> Section 21.03(1) (a) requires that an order of the federal Cabinet be made before a product can be added to the list.<sup>269</sup>

It has been suggested that the existence of this list is in contradiction with the provisions of the Doha Declaration in paragraph 1 which recognizes “the gravity of the public health problems” prevalent in developing countries and LDCs particularly those which are a consequence of “HIV/AIDS, tuberculosis, malaria and other epidemics”.<sup>270</sup> It is clear from this paragraph that the diseases mentioned do not by any means constitute an exhaustive list, because the diseases covered by the Doha Declaration are not limited to the ones mentioned; rather those mentioned were only used primarily for illustrative purposes. It would also follow naturally, therefore, that there should be no restriction whatsoever on the medicines to be exported under Canada’s amended Patent Act.

It also impinges on developing countries’ sovereignty as independent decision-makers in their domestic affairs to determine for themselves the pharmaceutical products that they will need in the public health context.<sup>271</sup> It is the law of the importing country which informs the decision whether a particular generic drug can be imported into that country and Canada, if it is to fully implement the waiver, should not be instructing a potential importing country on what medicines should be or not be imported.<sup>272</sup>

It is neither practical nor desirable to predict the pharmaceutical medicines needs of Members make efforts to protect their public health by promoting access to

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<sup>268</sup> List of medicines in Schedule 1 available online at <http://laws.justice.gc.ca/en/showdoc/cs/P-4/sc:1/en#anchors:1> accessed on 15/04/09

<sup>269</sup> Section 21.03 (1)(a)(i) requires “the Governor in Council may, by order, on the recommendation of the Minister or the Minister of Health, amend Schedule 1 by adding the name of any patented product that may be used to address public health afflicting developing countries. Subsection (ii) further provides that the Governor may also remove “an entry listed in Schedule 1” acting on the recommendations made by the Minister or the Minister of Health.

<sup>270</sup> (fn 252) 12.

<sup>271</sup> (fn 251) 18.

<sup>272</sup> (fn 251) 18.

medicines for all.<sup>273</sup> This is further reiterated by the Doha Declaration in Paragraph 5 (b).<sup>274</sup> The WHO, in a statement released soon after the WTO's waiver, affirmed that "the agreement covers all medicines" and that "countries will need to review the full range of medicines required".<sup>275</sup>

The pharmaceutical industry has also been instrumental in ensuring that a limited list was drawn by exerting pressure upon government to ensure that some crucial medicines did not make it into the list.<sup>276</sup>

A question which begs an answer is what criteria was used in compiling the list in Schedule 1. Canada's government had modeled the list in Schedule 1 using the WHO'S Model List<sup>277</sup> which activists pointed out that the WHO's Model List was simply a "model", intended for use by countries in coming up with their own national lists of essential medicines taking into account their needs and should not have been followed religiously.<sup>278</sup>

Developing countries have been quoted as saying that some of the medicines on the list are not relevant to their needs, rather they would prefer to see included in the list second and third line ARV therapy before CAMR can be said to be addressing their needs.<sup>279</sup>

One might say that the Canadian government is concerned about the possibility of the system being abused by importing countries. However, imposing this list in

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<sup>273</sup> "Canada and the Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health", Public health address at seminar hosted by the North-South Institute, 21 October 2003 available online at [www.aidslaw.ca](http://www.aidslaw.ca)

<sup>274</sup> This provision unequivocally states that "each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".

<sup>275</sup> Statement of the World Health Organization on WTO access to medicines Decision ( 1 September 2003).

<sup>276</sup> Elliot (fn 247) 101.

In this case the pharmaceutical company Bayer that holds the Canadian patent on the moxifloxacin drug reportedly made telephone calls to Canada's opposition New Democratic Party (NDP) objecting to this drug's inclusion in the Bill C-9. Subsequent to pressure from the industry motions to add specific drugs to the list were also withdrawn, products which all parties had been in consensus to add to the list.

<sup>277</sup> See fn 3.

<sup>278</sup> See fn 251, 19.

<sup>279</sup> Cohen-Kohler (fn 266) 3.

anticipation of abuse of the system is premature in the absence of any hint that the exploitation has occurred.<sup>280</sup>

Since the enactment of the amendment the Schedule 1 list, there have been two pharmaceutical products added to the list at the urging of generic makers and NGOs. In September 2005 a request was made by generic manufacturer Apotex to add a fixed-dose combination of AIDS drug.<sup>281</sup> A second addition was also made a year later in September 2006, for the anti-influenza drug oseltamivir which cures avian flu.<sup>282</sup>

The period of time taken to add a single drug and bureaucratic process involved reflects poorly on having a list in the first place. As such the system would have functioned better if developing countries themselves were allowed to decide which drugs are needed at a particular point in time to deal with public health problems.

#### **4.4.2 Exclusion of NGOs from obtaining generic pharmaceuticals for patients through the system**

The significance of the efforts by UN agencies and NGOs in getting medicines to patients cannot be overemphasized.<sup>283</sup> These organizations are active in providing humanitarian relief in the delivery of health care services in developing countries have to procure medication to carry out their tasks. Their exclusion from procuring drugs under Canada's legislation is therefore unsettling as it would directly have negative repercussions for patients in developing countries.

In terms of section 21.04 (2) (f) of the Act, in order to get a licence to provide medicines, a Canadian generic producer must file an application embodying particular details with "the government" of that country or "agent of that government" . A measure of liberty allowing these NGOs to contract directly with a

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<sup>280</sup> (fn 251) 20.

<sup>281</sup> Order Amending Schedule 1 of the Patent Act, SOR/2005-276 August 31, 2005, C Gaz 2005, 11, 2145

<sup>282</sup> Order Amending Schedule 1 of the Patent Act, SOR/2006-204, September 21 2006, C Gaz, 2006, 11, 1308

<sup>283</sup> (fn 251) 23.

Canadian generic manufacturer to acquire the drugs needed, without having to first enter into some kind of “agency” agreement envisaged by section 21.04(2) (f) with a government would be ideal in order for NGOs to continue fulfilling their mandate of delivering health to patients who cannot afford the drugs but are in need them.<sup>284</sup>

#### **4.4.3 Regulatory review of pharmaceutical products manufactured for the purposes of exportation**

As already mentioned previously the Patent Act together with the Food and Drugs Act were amended in order to implement the WTO’s waiver of article 31(f). Canadian does not generally require that drugs destined exclusively for export to meet the same regulatory standards as required for domestic consumption drugs. However section 37(2) of the Food and Drugs was amended to the effect that drugs for export have to comply with these standards.<sup>285</sup>

This is an entirely commendable step as it seeks to ensure that drugs destined for exportation are of the same quality, safety and efficacy standards as drugs for domestic consumption.<sup>286</sup> However given the bureaucracy involved in adding a product onto the list, the process might be time consuming. An expeditious process is therefore required particularly in light of the immense need of drugs in the developing world. Applying the same regulatory standards to both domestic export-destined drugs will inevitably disrupt the supply of much-needed medication to developing countries. A level of flexibility will therefore be required if the mechanism is to be “an expeditious” solution to get the generic medicines to the intended beneficiaries.

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<sup>284</sup> (fn 251) 23.

<sup>285</sup>The Patent Act now stipulates that in order for the Commissioner of Patents to grant a compulsory licence for the manufacture of a generic there must be, inter alia, a notification from the Minister of Health the generic drug in question meets the demands of the Food and Drugs Act.

<sup>286</sup>Elliot, “Delivering on the pledge: Global access to medicines, WTO rules, and reforming Canada’s law on compulsory licensing for export” *McGill International Journal of Sustainable Development Law and Policy* 50.

#### **4.4.4 Eligible countries that qualify to use the system as importers**

The Patent Act specifies that all LDCs are eligible to participate as importers regardless of their WTO Membership status and these countries are listed in Schedule 2. However Schedule 3 which lists developing countries gives different treatment as Membership to the WTO is a prerequisite for them to procure drugs from Canadian generic manufacturers. This restriction does not reflect well the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health, which in paragraph 4 makes reference to “promote access to medicines for all”. Differentiating between WTO and non-WTO Members is evidence of double standard as the Patent Act further requires that a non WTO Member must, inter alia, “declare a national emergency or situation of extreme urgency” which has been deemed unnecessary by the Doha Declaration.<sup>287</sup>

#### **4.4.5 The two year term of the compulsory licence**

The two years set as the maximum duration of the compulsory licence is disconcerting, particularly when taken together with the requirement that the licence will only be for a specified quantity as set out in the agreement between a generic producer and the purchaser for the eligible importing country. At the expiry of the stipulated two years, the generic maker will have to embark the whole process anew in the event that the manufacturer seeks to produce more of the generics. This process will again be for one product, one licence and for two years. Continued production of a generic under the compulsory licence after the two years is in contravention of the Patent Act’s provisions and could initiate expensive litigation. It has been suggested that a longer term for the compulsory licences under the system can be motivation for generic makers to enter into supply contracts with importing countries.<sup>288</sup>

It is submitted that the two year term might have negative consequences as some health problems such as HIV/ AIDS require long term measures as they cannot be

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<sup>287</sup> Elliot (fn 286) 52.

<sup>288</sup> Elliot (fn 286) 54.

possibly dealt within a short space of two years. The two year term also has negative impact even on the importing countries as their public health initiatives may be put on stand-by while a new compulsory licence is being negotiated. This might see patients in these countries having to go without treatment during that period and this might have dire consequences to their lives especially for HIV/AIDS patients who require continuous medication and a break in treatment may result in resistance to treatment when it is resumed.

Canada's Patent Act has also been criticised as being far removed from the realities of developing countries and the pharmaceutical industry.<sup>289</sup> This criticism is based on the reasoning that, not only does it lack commercial incentives for the generic manufacturers it also lacks the incentive for developing countries and LDCs to use it when they can import the drugs they need at lower cost from countries such as India.<sup>290</sup>

Moreover some officials from developing countries have lamented the lack of input into CAMR's legislative process by developing countries and LDCs, after all these countries are the intended beneficiaries as such some level of input from them would have gone a long way in alleviating their health problems.<sup>291</sup>

#### **4.5 The first use of the Act's provisions**

The provisions of Canada's Patent Act have only been used once by Rwanda as the importing country and Apotex the generic maker. In the following discussion the practical implementation of the Act's substantive provisions is given attention.

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<sup>289</sup> Cohen-Kohler (fn 266) 1.

<sup>290</sup> *ibid* Cohen-Kohler (fn 266) 1.

<sup>291</sup> *ibid* Cohen-Kohler (fn 266) 3.

#### **4.5.1 Medecins Sans Frontieres's willingness to test the Act**

In May 2004, the same month in which the amendments were passed as law, Medecins Sans Frontieres (MSF)<sup>292</sup> made a public commitment to test the expediency and efficacy of the amendments by placing an order for drugs needed for its field operations. In August 2004 a meeting was held between Health Canada (Canada's federal Health Department), the Canadian Generic Pharmaceutical Association (CGPA), MSF was requested to identify which drugs were extremely needed as a matter of urgency.<sup>293</sup> Finally in December 2004, Apotex Inc, a Canadian privately owned company agreed to produce a triple-combination antiretroviral combination for HIV/ AIDS.

#### **4.5.2 Apotex- the generic manufacturer**

The generic manufacturer Apotex then developed the Tri- Avir drug, (a fixed-dose combination). After that, Apotex had to contend with the problem that the drug was not on the list of products in Schedule 1. This necessitated an application to the federal Cabinet for the addition of the newly developed generic drug. In September 2005, the Cabinet made the requisite order amending the Schedule of the Patent Act.<sup>294</sup> In the same year Apotex submitted to Health Canada an application for approval, and the review process took approximately seven months.<sup>295</sup>

The next and most arduous task was the long-drawn-out process of negotiations engaged between Apotex and the patent-holding companies.<sup>296</sup> Apotex then engaged in negotiations with the patent holders as required by Canadian Patent

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<sup>292</sup> MSF has been one of the most prominent NGOs in the field of access to medicines in the poorest parts of the world. It has also been in the forefront in debates relating to access to medicines versus patent protection

<sup>293</sup> fn 260.

<sup>294</sup> fn 281.

<sup>295</sup> Hestermeyer, "Canadian-made drugs for Rwanda: the first application of the WTO waiver on patents and medicines." (2007) 11 *ASIL Insight International Economic Law Edition*. Available online at <http://www.asil.org/search.cfm?displayPage=363> (accessed 20.04/09)

<sup>296</sup> Hestermeyer (fn 295).

Nine patents are related to the FDC developed by Apotex. Four of the patents are held by GlaxoSmithKline (GSK), two by Wellcome Foundation, two by Shire Biochem and one by Boehringer Ingelheim.

Act, however progress was minimal reportedly because the patent holders could attach any condition to prevent an agreement.<sup>297</sup>

Apotex also could not satisfy one of the conditions for applying for a compulsory licence, namely that there was no importing country. Canada's Patent Act requires, in section 21.04, that the importer be identified, inter alia, before a compulsory licence can be issued. This reluctance has been attributed to the intense criticism that Brazil and Thailand received from the pharmaceutical industry as well as other governments when these two countries issued compulsory licences on patented drugs for domestic health programmes.<sup>298</sup>

#### **4.5.3 Rwanda-the importing country**

On July 19, 2007, as required by paragraph 2 (a) of the 30 August Decision, Rwanda became the first country to notify the TRIPS Council indicating that it wished to use the waiver to import a fixed-dose, triple combination HIV/AIDS drug manufactured by the Canadian generic pharmaceutical manufacturer Apotex.<sup>299</sup>

In this notification Rwanda informed the TRIPS Council that based on its evaluation of its public health needs, it would import during the next two years 260, 000 packs of the fixed-dose combination TriAvir, manufactured by Apotex. A unique feature of the notification is that it specifies that since it was not possible to give a certain prediction the extent of Rwanda's public health needs, the country reserved the right to modify their estimate specified in the notice as necessary or appropriate.<sup>300</sup>

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<sup>297</sup> Hestermeyer (fn 295).

<sup>298</sup> "Brazil issues compulsory licence for AIDS drug", Bridges Weekly Trade News Digest, Vol 11, Number 16, 9 May 2007. Available online at [www.ictsd.net/news/bridges/11643/](http://www.ictsd.net/news/bridges/11643/) (accessed on 11/04/09).

<sup>299</sup> IP/N/9/RWA/1 Council for Trade Related Aspects of Intellectual Property Rights-Notification under Paragraph 2(a) of the Decision of 30 August 2003 on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement, dated 19/07/07. Available online at [www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_import\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm) accessed on 12/04/09.

<sup>300</sup> The relevant excerpt of the Notification states "However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate."

It is difficult to imagine how Rwanda proposed to “modify their estimate specified in the notice as necessary” because if such a modification exceeded what was specified in Apotex’s compulsory licence then it would mean a new compulsory licence which would have to go through the same cumbersome process. It must be noted that a renewal of the licence can only be granted where the drug specified has not been manufactured or exported in its entirety.

The notice also specified that pursuant to paragraph 7 of the Doha Declaration Rwanda would not enforce rights provided for in Part II Section 5 of the TRIPS Agreement that may be granted within Rwanda’s territory with respect to the drug(s) intended to be imported.<sup>301</sup> This particular point important because if a patent exists for the drug intended for importation, the importing country is supposed to also issue a compulsory licence. However since LDCs are excluded from the obligation to grant patent protection as stipulated by the 2002 Decision extending their transition period then the requirement of also issuing a compulsory licence also falls away, provided of course the LDC has not granted a patent for that product.<sup>302</sup>

Noteworthy is the fact that Rwanda could have wholly avoided using the 30 August mechanism because the same combination that it sought to import from Canada was also available at comparable cost from India where the three drug components are not under patent protection.<sup>303</sup>

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<sup>301</sup> Paragraph 7 is a reaffirmation of developed-country Members commitment to provide incentives to their enterprises and institutions so as to encourage technology transfer to LDCs pursuant of article 66.2 of the TRIPS Agreement. In terms of this paragraph LDCs are not required, with regard to pharmaceutical products, to enforce sections 5 and 7 of Part II of the TRIPS Agreement until 1 January 2016.

<sup>302</sup> Fn 75.

<sup>303</sup> Hestermeyer (fn 295).

A similar combination is available in India at a cheaper price of US\$0.14 per tablet, while Apotex sold it for US\$0.40 per tablet

#### **4.5.4 The issuing of the first compulsory licence**

On 4 September 2007 Apotex filed the first compulsory licence under the system to the Canada's Commissioner of Patents which was granted on 19 September 2007 pursuant to section 21.04 of the Patent Act.<sup>304</sup>

In terms of this "authorization"<sup>305</sup> the quantity of the pharmaceutical product to be manufactured was specified as 15, 600, 000 tablets. This authorization also specified that it would be in force for a period of two years from the date it was granted on 19 September 2007. This means that the compulsory licence will expire in September 2009.

After the authorization was granted Canada notified the WTO's TRIPS Council in October 2007 pursuant to paragraph 2(c) of the 30 August Decision which requires such notification from Members intending to use the system as exporters.<sup>306</sup> The authorization was also attached to the notification.

In September 2008 the first consignment of the ARV drugs for HIV/AIDS arrived in Rwanda after a four- year processand. As a result an estimated 21, 000 Rwandans living with AIDS would be able to receive treatment for a year.<sup>307</sup>

#### **4.6 Lessons taken from Canada's Patent Act**

While Canada's Patent Act has noble intentions aimed at enabling countries lacking pharmaceutical manufacturing capacity to access medicines, Rwanda's scenario has demonstrated beyond any doubt that implementing the decision is not an easy task.

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<sup>304</sup> Gervais (fn 36) 68.

<sup>305</sup> Authorization under section 21.04 of the Patent Act. Available online at [http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/RCAM\\_ autorisations-CAMR\\_ authorizations-eng.pdf/\\$file/RCAM\\_ autorisations-CAMR\\_ authorizations-eng.pdf](http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/RCAM_ autorisations-CAMR_ authorizations-eng.pdf/$file/RCAM_ autorisations-CAMR_ authorizations-eng.pdf) (accessed 13/04/09).

<sup>306</sup> IP/N/10/CAN/1 Council for Trade Related Aspects of Intellectual Property Rights-Notification under paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, dated 08/ 10/07. Available online at [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_export\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm) accessed on 12/04/09.

<sup>307</sup> fn 23.

After discussing all the controversies that CAMR's enactment and implementation has courted, a pivotal question that has to be asked is whether these defects render it an ineffective process in the bid to ensure access to essential medicines in the developing world.<sup>308</sup> It has been suggested that the difficulties experienced by Apotex may well be ordinary "start inefficiencies", however it must be remembered that most of these problems were predicted and highlighted by NGOs and the generic makers through out the legislative.<sup>309</sup>

The fact that a G-7 country took the step to enact such legislation is noteworthy as it generates needed political impetus from a developed country behind the implementation of the Decision.<sup>310</sup>

The amendment confirms the fears that have been raised by public health advocates, regarding the effectiveness of the 30 August Decision. The Rwanda and Canada is a clear indication that the decision is "neither a solution, nor expedient".<sup>311</sup> Although the drug was finally delivered with the 21 000 patients benefiting, the process of merely securing the drug was arduous and complicated and simply confirms the criticism levelled against the 30 August Decision.

With regard to the requirement that Canada's Patent Act first requires negotiations for a voluntary licence it must be remembered that the TRIPS Agreement in article 31(b) waives this requirement of prior negotiations. On this point Canada has steadfastly refused to acknowledge that the 30 August Decision allows the waiver of prior negotiations.<sup>312</sup>

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<sup>308</sup> Abbott (fn 255) 1127.

<sup>309</sup> Abbott (fn 255) 1127.

<sup>310</sup> "Steps forward, backward and sideways: Canada's bill on exporting generic pharmaceuticals". Available online at <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=327> (accessed on 15/04/09).

<sup>311</sup> Fn 260.

<sup>312</sup> Abbot (fn 255) 1127.

As to the requirement that the generic maker must first identify an importing country prior to applying for authorization, public health officials from developing countries, NGOs and generic makers have also highlighted the inefficiency of this requirement.<sup>313</sup> They pointed out that the bulk of government pharmaceutical purchasing is done from public tendering processes, such that the identification of an importing country prior to applying for a compulsory licence is incompatible with customary practices.<sup>314</sup>

The pitfalls highlighted must be taken note of namely, the limited list of medicines that can be manufactured for export, the fact that developing countries who are non-WTO Members cannot make use of the mechanism is a flaw as it distinguishes LDCs and developing countries and not conferring the same treatment in public health issues.

The provisions excluding NGOs from making use of the Patent Act to procure medication for patients in the developing world is a regrettable feature in the Act as these organisations play a crucial role in getting treatment to those in need. Their exclusion will hamper their efforts in this regard and the patients are the ones who will inevitably bear the brunt of this provision. Another cause of concern is the duration of a compulsory licence granted in terms of the amendment already discussed. It has been shown how cumbersome the process is just to get a licence, moreover after the end of the period if the medical crisis still exists a new application process will have to be embarked upon.

However the amendment is not without its redeeming features as it sets a positive precedent in defining licensing negotiations and also defining royalties. The Act brought with it some clarity on the vague notion of “reasonable remuneration”. In article 31(b) of the TRIPS Agreement under normal circumstances the party that wishes to obtain a compulsory licence must first make attempts to obtain such authorization voluntarily from the patent holder “on reasonable terms and

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<sup>313</sup>Abbott (fn 255) 1128.

<sup>314</sup>Abbott (fn 255) 1128.

conditions”, it is only after such attempts have foundered “within a reasonable period of time” can be granted.<sup>315</sup>

The Act brings clarity as to what constitutes “a reasonable period of time” for attempting to negotiate a voluntary licence by proving that the Commissioner of Patents “shall” issue a compulsory licence provided that , in addition to satisfying the other statutory requirements, the applicant has 30 days prior filing the application provided the patent holder the information required by statute and that the applicant’s efforts in obtaining a voluntary licence “on reasonable terms and conditions” have not been met with success. The stipulation of the 30 day period is indeed a positive precedent.<sup>316</sup>

However must be remembered that the TRIPS Agreement in article 31(b) waives this requirement of prior negotiations. On this point Canada has steadfastly refused to acknowledge that the 30 August Decision allows the waiver of prior negotiations.<sup>317</sup>

On the same strength the statute also brought clarity as to amounts to “adequate remuneration” payable to the patentee upon the granting of a compulsory licence as required by the TRIPS Agreement. The Act now provides that the calculation of the royalty in any given case would be guided by a formula set out in the complementary regulations.<sup>318</sup> The Commissioner therefore has no discretionary powers when granting a compulsory licence neither can the Commissioner vary the royalty payable.

#### **4.7 Review of the Patent Act**

Review of the Patent is provided for by the amendment in section 21.02 which requires that the Minister of Industry to complete a review of the provisions related

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<sup>315</sup> Elliot (fn 286) 44.

<sup>316</sup> Elliot (fn 247) 99.

<sup>317</sup> Abbot (fn 255) 1127.

<sup>318</sup> Use of patented products for international humanitarian purposes regulations, S.O.R 2005/143.

to Patent Act within two years of its entry into force. A report regarding the review of the new sections of the Patent was made in May 2007.<sup>319</sup>

The process of reviewing the statute took “into account all” submissions made by the industry as well as NGOs involved in the field of delivering medication in developing countries. The report concluded with the finding that “insufficient time” had elapsed and “insufficient evidence” had accumulated since the coming into force of the amendment to necessitate legislative changes. The report went on further to state that government of Canada should rather focus on “non-legislative measures to improve access to medicines in the developing world, until a more sufficient assessment could be made”. These “non-legislative” measures include a federal budget for 2007 which introduced a tax incentive to encourage pharmaceutical manufacturers to donate greater amounts of needed medication to developing countries and LDCs.<sup>320</sup>

#### **4.8 Use of other flexibilities in the Post Doha era**

The Doha Declaration re-affirmed all the other flexibilities in the TRIPS Agreement. This chapter discusses the implementation of the flexibilities as clarified in the Doha Declaration. Examples of countries which made use of the flexibilities are also included in order to understand how the countries went about implementing the flexibilities.

From 2001 to the end of 2007 it has seen 52 developing countries and LDCs issuing post-Doha compulsory licences for the production or importation of generic forms of patented drugs, government–use provisions have also been used as well as the implementing the provisions on non-enforceable patents.<sup>321</sup>

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<sup>319</sup> Report on the Statutory Review of sections 21.01- 21.19 of the Patent Act by Jim Prentice, Minister of Industry. Available online at [www.camr-rcam.gc.ca/review-reviser/camr\\_rcam\\_report\\_rapport\\_e.html](http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_report_rapport_e.html) (accessed on 11 April 2009).

<sup>320</sup> Gervais (fn 36) 69.

<sup>321</sup> Hoen (fn 221) xvi.

Many countries also successfully made use of the flexibilities as leverage in price negotiations with pharmaceutical companies and an apt example in this regard is Brazil which has made numerous threats to issue compulsory licences and succeeded in getting significant price reductions.<sup>322</sup>

#### **4.9 The case of Brazil- a developing country**

In September 2003, Brazil's government issued a pronouncement that would allow it to issue a compulsory licence produce or import generic versions of patented HIV/AIDS medication.<sup>323</sup> Brazil's Minister stated that this decision had been necessitated by the fact that the patent holder Merck had failed to offer adequate price reductions.<sup>324</sup> Following this declaration of intention to issue a compulsory licence Brazil and Merck reached consensus later that year and a compulsory licence was averted.<sup>325</sup>

In yet another incident in 2005 Brazil's Health Minister issued a decree declaring the patent of the ARV Kaletra drug in the public interest and therefore eligible for compulsory licensing.<sup>326</sup> Subsequently pharmaceutical company Abbott agreed to reduce the price of the drug by 46 percent and a compulsory licence was once again averted.<sup>327</sup>

In the same year the government of Brazil declared that it was considering issuing a compulsory licence to authorize the manufacture of Viread, whose patent is held by pharmaceutical company Gilead.<sup>328</sup> Threatened with a compulsory licence Gilead was out of options and agreed to reduce the price of the drug by 50 per cent.<sup>329</sup>

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<sup>322</sup> Shaffer et al (fn 64) 32.

<sup>323</sup> Love, "Recent examples of the use of compulsory licences on patent" (2007) Knowledge Ecology International Research Note 16.

<sup>324</sup> Love (fn 323) 16.

<sup>325</sup> Love (fn 323) 16.

<sup>326</sup> Love (fn 323) 16.

<sup>327</sup> Love (fn 323) 16.

<sup>328</sup> Love (fn 323) 16.

<sup>329</sup> Love (fn 323) 16.

These threats by the Brazilian to issue compulsory licences and not actually issuing one led to a campaign dubbing the government of Brazil a “tiger without teeth” in September 2005 organized by a national gathering of non-governmental organizations working on HIV/ AIDS in Brazil.<sup>330</sup>

However it is submitted that even though Brazil’s government did not actually proceed to issue the threatened compulsory licences in the above instances it should be noted that the desired result of reducing the prices was achieved. Pharmaceutical companies in these cases when faced with prospects of compulsory licences being issued had little choice but to reduce prices. As such the significant power that compulsory licences wield in ensuring access to medicines is significant even when they are actually not issued.

On 24 April 2007 Brazil’s Minister of Health signed Ministerial Ordinance 866 declaring the HIV/AIDS efavirenz drug to be of public interest for purposes of granting a compulsory licence for public non-commercial use.<sup>331</sup>

This decision was taken after a number of failed attempts initiated by the Brazilian government to negotiate an agreement with the patent holder multinational pharmaceutical company Merck Sharpe and Dome (MSD-hereinafter Merck).<sup>332</sup>

It is noteworthy that the TRIPS Agreement in article 31(b) waives the requirement to engage in negotiations before issuing a compulsory licence for public non-commercial use . Therefore the Brazilian government’s efforts to reach a mutually agreed solution with Merck was actually not required and could probably be described as a show of good faith on the part of the government.

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<sup>330</sup> Hoen, (fn 221) 45.

<sup>331</sup> Brazilian government declares efavirenz to be of public interest (24 April, 2007) Available online at <http://www.aids.gov.br/data/Pages/LUMISE77B47C8ITEMIDD3ED04F71D8D46819F52E948F99783B3ENIE.htm> (accessed on 10/05/09).

<sup>332</sup> Balasubramanian, Brazil moves on compulsory licence after failed talks with drug company (May 2007). Available online at <http://www.twinside.org.sg/title2/wto.info/twninfo050703.htm> (accessed on 10/05/09).

The Ministerial Ordinance stated that its ultimate purpose was to ensure the survival of its National Sexually Transmitted Diseases and AIDS Programme.<sup>333</sup> In the Ordinance Brazil relied on its domestic legislation as well as the Doha Declaration. Brazil also made it clear that it had engaged in negotiations with Merck which were unsuccessful, that the drug was pivotal in implementing the above mentioned Programme, that due to the steady increase in the number of people infected with HIV/AIDS and the current prices of the drug, the situation was untenable.<sup>334</sup>

This time Brazil issued a compulsory licence. After Merck failed to match the 60 per cent price reduction sought by Brazil (Merck had offered a maximum of 30 per cent) the government issued a compulsory licence in May 2007 for the efavirenz drug.<sup>335</sup>

In a further development in September 2008, after extensive investigations Brazil's National Institute Industrial Property rejected a patent application by pharmaceutical company Gilead.<sup>336</sup> The application's rejection was based on lack of inventiveness as it did not represent an invention because its major ingredient was already present in other drugs pharmaceutical agents.<sup>337</sup>

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<sup>333</sup> Ministerial Ordinance of 24 April 2007. Available online at <http://www.aids.gov.br/data/Pages/LUMISE77B47C8ITEMIDD3ED04F71D8D46819F52E948F99783B3ENIE.htm> (accessed on 10/05/09).

<sup>334</sup> At that time the drug was being sold in Brazil for approximately US\$580 per patient per year (PPY), while generic versions that have been pre-qualified by the WHO had been offered for US\$163 PPY. It was estimated that 75,000 patients would be using the drug at the end of that year and despite the increasing number of people using the drug had not gone down. Projections were made which estimated that the government would make saving in expenditure amounting to US\$236 million. Available online at <http://www.aids.gov.br/data/Pages/LUMISE77B47C8ITEMIDD3ED04F71D8D46819F52E948F99783B3ENIE.htm> accessed on 10/05/09).

<sup>335</sup> Alcorn, Brazil issue a compulsory licence on efavirenz (7 May 2007). Available online at <http://www.aidsmap.com/en/news/0550CE62-3F90-4603-932C-EF69E1B4485D.asp> (accessed on 10/05/09).

Merck's spokesperson was reported as warning that actions such as Brazil were going to dissuade pharmaceutical companies from investing into research and development into diseases affecting developing countries.

<sup>336</sup> Alcorn, Brazil rejects tenofovir patent (05 September 2008). Available online at <http://www.aidsmap.com/en/news/945B0134-C898-40D0-9DC6-9C765352E158.asp> (accessed 10/05/09).

<sup>337</sup> fn 336.

#### **4.10 The case of Thailand**

In 2007 Thailand captured international attention after it had issued a series of compulsory licences on patented drugs, with little prior negotiations or warnings at a royalty of 0.5 percent of the sale price – considerably lower than the market price sold by the patent holders.<sup>338</sup>

Thailand has a national mandate to supply access to essential medicines to all its citizens pursuant to the National Health Security Act of 2002 and access to ARVs for all AIDS patients since 2003.<sup>339</sup>

##### **4.10.1 The efavirenz compulsory licence**

On November 2006, Thailand issued a compulsory licence to its Government Pharmaceutical Organization (GPO) on Merck's patented drug efavirenz (an effective and expensive first line treatment for AIDS which has fewer side effects and is also on Thailand's National List of ARVs).<sup>340</sup> In issuing the compulsory licence Thailand relied on its domestic law<sup>341</sup> as well as the Doha Declaration.

Article 51 of the Thai Patent Act provides that for the public use ministries, bureaus or departments may exploit any patent without further negotiation with the patent holder. In the Announcement Thailand went on to elaborate that this made it clear that for non-commercial use, especially in public affairs of the government such as public health services, the Government was well within its rights. Thailand also stated that the Doha Declaration allows Members to put in place measures to

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<sup>338</sup> Ho (2008), "On breaking patents: Separating strands of fact from fiction under TRIPS" *The selected works of Cynthia M Ho*, 28. Available online at [http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=cynthia\\_ho](http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=cynthia_ho) (accessed on 14/04/09).

<sup>339</sup> Thai National Health Security Act B.E. 2245.

<sup>340</sup> Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the public use of patent pharmaceutical products (29 November 2006). Available online at <http://www.cptech.org/ip/health/c/thailand/thaic14efavirenz.html> accessed on 21/04/09

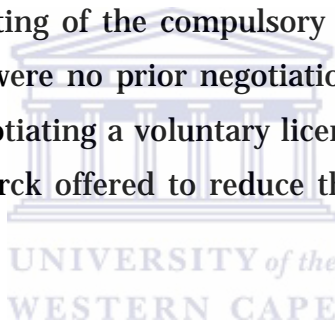
<sup>341</sup> Specifically article 51 of the Thai Patent Act B.E 2522 (as amended by the Thai Patent Act 2535 and no. 3 B.E 252).

The licence also stated that it was for non-commercial purposes and solely for public interest in order to achieve its policy of universal access for Thai citizens in need for long-term use of ARVs. Furthermore the licence also pointed out that the high cost of the drug in the absence of the compulsory licence would result in numerous patients not being able to access treatment. The licence was set to benefit 200, 000 patients each year.

protect public health, especially for universal access to essential medicines using compulsory licensing on the patents of pharmaceutical products. In addition the Announcement also stipulated that Department of Disease Control will notify the patent holder and Department of Intellectual Property, Ministry of Commerce with immediate effect.

The licence which will be valid until 31 December 2011 authorizes Thailand's Government Pharmaceutical Organization to import generic efavirenz from India where drug is not patented and to manufacture the drug itself. A royalty fee of 0.5 percent of the GPO's total value of the imported or locally produced efavirenz will be payable to the patent holder Merck.

Merck objected to the granting of the compulsory licence on grounds it was not TRIPS compliant as there were no prior negotiations and considered selling the drug at lower prices or negotiating a voluntary licence for the manufacture of the drug generic version.<sup>342</sup> Merck offered to reduce the price by more than half its market price<sup>343</sup>



It is submitted that Merck's contention is an error because Thailand's licence is fully TRIPS-compliant. First of all article 31(b) of the TRIPS Agreement provides that the requirement for prior negotiations may be waived by a Member in cases of public non-commercial use, and to that end Thailand licence stated that it was indeed for public non-commercial use, therefore the need for prior negotiations was waived. Article 31(b) further requires that in cases of public non-commercial use the right holder shall nevertheless be notified of the compulsory licence as soon as reasonably practicable. It is further submitted that this particular requirement

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<sup>342</sup> Steinbrook, "Thailand and the compulsory licensing of efavirenz" (2007) 356 *The New England Journal of Medicine* 546. Available online at <http://content.nejm.org/cgi/content/full/356/6/544> (accessed on 21/04/09).

<sup>343</sup> "Timeline for Thailand's compulsory licences" *Programme for Information, Justice and Intellectual Property* (2 March 2008) 5. Available online at <http://www.wcl.american.edu/pijip/documents/timeline.pdf?rd=1> accessed on 17/04/09. Notably the brand-name drug Efavirenz sold at close to 1,400 baht per bottle (Thailand currency) while India's generics producer Ranbaxy sold the generic version for 650 baht per bottle.

was fulfilled because the Announcement clearly stipulated that the patent owner would be notified with immediate effect.

#### **4.10.2 The Kaletra licence**

The Thailand government issued yet another compulsory licence, on 25 January 2007, for AIDS drug Kaletra whose patent is owned by Abbott.<sup>344</sup> This particular licence was also crafted to augment an increased number of patients and consequently save lives.

In essence the Kaletra licence replicated the provisions of the Efavirenz licence, regarding Thailand's reliance on its national patent legislation as well as the Doha Declaration, the 0.5 per cent royalty, and notification of the patent owner with immediate effect. The Decree stated that the compulsory licence would be valid until 31 January 2012.

Abbott opposed the Kaletra licence in response withdrew its applications to sell seven new drugs in Thailand.<sup>345</sup> The pharmaceutical heavily criticized Thailand's actions and was quoted accusing Thailand of "stealing and seizing patents", that "there was no emergency" as well as "taking advantage of the vague language in the WTO regulations".<sup>346</sup>

It is submitted that once again the industry is in error. Regarding the issue of emergency the Doha Declaration unequivocally states in Paragraph 5(c) that each Member is at liberty to determine what constitutes national emergency, it being understood that public health crises, including to HIV/ AIDS, among others, can

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<sup>344</sup> Decree of the Department of Disease Control, Ministry of Public Health, regarding exploitation of patent on drugs and medical supplies by the government on combination drug between Lopinavir and Ritonavir (29 January 2007). Kaletra is a patented combination of two ARVs often used for patients who have developed resistance to basic formulations of HIV therapy.

The licence was set to benefit Thailand's 250, 000 patients per year. Available online at [http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra\\_en.pdf](http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra_en.pdf) (accessed on 18/04/09).

<sup>345</sup> "Abbot to stop launching new drugs in Thailand in response to country's compulsory licence for antiretroviral Kaletra" *Kaiser Daily News HIV/AIDS Report* (14 March 2007). Available online at <http://www.hivdent.org/uspublicpolicy/Archives/2007/ppATSL0307.htm> (accessed on 18/04/09).

<sup>346</sup> fn 345

represent a national emergency. Therefore Thailand was well within its rights to classify the HIV/AIDS epidemic as a national emergency.

The contention that Thailand was “taking advantage of the vague language in the WTO language” is once again a misconception, it is submitted that there is nothing “vague” about the TRIPS Agreement or Doha Declaration. Rather this is the very flexibility built into the TRIPS Agreement, the room for countries to manoeuvre and exercise discretion in issues of public health, which Thailand exercised and rightly so in order to ensure access to essential medicines.

All in all it is once again submitted that the Kaletra is with the TRIPS Agreement as well as the Doha Declaration.

#### **4.10.3 The Plavix licence**

On the same day as the Kaletra licence was issued, the Thai government also issued another compulsory licence to the GPO for Bristol Myer’s drug Plavix, useful for treating heart ailments.<sup>347</sup> The licence made mention of the fact that heart disease is one of the top three causes of deaths in Thailand, and even though there existed some non-drug measures, there is need for drug treatment to curb unwarranted deaths.<sup>348</sup>

The Plavix licence also replicates the provisions of the two earlier compulsory licences regarding the reliance on article 51 of the Thai Patent Act, the Doha Declaration, the 0, 5 percent remuneration as well the expedient notification of the patent owner Bristol Myer. However the unique feature of this licence is that it

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<sup>347</sup>Ministry of Public Health Announcement regarding exploitation of patents on drugs and medical supplies for Clopidogrel ( 29 January 2007). Available online at [http://www.cptech.org/ip/health/c/thailand/thai-cl-clopidogrel\\_en.pdf](http://www.cptech.org/ip/health/c/thailand/thai-cl-clopidogrel_en.pdf) (accessed on 18/04/09).

<sup>348</sup>Such other non-drug preventive measures include diet control as well as mental and physical exercise, but these would be inadequate as the incidents are high and need medicines for treatment to avoid morbidity and mortality. The Thai government also clarified that without this licence only 20% of government patients could access the medicine, which would be inconsistent with the Thai policy of universal access. The licence also stipulated that it would cover all patients suffering from the cardiovascular ailment covered under the National Health Security Act, the Social Security Act, and the Civil Servants and Employees Medical Benefit Scheme.

does not have a specific date on which it will expire, rather the licence provides that it shall be valid until the patent expires or when the “essential need” ceases.<sup>349</sup>

#### **4.10.4 Thailand’s “Ten burning facts about Thailand” White Paper**

In February 2007, subsequent to the issuance of the three compulsory licences Thailand issued a white paper entitled “Ten burning facts about Thailand”, including supporting documentation defending its three licences,<sup>350</sup> wherein the Thai government went to lengths to explain its health needs, explaining that the rationale of its actions was based on its policy to ensure universal access to essential medicines, that its licences were indeed TRIPS-compliant. In defending its stance for not engaging in prior negotiation the Thai government asserted that issuing compulsory licences without prior negotiations is generally more effective and successful.

#### **4.10.5 Reactions drawn by the compulsory licences**

The pharmaceutical industry was quoted criticizing Thailand on grounds that conditions such as heart disease and cancer are “lifestyle” diseases that should not be the subject of compulsory licences.<sup>351</sup>

Conversely humanitarian organizations, such as the Nobel-winning MSF, were quoted applauding Thailand’s actions in making use of this flexibility.<sup>352</sup> In December 2007 the UN’s Secretary General Ban Ki-Moon was also quoted

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<sup>349</sup> The licence provides that “ the use of the above patent rights is effective from today until the patent expires or no essential need”.

<sup>350</sup> “Facts and evidence on the 10 burning issues related to the government use of patents if three patented essential drugs in Thailand-Document to support strengthening of social wisdom on the issue of drug patents”, The Ministry of Public Health and the National Health Security Office, Thailand , February 2007. Available online at <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> (accessed on 14/04/09).

<sup>351</sup> Wong, “Thailand backs off threat to break drug patents” (8 February) Available online at <http://www.scidev.net/en/news/thailand-backs-off-threat-to-break-drug-patents.html> (accessed on 14/04/09).

<sup>352</sup> fn 39.

applauding Thailand's efforts in addressing the HIV/AIDS crisis and singling out compulsory licences as pivotal in ensuring equitable access to medicines.<sup>353</sup>

It is noteworthy that Abbott's unilateral action to withdraw its applications for the seven new drugs in Thailand was actually regarded as constituting anti-competitive conduct in some quarters.<sup>354</sup> It is submitted that if Thailand's Competition Commission had actually confirmed this claim the consequences would have been dire for Abbott as Thailand would legitimately issue compulsory licences for these drugs.

#### **4.10.6 The Special 301 Watch List**

Due to these compulsory licences Thailand was "elevated" to the USA's Special 301 Watch list.<sup>355</sup> In a 2007 Special 301 Report reasons given for the inclusion of Thailand in the List ranged from "indications of a weakening of respect of patents" to "lack of transparency and due process" in the issuance of the three compulsory licences and thus justifying a serious concern to the USA's Administration.<sup>356</sup>

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<sup>353</sup> "Timeline for Thailand's compulsory licences" Programme for Information, Justice and Intellectual Property (2 March 2008) 13. Available online at

<http://www.wcl.american.edu/pijip/documents/timeline.pdf?rd=1> accessed on 17/04/09

In July 2007, the EU, in a letter through its Trade Commissioner was also reported as having castigated Thailand for its seemingly unbridled use of compulsory licensing. The EU latter denied this claim in a March 2008 statement wherein it affirmed that Thailand's actions were indeed WTO-complaint. Switzerland was also reported as also having written a letter to the Thai government condemning it for issuing the compulsory licences in February 2008.

<sup>354</sup> (fn 353) 13.

HIV/AIDS activists viewed Abbott's actions as constituting anti-competitive practice and brought the matter before Thailand's Competition Commission. However the Commission rejected these claims. The issue of anti-competitive practices is dealt with by the TRIPS Agreement in article 31(k) which actually permits the granting of a compulsory licence to remedy anti-competitive practices after a judicial or administrative process has determined that anti-competitive conduct has indeed taken place.

<sup>355</sup> Love, "KEI Statement on USTR 301 List reference to Thailand". Available online at <http://lists.essential.org/pipermail/ip-health/2007-April/011055.html> (accessed on 18/04/09).

<sup>356</sup> 2007 Special 301 Report Office of the United States Trade Representative. Available online at [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2007/2007\\_Special\\_301\\_Review/asset\\_upload\\_file230\\_11122.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf) (accessed on 18/04/09).

In the report the USTR cited Thailand's intellectual property rights protection as being deficient and that Thailand's compulsory licences was indicative of a weakening of respect for patents. The report stated that the USA was seriously concerned about the lack of transparency and due process exhibited in Thailand supposedly exhibited by the three compulsory licences. The Report further stated that it was dedicated to addressing the serious the serious health problems, such as HIV/AIDS afflicting developing and least developed countries alike. The Report went on to state

It is submitted that the USA's reiteration of its commitment to the Doha Declaration leaves a lot to be desired, it appears as if it simply pays lip service to the Doha Declaration while its actions and that of the pharmaceutical industry contradict these statements.

With reference to the USA's claim that Thailand's actions "lack transparency and due process", it has been suggested rather that what lacks transparency is the very arbitrary and political process for creating the 301 List and that the question of the "due process" of the List is questionable.<sup>357</sup>

The USA itself has made extensive use of compulsory licensing ranging from the licence for the anthrax drug Cipro whose patent was held by Bayer, to compulsory licences to benefit Toyota and Microsoft, to mention but a few, that had absolutely nothing to do with public health.<sup>358</sup> As such the reaction by the USA displays double standards.

#### **4.10.7 Thailand makes use of the patentability criteria**

In 2006 Thailand's Health and Development Foundation filed a legal challenge against GlaxoSmith-Kline (GSK)'S application for a patent on an ARV FDC. The Foundation's argument was that the drug did not satisfy the "newness" requirement stipulated by article 27(1) of the TRIPS Agreement and that the combination of two known drugs neither of which was patented in Thailand could not be considered sufficiently inventive to deserve a patent. <sup>359</sup>

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that the USA was firmly of the view that the TRIPS Agreement sufficient flexibility to address public health problems and also affirmed its support of the Doha Declaration.

<sup>357</sup> Fn 355.

<sup>358</sup> Love, "Racist and ignorant reactions to Thailand's compulsory" Huffington Post (25 January 2007). Available online at [http://www.huffingtonpost.com/james-love/racist-and-ignorant-react\\_b\\_39618.html](http://www.huffingtonpost.com/james-love/racist-and-ignorant-react_b_39618.html) (accessed on 08/03/09).

<sup>359</sup> Ford et al, "Sustaining access to antiretroviral therapy in developing countries: Lessons from Brazil and Thailand".(2007) Medecins sans Frontieres Publications . Available online at [http://www.msfaccess.org/fileadmin/user\\_upload/diseases/hiv-aids/Sustaining%20access%20to%20ARV%20lessons%20from%20Brazil%20and%20Thailand.pdf](http://www.msfaccess.org/fileadmin/user_upload/diseases/hiv-aids/Sustaining%20access%20to%20ARV%20lessons%20from%20Brazil%20and%20Thailand.pdf) (accessed on 15/04/09).

#### 4.11 The case of the developing world's pharmacy-India

India has earned the reputation as being the “developing world’s pharmacy” as it is the major supplier essential medicines to developing countries, not only for HIV/AIDS medicines, but other medicines as well, with 67% of India’s generic medicines being exported to developing countries.<sup>360</sup> Unlike other developing countries India took advantage of the 10 year transition period by developing and maintaining a world-class generics production capacity, it this attribute that has enabled Indian manufacturers to drive down prices for key ARV treatment.<sup>361</sup>

The consequences of introducing patent protection in India with the lapsing of the grace period in 2005 are two-fold.<sup>362</sup> Firstly, newly developed drugs after 1 January 2005 will be subject matter for patenting.<sup>363</sup> For example in the area of ARVs for the treatment of HIV/AIDS, where drug resistance develops, if new drugs are developed to address drug resistance, cheaper generic versions of these new drugs will not be available because of patent protection unless India or another country issues a compulsory licence.<sup>364</sup>

Secondly, after the 2005 deadline, India had to process patent applications submitted under the “mail box” mechanism since 1 January 1995 , with the result that drugs falling within the mailbox provision will be patented (provided they

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<sup>360</sup> “Examples of the importance of India as the “pharmacy of the developing world”, (2007) Medecines sans Frontieres Publications. Available online at [http://www.msfacecess.org/fileadmin/user\\_upload/medinnov\\_accesspatents/Overview%20Jan%202007%20FINAL.pdf](http://www.msfacecess.org/fileadmin/user_upload/medinnov_accesspatents/Overview%20Jan%202007%20FINAL.pdf) (accessed on 15/04/09).

India is the primary source of affordable ARVs as it is one of the few countries with the capacity to producer theses newer medicines as generics; as such all AIDS programmes use India as their main source of products. Approximately 50% of essential medicines that UNICEF distributes in developing countries are sourced from India. Zimbabwe sources 90% of its ARVs for its national treatment programmes from India. Not only does it export finished products, India also exports raw materials to other countries such as Brazil for local production of low-cost medicines.

<sup>361</sup> Abbott and Reichman (fn 39) 934.

<sup>362</sup> Abbott (fn 51) 321.

<sup>363</sup> Abbot (fn 51) 321.

<sup>364</sup> Abbott (fn 51) 321.

satisfy India's patentability criteria) for the remainder of the twenty- year term from the date of filing of their mailbox application.<sup>365</sup>

#### **4.11.1 Amendments to India's Patent Act**

India's Patent Act of 1970 has undergone three amendments between 1995 and 2005, while its pharmaceutical industry is a force to be reckoned within the global pharmaceutical sector.<sup>366</sup>

Some of the important provisions in the Amendment of 2005 include a new meaning to the term "new invention",<sup>367</sup> restrictions the scope for patentability,<sup>368</sup> "bolar exception",<sup>369</sup> as well parallel importation.<sup>370</sup>

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<sup>365</sup>Abbott (fn 51) 321.

India's patent regime did not, until 2005, recognize patents for pharmaceutical products and this had enabled Indian generic companies to manufacture generic versions of patented drugs including HIV/ AIDS treatment and this earned the reputation of being dubbed the "developing world's pharmacy". However December 31 2004 marked the developing countries end of their transition period as they had to comply fully with all of the TRIPS Agreement's provisions, patents included, as of 1 January 2005

<sup>366</sup> Sharma, "New patent regime in India- challenges and the future of the pharmaceutical industry" (2007) 4.

India's pharmaceutical sector is currently ranked 4<sup>th</sup> and 13<sup>th</sup> in terms of volume and value, respectively, in the global pharmaceutical business. The first amendment in 1999 served to incorporate the "mailbox provision" to provide an avenue by which patents could be filed with effect from 1 January 1995. The purpose of the second amendment in 2002 was to bring the Act into conformity with the TRIPS Agreement by incorporating all of the Agreement's substantive provision including the extension of the patent term to 20 years, re-defining patentable subject matter as well as compulsory licensing. However provisions relating to product patents were excluded because the 2005 deadline had not expired. In March 2005 India passed the Patent Bill No. 32-C to effect the third amendment signalling a new era in India's patent regime. It adopted a definition of "pharmaceutical substance", excluded "mere discovery of a new form known substance" and "new use of known substance" as well as protecting the interests of those who are already producing the product which may be granted patent protection.

<sup>367</sup> Section 2(1) defines a new invention as "any invention or technology which has not been anticipated by publication in any document or used in the country or anywhere else in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art."

<sup>368</sup> Section 3(d) excludes from patentability "the mere discovery of any form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant."

<sup>369</sup>Section 107 A (a) stipulates that "certain acts cannot be considered as infringement. For the purposes of this Act – (a) any act of making, constructing, using or selling a patented version solely for uses reasonably relating and development and submission of information required under any

A commendable feature of India's new patent legislation requires that a "new invention" must not have been anticipated either through publication in any document or used in India or anywhere else in the world. In other words "absolute novelty" is required for new inventions. This form of novelty means that the invention is truly inventive in that it is universally new throughout the world.<sup>371</sup> It is submitted that this will go a long way in addressing health issues in that only true medicinal drugs will be patented.

Another commendable feature of India's new patent legislation is the system of automatic licensing for a generic manufacturer who is already producing and marketing the medicine in India and has made a "significant investment", permitting continued production regardless of a patent's existence. The generic manufacturer is however required to pay a "reasonable royalty" to the patent-holding company.<sup>372</sup>

It is submitted that the 2005 Amendment is an exceptional example of how a country can fully incorporate the legitimate TRIPS flexibilities as envisaged by the Agreement.

#### **4.11.2 Norvatis sues India**

The provisions of section 3(d) were subjected to adjudication when in 2006 India's High Court, for the first time ever, rejected a patent application brought by Norvatis (a Swiss based pharmaceutical company).<sup>373</sup>

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law for the time being in force, in India, or in any country other than India that regulates the manufacture, the construction, use of any product."

<sup>370</sup> Section 107 A (b) provides that "any importation of patented products by any person from a person, who is duly authorized by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights".

<sup>371</sup> Correa, 'A guide to pharmaceutical patents' (2008) South Centre 2.

<sup>372</sup> The amended section 11 A(7) now provides that "after a patent is granted in respect of applications made under sub-section 2 of section 5, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1<sup>st</sup> day of January 2005, and which continues to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises."

<sup>373</sup> Capdevilla, *India verdict welcomed by advocates for affordable medicines*. Available online at <http://www.ipsnews.net/news.asp?idnews=38805> (accessed on 11/04/09).

Prior to the matter being brought before the High Court, Novartis had filed for a patent for its leukaemia drug Glivec (also known as Gleevec) and India's patent office (the Controller General of Patents and Designs) had ruled that the drug was merely a new form of an existing treatment which was developed before 1995.<sup>374</sup>

The amendment to section 3(d) of the Principal Act precluded from patentability any new form of a known drug which did not "result in the enhancement of the known efficacy" of that drug. Novartis then brought the matter before the Court challenging the constitutionality of section 3(d), seeking an annulment of the said section, as well as seeking the Court to grant the patent.<sup>375</sup> Novartis' arguments were based on grounds that section 3(d) violated articles 27(1) and 27(2) of the TRIPS Agreement as well as articles 253 and 51 (c) of India's Constitution, and the arbitrariness by the Controller General in rejecting the patent application.<sup>376</sup> The High Court of Chennai rejected Novartis' argument and declared that section 3(d) was indeed constitutional. The decision was applauded by advocates for affordable medicines as "having a positive impact on public health" and would propel the cause of promoting patients' access to affordable essential medicines.<sup>377</sup> This High

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<sup>374</sup> Novartis AG v Union of India. In the High Court of Judicature at Madras (Special Jurisdiction) W.P. NO. 24759 of 2006.

Six other respondents cited in the matter were: The Controller General of Patents and Designs, Natco Pharma Ltd, Cipla Ltd, Hetro Drugs Ltd, Cancer Patients Aid Association, and Ranbaxy Laboratories Ltd.

Available online at <http://www.cptech.org/ip/health/c/india/novartis-v-india.doc> (accessed on 11/04/09).

<sup>375</sup> Sharma (fn 366) 8.

<sup>376</sup> Sharma (fn 366) 9.

Articles 253 and 51(c) of India's Constitution require that India's domestic laws be brought into line with international treaties.

Article 253 provides that "the Parliament has power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country or countries or any decision made at any international conference, association and other body."

Article 51(c) stipulates that "the state shall endeavour to foster respect for international law and treaty obligations of organized peoples with one another."

In addition Novartis also claimed that section 3(d)'s provision dealing with a "new form" was illogical and contrary to the concept of patents which is supposed to encourage creativity by rewarding persons associated with such acts which benefit the public.

<sup>377</sup> Bidwai, "Health India: Novartis patents case far from dead". Available online at <http://ipsnews.net/news.asp?idnews=38840> (accessed on 11/04/09).

Court's judgement was also seen as a vindication of India's Patents Act, particularly section 3(d).

Contrary to the view held by the pharmaceutical industry that India's patent laws would discourage innovation; the considered view is that India's patent laws do not discourage research and inventiveness.<sup>378</sup> Rather section 3(d) only precludes incremental innovation thereby promoting genuine ingenuity, and deservedly so.<sup>379</sup>

The defeat of Norvatis had significant implications particularly in light of thousands of patent applications in India's 1995-2005 "mailbox" which would have to be granted had Norvatis won the case.<sup>380</sup>

The "ever greening" mechanism which has become quite prevalent effectively means that there is no originality but simply re-working an existing compound.<sup>381</sup> There is also evidence to suggest that while only a minimal number of new chemical compounds are approved annually, numerous patents are applied for to protect variants of existing products and processes.<sup>382</sup>

#### **4.12 The case of Malawi- a least developed country**

Malawi is included because it is a LDC and the WTO Decision of 2002 exempts all LDCs' transition period has been extended until 2016 and as such they are exempted from implementing obligations regarding pharmaceutical patents.<sup>383</sup>

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<sup>378</sup> Sharma (fn 366) 10.

<sup>379</sup> Sharma (fn 366) 10.

<sup>380</sup> Baker, "2007 Victories: Fewer deaths and more compulsory licences". Available online at <http://www.healthgap.org/trips/2007victories.htm> (accessed on 15/04/09).

<sup>381</sup> Kameni, "Implications of the Indian intellectual property law on Sub-Saharan Africa countries" (2008) 2 *The Botswana Review of Ethics, Law and HIV/AIDS* 65.

<sup>382</sup> Correa, "Guidelines for the examination of pharmaceutical patents: developing a public health perspective" (2007) a *ICTSD-UNCTAD-WHO Working paper*, 1. Available online at [http://ictsd.net/downloads/2008/06/correa\\_patentability20guidelines.pdf](http://ictsd.net/downloads/2008/06/correa_patentability20guidelines.pdf) (accessed on 12/04/09).

<sup>383</sup> Fn 75.

#### **4.12.1 Malawi's Patents Act**

Malawi's Patents Act<sup>384</sup> does not take full advantage of the key flexibilities, such as parallel importation, under the TRIPS Agreement, the Doha Declaration or the 30 August Decision although it does have some potential flexibilities built in.<sup>385</sup> Malawi's entire patent regime could best be described as TRIPS-plus because it prematurely grants patent protection for medicines, this is illustrated by a provision which mandates extension of patents for periods ranging between 5 and 10 years which can be granted on grounds of hostility or inadequate "remuneration".<sup>386</sup>

#### **4.12.2 Malawi's roll-out programme of ARV therapy**

As already alluded to, most LDCs have provided patent protection before they have been required to.<sup>387</sup> Therefore in order for LDCs to make use of the extended transitional period regarding pharmaceutical patents, they will have to make the necessary changes to their national laws to incorporate the exemption for pharmaceuticals.<sup>388</sup>

In its roll-out programme exclusively based on Cipla's HIV/AIDS drug Triomune (a fixed-dose combination) imported from India, Malawi realized that the drug would infringe patents valid in Malawi.<sup>389</sup> Malawi reportedly sought the assistance of an international legal consultant which resulted in a letter issued by the Government of Malawi, wherein Malawi invoked Paragraph 7 of the Doha Declaration in its request to UNICEF for the procurement of generic versions of an attached list of

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<sup>384</sup> Chapter 49:02 of the Laws of Malawi

<sup>385</sup> Lewis- Lettington, Banda, "A survey of policy and practice on the use of access to medicines-related TRIPS flexibilities in Malawi" (2004) 17 *DFID HRSC Issue Paper*. Available online at <http://www.dfidhealthrc.org/publications/atm/Lettington.pdf> (accessed on 05/10/08).

<sup>386</sup> Section 30 of Malawi's Patents Act.

<sup>387</sup> Thorpe fn 76.

<sup>388</sup> Masungu, Oh (fn 4) 14.

<sup>389</sup> Lettington (385) 38.

pharmaceutical products.<sup>390</sup> However this letter reflects a fundamental misconception of the meaning of Paragraph 7 of the Doha Declaration.<sup>391</sup>

However some doubt exists as to how countries may proceed to deal with pharmaceutical patents already granted, as the Decision extending the transitional period for LDCs does not seem to terminate existing patent holders' rights under domestic law.<sup>392</sup> Suggestions have been made an LDC declare its intention to suspend patent protection pursuant to the Decision however there is a real risk of a claim from a patent holder unless the national law on suspension or non-voluntary has been properly adhered to.<sup>393</sup>

It is submitted that LDCs will do well to take full advantage of this flexibility and refrain from granting pharmaceutical patents.

#### **4.13 The Decision to amend the TRIPS Agreement**

Paragraph 11 of the 30 August Decision envisioned a permanent solution of article 31(f), wherein the TRIPS Council was tasked with initiating work for the amendment of the TRIPS Agreement by the end of 2003 with a view to the amendment's adoption by the end of six months.<sup>394</sup>

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<sup>390</sup> Lettington (385) 39.

A relevant excerpt of the letter provides as follows;

“Malawi invokes Paragraph 7 of the Doha Declaration on TRIPS and Public Health to request UNICEF to procure generic versions of the attached pharmaceutical products, diagnostic kits and related medical supplies. Malawi notes that footnote 6 of Paragraph 2 (a) (iii) of the 30 August Decision of the General Council of the WTO on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health provides that the subparagraph is without prejudice to article 66(1) of TRIPS. Article 66(1) of TRIPS provides that Malawi and other least-developed countries have a transitional period of 10 years to comply with TRIPS, which had been extended to 2016. This means that Malawi is not currently required to grant a compulsory licence in relation to any products which may be subject to patent within its territory. As required, Malawi will notify the WTO TRIPS Council of the attached list.”

<sup>391</sup> Lettington (fn 385) 39.

The misconception is that Paragraph 7 extends Malawi's general TRIPS implementation until 2016, which is a gross error because Paragraph 7 extends obligations solely with regard pharmaceutical patents.

<sup>392</sup> Masungu (fn 4) 14.

<sup>393</sup> Masungu (fn 4) 15.

<sup>394</sup> The second part of Paragraph 11 states that “ The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred in paragraph 45 of the Doha Ministerial Declaration”

Given the divergent interests of Members, the time deadline laid out in paragraph 11 could not be met. There were disagreements between Members as to the form of the Amendment, with some Members suggesting that it takes the form of a footnote to article 31 of the TRIPS Agreement.<sup>395</sup> Members opposed to the footnote proposal regarded this suggestion as an attempt to downplay the significance of the Decision and upgrading of the Chairperson's Statement, they therefore argued for a full incorporation in the TRIPS Agreement.<sup>396</sup>

Finally consensus was reached on 6 December 2005 when the General Council adopted the Decision on the Amendment of the TRIPS Agreement making permanent the 30 August Decision, barely a week before the Hong Kong Ministerial Conference.<sup>397</sup>

#### **4.13.1 Article 31 *bis***

The amendment which will insert a new article, namely article 31 *bis*, designed to mirror the 2003 waiver as closely as possible comprises of 5 paragraphs under article 31 *bis* (i.e. an additional article after article 31).<sup>398</sup>

The first paragraph permits the export to countries lacking the sufficient manufacturing capacity of pharmaceutical generic-version products manufactured under compulsory licences. The second paragraph deals with article 31(h) waiver, the flexibility granted to regional trade agreements involving developing countries and LDCs is dealt with in paragraph 3. The issue of "non-violation" is addressed in paragraph 4, which provides that Members may not use article XXIII of GATT

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<sup>395</sup> Hestermeyer (fn 53) 273.

<sup>396</sup> Hestermeyer (fn 53) 273.

<sup>397</sup> WT/L/641 Decision on the Amendment of the TRIPS Agreement adopted by the General Council, 6 December 2005. Available online at . The Decision to amend the TRIPS Agreement came a week after Members adopted the Decision to extend the transitional period for LDCs in complying with their TRIPS obligations. [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm) accessed on 19/02/09

<sup>398</sup> "Members ok amendment to make health flexibility permanent", 6 December 2005. At this time Norway, Canada and India had informed the WTO that their laws implementing the waiver are complete, while the Republic of Korea and the EU intimated that their new laws were on the verge of coming into force. Available online at [http://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr426_e.htm) accessed on 10/02/09.

1994 to challenge measures taken in terms of article 31 *bis*.<sup>399</sup> Paragraph 5 retains all existing flexibilities under the TRIPS Agreement.

A new annex to the TRIPS Agreement, which also contains the same provisions as the 30 August Decision, adds a further 7 paragraphs setting out the terms for using the system, definitions, notifications, measures to prevent diversion of pharmaceutical products into the wrong markets, developing regional systems to allow economies of scale and annual reviews in the TRIPS Council. An “appendix” to this annex addresses with assessing lack of manufacturing capacity in the importing country, this was originally an annex to the 2003 Decision. The new article 31 “bis” and annex of the TRIPS Agreement are attached to a Protocol of Amendment. This was then attached to a General Council Decision adopting the Protocol and opening it for members to accept it by 1 December 2007.

#### **4.13.2 Article X Marrakesh Agreement Establishing the WTO**

Article X of the Marrakesh Agreement in article X deals with the issue of amending of the multilateral trade agreements.<sup>400</sup> Article X (3) deals with the procedure relating to the coming into force of amendments.<sup>401</sup>

From these provisions the amendment will only come into force upon acceptance by a two thirds majority of the WTO’s Membership. Once the two thirds majority has formally accepted it, the amendment will become effective on those Members and will replace the 2003 waiver for these countries. For each of the remaining Members the waiver will continue to apply until that member accepts the amendment and it takes effect. To date only twenty one Members have accepted

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<sup>399</sup> Fn 231.

<sup>400</sup> Article X titled “amendments” , in paragraph 1 it deals with issues at to the procedure of amending any of the multilateral trade agreements, how proposals to amend are to be tabled among other things.

<sup>401</sup> Paragraph 3 provides that “amendments to the multilateral trade agreements of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have accepted them upon acceptance by two thirds of the Members and thereafter for each Member upon acceptance by it.”

the amendment the first acceptance was by the United States on 17 December 2005 with the latest acceptance being made on 26 January 2009 by Albania.<sup>402</sup>

At a glance of Members who have accepted the amendment, the absence of African countries is conspicuous. The question which then begs an answer is why this is so particularly in light of the fact that the Doha Declaration was adopted at the prompting of the Africa Group and other developing Member countries. It is the Declaration which ultimately led to the adoption of the 30 August Decision and later the Decision to amend the TRIPS Agreement.

One would therefore naturally expect developing countries and LDCs to exhibit some enthusiasm by accepting the amendment. This has obviously not been so and this could be pointing to the ineffectiveness of the system, the unwieldy and cumbersome process involved which has made these countries reluctant to adopt the amendment. This should be an indication to the WTO itself that the step to make permanent the waiver was not the best option as the waiver itself is flawed.

Members of the WTO had originally set 1 December 2007 as the deadline for acceptance of the amendment.<sup>403</sup> This deadline was not met because by 1 December 2007 only 14 countries had accepted the amendment. In 2008 the deadline was further extended by the Decision to extend deadline to 31 December 2009 for accepting TRIPS Agreement amendment with the possibility of a further extension if the deadline is not met.<sup>404</sup>

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<sup>402</sup>List available online at [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (accessed on 15/04/09).

<sup>403</sup> Paragraph 2 of the Decision to amend the TRIPS Agreement stipulates that “the Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.”

<sup>404</sup> WT/L/711 “Decision to extend deadline for accepting TRIPS Agreement amendment” wherein Members agreed that the period for acceptance by Members of the Protocol Amending the TRIPS Agreement “shall be extended until 31 December 2009 or such later date as may be decided by the Ministerial Conference.”

#### **4.13.3 The General Council Chairperson's Statement**

It must be noted that Members had to agree on the text of the Chairperson's Statement that was to be delivered before the adoption of the Decision amending the TRIPS Agreement by the Council.<sup>405</sup>

The Statement made by the Chairperson prior to the Decision amending the TRIPS Agreement mirrors the Chairperson's Statement delivered at the adoption of the 30 August Decision.<sup>406</sup> A unique feature of the 2005 Statement is that it makes reference to non-violation complaints and stipulates that "paragraph 4 of article 31 *bis* in the proposed amendment is not with prejudice to overall question of the applicability of sub-paragraphs 1(b) and 1(c) of article XXIII of GATT 1994."<sup>407</sup> As already discussed earlier there is lack of agreement as to the status of the Chairperson's Statement.<sup>408</sup>

The decision to amend the TRIPS Agreement drew mixed reactions from stakeholders in the sphere of access to medicines. In a WTO press release the Director General Pascal Lamy applauded the this amendment as "confirming once again that Members are determined to ensure the WTO's trading system contributes to humanitarian and development goals."<sup>409</sup>

In addition the Decision means that for the first time in the history of the international trade body a core WTO trade agreement will be amended.

#### **4.13.4 Reactions to the Decision to amend the TRIPS Agreement**

At a press conference soon after the adoption of the decision the General Council Chairperson was quoted as saying that the decision to amend the TRIPS

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<sup>405</sup> Hestermeyer (fn 53) 274.

<sup>406</sup> Fn 235.

<sup>407</sup> Fn 231.

<sup>408</sup> Fn 235.

<sup>409</sup> Press/ 426 "Members ok amendment to make health flexibility permanent", 6 December 2005. Available online at [http://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr426_e.htm) (accessed on 10/02/09).

Agreement was “extremely important”, that “gives the WTO a very human face”.<sup>410</sup> The Chairperson further said that the waiver “had delivered”, although at that time it had not been used by any country, its success could not be judged by the frequency of its use, as just the fact that the system was in place could bring comfort, therefore it is not flawed just because it had not been used. According to the Chairperson the waiver had done just what it had set out to do, namely address the public health issue and crisis in poor countries and it had also worked to lower prices on medicines for diseases such as HIV/AIDS. The General Council’s Chair attributed the non-use of the mechanism to the fact that it took time for countries to implement necessary changes in domestic laws and that up to that time it had been possible to import cheap medicines or active substances from India which only introduced patent protection for pharmaceuticals in that year in 2005, and in light of this there was greater likelihood that countries would now make use of the waiver.

In a press release dated 6 December 2005 MSF<sup>411</sup> “expressed alarm” at the WTO’s Decision to make permanent the waiver of article 31(f) of the TRIPS Agreement. The NGO drew attention to the fact that at that time no single drug had been manufactured and exported in terms of the Decision. Moreover the far better option would have been to delay the amendment giving the opportunity to test and improving the system in practice. MSF was also quoted pointing out the fact that “the amendment does not allow for the procurement medicines through international tendering, which is the most common and efficient way of purchasing drugs” and the decision reflected that the international trade body was “ignoring the day-to-day reality of production and procurement”.<sup>412</sup>

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<sup>410</sup> Fn 244.

<sup>411</sup> “Amendment of the WTO TRIPS Agreement makes access to affordable medicines even more bleak”, 6 December 2005. Available online at <http://doctorswithoutborders.org/press/release.cfm?id=1640> (accessed on 08/04/09).

<sup>412</sup>Fn 244.

#### **4.14 Have the Doha Declaration and 30 August Decision delivered?**

It can be said that the Doha Declaration has had some measure of success particularly with the regard to the use of compulsory licences. It has been shown that there has been an increase of compulsory licences issued after the Doha Declaration in fact it has been the most widely used mechanism among developing countries and the result has been achieved where used. However in light of the fact that a third of the world's population still lacks access to essential medicines (with this figure concentrated in Asia and Africa), it is submitted that the issue of access to medication is still far from being achieved.<sup>413</sup>

It must be noted that the use of compulsory licensing should not over-shadow other flexibilities in the TRIPS Agreement. In this regard India's Amendment in 2005 is a noteworthy case in point wherein the other flexibilities such as bolar exception and exclusions from patentability have been incorporated into domestic legislation. This however has still been met with resistance by the pharmaceutical industry as well as some developed countries.

After the Doha Declaration's adoption, countries implementing the flexibilities have expressly relied on the Declaration's spirit, purport and provisions. It is submitted that in this regard the Declaration has achieved its purpose in terms of providing legal backing to substantiate developing countries' implementation. Therefore it will be difficult for industrialized countries to challenge these actions if they are TRIPS compliant and are based on the Declaration.

Indeed the Doha Declaration has been cited as one of the major causes for the decline on prices for ARVs.<sup>414</sup> With regard to the 30 August Decision it has been although it is by no means the panacea to the prevalent HIV/AIDS pandemic and a host of other public health problems facing developing countries, it does however

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<sup>413</sup> Kerry (fn 34) 2.

<sup>414</sup> Avafia "TRIPS and public health: the unresolved debate" *Tralac Trade brief* (2005) 3. Others examples cited include the law suit brought by the pharmaceutical industry against the President of the Republic of South Africa, Brazil's threats to issue compulsory licences, donations of ARVs by pharmaceutical companies, as well as the massive lobbying by NGO groups.

constitute a helpful piece of a much larger public health puzzle.<sup>415</sup> Indeed the Doha Declaration recognizes in Paragraph 2 that the TRIPS Agreement is part of the wider national and international action to address these problems.

The thesis has shown clearly that the issue of access to essential medicines is not confined to HIV/AIDS as the anthrax episode in USA and Canada, Thailand's Plavix compulsory licence have all demonstrated. Ultimately the issue of what medicine can be classified as "essential" within a particular is entirely a matter to be determined by a country taking into account its unique needs.<sup>416</sup>

The lack of appropriate legislation in many developing countries to incorporate under the TRIPS Agreement and the Doha Declaration has remained a key challenge.<sup>417</sup> This is significant because the TRIPS flexibilities are not self-executing, they require legislative implementation. Although some developing countries have enacted legislation to take advantage of some of the flexibilities, there are significant legislative and administrative obstacles confronting the introduction and implementation of the flexibilities.<sup>418</sup> In addition IP protection in many developing countries and LDCs is "TRIPS-plus", that is, often stronger than the minimum required by the TRIPS Agreement.

The utilization of the flexibilities can indeed promote access to medicines in developing countries.<sup>419</sup> Their implementation has seen an increased number of people accessing the medication as well as well as the significant price reductions of the drugs either through generic versions entering the market or the patent holders reducing the prices.

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<sup>415</sup> Abbott (fn 51) 318.

<sup>416</sup> Fn 3.

<sup>417</sup> Kerry (fn 34) 5.

<sup>418</sup> "Access to medicines in under-served markets: What are the implications of changes in intellectual property rights, trade and drug registration policy." (2004) *A DFID HRSC Overview Paper (drawing on seven studies) Commissioned by DFID UK 6*. Available online at [http://www.dfidhealthrc.org/publications/atm/DFID\\_synthesis\\_aw.pdf](http://www.dfidhealthrc.org/publications/atm/DFID_synthesis_aw.pdf) (accessed on 04/10/08)

<sup>419</sup> Musungu (fn 4) xii.

On a more positive note Thailand must be commended for making use of compulsory licensing in order to address the public health concerns of its citizens, and ensure universal access to medicines pursuant to its National Health Security Act. It is regrettable that Thailand's exercise of the legitimate flexibility, once again, has been met with stiff opposition from the pharmaceutical industry as well as the USA administration as evidenced by the placing of Thailand on the USA's Special 301 Watch List. The actions by the USA and the pharmaceutical industry are in stark contradiction with the Doha Declaration which stipulates in Paragraph 4 that the TRIPS Agreement "can and should be interpreted" in a way that supports "Members' right to protect public health and in particular to promote access to medicines for all".

It has been suggested that these reactions by the industry could possibly be one of the reasons deterring Members from fully utilizing the flexibilities.<sup>420</sup> The actions by Thailand should actually serve as motivation for other developing countries, because none of the pharmaceutical companies have taken the matter to the WTO's Dispute Settlement Body because it based on the Doha Declaration. This should be taken as an indication that even the WTO will not find in favor of the industry provided that such flexibilities are implemented in a TRIPS-compliant manner. The inclusion of Thailand by the USTR on the Special 301 Watch List leaves a lot to be desired. Despite the USA's assurances that it is committed to the Doha Declaration its actions and those of the pharmaceutical industry reverse the gains developing countries made by the adoption of the Doha Declaration.

With regard to the issue that the Decision has only seen one drug being imported under the system it has been suggested that the reason could be that many of the first line ARVs are "pre-TRIPS", meaning that they are not patented in India and therefore generic versions are still available.<sup>421</sup> However as pharmaceutical product patents have to be granted in all countries (except in LDCs) it is hoped that the system will be used more often.

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<sup>420</sup> Hestermeyer (fn 295).

<sup>421</sup> Hoen (fn 221) 37.

The 30 August Decision's widely noted cumbersome administrative procedures, the fear by developing countries that using the system might attract economic sanctions, inter alia, were confirmed by the amendments to Canada's Patent Act. In 2006 CIPIH made recommendations that the system be kept under review taking into account changes that might be needed to make the system more effective.<sup>422</sup> On this point it is important to note that paragraph 8 of the 30 August Decision requires annual reviews of the Decision by the TRIPS Council with the annual reports to the General Council. It is submitted that if there is constant usage of the system, it might serve to highlight even more its flaws which might provide impetus for its review.

There is certainly hope that if developing countries are able to overcome the attendant administrative burdens in the 30 August Decision, there may be long term benefits realised regarding access to medicines.<sup>423</sup>

#### **4.14.1 Dutch episode**

The confiscation of a consignment of drugs by the Dutch customs en route to Brazil from India in December 2008 sparked indignation among developing countries and put the issue of access to medicines back on WTO's agenda.<sup>424</sup> In response India and Brazil reportedly raised the issue first with the General Council on the basis that such action could not be reconciled with the Doha Declaration's terms. When Brazil raised the issue with the TRIPS Council it is reported to have revealed that based on its investigations there was evidence to suggest that the losartan incident was neither isolated nor exceptional as its investigations showed that such similar incidents had occurred. The incident was also described as one of the most

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<sup>422</sup> Hoen (fn 221) 37 .

<sup>423</sup> Matthews, "History repeating itself? The outcome of negotiations on access to medicines, the HIV/AIDS pandemic and intellectual property rights in the World Trade Organization" (2004) 1 *Law, Social Justice and Global Development Journal* 12.

<sup>424</sup> "Access to medicines back on centre stage at the WTO, Bridges" Weekly News Update (March 2009) 13. Available online at <http://ictsd.net/i/news/bridges/44203/> (accessed on 30/03/09).

troubling post Doha Declaration actions affecting the public health interests of developing countries.<sup>425</sup>

It is apparent that such actions by some developed countries are not assisting the realisation of the spirit and purpose of the Doha Declaration.

#### **4.14.2 The research and development gap**

The issue of access to essential medicines is closely linked to R & D issues. In the first place for one to talk about access to essential medicines, the medicines themselves must be available. The reality is that if the medicines are not available then there can never be access, in other words, access to essential medicines is dependant on the availability of the drugs which is naturally determined by the funding invested into R & D for the diseases.

It is regrettable that the Doha Declaration and the Paragraph 6 Decision do not address the pivotal issue of underinvestment in R & D for health conditions that principally affect developing countries.<sup>426</sup> Statistics have indicated that the global spending on health research is skewed towards the world's wealthy markets, with 90 percent of the spending directed at health problems of less than 10 percent of the world's population, commonly referred to as the 10/90 gap.<sup>427</sup> Medical innovation is directed towards drugs that give commercial needs, not the greatest therapeutic benefits, while diseases that take the heaviest toll among the world's poor do not attract much in the way of investment into R& D and therefore remain grossly insufficient.<sup>428</sup>

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<sup>425</sup> Abbott, "Worst fears realised: the Dutch confiscation of medicines bound from India to Brazil" Bridges Weekly News Update 13 (March 2009). Available online at <http://ictsd.net/i/news/bridges/44192/> ( accessed on 30/03/09).

<sup>426</sup> Kerry (fn 34) 4.

<sup>427</sup> Kerry (fn 34) 5.

<sup>428</sup> "What is wrong with R& D today?" MSF Publications. Available on line at <http://www.msfaccess.org/main/medical-innovation/introduction-to-medical-innovation/what-is-wrong-with-r-d-today/> accessed on 12/04/09.

A study revealed that in addition to the research gap, there appears to be an even greater medical information gap between the world's rich and poor countries, with diseases ravaging poor countries being significantly under reported.<sup>429</sup>

### **The Report by the CIPIH**

Fortunately the WHO addressed the issue of R& D. In April 2006 the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) released a report wherein it concluded that the problems of access to medicines and medical innovation had to be addressed together and that addressing this nexus is important if the problem is to be solved.<sup>430</sup> The Report highlighted the fact that even though new products may be developed, such innovation is of no value if the medicine cannot be made available and accessible to those in need.<sup>431</sup>

The Report also noted, with concern, that current government policies including incentive and funding mechanisms, both in developed and developing countries have not generated sufficient innovation relevant to the needs of most developing countries.<sup>432</sup> Numerous well considered recommendations were then proffered among them were: governments of developed countries should devote a growing proportion of their total health R&D funding to the health needs of the developing world. Developing countries were also advised to establish, implement and strengthen national programmes for health research, with appropriate political support and long term funding.<sup>433</sup>

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<sup>429</sup> Lown, The developing world and The New England Journal of Medicine (2006) 2 Globalization and Health 1. Available online at <http://www.globalizationandhealth.com/content/2/1/3> (accessed 14/04/09).

The study examined 416 weekly issues of the New England Journal of Medicines over an 8 year period between January 1997 and December 2004. It revealed that less than 3 percent of these publications dealt with health issues specific to the developing world. With regard to other medical publications, the study showed that 8 industrialised countries accounted for close to 85 percent of scientific articles, while 163 low- income countries only contributed a paltry 2,5 per cent.

<sup>430</sup> "Public Health, Innovation and Intellectual Property Rights- Report of the Commission on Intellectual Property, Innovation and Public Health". Available online at [http://www.msfaaccess.org/fileadmin/user\\_upload/medinnov\\_accesspatents/CIPIH%20report.pdf](http://www.msfaaccess.org/fileadmin/user_upload/medinnov_accesspatents/CIPIH%20report.pdf) (accessed on 03/05/09).

<sup>431</sup> (Fn430) 97.

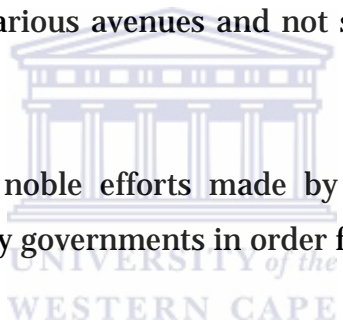
<sup>432</sup> (Fn 430) 172.

<sup>433</sup> (Fn 430) 175.

Subsequent to the CIPIH's recommendations the Intergovernmental Working Group for Public Health, Innovation and Intellectual Property (IGWG) was established to examine ways to encourage innovation while improving access.<sup>434</sup> In negotiation sessions of the IGWG, Ministers of Health and WHO were tasked with formulating a strategy and plan of action to address the twin problems of access to medicines and the lack of R & D into diseases mostly affecting the poor. Although governments agreed on a decision to pursue discussions on an essential health and biomedical R & D treaty, minimal progress was made with regard to IP issues and these remain contested.<sup>435</sup>

The proposed R & D treaty is based on recommendations made by Hubbard and Love, who propose a trade framework with emphasis on equitable contribution to the cost of R& D through various avenues and not solely through the granting of patent rights.<sup>436</sup>

It is submitted that these noble efforts made by CIPIH AND IGWG need to be matched with political will by governments in order for the recommendations to be effected.



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<sup>434</sup> “Reshaping a new R & D agenda”, MSF Publications. Available online at <http://www.msfacess.org/main/medical-innovation/introduction-to-medical-innovation/shaping-a-new-r-d-agenda/> (accessed on 03/05/09).

<sup>435</sup> “IGWG negotiations progress- UN health talks make progress on R & D, but run out of time” MSF Publications. Available online at <http://www.msfacess.org/main/medical-innovation/igwg-negotiations-progress/> accessed on 03/05/09

<sup>436</sup> Hoen (fn 221) 97.

## **CHAPTER 5:**

### **Conclusion and Recommendations**

#### **5.1 Conclusion**

The tensions that exist between developing countries, on the one hand, and developed countries on the other hand in issues of access to essential medicines are nothing new. They are simply a replication of the same differences that existed at the time when the TRIPS Agreement was being negotiated up until it was finally adopted in 1994.

The flexibilities, the Doha Declaration and the 30 August Decision represent a middle ground between the competing interests. In light of the foregoing discussion it can be said that although there have been successes by some countries in implementing the flexibilities; there has been the same resistance that developing countries have always faced from the pharmaceutical industry and developed Members in the pre-Doha era.

While the Doha Declaration as well as the subsequent 30 August Decision cannot be described as absolute successes, they do however represent a commendable step forward in addressing the realities that exist among the world's poor. However there is a lack however of political commitment by industrialized countries in respecting these decisions taken in the multilateral trading system. Therefore there is still a long way to go in ensuring that access to medicines for all is achieved.

#### **5.2 Recommendations**

It is recommended that developing countries make full use of the full range of flexibilities where they have not done so; an example in this regard is India's 2005 Amendment, in order to address their public health concerns by making available lower priced medicines. It has been suggested that implementing this policy space by developing countries does not prejudice the interest of developed Members or

the pharmaceutical industry because the industry is not significantly dependant on profits from developing countries.<sup>437</sup>

With regard to LDCs it is a considered recommendation that they must take full advantage of the 2002 Decision extending the transition period for LDCs regarding their pharmaceutical obligations, wherein they are not obliged to grant pharmaceutical patents until 2016. It is suggested that where LDCs have granted pharmaceutical patents, they are allowed to “roll back” on these patents and use their transition as article 65(1) does not apply to article 66 (1).<sup>438</sup>

Developed Member countries should incorporate in their domestic laws, the provisions of the 30 August Decision whose main advantage is that it enables the production of pharmaceutical products wholly for export to members lacking manufacturing capacity.<sup>439</sup> Other developed Members can take a leaf from Canada’s Patent Act, for example, on the issue of “adequate remuneration”, as well as “reasonable” time before a compulsory licence can be granted. However, the other features of Canada’s regime, such as the limited list of products, must be avoided at all costs. Developed country governments must bear in mind that incorporating the 30 August Decision’s provisions into their domestic laws is not just a matter of mere convenience or political choice but that the Decision has created international obligations that must be complied with in good faith.<sup>440</sup>

Paragraph 3 of the proposed article 31 *bis* whose purpose it harness economies of scale with the aim of enhancing purchasing power for and facilitating, the local production of pharmaceutical products. It allows for the re-exportation of products under the system to another Member without issuing another licence within the same regional configuration provided that more than half of the Members are designated as LDCs by the United Nations. This flexibility was included with African countries in mind.

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<sup>437</sup> Abbott (fn 59) 6.

<sup>438</sup> Hestermeyer (fn 53) 73

<sup>439</sup> Mmeta (fn 245) 8.

<sup>440</sup> Correa(fn 230) 8.

The criticism levelled against cumbersome procedures in the 30 August Decision as well as the 2005 Decision to amend the TRIPS Agreement is deserved. Indeed these two instruments do not represent the most advantageous remedy for those seeking a simple and expeditious mechanism allowing the issuance of compulsory licences.<sup>441</sup> However, what must be borne in mind these instruments are the product of a long and protracted negotiating process involving very divergent views with regards to an “optimal solution”.<sup>442</sup> With that in mind these two instruments represent a formal lowering of IP protection,<sup>443</sup> which must be taken advantage of. Since the 30 August Decision has only been used once by Rwanda, there is a lack of substantial empirical evidence to support either recommending acceptance of the Amendment or declining acceptance.<sup>444</sup> It has been suggested that seeking an “improved deal” is not possible in the prevailing global political climate; however, the Amendment has the potential to bring net gains to the public health sector.<sup>445</sup> These and other considerations must inform the choice to either accept or reject the Amendment.

Countries must boldly use the full range of the flexibilities in order to satisfy their public health needs. In light of the preceding discussion it is a considered recommendation that developing countries make efforts to use the 30 August Decision in order to address their public health needs. Even though the Decision is still an interim solution, the granting of licences and waivers under the Decision will not be challenged, in all probability, if implemented in compliance with the Decision.<sup>446</sup> Furthermore, as already discussed paragraph 10 of the Decision actions taken under its provisions will not be the subject to dispute settlement.

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<sup>441</sup> Abbott(fn 39) 932.

<sup>442</sup> Abbott(fn 39) 933.

<sup>443</sup> Abbott (fn 39) 933.

<sup>444</sup> Abbott (fn 39)933.

<sup>445</sup> Abbott (fn 39) 933

<sup>446</sup> Gervais (fn 36) 58.

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