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## ***Compulsory Licensing of Patents: the Bayer-Natco Case***

*On 9<sup>th</sup> March 2012 the Indian Controller of Patents granted the first compulsory licence in India. Indian generics producer Natco Pharma Ltd. has been granted the right to produce and sell in India Bayer's patented medicine "Sorafenib", which is useful for treating advanced stage liver and kidney cancer.*

*After a brief introduction on compulsory licences under the TRIPS Agreement and the Paris Convention, the author verifies whether the decision of the Controller of Patents satisfies the conditions set forth by these international treaties in relation to compulsory licences. He concludes inter alia that the ruling might be in violation of the non discrimination principle enshrined in Article 27(1) TRIPS.*

*General comments are also made about the role of compulsory licensing in guaranteeing the availability of patented products to a wide range of consumers and in general the transfer and dissemination of the associated technology.*

### *Introduction*

On 9<sup>th</sup> March 2012 the Indian Controller of Patents granted the first compulsory licence in India<sup>1</sup>. Indian generics producer Natco Pharma Ltd. has been granted the right to produce and sell in the Indian territory Bayer's patented medicine "Sorafenib", which is useful for treating advanced stage liver and kidney cancer<sup>2</sup>. Natco will pay Bayer a quarterly royalty at 6% of the net sales of the drug.

Bayer extended its patent application to India in 2001 and the registration was granted in said country in March 2008. Bayer was granted regulatory approval for marketing the drug in question (commercially known as "Nexavar") in India in 2008.

The Controller considered that Bayer had not sold the medicine in India at all in 2008 with only small quantities sold in 2009 and 2010. Thus, according to the Controller, Bayer was not making the drug accessible to many needy Indian patients.

In the following paragraphs, after a brief introduction on compulsory licences under the TRIPS Agreement and the Paris Convention, the author will verify whether the decision of the Controller of Patents satisfies the conditions set forth by these international treaties and in particular Article 31 TRIPS. General comments will also be made about the role of compulsory licensing in guaranteeing the availability of patented products to a wide range of consumers and in general the transfer and dissemination of the associated technology.

### *Compulsory licences under TRIPS. How the Natco/Bayer licence fits in*

As is known, compulsory licences allow third parties to exploit a patented invention without the consent of the patentee. They therefore deprive patentees from their most important right, *i.e.* the right to say "no" to the exploitation of their invention by third parties<sup>3</sup>. Compulsory licences are

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<sup>1</sup> The Indian Office of the Controller General of Patents, Designs & Trade Marks administers the Indian Patent Office. It is a subordinate office of the Indian government and in general administers the Indian law of Patents, Designs and Trade Marks.

<sup>2</sup> The decision can be downloaded at [http://www.ipindia.nic.in/ipoNew/compulsory\\_License\\_12032012.pdf](http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf) (last accessed on 20 April 2012).

<sup>3</sup> N. Pires de Carvalho, *The TRIPS Regime of Patent Rights* (London, The Hague, New York, Kluwer Law International, 2002), p. 231.

usually granted through administrative procedures managed by a governmental body<sup>4</sup>. As has been noted “*compulsory licences are granted by governments which, thereby, substitute their authority for the consent of the patent owner. Compulsory licences are administrative contracts*”<sup>5</sup>.

These licences are different from the so-called “licences of right” envisaged by some national legislations as well as Article 43 of the Community Patent Convention (CPC). Licences of right are basically a mix between compulsory and voluntary licences and their issuance is triggered by patentees through an offer to the public: ie the patentee files a written statement with the patent office that it is ready to allow any third party to use its invention as a licensee in return for appropriate compensation.

Article 31 TRIPS addresses compulsory licences and sets forth the conditions for their issuance. Its wording does not include the term “compulsory licence”, but it generally refers to “*Other Use Without Authorization of the Right Holder*”. This is probably due to political reasons and in particular to the fact that the Uruguay Round negotiators wanted to avoid using a strong word: indeed the term “compulsory licence” might have been perceived, especially in industrialized and R&D intensive countries, as synonym of expropriation of property rights. In the old days it had been ironically noted that “*compulsory licensing was a derogation of the right of property and compared the inventor subject to such licensing to a man who owned his house but was required to allow all who requested it, to live with him on the payment of a rental*”. This is the opinion of a prominent French lawyer, M. Charles Lyon-Caen, expressed at the Paris Conference in 1878 during the negotiations that led to the adoption of the Paris Convention<sup>6</sup>.

Yet the term in question does not constitute anymore a taboo in the context of WTO and TRIPS, as it has been used in the Doha Declaration on the TRIPS Agreement and Public Health (this declaration was adopted on 14 November 2001 by the WTO Ministerial Conference and strongly reaffirmed the rights of WTO Member States to use the flexibilities envisaged by TRIPS with a view to guaranteeing better access to essential medicines).

Article 31 TRIPS does not expressly state that compulsory licences should be made available by States. It just clarifies that “[W]here the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder [...] the following provisions shall be respected”. Moreover, it does not limit the grounds upon which the licences can be granted, thus leaving states free to establish the relevant grounds. This is buttressed by Paragraph 5(b) of the above Doha Declaration, according to which “*each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted*”. This freedom however should not boil down in states being entitled to grant compulsory licences in an arbitrary and unjustified way<sup>7</sup>.

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<sup>4</sup> For an historical analysis of some legislations on compulsory licences see J. H. Reichman – C. Hasenzahl, *Non-voluntary Licensing of Patented Inventions – Historical Perspective, Legal Framework under TRIPS, and An Overview of the Practice in Canada and the USA*, UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No. 5, Geneva, 2003 (available on the Internet at [www.ictsd.org/pubs/ictsd\\_series/iprs/CS\\_reichman\\_hasenzahl.pdf](http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf), last accessed on 20 April 2012). For a list of recent cases of compulsory licences see R. Beall – R. Kuhn, *Trend in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, in *PLoS Medicine*, Volume 9, Issue 1, January 2012.

<sup>5</sup> Pires de Carvalho, above note 3, p. 230.

<sup>6</sup> E. Penrose, *The Economics of the International Patent System* (1951), in F. Abbott – T. Cottier – F. Gurry, *The International Intellectual Property System. Commentary and Materials* (The Hague, London, Boston, Kluwer Law International, 1999), pp. 640-641.

<sup>7</sup> Pires de Carvalho, above fn. 3, p. 232. Yet it should be noted that the US recently entered into several free trade bilateral or multilateral treaties with other countries, these agreements limiting the grounds upon which compulsory licences can be granted: eg just in cases of national emergencies, circumstances of extreme urgency, and unfair competition. See the treaties signed between US and Australia in 2004 (Article 17, para. 9.7) and between US and Singapore in 2003 (Article 16, para 7.6).

It can therefore be inferred that the TRIPS Agreement accepts that under certain circumstances, especially in developing and least developed countries, public interest in accessing and exploiting patented technologies should prevail over patentee's private interests<sup>8</sup>. Compulsory licences may thus constitute an important tool for governments to assure the availability of patented products to the public, especially pharmaceuticals, e.g. when such products are not sold by the patentee, their prices are unaffordable<sup>9</sup> or generally in situations of extreme urgency.

Having said that, it seems that the compulsory licence in Natco/Bayer falls within the above circumstances.

As noted by the Controller of Patents, Bayer had not imported the Nexavar at all in 2008 with only small quantities sold in 2009 and 2010<sup>10</sup>. In the proceedings Bayer argued that Cipla, another generic drugs manufacturer marketed a generic version of the drug in India at a low price since April-May 2010, such that no objection regarding the medicine's availability could be legitimately raised. However, the Controller noted that Bayer itself had sued Cipla for patent infringement and thus the sales of an alleged infringer should not be taken into account to support Bayer's position (it is the patentee's conduct, stressed the Controller, which is relevant in these circumstances). Further, Cipla runs the risk of its sales being enjoined by a court as a consequence of Bayer's legal action and Indian patients who suffer from liver and kidney cancer cannot be left at the mercy of an uncertain drug supply. The Controller further emphasised that Bayer relied on an inadmissible two-faced approach. On the one hand, in the administrative proceedings against Natco tried to convince the Controller that the availability of the medicine was not at risk due to Cipla's sales of the corresponding generic drug. On the other hand, in the proceedings against Cipla the patentee sought to stop its competitor from distributing a generic version of the drug, which would reduce its availability in the Indian market<sup>11</sup>.

The Controller also found that the price of the patentee's drug Nexavar was unaffordable to Indian consumers and thus unreasonable<sup>12</sup>. Indeed, Bayer's Nexavar-based therapy cost Rs. 280,000 (around US\$ 5,404) per month and Rs. 3,365,136 (around US\$ 64,947) per year. As Natco submitted, an Indian public sector worker would have to work for three and a half years to be able to buy a single month's treatment at the above price. As the life expectancy of this category of patients is not more than four months, that worker would not have time to earn the money to purchase the drug. Also considering that 72% of India's population is below the poverty line, the high price would push many patients suffering from kidney and liver cancer into even deeper poverty<sup>13</sup>. In light of the above, the Controller concluded that Bayer's proposed price was not a reasonably affordable one. He also added that the concept of a reasonably affordable price should be construed with exclusive reference to the needs of the public, and not to interests of the patent owner<sup>14</sup>, as Bayer instead suggested. The patentee argued unsuccessfully that the Controller should consider the high cost of R&D and the cost of manufacturing Nexavar when establishing the level of the "reasonably affordable price"<sup>15</sup>.

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<sup>8</sup> UNCTAD/ICTSD, Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, available at <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm> (last accessed on 20 April 2012), p. 461.

<sup>9</sup> J. Watal, *Intellectual Property Rights in the WTO and Developing Countries*, Kluwer Law International, The Hague, London, Boston, 2001, p. 317.

<sup>10</sup> See p. 54 of the decision.

<sup>11</sup> See pp. 11, 15, 20 and 21 of the decision.

<sup>12</sup> See p. 36 of the decision.

<sup>13</sup> See p. 25 of the decision.

<sup>14</sup> See p. 36 of the decision.

<sup>15</sup> See p. 30 of the decision.

The Controller also impliedly held that, if Bayer had adopted a wise policy based on differential pricing for different classes or members of the public, it could have avoided the issuance of the compulsory licence. However, Bayer did not adopt any differential pricing policy. As Bayer itself noted in its affidavit, it sells the drug in question at a similar price to all patients throughout the world, subject to variations in exchange rate<sup>16</sup>.

The Controller also rejected Bayer's argument that the much lower price of Cipla's generic versions – ie Rs 30,000 (around US\$ 579) monthly – should be a relevant factor to be taken into account when determining whether the drug was affordable to local consumers. The Controller promptly dismissed this argument by noting again that Cipla's sales were not relevant for the reasons highlighted above and could not prevent the issuance of the compulsory licence<sup>17</sup>.

The Controller then identified a fair and reasonable price of the drug in question for the Indian market. He found that the price of the medicine manufactured by the licensee under the compulsory licence should not be more than Rs 8,880 (roughly US\$ 171) for a pack of 120 tablets, which is required for one month's treatment<sup>18</sup>. This price is far lower and more affordable than the one chosen by Bayer - Rs 8,880 monthly (roughly US\$ 5,404).

#### *Compulsory licences and the working requirement. How the Natco/Bayer licence fits in.*

Under Article 31 of the TRIPS Agreement compulsory licences can be issued subject to strict requirements<sup>19</sup>. These conditions limit states' freedom of action (in the following paragraph the author will verify whether the Natco/Bayer licence satisfies each of these requirements). They are also more stringent than the requirements set forth in the Paris Convention, which contains just a few provisions regarding compulsory licences. In particular, Article 5(A)(2) of the latter treaty provides that states shall have the right to take legislative measures providing for the grant of compulsory licences in order to prevent any abuse of patent rights, for example failure to work. It also adds that compulsory licences shall be refused if the patentee justifies its inaction by legitimate reasons<sup>20</sup>. This provision therefore does not mandate strict requirements for the issuance of the licence. It does not even cover other kinds of compulsory licences other than licences for failure of working.

Article 5(A)(2) Paris Convention has been incorporated into the TRIPS Agreement as along with Article 5(A)(1)<sup>21</sup>. This latter provision, even though not directly related to compulsory licences, is relevant for the purposes of this analysis. Article 5(A)(1) states that importation of patented products by the patent owner does not entail the forfeiture of the patent. However, the Controller of Patents in Natco/Bayer inferred from this provision that the mere importation of patented goods could still result in and thus justify "*something less than forfeiture, such as a compulsory licence*"<sup>22</sup>. In other words, the Controller held that the mere importation of a patented product does not bar the issuance of a compulsory licence (as we have seen, in the case at hand Bayer imported into India some quantities of its patented drug). Only the local production of the relevant goods by the patent owner or a company authorized by it could prevent said issuance. Yet, this did not occur in Natco/Bayer as Bayer did not produce any pills of Nexavar in India (even though it could have done so). As the Controller noted, the patentee claimed to have manufacturing facilities in India for

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<sup>16</sup> See pp. 35 and 53 of the decision.

<sup>17</sup> See p. 35 of the decision.

<sup>18</sup> See point a) of the order, p. 60 of the decision.

<sup>19</sup> See also D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Sweet & Maxwell, London, 2003, p. 250.

<sup>20</sup> Article 5(A) Paris Convention also provides that compulsory licences "*shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-licence, except with that part of the enterprise or goodwill which exploits such licence*".

<sup>21</sup> See Article 2(1) TRIPS.

<sup>22</sup> See p. 41 of the decision.

several products, including oncology-related drugs, so that there was no obstacle preventing Bayer from locally manufacturing the medicine or in any case from granting a voluntary licence on reasonable conditions to another producer including Natco<sup>23</sup>. The Controller also rejected Bayer's argument that the low quantities of drugs required in India did not justify setting up a manufacturing facility in the country<sup>24</sup>.

In reaching its decision, the Controller also relied on three provisions of the Indian Patent Act, ie Sec. 83(b), (c) and (f)<sup>25</sup>. The first provision states that patents are not granted merely to allow patent owners to enjoy monopolistic rights for the importation of the patented goods. The second one provides that the issuance of patents should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Sec. 83(f) states that patent rights should not be abused so as to unreasonably restrain trade or jeopardize the international dissemination of technology. In particular, Sec. 83(c) and (f) are very important – stressed the Controller – because they confirm that patent owners are obliged to contribute towards the national and international transfer of technology, so as to balance their rights with their obligations. How can the patentees achieve that? The Controller had no doubts: the patent holder should either produce itself the patented product *in loco* or grant a local third party a licence to manufacture it<sup>26</sup>. Oddly enough, in this specific regard<sup>27</sup> the Controller made no reference to neither Article 7 TRIPS (which states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to its transfer and dissemination) and Paragraph 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health according to which, as shown above, countries have “*the freedom to determine the grounds upon which such licences are granted*”.

Having said that, it seems that the Controller's findings do not give due consideration to the TRIPS debate surrounding the working requirement and might be in violation of TRIPS itself. It is indeed believed that the above provisions of the Paris Convention as well as Article 31 TRIPS have to be read and interpreted together with Article 27(1) TRIPS, according to which “*patents shall be available and patent rights enjoyable without discrimination as to [...] whether the products are imported or locally produced*”. In other words, this provision clarifies that where national legislations impose a local working requirement (as the Indian Patent Act does), a patentee should have the opportunity to satisfy such requirement by demonstrating that it has imported the patented product in the country in question. There is no doubt therefore that, contrary to what affirmed by the Controller of Patents in Natco/Bayer<sup>28</sup>, the concept of working under TRIPS includes both the local production of the patented goods and their importation<sup>29</sup>. Article 27(1) has therefore an impact on the issuance of compulsory licences. This conclusion is confirmed by the WTO Panel's decision in *Canada - Patent Protection of Pharmaceutical Products* where it was held that the non-discrimination principle under Article 27(1) also applies to Article 31<sup>30</sup>. It follows that, when resorting to compulsory licences, states are not allowed to discriminate on the basis of whether the products are imported or locally manufactured.

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<sup>23</sup> See p. 45 of the decision.

<sup>24</sup> See p. 39 of the decision.

<sup>25</sup> See p. 43 of the decision.

<sup>26</sup> See p. 43 of the decision.

<sup>27</sup> See pp. 43 and 44 of the decision.

<sup>28</sup> See pp. 41-42 of the decision.

<sup>29</sup> See also Pires de Carvalho, above note 3, pp. 163-164 (noting that the local working requirement had already been assessed and found in conflict with GATT 1947 provisions on prohibition of quantitative restrictions in the dispute *The United States Manufacturing Clause*. The “Manufacturing Clause” (Section 601 of Title 17 of the US Code) prohibited the importation in the US of a copyrighted work which consisted predominantly of non-dramatic literary material in English, whose author was a US domiciliary, unless the portions consisting of such material had been manufactured in the US or Canada).

<sup>30</sup> See the report of the WTO Panel of 17 March 2000, para 7.91, WT/DS114/R.

The insertion of this provision into TRIPS had been unsuccessfully opposed by several developing countries during the Uruguay Round negotiations. These countries believed that – as also noted by the Controller in Natco/Bayer<sup>31</sup> - obliging patentees to locally manufacture the patented product would bring to the state in question human, capital and technological resources associated to the invention, thus contributing in building and strengthening local industries and accelerating technology transfers (which would not take place in case of mere importation of the patented goods)<sup>32</sup>.

Brazil also shared this opinion. In particular, a provision on compulsory licences was included into the Brazilian Industrial Property Code of 1996. It regarded the grounds upon which compulsory licences can be granted and included amongst those grounds the failure to locally manufacture the patented invention<sup>33</sup>. The provision was conceived with specific reference to pharmaceuticals and aimed at strengthening the domestic pharmaceutical industry, especially as far as antiretroviral drugs are concerned. It basically aimed at increasing the contractual power of local producers *vis-à-vis* foreign patentees. Patent owners, indeed, would prefer to grant local manufacturers voluntary licences on reasonable terms rather than passively waiting for the issuance of a compulsory licence. It does not come as a surprise that this provision was challenged by the US at WTO level for an alleged violation of Article 27(1) TRIPS<sup>34</sup>. The case was then amicably settled before a Panel could release a decision<sup>35</sup>. The agreement between Brazil and US provided that, should arise the need to grant a compulsory licence in relation to a patent owned by a US entity pursuant to the provision in question, Brazil shall start negotiations with the US with a view to finding a solution acceptable to both parties. Some commentators criticized such agreement as the availability of the Brazilian government for preliminary negotiations should be extended to all other WTO countries as a result of the application of the most-favored national clause under Article 4 TRIPS<sup>36</sup>. On the other hand, the US withdrew the WTO action, recognizing that until that date the provision in question had never been invoked to issue a compulsory licence and stressing that their initiative did not aim at thwarting Brazil's anti-AIDS programme<sup>37</sup>: a programme which aimed at reducing the prices of patented medicines and accordingly at making them more affordable to needy patients. In a press release of 24 June 2002 the United States Trade Representative labeled the agreement between US and Brazil as “*a positive step in the common fight against HIV/AIDS [...]. It permits more effective and less confrontational consideration of intellectual property issues and ensures that such discussions do not divert attention away from the shared goal of combating the spread of HIV/AIDS*”. As a result of the agreement, also the Brazilian government withdrew an action taken at

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<sup>31</sup> See p. 43 of the decision.

<sup>32</sup> A. Tankoano, *L'accord relatif aux aspects des droits de propriété intellectuelle liés au commerce (TRIPS)*, Droit et Pratique du Commerce International, 20, 1994, p. 456 (sharing the position of several developing countries during the Uruguay Round. The author also notes that in the 70s of last century less than 5% of patented inventions owned by foreign patentees in developing countries had been worked through local production). It has also been argued that a local working requirement could be imposed in derogation of Article 27(1) TRIPS by relying on Article 8(1) of the same treaty. This latter provisions states that countries may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. See G. Ghidini, *Equitable Sharing of Benefits of Biodiversity-Based Innovation: Some Reflections under the Shadow of a Neem-Tree*, in *Italian Intellectual Property*, 2002, pp. 48-49. Yet this opinion is unlikely to be accepted as Article 8(1) itself clarifies that the above measures can be adopted provided that they are consistent with TRIPS provisions (including therefore Article 27).

<sup>33</sup> See Article 68, para 1(I)(II) of Brazilian Law No 9279 of 14 May 1996.

<sup>34</sup> *Brazil – Measures Affecting Patent Protection, Request for Consultations by the United States*, 8 June 2000, WT/DS199/1.

<sup>35</sup> *Notification of Mutually Agreed Solution*, 7 February 2001, WT/DS224/1.

<sup>36</sup> Pires de Carvalho, above note 3, p. 167 (note 462). Article 4 TRIPS states that “[...] any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members”.

<sup>37</sup> Other scholars believe instead that such initiative did aim at thwarting Brazil's programme. See eg F. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, in *Journal of International Economic Law*, 2002, p. 471.

the WTO against the US, such action focusing on two allegedly discriminatory provisions of the US Patent Act (Sec. 204 and 209, Chapter 8), which establish a local working requirement in relation to patents obtained with the federal assistance<sup>38</sup>.

It is likely that both the Brazilian and US provisions in question would have been condemned by WTO Panels for violating Article 27(1) TRIPS, if the cases had not been abandoned. Likewise, for analogous reasons the decision in Natco/Bayer might expose India to a similar challenge at the WTO. As already shown, Article 27(1) TRIPS also applies to compulsory licences, although a more complete and detailed regulation of these licences is given by Article 31. Article 27(1) should therefore be interpreted as not allowing any limitation of patent owner's rights, including the issuance of a compulsory licence, merely because the patentee does not produce locally the relevant goods: exactly what the Controller refused to accept in Natco/Bayer. The author also believes that the above mentioned Paragraph 5(b) of the Doha Declaration on TRIPS Agreement and Public Health (according to which countries have the freedom to determine the grounds upon which such licences are granted) could not be invoked to justify the need of a local production requirement. Such paragraph should indeed be read in the broader context of TRIPS and in particular in light of Article 27(1) which mandates that states should not discriminate as to whether the patented products are imported or locally produced. This interpretation of Article 27(1) is in line with the spirit and aim of TRIPS and WTO (as is known, WTO aims at boosting the international trade of goods) and does not jeopardise public interests such as the protection of health. For example, governments could still issue compulsory licences in case patented products imported by the patentee or with its consent do not satisfy the local demand or are sold at an unaffordable price. This is what happened in Natco/Bayer as Bayer did not import in India the Nexavar at all in 2008 and imported (and sold at a high price) just small quantities in 2009 and 2010. It is believed that invoking only these circumstances would have been more TRIPS-compliant than also relying on a farfetched interpretation of Article 27(1) TRIPS and Article 5(A)(1) of the Paris Convention.

EU law also rejects the local production requirement. In Case C-235/89 the Court of Justice of the European Union (at that time it was called the European Court of Justice) released a decision with reference to the old Italian provisions on compulsory licences, according to which said licences were granted in cases where the patentee did not manufacture locally the relevant products. The Court held that this provision basically had the effect of forcing patent owners to locally produce the patented products rather than to import them from other Member States. The provisions therefore amounted to, the Court found, measures having an equivalent effect to quantitative restrictions on imports under (what is now) Article 34 of the Treaty for the Functioning of the European Union<sup>39</sup>. The arguments put forward by the Court of Justice of the European Union could and should be transposed from the EU to the WTO/TRIPS scenario. Indeed the WTO and the EU share analogous general principles and similar objectives, ie elimination of barriers to trade.

Finally, as we have seen above, the Indian Controller of Patents also based his (incorrect) finding on the local production requirement on *inter alia* a specific provision of the Indian Patent Act, ie Sec. 83(b). This latter provision states that patents should not be granted merely to allow patent owners to enjoy monopolistic rights for the importation of the patented goods. Yet, relying on a national provision to justify its position does not provide a safe harbor for India and thus exclude the alleged infringement of Article 27(1) TRIPS. Indeed, due account must be taken of Article 27 of the Vienna Convention on the Laws of Treaties which states that "*a party may not invoke the provisions of its internal law as justification for its failure to perform a treaty*".

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<sup>38</sup> *United States – US Patent Code, Request for Consultations*, 7 February 2001, WT/DS224/1.

<sup>39</sup> Case C-235/89, decision of 18 February 1992, para. 23.

*The conditions set forth by Article 31 TRIPS. How the Natco/Bayer licence fits in*

We now proceed to verify whether the compulsory licence in Natco / Bayer complies with the conditions specifically required under Article 31 TRIPS. The analysis will be preceded by a concise description of each relevant condition.

(i) Article 31(a) states that the “*authorization of such use shall be considered on its individual merits*”. The wording is not very clear. It is believed that this provision should be interpreted as prohibiting the automatic issuance of compulsory licences, e.g. states could not pass laws providing the automatic granting of compulsory licences in a specific field, or vis-à-vis certain patentees. The compulsory licence in Natco/Bayer satisfies this condition as it was granted in the context of an *ad hoc* administrative proceedings before the Indian Controller of Patents, and not as a result of a local law or regulation automatically providing licences in the pharmaceutical field or just against Bayer.

(ii) Compulsory licences can be granted only where the prospective licensee has made efforts to obtain authorization from the patentee on “*reasonable commercial terms and conditions*” and that such efforts have not been successful within a reasonable period of time (Article 31(b) TRIPS). This provision implies that before applying for a compulsory licence the proposed user has a duty to negotiate a voluntary licence with the patentee and that a compulsory licence can be granted only where the patent holder has arbitrarily refused to enter into a voluntary agreement with the applicant<sup>40</sup>. The concept of reasonableness of terms and conditions is not clearly defined. This is due to the fact that such concept may vary depending on the nature of the technology and on the level of development of the country which grants the licence<sup>41</sup>.

From the decision in Natco/Bayer it is not possible to infer whether the patent owner arbitrarily refused to grant Natco a voluntary licence. The Controller just noted that Bayer categorically refused to grant Natco a voluntary licence without adding any further information<sup>42</sup>. In any case Article 31(b) TRIPS also clarifies that in case of national emergencies, extreme urgency or for public non-commercial use of the patented invention compulsory licences can be obtained without the need to previously start negotiations with the patentee<sup>43</sup>. Having said that, Natco/Bayer seems to be an emergency case. This is impliedly confirmed by the decision of the Controller, which clarifies that Natco shall supply the patented drug to at least 600 needy and deserving patients per year free of cost<sup>44</sup>. It should also be noted that Paragraph 5(c) of the Doha Declaration on TRIPS Agreement and Public Health states that countries have “*the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises [...] can represent a national emergency or other circumstances of extreme urgency*”. This is a corollary of Paragraph 5(b) of the same Declaration according to which, as shown above, states have the freedom to determine the grounds upon which compulsory licences are granted.

(iii) Article 31(d) TRIPS then provides a proportionality rule by stating that the scope of the licence must be limited to the purpose for which it was granted. For example, compulsory licences could be granted only in relation to certain claims of a patent<sup>45</sup>; in a specific field such as in the military sector (excluding authorization in the civilian sector)<sup>46</sup>; for a certain territory<sup>47</sup>. In Natco/Bayer the

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<sup>40</sup> Watal, above note 9, p. 323.

<sup>41</sup> Gervais, above note 19, p. 251.

<sup>42</sup> See p. 10 of the decision.

<sup>43</sup> However, in case of national emergencies and other cases of urgency the patent owner must be notified as soon as reasonably practicable about the issuance of the compulsory licence and in case of public non-commercial use the patent owner must be informed promptly.

<sup>44</sup> See let. h) of the order, p. 61, of the decision.

<sup>45</sup> Gervais, above note 19, p. 251.

<sup>46</sup> UNCTAD/ICTSD, above note 8, p. 472.

<sup>47</sup> Pires de Carvalho, above note 3, p. 238.

scope of the licence seems to be limited. This is confirmed by the following terms and conditions of the compulsory licence: Natco has been given the right to produce the patented drug only at its own manufacturing facility and is prohibited to outsource the production; the licence just covers the use of the patent for treating renal cell carcinoma (RCC) and unresectable hepatocellular carcinoma (HCC) in humans within the Indian territory; moreover, Natco has not been given the right to import the patented medicine<sup>48</sup>.

(iv) Compulsory licences must be non-exclusive. It means that the patentee can continue to exploit the invention and directly compete with the licensee as well as grant any voluntary licences it wishes (Article 31(d)). This condition is met in Natco/Bayer<sup>49</sup>. The Controller indeed held that Bayer is free to do whatever it wants with its residual patent rights and in particular is free to compete with Natco and to grant licences to third parties to compete with Natco<sup>50</sup>. A competitive spiral might thus be triggered, which could be even more beneficial to Indian patients as more competition would push prices further down.

(v) Compulsory licences must also be non-transferable except with the part of the enterprise or goodwill which enjoys such use (Article 31(e)). This provision aims at preventing the development of a market of compulsory licences as instruments with independent value<sup>51</sup>. This condition is also met in the case in question<sup>52</sup>.

(vi) The use of the invention must be authorized “*predominantly*” for the supply of the domestic market of the country authorizing such use (Article 31(f)). This provision compels licensees to sell products for the most part in the country where the compulsory licence is granted. The sale abroad is permitted just in limited cases, eg only involuntary and unintended surpluses may be exported<sup>53</sup>. This condition is also met in Natco/Bayer as the scope of the licence is limited to the production and sale of the patented drug in the Indian territory<sup>54</sup>.

(vii) Under Article 31(g) compulsory licences should expire when the circumstances which led to them cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances. This provision entails that compulsory licences are not automatically granted for the entire duration of the patent. They therefore could be terminated if the conditions under which they were granted are not met anymore<sup>55</sup>. This provision should be read in conjunction with Article 31(c) above<sup>56</sup>.

Having said that, in Natco/Bayer the licence has been granted for the balance term of the patent. There is no reference in the decision of the Controller to the termination of the licence when the circumstances which have justified it cease to exist and are unlikely to recur, eg if and when Bayer starts marketing the Nexavar at an affordable price in India. Yet, the lack of an express reference to a termination of the licence in the ruling is not conclusive and does not entail a violation of TRIPS

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<sup>48</sup> See points c), g) and i) of the order, p. 61 of the decision.

<sup>49</sup> See point d) of the order, p. 61 of the decision.

<sup>50</sup> See lett. m) of the order, p. 62 of the decision.

<sup>51</sup> UNCTAD/ICTSD, above note 8, p. 473.

<sup>52</sup> See point e) of the order, p. 61 of the decision.

<sup>53</sup> Pires de Carvalho, above note 3, pp. 240-241.

<sup>54</sup> See again point g) of the order, p. 61 of the decision.

<sup>55</sup> Article 31(g) TRIPS also takes into consideration the legitimate interests of licensees. Indeed, after the issuance of the compulsory license, they may invest considerable sums of money for the production and marketing of the relevant products, so that it would be unfair if the licence is terminated before licensees have recouped all the investments made in connection with the licence. That is why the provision in question takes pain to stress that the termination of compulsory licences shall be “*subject to adequate protection of the legitimate interests of the persons so authorized*”.

<sup>56</sup> Article 31(c) states that the duration of the licence must be limited to the purpose for which it was granted. Sec. 90(1)(vi) of the Indian Patent Act is in line with this provision, as it states that compulsory licences are “*for the balance of the patent unless a shorter term is consistent with public interest*”.

as Sec. 94(1) of the Indian Patent Act provides that the licence may be terminated by the Controller “if and when the circumstances that gave rise to the grant thereof no longer exist and such circumstances are unlikely to recur”.

(viii) Under Article 31(h) TRIPS the patentee must receive an adequate remuneration depending on the circumstances of each case, taking into consideration the economic value of the licence. Thus, even though a compulsory licence entails a curtailment of patentee’s rights, the latter is entitled to be paid an adequate compensation. This is in line with the very nature of intellectual property rights and in particular the fourth recital of TRIPS which recognizes that said rights are private rights.

It seems that the remuneration to patentee established in Natco/ Bayer – i.e. a royalty rate of 6% of the net sales of the medicine on a quarterly basis<sup>57</sup> - satisfies the above criteria. Indeed, in such a way Bayer receives constant revenue from the production and sale of its patented drugs in a country where the relevant patent has not substantially been exploited thus far. Further, the Controller carefully assessed the royalty practices and guidelines adopted globally and in particular the royalty rate specifically recommended by the United Nations Development Program (UNDP). UNDP recommends that royalty rates be set at 4% and modified upwards as much as 2% in case of products of particular therapeutic value. Controller was therefore satisfied that in this case anything lesser than 6% would not be an adequate remuneration<sup>58</sup>.

*Another condition of the Natco/Bayer licence: avoiding confusion between Natco and Bayer products*

The Controller also ordered Natco not to represent publicly or privately that its drugs are the same as Bayer’s ones or that the two companies are in any way associated. In particular, Natco’s medicines should be visibly different from Bayer’s drugs, eg in color and/or shape; the trade name and packaging should also be different from the patentee’s ones<sup>59</sup>. These conditions aim at guaranteeing that, in case Bayer starts selling again the Nexavar in India, Indian consumers do not get confused and can make educated choice. Said requirements echo analogous conditions set forth in the Decision of the WTO General Council of 30 August 2003 which implemented Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (this decision envisaged the so-called “waiver”, which removes the limitation on exports under compulsory licence to countries that cannot manufacture the patented pharmaceuticals themselves<sup>60</sup>). Paragraph 2(b)(ii) of this decision as well as the recently proposed Article 31-*bis* TRIPS<sup>61</sup> clarify that products manufactured under the licence shall be clearly identified as being produced under the system in question through specific labeling or marking and that suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves.

*Other recent cases of granted or threatened compulsory licences*

As mentioned above, in Natco/Bayer the Indian government has issued its first compulsory licence (the decision has been appealed by Bayer, though). Government usually rely on this tool as *ultima ratio* (ie last resort), when the negotiations between the patent holder and the prospective licensee break down. Sometimes, just the threat of a compulsory licence persuades patentees to soften their negotiating position<sup>62</sup>. They therefore may choose to accept the terms and conditions proposed by

<sup>57</sup> See point f) of the order, p. 61 of the decision.

<sup>58</sup> See p. 60 of the decision.

<sup>59</sup> See point k) of the order, pp. 61-62 of the decision.

<sup>60</sup> The limitation is provided by the above mentioned Article 31(f) TRIPS.

<sup>61</sup> In December 2005 the decision of 30 August 2003 was replaced by another WTO decision, which would amend TRIPS itself once accepted by two thirds of WTO countries and would introduce a new Article 31-*bis* that formally removes the limitations set forth by Article 31(f).

<sup>62</sup> Abbott – Cottier – Gurry, above note 6, p. 291

the aspiring licensee, or generally to adjust prices and other strategies to the market conditions of the country where the prospective licensee is located<sup>63</sup>. This is what happened in July 2005 during the negotiations between the Brazilian government and the pharmaceutical company Abbott Laboratories which owns the patent covering the antiretroviral drug Kaletra. Brazil threatened to grant a compulsory licence for the local production and sale of Kaletra. This convinced Abbott Laboratories to reduce the selling price of Kaletra in Brazil<sup>64</sup>. A similar outcome – ie a price drop after the threat of granting a compulsory licence – stemmed in 2001 from the negotiations between the Brazilian government and the companies Roche and Merck which owned patent rights on the drugs Nelfinavir and Efavirenz<sup>65</sup>.

The threat of issuing a compulsory licence, moreover, might convince the patent holder to supply itself the patented product at a lower price and thus to make it more affordable to local consumers. It is believed that this solution is efficient, as the patentee is in a privileged position to supply rapidly the goods covered by its patent, eg it might have large stocks ready to be distributed<sup>66</sup>.

Negotiations had also been held between the company Roche and some governments in the context of the H5N1 virus crisis (also known as bird flu crisis). The Swiss multinational owns the patent rights for the antiviral Tamiflu, which is considered the only efficient remedy against that disease. In many countries Roche avoided the issuance of compulsory licences by increasing the global production and distribution of Tamiflu and declaring itself ready to grant generics manufacturers voluntary licences. In Taiwan, however, the negotiations failed, and the Taiwanese government granted in November 2005 a compulsory licence on Tamiflu.

In November 2006 and in January 2007, moreover, the Thai government granted compulsory licences for *inter alia* the production and sale of the above mentioned drugs Efavirenz and Kaletra. In May 2007 the Brazilian government, after interrupting the negotiations with Merck, granted a compulsory licence for the production and sale of Efavirenz. That was the first compulsory licence granted in Brazil, which – it is believed - saved around 30 million dollars to Brazilian government only in 2007<sup>67</sup>. Finally, in April 2010 the Ecuador government granted the local distributor for the Indian generic producer Cipla its first compulsory licence, this licence covering the antiretroviral drug Ritonavir, whose patent is owned by Abbott Laboratories.

### *Concluding remarks. Compulsory licences and international dissemination of technology*

We have seen that over the last years some countries such as Brazil, Ecuador and Taiwan have granted compulsory licences in the pharmaceutical field. India is just the latest country which has relied on this tool.

First, there is no doubt that the main purpose of compulsory licences is to face situation of social emergency, eg food shortage, natural disasters or as in Natco/Bayer in case the patentee does not supply sufficient quantities of drugs or does not supply them at all. In these cases the issuance of a

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<sup>63</sup> UNCTAD, *The TRIPS Agreement and Developing countries*, Geneva, 1996, p. 34.

<sup>64</sup> For further details on the negotiations see *The Economist* of 23-29 July 2005, p. 61.

<sup>65</sup> C. Correa, *Can the TRIPS agreement foster technology transfer to developing countries?*, K.E. Maskus - J.H. Reichman (eds.), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, Cambridge University Press, 2005, p. 250 (note 120).

<sup>66</sup> P. Vandoren – P. Ravillard, *A New EC Initiative to Allow Export of Medicines under Compulsory Licences to Poor Countries*, in *The Journal of World Intellectual Property*, Vol. 8, No 2, 2005, p. 111.

<sup>67</sup> *The Economist*, 15-21 March 2008, p. 62 as well the website at <http://www.ip-watch.org/2007/05/07/brazil-takes-steps-to-import-cheaper-aids-drug-under-trade-law/?res=1024> (last accessed on 19 April 2012)

compulsory licence can guarantee that needy patients are supplied with useful and cheap products<sup>68</sup>. Under these circumstances compulsory licences seem to be the right tool, which is also compliant with Article 8 TRIPS<sup>69</sup> (as shown above, this provision stresses that the protection of intellectual property rights should promote the public interest in sectors of vital importance to countries' socio-economic and technological development). That compulsory licences are relevant for the furtherance of public interests is also buttressed by the Doha Declaration on the TRIPS Agreement and Public Health, which considers them as an instrument useful to increase the availability of patented pharmaceutical products, especially in situations of extreme urgency.

There are however different schools of thought on whether compulsory licences are really capable of triggering the dissemination of patented technologies.

On the one hand, it is believed that compulsory licences constitute a necessary tool to trigger the transfer of patented technology from industrialised to developing countries<sup>70</sup>. It has been noted that this is an efficient and flexible means to allow countries, especially developing ones, “*to ensure that patented new techniques developed abroad are available to domestic industries who wish to use them*”<sup>71</sup>. Indeed, corporations from industrialised countries – where most of research and development investments take place – are often reluctant to grant companies hailing from developing or least developed states voluntary licences on conditions that enable such companies to compete on international markets. Thus, developing and least developed countries consider compulsory licences a sort of Robin Hood's weapon to be used against developed countries to protect their own interests and guarantee the transfer of patented technology<sup>72</sup>. Other tools identified by TRIPS – such as the mechanism under Article 66(2) - are instead considered inefficient and inappropriate for that purpose. Said provision states that developed countries should provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed states in order to enable them to create a sound and viable technological base. Although the WTO Ministerial Decision on Implementation-Related Issues and Concerns of 14 November 2001 affirmed the binding nature of this provision, it remains difficult for beneficiary countries to prove the breach of such obligation by industrialised countries<sup>73</sup>.

On the other hand, especially in industrialised nations, the negative effects of compulsory licences are stressed. The main argument is that granting these licences not only harms patent holders, depriving them of exclusive rights on their own invention, but also reduces the incentives for developing and least developed countries to invest in research and development. As a result, reduced research and development activity – which are crucial for the economies of emerging countries, especially for building independent industrial systems capable to satisfy the demand of local consumers – may have a negative impact on the welfare of citizens, at least in the long run<sup>74</sup>. Empirical data seem to confirm this school of thought. In particular, Pires de Carvalho noted that before TRIPS, in the few countries where compulsory licences were granted, local industries which invested in independent research and development closed down. One of these countries is Canada where – because of permissive legislation on compulsory licences – several research-based

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<sup>68</sup> Watal, above note 9, p. 317.

<sup>69</sup> See also Correa, above note 65, pp. 247 et sqq.

<sup>70</sup> UNCTAD/ICTSD, above note 8, p. 487.

<sup>71</sup> Penrose, above note 6, p. 262.

<sup>72</sup> G. Ghidini, *Developing countries' Access to Patented Essential Medicines. A Possible Alternative to Compulsory Licences*, Studies for Alberto Bercovitz (AIPPI Spain), Barcelona, 2005.

<sup>73</sup> Gervais, above note 19, p. 352.

<sup>74</sup> UNCTAD/ICTSD, above note 8, p. 488.

pharmaceutical companies closed down while industries merely specialized in generics mushroomed<sup>75</sup>.

In addition to harming patentees and reducing the incentives for investing in research and development, it has been noted that compulsory licences might be even useless. This can occur when patentees have developed and not disclosed in the application a significant know-how on how to work the invention. Under these circumstances, even if a compulsory licence is granted, the licensee would have no chance of working the invention successfully<sup>76</sup>, and accordingly no transfer of technology would take place<sup>77</sup>.

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<sup>75</sup> Pires de Carvalho, above note 3, p. 231 (note 598) (noting that the Uruguay Round negotiators took into due account the relatively high number of compulsory licences granted in Canada and accordingly decide to insert Article 70(6) into the TRIPS. This transitional provision states that WTO Members are not required to apply Article 31, or the requirement in Article 27(1), to compulsory licences where said licences had been granted by the government before TRIPS. According to the author this provision was addressed to Canada and aimed at preserving the validity of compulsory licences granted in that country before TRIPS).

<sup>76</sup> Abbott – Cottier – Gurry, above note 6, p. 718.

<sup>77</sup> Watal, above note 9, p. 318.