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Use it or Lose it? Assessing the Compatibility of the Paris Convention & TRIPS with respect to Local Working Requirements

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Can or should countries impose the local production of inventions for which they grant a patent? In times of trade in components, in times of 'made in the world'; the answer seems given: no. However, the calculation of costs and benefits of a local production requirement on the local community depend on a number of factors. The results of the calculation are likely to vary among regions and technology sectors, and the answer thus appears nuanced. What does international law impose in this regard? Does it sufficiently (allow to) reflect these differences, and how to bring the economic reality into play when discussing the legal interpretation of (international) laws? This paper offers a case study on these questions analysing the apparent legal conflict between Article 5 of the Paris Convention and Article 27 of the TRIPs Agreement.

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I. Introduction

In his "Poor Man's Tale of a Patent", Charles Dickens's protagonist questions whether it is "reasonable to make a man feel as if, in inventing an ingenious improvement meant to do good, he had done something wrong" (Dickens 1869). This is a question that many British inventors likely asked themselves in the early 20th century. At the time, the United Kingdom saw a revival of the Elizabethan forfeiture clauses that were – in former times – inserted into patent grants, declaring them void unless the patentee put the patent into practice locally within a limited period. In this context, barrister, Ernest Lunge commented that such local working requirements were "vexatious and injurious to inventors without producing any advantage to the community". In his view, a system of compulsory licenses or reciprocal treaties was more 'intelligent' (Lunge, 1910).

The Paris Convention for the Protection of Industrial Property (the "Paris Convention") was the first such 'reciprocal treaty' regulating intellectual property.[1] Its Article 5(A)(2) allows Contracting Parties to:

> […] take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

This possibility is, however, subject to a number of conditions as set out in Article 5(A)(4) of the Paris Convention.

Read together, Articles 5(A)(2) and 5(A)(4) of the Paris Convention strike what Lunge would likely have perceived as an 'intelligent' balance between the interests of patentees and the community. But are local working requirements truly in the interests of the local community that they are meant to supply/serve? The calculation of costs and benefits of a working requirement on the local community depend on a number of factors, including whether the local demand for a patented invention can be met in a more efficient and economic manner through importation. The results of the calculation are, therefore, likely to vary among regions and technology sectors.

A number of Contracting Parties to the Paris Convention have nevertheless and potentially to their detriment, enacted local working requirements that indiscriminately exclude importation as a means of meeting these requirements. Their national legislation thereby appears to fly in the face of Article 27.1 of the World Trade Organization (WTO) Agreement on Trade-

[1] Compulsory Licensing was not mentioned in the 1883 Paris Convention and was only introduced in the 1925 Hague Revision.

Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"), "the most comprehensive multilateral agreement on intellectual property":[2]

> […] patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

While Article 27.1 of the TRIPS Agreement specifically requires Contracting Parties to treat patented inventions on a non-discriminatory basis irrespective of whether they are produced locally or imported, the non-working or insufficient working of a patented invention in a jurisdiction that has adopted 'exclusively local' working requirements – though not subject to forfeiture – may result in potentially discriminatory restrictions on the patentee's rights.

The interface between Article 5(A)(2) of the Paris Convention and Article 27.1 of the TRIPS Agreement clearly causes difficulties, and while the latter is more recent than the former, it cannot simply be given predominance. This paper suggests that the two provisions are compatible and that social and economic welfare costs and benefits must be factored into decisions to either (i) import patented inventions through trade or (ii) require local working of patented inventions through foreign direct investment (FDI). The first part of the paper looks to relevant cases and legislated working requirements from a selection of WTO Member States. Then, in order to address the "legal uncertainty about local working requirements after the TRIPS Agreement" (Champ and Attaran, 2002), special consideration is given to legal doctrine on point and the canon of treaty interpretation under the Vienna Convention on the Law of Treaties (the "Vienna Convention").[3]

Treaty interpretation points to economic factors discussed in the *travaux préparatoires* of the TRIPS Agreement. As such, the second part of the paper analyses the extent to which the Paris Convention and the TRIPS Agreement can be reconciled with the economic literature on point. A rubric / checklist of elements to be considered in evaluating the economic benefits of the local working requirements is offered in addition to informed policy recommendations regarding exceptions to obligations under the TRIPS Agreement. In our view, since the economic impact and welfare effects of requiring local working will vary depending on a State's level of economic development and the patented technology in question, such exceptions are

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[2] World Trade Organization: *Overview: The TRIPS Agreement* [online]. World Trade Organization. Available at <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> [Accessed on 06.2013].

[3] Questions of interpretation of treaty norms related to international intellectual property rights are generally addressed by reference to the law of treaties. The Vienna Convention applies with respect to the TRIPS Agreement in disputes before the WTO. See Report of the WTO Appellate Body, AB-1997-5, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products WT/DS50/AB/R (19 December 1997).

warranted below a certain threshold, which is malleable to the principle of graduation (Cottier 2006).[4]

II. Background

There is a dearth of precedent-setting case law at the World Trade Organization[5] on the relationship between Article 5(A)(2) of the Paris Convention and Article 27.1 of the TRIPS Agreement and "the lack of a definitive interpretation of the appropriate scope of compulsory licensing by a WTO panel leaves an interpretative vacuum that may allow incorrect perceptions to flourish" (Ho, 2009, p. 380). The legal literature also seems inconclusive on the issue: on the one hand, the Paris Convention, seen as providing countries with the right to require local production, is lauded by developing countries seeking to enhance industrial development (Halewood, 1998, p. 245; Khastgir and Dev, 2011, p. 24); on the other hand, the TRIPS Agreement, with its principle of non-discrimination, is seen as repudiating local production requirements but also as the expression of a very essential principle of international trade law (De Carvalho, 2010, p. 285; Ghidini, 2010).

Over ten years ago, a conflict arose at under the WTO Dispute Settlement Understanding regarding the legality of local working requirements but a settlement was reached and any hope of guidance was postponed indefinitely. At issue was Article 68 of Brazil's Law No. 9,279 of 14 May 1996, which establishes a local working requirement for patents that can only be satisfied by local production of the patented invention.[6] The Permanent Mission of the United States questioned the provision's compliance with the TRIPS Agreement, in particular Article 27 (Liu, 2009), but given pressure from world leaders and health organizations, the United States withdrew its complaint because of the potential damage to Brazil's HIV / AIDS Program (Condon and Sinha 2008, p. 40; De Carvalho 2010, p. 291).[7]

At the time when the two countries reached a settlement, scholars were already anticipating a future conflict involving a developing country looking to compulsory licensing (Champ and Attaran, 2002, p. 366). The inevitable occurred on March 9, 2012 when the Indian Controller of Patents (the "Indian

[4] Inspired by progressive liberalisation, the doctrine of graduation generally relates to the individual scheduling of commitments for countries in a manner that corresponds to their diverging levels of economic development: as development progresses, countries can 'graduate' to a higher level of international commitment.

[5] Note that the observed lack of guidance is specifically with respect to the WTO. By contrast, in *Commission v. Italy*, C-235/89, the European Court of Justice held that the local working requirements of a Member State of the European Union are satisfied by the importation of products manufactured in another Member State of the European Union.

[6] Brazil – Measures Affecting Patent Protection - Request for Consultations by the United States, WT/DS199/1, G/L/385, IP/D/23 (8 June 2000).

[7] Brazil - Measures Affecting Patent Protection - Notification of Mutually Agreed Solution, WT/DS199/4, G/L/454, IP/D/23/Add.1 (19 July 2001).

Controller") granted a compulsory license over Bayer's "Sorafenib", commercially known as "Nexavar". The advanced-stage liver and kidney cancer drug was licensed to the Indian generics producer, Natco Pharma Limited.[8] The Indian Controller inferred from Article 5(A)(1) of the Paris Convention, which provides that importation of patented inventions shall not entail forfeiture, that mere importation could justify "something less than forfeiture, such as a compulsory license."[9]

While it is true that Article 5(A)(1) of the Paris Convention limits a patentee's risk of forfeiture for importation of patented inventions, there is considerable support for the view that importation meeting local demand for a patented product satisfies local working requirements (Taubman, 2011; Bonadio 2012). A review of the national legislation of a selection of WTO Member States reveals that such is the case, for instance, in Ghana, Jordan, Mexico, Philippines, South Africa and Uruguay. The relevant patent laws in each of these countries explicitly provide for importation as a means of satisfying local working requirements. Interestingly, all of these WTO Member States also have relatively strong IPRs (Ginarte and Park 1997, Park 2008). Similarly, in Brazil, where the strength of IPRs is said to be high, importation can satisfy local working requirements where there is a lack of economic feasibility for the local manufacture of the patented invention.

While Brazil's local working requirement explicitly factors in economies of scale, other countries' working requirements are either unqualified or explicitly exclude importation as a means of meeting local demand for patented inventions. There are even some legislated local working requirements that allow for the outright revocation of patents, which *a priori* violates Article 5(A)(3) of the Paris Convention according to which the remedy of forfeiture/revocation is subsidiary to the issuance of a compulsory license (Reichman and Hasenzahl, 2003; De Carvalho, 2010, p. 283, Busche *et al.* 2009).

Though not explicit in its wording, Indian legislation requires patented inventions to be locally manufactured to some extent (Khastgir and Dev, 2011). But this was not the reason for the ruling in *Natco/Bayer.* Rather, the Indian Controller relied on Section 83(b) of the Indian Patent Act, to issue the compulsory license over "Nexavar". The relevant provision reads as follows:

> 83. Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely,— (a) that patents are

[8] *In the matter of Natco Pharma Limited and Bayer Corporation*, Application for Compulsory License under Section 84(1) of the Patents Act, 1970, in respect of Patent NO. 215758 [hereinafter *Natco/Bayer*] [online].
Available at <http://www.ipindia.nic.in/ipoNew/compulsory_1License_12032012.pdf> [Accessed on 06.2013].

[9] *Ibid.*, p. 41.

> granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay; and (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

According to some, the Indian Controller's reliance on this section was contrary to Article 27 of the Vienna Convention, which states that "a party may not invoke the provisions of its internal law as justification for its failure to perform a treaty". The idea is that the Indian Controller failed to consider Article 27.1 of the TRIPS Agreement, which precludes India, as a Party to the Agreement, from discriminating between patented products that are imported and those that are locally produced (Bonadio 2012, p. 250).

Needless to say, the decision of the Indian Controller has opened up Pandora's Box for pharmaceutical patent holders: earlier this year, another compulsory license application was filed by Mumbai-based BDR-Pharma for the drug Sprycel (dasatinib), currently protected by a patent granted in 2006 to Bristol-Myers Squibb and used for the treatment of chronic myeloid leukaemia. And the applications in India are unlikely to stop: according to news sources, the Indian Health Ministry has recommended that additional compulsory licenses be issued for cancer drugs, trastuzumab and ixabepilone.[10]

Interestingly, a more 'TRIPS-compliant' ruling was possible in *Natco/Bayer*, as Bayer had failed to meet Indian demand for "Nexavar" at reasonable prices between 2008 and 2010, and this could have been regarded as 'abusive'.[11] Indeed, legal scholars have cited, as potentially 'abusive', the refusal, without reasonable grounds, by a patentee to license a pharmaceutical ingredient to a manufacturer of a life-saving pharmaceutical formulation and the failure by a patentee to meet demand in the patent-granting country (De Carvalho, 2010, p. 293-294; Straus 1998). For this reason, the decision of the Indian Controller has been the subject of extensive criticism not only by patent holders who hope Elpis is at the bottom of the box, but also by international legal scholars, who anticipate a future conflict exposing India to challenge at the WTO (Chopra and Muthappa, 2012; Bonadio, 2012, p. 250).

III. Reconciling Local Working Requirements and the TRIPS Agreement

India is just one of many WTO Member States that has legislated local working requirements. In fact, until the 1990s, almost every country had

[10] Bennett, Coleman and Co. Ltd. (2013) 'DIPP seeks details on 3 cancer drugs for compulsory licencing' *The Economic Times*, June 2013.

[11] It is important to bear in mind that high prices can be charged for imported and locally produced products alike. De Carvalho (2010) remarks that even locally manufactured products have been subject to price controls in patent-granting countries with local working requirements.

legislated local working requirements to be satisfied by local production, importation or both (Julian-Arnold, 1993) and today, the laws of many Developing Countries (DCs) and Least Developed Countries (LDCs) continue to impose local working requirements for patented inventions (Correa 2005). Some of these DCs and LDCs claim that few inventions and processes patented domestically are actually used in domestic production; that the monopoly created by Intellectual Property Rights (IPRs) is being used to restrict competitors' access to internal markets; and that IPRs are driving up the prices of new technologies and hindering their development (Ahmed Yusuf, 1991; Beier, 1986). These countries have a claim to international technology transfer and consider local working requirements to be a useful means to that end.

The legal basis for local working requirements and the limitations to these requirements are spread across the Paris Convention at Articles 5 and 19 and the TRIPS Agreement at the preamble and Articles 2.2, 7, 8, 27.1, 30, and 31. We focus here on Article 5(A)(2) of the Paris Convention and Articles 27.1 and 31 of the TRIPS Agreement. The Declaration on the TRIPS Agreement and Public Health (the so-called "Doha Declaration"),[12] issued in 2001, must also be taken into account if we assume that it is a subsequent agreement[13] among all of the parties to the TRIPS Agreement (Correa 2002, Ho 2009).

The Paris Convention and the TRIPS Agreement are to be interpreted along principles of treaty interpretation of the Vienna Convention, which is customary international law. The starting point for a good faith interpretation under Article 31 of the Vienna Convention is the ordinary meaning given to the terms of the treaty at stake. Then, the context, object and purpose, any authentic means of interpretation, and any relevant rules of international law follow.[14] To confirm the meaning of a treaty provision resulting from the application of Article 31 of the Vienna Convention or where the application of Article 31 leads to an unreasonable result, recourse may be had to the preparatory work of the treaty pursuant to Article 32 of the Vienna Convention.

Legal scholars have devoted countless pages to interpreting the relevant provisions of the Paris Convention and the TRIPS Agreement along Vienna Convention principles. According to some, the interpretation of open-ended provisions should give deference to national laws (Frankel, 2005, p. 385) given

[12] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (20 November 2001).

[13] Under Article 31 of the Vienna Convention, "[t]here shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; […]".

[14] There is some debate as to whether or not these criteria should be assessed on an equal level: see WT/DS152/R, Report of the Panel, *Unites States – Sections 301-310 of the Trade Act of 1974* (22 December 1999), para. 7.22 and Shanker (2002).

the "multiple objectives inherent in TRIPS" (Ho, 2009, p. 390) and the fact the TRIPS Agreement provides only minimum standards. Others, by contrast, attempt to assess the weight to be given to relevant provisions: Champ and Attaran (2002, p. 367), for instance, argue that Article 27.1 of the TRIPS Agreement is a general provision that is subject to specific exceptions contained in Articles 30 and 31 of the TRIPS Agreement, "and possibly Article 5A of the related Paris Convention". Based on the principle *lex specialis derogate legi generali* (a specific legal provision will prevail over a conflicting general provision), Champ and Attaran argue that despite the principle of non-discrimination at Article 27.1 of the TRIPS Agreement, the specific exceptions at Articles 30 and 31 of the TRIPS Agreement and at Article 5(A) of the Paris Convention allow compulsory licenses to be issued for a failure to work.

While we agree with Champ and Attaran (2002) on the ordinary meaning of Article 5(A) of the Paris Convention, we avoid the 'controversial'[15] view that Article 27 of the TRIPS Agreement is a general provision that may be subject to an exception expressed at Article 5(A) of the Paris Convention. Although this is consistent with the view that exceptions and flexibilities in the Paris Convention may have been curtailed by the TRIPS Agreement (Gervais 2012), Article 30, entitled "Exceptions to Rights Conferred", appears to be a counter-provision to Article 28 of the TRIPS Agreement, entitled "Rights Conferred", rather than an exception to Article 27 of the TRIPS Agreement, as suggested by Champ and Attaran. Moreover Article 31 bears the title "Other Use Without Authorization of the Right Holder", which could simply refer to 'additional' reasons for granting compulsory licenses rather than an 'exception'. Finally, we regard the provisions of the Paris Convention and the TRIPS Agreement as not only binding on Parties to both treaties by virtue of Article 2.2 of the latter, but also applicable on an equal footing, and in our view, Article 5(A) of the Paris Convention and Article 27 of the TRIPS Agreement balance rights and obligations rather than rights and exceptions unless the contrary is explicitly stated.

In terms of reconciling local working requirements and the principle of non-discrimination, we agree with the views expressed by Champ and Attaran (2002), as well as Ho (2009) that a local working requirement that sanctions an 'abusive' failure by a patentee to work a patented invention does not constitute 'discrimination' within the terms of Article 27.1. Such a local working requirement can be considered justified differential treatment and there is no discrimination where differentiations are justified, *i.e.* where there are *bona fide* reasons for differentiating, as the WTO Panel has confirmed.

[15] Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R (17 March 2000), para. 5.36.

A. The Paris Convention

Our analysis begins with what we consider to be the most relevant provisions in the context of local working. Looking to the ordinary meaning of Article 5(A), we note that importation, referred to at Article 5(A)(1) and the possibility of legislating local working requirements pursuant to Article 5(A)(2) are not mutually exclusive. We find that subject to certain conditions, as set out in Article 5(A)(3), the issuance of a compulsory license is allowed under Article 5(A)(2) in case of 'failure to work' (which is considered abusive), unless the 'patentee justifies his inaction by 'legitimate reasons' as per Article 5(A)(4).

Dictionary definitions shed no light on the meaning of the terms 'failure to work', and it remains unclear whether the terms refer to failure to import, failure to produce locally or both. Since such terms are left to be defined by Member States (Pflüger 2008), local working requirements are varied across these States. Article 5(A)(2) suggests that 'failure to work' is invariably an abuse and although several practices involving "restrictive licensing conditions, technology grant-backs, tied sales, [cross-licensing agreements, vertical controls preventing] competition, price discrimination or predation against local firms" (Maskus 1998) could be considered 'abusive', 'failure to work' is the only example of an abuse offered in the Paris Convention.

Article 5(A)(4) implies that there may be legitimate reasons for 'failure to work' a patented invention. An early commentary on the Paris Convention, as revised at Stockholm in 1967, states that such 'legitimate reasons' could be legal, economic or technical obstacles to exploitation. The same commentary, which can be regarded as "an authentic means of interpretation", states that 'working' implies local working (Bodenhausen, 1968). However, nothing in the language of Article 5(A)(2) points to this conclusion.

Looking to the context, object and purpose of Article 5(A)(2), we find that local working requirements were an extension of the fourteenth century bargain between sovereign authorities and skilled inventors. Inventors benefiting from monopolistic patent rights granted by the sovereign authority were required to make their inventions locally: their inventions would be protected from competitors and the sovereign would benefit from the development of local expertise through apprenticeships (Lunge, 1910). The Paris Convention was drafted to better serve sovereign/national interests in industrial progress through a multilateral, standardised regime (Halewood, 1998, p. 252), but did not initially mention the concept of 'compulsory licensing' (Penrose, 1951). The concept was introduced in revisions made at The Hague in 1925 in order to restrict the remedy of forfeiture in cases of 'failure to work' or other abuses (Halewood, 1998, p. 285; De Carvalho, 2010, p. 283).

Turning to the preparatory work of the Paris Convention, pursuant to Article 32 of the Vienna Convention, we find that there was some disagreement regarding the meaning of "non-working" during the first revisions of the Paris

Convention. While France argued that importation should be grounds for invalidating a patent, Belgium took the view that working requirements could be satisfied by the working of a patented invention within the Paris Union (Stack, 2011). This confirms our findings as a result of the application of Article 31 of the Vienna Convention: there is considerable ambiguity relating to the terms 'failure to work' at Article 5(A)(2) of the Paris Convention and it is not clear whether these terms refer to failure to import, failure to produce locally, or both.

B. The TRIPS Agreement

Turning to the WTO Agreements, we see that under Article 2.2 of the 1994 TRIPS Agreement, Articles 1 through 12, as well as Article 19 of the Paris Convention, are incorporated into the WTO legal system: "[n]othing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention". This includes Articles 5(A) and 19 of the Paris Convention, which states that subsequent 'special agreements for the protection of industrial property' cannot contravene the provisions of the Paris Convention. These provisions thereby become fully part of the WTO legal system and Article 19 is explicitly singled out. Abbott (2001) suggests that incorporation "was mainly undertaken in order to link the provisions of the Berne and Paris Conventions to the WTO dispute settlement and render them enforceable within the multilateral trading system."

1. Article 31 of the TRIPS Agreement

Looking at substantive WTO law relating to compulsory licensing, we turn first to Article 31 of the TRIPS Agreement, entitled "Other Use Without Authorization of the Right Holder", which deals with compulsory licenses. This provision neither defines the circumstances under which a compulsory license may be granted (Gervais, 2012, p. 165), nor does it explicitly mention 'failure to work' as grounds for issuing a compulsory license. Rather, the provision sets out procedural and substantive conditions relating to a country's right to issue a compulsory license, an administrative contract granted by the government, rather than the patentee, for use of the patent at a relatively lower government-imposed royalty rate (Reichman, and Hasenzahl, 2003).

Article 31 is a lengthy provision that is difficult to understand and is frequently "misunderstood and mischaracterized" (Ho, 2009, p. 462). For ease of reference, we have reproduced the provision below, though most of the provisions from (a) to (l) are irrelevant for our purposes:

> Where the law of a Member allows for other 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:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

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

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it 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;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

What is important to retain from Article 31 is that although its conditions are slightly limiting, they do not prohibit the issuance of compulsory licenses for 'failure to work'.

Article 31 remains, nonetheless, a "vague tool lacking substantive guidance" (Andrew 2011, p. 416) and there are extensive debates as to what constitutes "a national emergency or other circumstances of extreme urgency" under Article 31(b). For instance, are cancer and heart disease merely "lifestyle" issues rather than "circumstances of extreme urgency"? Is HIV the only real "extreme urgency" in our day? According to the World Health Organization, deaths from non-communicable diseases will account for many more deaths

than those from communicable diseases by 2015.[16] So are compulsory licenses over cancer drugs, issued by Thailand and India, covered by the terms of Article 31?

Some clarification regarding Article 31 of the TRIPS Agreement has arguably been provided 'by subsequent agreement' through the Doha Declaration. According to paragraph 5 of the Declaration, "[e]ach member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted". Moreover, the eventual implementation of paragraph 6 of the Declaration, at Article 31*bis* of the TRIPS Agreement,[17] will presumably broaden Article 31(f), which provides that compulsory licenses "shall be authorised predominantly for the supply of the domestic market […]". Under Article 31*bis,* which is not yet in force and apparently involves onerous procedures, a country issuing a compulsory license for a vital drug will be able to export part of these locally produced pharmaceuticals to DCs and LDCs lacking the infrastructure to manufacture their own supply.[18] We come back to this important point in our economic analysis in the next part of this paper.

2. Article 27.1 of the TRIPS Agreement

Article 27.1 of the TRIPS Agreement sets out important obligations of patent-granting countries: "[…] patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." Limiting the rights of a patentee who engages in large-scale importation rather than locally producing his patented invention might be considered an example of discrimination relating to importation within the meaning of Article 27.1. Such large-scale importation was historically considered by some to be "mock working" and threatening to national industries: only importation of patented inventions in limited quantities was permissible so as not to "interfere with serious exploitation of the invention in the country where the patent was taken out" (Penrose, 1951, p. 76).[19]

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[16] World Health Organization, *Preventing Chronic Diseases: A Vital Investment* [online]. World Health Organization.

Available at

< http://www.who.int/chp/chronic_disease_report/contents/part1.pdf> [Accessed on 06.2013].

[17] *Amendment of the TRIPS Agreement*, Decision of 6 December 2005, WT/L/641 (8 December 2005).

[18] See *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, Decision of the General Council of 30 August 2003, WT/L/540 and Corr.1 (1 September 2003).

[19] A similar view seems to have been adopted by the legislators in Nigeria, Zambia and Zimbabwe. See the Appendix to this paper, which points to the relatively low strength of IPRs in these countries.

Looking past the ordinary meaning of Article 27.1 to "subsequent practice in the application of this provision, we find that in the WTO Canada Patents case, Article 27 was indeed held to apply to Article 31 on compulsory licenses.[20] In that case, the Panel observed that there may be "*bona fide* exceptions to deal with problems that exist only in certain areas". Much is a matter of how one interprets the notion of 'discrimination'. Discrimination generally occurs when a differentiation is made without justification – or as the Panel in the WTO Canada Patents case put it – without *bona fide* reasons, but a compulsory license that singles out an abuse presumably does so for *bona fide* reasons.

In any event, the TRIPS Agreement appears to allow such differential treatment. Despite requiring that patents be available without discrimination based on technology, the TRIPS Agreement differentiates with respect to licenses on semi-conductor technology and with respect to pharmaceutical technologies not only in terms of compulsory licenses for public health under the Doha Declaration, but also in terms of patent extensions (Champ and Attaran, 2002, p. 389).[21] This, in our view, seems to be an analogous approach to that of Article 5(A)(4) of the Paris Convention, which refers to 'legitimate reasons' for the 'failure to work' a patented invention.

3. The Context, Object and Purpose of the Relevant Provisions

In assessing the context of Articles 27.1 and 31 of the TRIPS Agreement, Article 31 of the Vienna Convention invites us to consider, "in addition to the text," the preamble. The preamble of the TRIPS Agreement accurately conveys the 'dilemma' of the local working requirement. On the one hand, the "Agreement aims to reduce distortions and impediments to international trade". On the other hand, it "recognises the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives". It also emphasises the special needs of LDCs with respect to "maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base". Whereas the need for equal conditions to trade finds its expression in the non-discrimination provision of Article 27.1, the developmental objectives and the needs of developing countries are elaborated at Articles 7 and 8 of the TRIPS Agreement.

We look to Articles 7 and 8 of the TRIPS Agreement, respectively entitled *Objectives* and *Principles*, in order to ascertain the object and purpose of Articles 27.1 and 31 of the TRIPS Agreement. Article 7 provides that IPRs

[20] Canada – Patent Protection of Pharmaceutical Products, *supra*, note 15, para. 7.91.

[21] See, for example, *European Communities – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS153/1IP/D/15/G/L/283 (7 December 1998).

"should contribute to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to social and economic welfare" that balances rights and obligations. It is a 'should' provision, which in legal texts is always weaker than a 'shall' provision. It may, therefore, not serve to reduce or limit 'shall' provisions (Gervais, 2012, p. 203), and its main function lies in the interpretation of other provisions – as we use it here.

In looking to Article 7 of the TRIPS Agreement, it is important to recall that good faith, which is at the centre of the general rule of Article 31 of the Vienna Convention, presumes that treaty terms are intended to *mean something rather than nothing* (Villiger, 2009; Jacobs, 1969).[22] Thus, a good faith interpretation of Article 7 must give due consideration to the economic language of this provision, which refers to the welfare effects of 'technology transfer'. While technology transfer may be the "primary goal" of a local working requirement (WIPO, 1997), local working is not the only means of achieving technology transfer. It is simply preferred for its spillover effects, and, for this reason, has been described as a form of 'protectionism' (D'Amato and Long, 1997). But, the tenets of international trade law require equal conditions for trade, and the theory of comparative advantage – underlying the WTO system – calls for the removal of 'artificial barriers to trade': protectionism is to be eliminated to find the most efficient and cheap way of producing and trading.

Technology transfer can be achieved through 'market channels' other than local working through Foreign Direct Investment (FDI), including trade and licensing. It can also be achieved through 'non- market channels', including reverse engineering and imitation (Maskus, 2004). The ordinary meaning of Article 7 consequently calls for decision-making as to which of these means is "conducive to social and economic welfare and to a balance of rights and obligations". Both the patentee and the patent-granting country have rights and obligations and can factor economies of scale into their decisions regarding the most optimal means of technology transfer for particular patented technologies. It is important not to lose sight of this when reading Article 8 of the TRIPS Agreement and the Doha Declaration, which devote more words to the rights of patent-granting countries and the obligations of patentees.

Article 8 of the TRIPS Agreement establishes the legitimacy of measures "to promote the public interest in sectors of vital importance to Member States' socio-economic and technological development". While such measures may

[22] See also *United States – Section 211 Omnibus Appropriations Act of 1998 AB-2001-7*, WT/DS176/AB/R (2 January 2002), para. 338-339: "[o]ne of the corollaries of the 'general rule of interpretation' in the *Vienna Convention* is that interpretation must give meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility."

be needed to prevent abuses of IPRs or "the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology", they must also be consistent with the provisions of the TRIPS Agreement. Article 8 appears to establish a necessity test: Member States may "adopt measures necessary to" prevent abuses. The reference to 'abuses' demonstrates that the TRIPS Agreement, as much as the Paris Convention, acknowledges the need to curtail abuses with necessary / appropriate measures.

Finally, the Doha Declaration reaffirms "the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose". Indeed, as we have seen, there is considerable flexibility for this purpose under Article 31 of the TRIPS Agreement. The Doha Declaration arguably adds increased flexibility, as – unlike under Article 5(A)(4) of the Paris Convention – there is presumably no three-year wait to file a compulsory license (Champ and Attaran, 2002, p.392).

4. The Preparatory Work Leading to the Adoption of the Relevant Provisions

Although the review of Articles 7 and 8 of the TRIPS Agreement provides insight as to the object and purpose of Articles 5(A)(2) of the Paris Convention and Articles 31 and 27.1 of the TRIPS Agreement, the preparatory work of the TRIPS Agreement is most helpful in reconciling these provisions. Under Article 32 of the Vienna Convention, recourse may be had to such preparatory work in order to clarify ambiguities resulting from the application of Article 31. As such, we turn to the early drafts of the TRIPS Agreement, namely Chairman Lars Anell's Draft of July 1990 (the "Anell Draft")[23] and the similar consensus draft of December 1990 to the Ministers in Brussels (the "Brussels Draft").[24] We find that consequences for failure to work that were included in these drafts were ultimately excluded from the final TRIPS Agreement and "there is no record of the […] informal sessions during which progress was made on successive versions of the Chairman's text (Gervais 2012, p. ix).

Suffice it to say, both the Anell and Brussels Drafts precluded the grant of compulsory licenses for failure to work or insufficient working where the right holder could provide "legal, technical or commercial reasons" in the words of the Anell draft, and "legal, technical or economic justification" in the words of the Brussels Draft. More significantly perhaps, the Brussels draft precluded the issuance of compulsory licenses where importation was adequate to supply the local market. It is noteworthy not only that large-scale importation

[23] Chairman's Report to the GNG on the Status of Work in the Negotiating Group, GATT Doc. MTN.GNG/NG11/W/76 (18 July 1990).

[24] MTN.TNC/W/35/Rev. 1 (3 December 1990).

was seen as compatible with working requirements in the Brussels draft, but also that both drafts placed a great deal of importance on commercial/economic reasons that could justify a 'failure to work'. This evaluation of economic factors in the assessment of whether or not to grant a compulsory license is consistent with Article 7 of the TRIPS Agreement and theoretically allows economic evidence to inform the debate on local working requirements.

C. Conclusions

Attempts to reconcile local working requirements and the TRIPS Agreement have resulted in various proposals, for instance to eliminate references to 'importation' and 'local production' in Article 27.1 of the TRIPS Agreement (Kur and Levin, 2011), or to strengthen local working requirements in national patent laws (Beier, 1986, p. 363). In fact, many developing countries have adopted this solution in their patent laws and some, such as India in the recent *Natco/Bayer* case have taken legal measures meant to restrict the use of patents as conferring import monopolies (Ho, 2009, p. 416).

Needless to say, this has sparked a debate regarding the compatibility of these measures and the TRIPS Agreement. Based on a review of the relevant provisions, which remain vague and largely undefined (Ho, 2009, p. 386), and using the canon of treaty interpretation under the Vienna Convention, we find that countries are not prohibited from issuing compulsory licenses for 'failure to work' a patented invention. However, since compulsory licenses are issued to address effects of 'property holdups' (Bird and Cahoy, 2008, p. 290), and property that is not locally produced is not necessarily held up, there are limitations to compulsory licensing, and these are expressed at Articles 31 and 27.1 of the TRIPS Agreement.

While Article 31 provides procedural limitations, Article 27.1 provides substantive limitations. It is neither an exception to, nor subject to Article 31, but rather sets out obligations of patent-granting countries, precluding them from discriminating on the basis of whether patented inventions are imported or locally produced. For this reason, Article 27.1 has been said to prohibit local working requirements. In our view, however, there is no discrimination within the terms of Article 27.1 where differential treatment is justified. In other words, there is no discrimination where the wording of a legislated local working requirement captures only a particular patentee's abusive 'failure to work' the patented invention.

By contrast, discrimination exists where all patentees who import their technologies are sanctioned without justification, as would be the case where a local working requirement explicitly excludes importation as a means of meeting local demand for patented inventions.[25] Our review of the

[25] This appears to be the case in Egypt. See the Appendix to this paper.

preparatory work of the TRIPS Agreement lends support to this view, as it reveals that local working and importation were never mutually exclusive. These concepts may even be complementary where, pursuant to Article 7 of the TRIPS Agreement, social and economic welfare is taken into account to determine the quantities of a patented technology to be manufactured locally and the quantities to be imported from abroad.

IV. Social and Economic Welfare of Technology Transfer

In the background to this paper, we saw that local working requirements are generally drafted so as to reflect the micro- and macro-economic-based considerations for principles of international division of labour in research, development and production. Requiring local working in the traditional sense, *i.e.* requiring patented inventions to be manufactured in the patent-granting country is an old mechanism that is simply no longer in tune with today's reality. Today's trade environment is characterised by what is called trade in components, rather than trade in finished commodities. Supply chains are increasingly diversified geographically and finished commodities are 'made in the world' (Friedman, 2012):

> In most cases it is only possible and practical, for micro-economic as well as macro-economic reasons, to produce the patented products in a sufficiently large quantity in a few countries for a larger, generally regional marketing area. It necessarily follows that the different markets within this region can be supplied better and cheaper through imports than through domestic, licensed products (Beier, 1996, p. 363).

In light of the relationship between patent law and trade law, as well as the fact that manufacturing processes are increasingly international, there is support, particularly in the economic literature, for the view that importation should be able to satisfy working requirements either partially or fully (Taubman 2011).

Since local working requirements are meant to benefit the public rather than the patentee, and the public benefit from such requirements is not measured solely in terms of domestic manufacture (Taubman 2011, p. 104), it should theoretically factor-in the supply of the patented invention to the domestic population (Gamharter 2004), as well as any economic reasons for which local working might not be beneficial to the local population. If we consider these factors, it should be possible to import patented inventions on a large scale such that there is no 'local' working *per se*, yet the technology transfer and dissemination requirements of Article 7 of the TRIPS Agreement are still met. In this part of our paper, we discuss the question of economic factors to consider in assessing when it is appropriate and beneficial to require local working.

A. Local Working Requirements and FDI Incentives

FDI by Multinational Enterprises (MNEs), through the acquisition/establishment of subsidiaries, is inherently linked to local working and has significant spillover effects in terms of employment creation, industrial capacity building, and technology transfer (Macleod, 1988; Penrose 1951). MNEs engage in FDI where cost or efficiency advantages outweigh disadvantages such as distance, potential language and cultural barriers and different tax treatment (Maskus, 1998). The Eclectic Paradigm, otherwise known as Dunning's 'OLI' framework, explains the main factors determining a MNE's decision to undertake FDI (Dunning, 1977).

The 'OLI' framework refers to ownership, localisation, and internalisation advantages. In the context of IPRs, an ownership advantage, such as a patent, confers market power and cost efficiencies. A location advantage, such as strong IPRs in a particular country, makes production in one location more profitable than in another; examples include large market size, high local demand, high trade and transport costs (in other words, high tariffs in relation to fixed costs so as to favour FDI over trade), short distances from markets, abundant natural resources, modern infrastructure and low fixed costs for building, transparent government procedures, highly-skilled labour relative to wage costs, and proximity to customers (Maskus, 1998, p. 123). An internalisation advantage makes technology transfer through a subsidiary, *i.e.* internally, more prudent than through licensing.

While it is difficult to draw correlations among investment decisions, technology transfer and the strength of IPRs, most empirical economic studies suggest that strengthened IPRs positively influence technology transfer through FDI (Javorcik, 2004; Lee and Mansfield, 1996; Park and Lippoldt, 2007; Seyoum, 1996).[26] But the decision to engage in local working through FDI rather than licensing does not depend entirely on the strength of IPRs; it may arise where IPRs are weak and competition is strong (Maskus, 1998, p. 121; Teece, 1986), as valuable information and know-how could otherwise be imitated in the patent-granting country (Kennedy, 2003).

In her study of 96 countries, including developed countries, DCs and LDCs, Smith found that strengthened patent protection increased the flow of United States exports to countries with strong imitative abilities, but decreased exports to those with weak imitative abilities (Smith, 1999). Likewise, in Co's study on United States royalties and license fees from 1989-2002, strong patent

[26] Technology transfer to countries with weak IPRs, such as China, is ironically often significant, and most likely due to market size, and therefore exceptional.

protection, as measured by the Ginarte-Park Index,[27] was found to positively influence licensing activities where local imitative abilities were strong, whereas strong patent protection was found to negatively influence licensing activities where local imitative abilities were weak (Co, 2007).

B. FDI Incentives and Location Advantages

That countries with a certain level of economic development are more likely to grant patents or compete with 'northern' countries is no longer an accurate statement: there is no hard and fast rule (Ho, 2009, p. 382). From a review of FDI inflows and outflows for representative nations studied in the International Monetary Fund's Balance of Payments Statistics, Maskus notes rising FDI levels in emerging economies due to what Dunning would characterise as their 'location' advantages. By contrast, he highlights the limited ability of LDCs to attract investment due to their lack of 'location' advantages (Maskus, 1998; Gumbel, 2008). Likewise, in an article based on a game theory framework, Bird and Cahoy (2008) cite location advantages as being key factors differentiating Egypt and Brazil in their experiences with certain MNEs.

Although Egypt and Brazil are both considered Middle Developed Countries (MDCs), as measured by the United Nations Development Programme's Human Development Index, Egypt was susceptible to FDI losses when its Ministry of Health decided to grant a compulsory license over Viagra: Pfizer put an end to its plans to build a modern production facility there (Castellano, 2006). By contrast, FDI inflow to Brazil has continued despite not only Brazil's legislated local working requirement, but also the United States' complaint to the WTO regarding this requirement. Since the complaint was sparked by a conflict over patented antiretroviral drugs and Brazil has more than 50% of all reported HIV/AIDS cases in Latin America and the Caribbean, the State had what Dunning would consider a 'location' advantage for those patented drugs in terms of its large market size and high local demand (Condon and Sinha, 2008; Gumbel, 2008, p. 174; De Carvalho, 2010; Mayer, 2002), not to mention its other advantages (Park and Lippoldt, 2007, p. 27; Valach, 2005).[28]

Through the example of Egypt, Bird & Cahoy (2008) demonstrate that one element of patent law, such as a compulsory license or a local working

[27] The Ginarte-Park index was elaborated by J.C. Ginarte and W.G. Park in 1997 and updated in 2008 by W.G. Park. It constitutes the most widely used legislation-based IPR index, and according to Maskus (2000), the impact of working requirements on patent value can be estimated econometrically because these requirements are identified in the Ginarte-Park Index.

[28] Moreover, Brazil is host to a number of global automobile manufacturers and stands to be the fifth largest automobile producer in the world. In addition, Article 68 of the Brazilian law was seen as similar to Sections 204 and 209 of the US Patents Act; thus, a ruling against Brazil in this dispute would have led to a ruling against the United States in a dispute that arose subsequently: see United States - *US Patents Code* - Request for Consultations by the United States, WT/DS224/1 (7 February 2001).

requirement, meant to induce local production and manufacturing in MDCs, may ironically make certain MDCs more susceptible to FDI losses than others. This is the case in the pharmaceutical industry, in particular, given opposition by drug companies to the idea of MDCs using compulsory licenses. The opposition is due to the common misconception that MDCs can afford drugs at the prices set by patent holders despite wide disparities in income level within these countries (Ho, 2009, p. 377).

By contrast, LDCs are perceived as more deserving of reduced rate drugs. Moreover, given the lack of location advantages, including infrastructure, workforce, supplies, organisational abilities, technical know-how and access to raw materials, in most LDCs, local working requirements and threats of compulsory licensing in these countries are likely to have little impact – positive or negative – on FDI incentives (Hestermeyer, 2007; Maskus, 1998, p. 121).

Bird & Cahoy's case study illustrates that, at least in terms of the pharmaceutical sector, location advantages, such as market size and market demand forces have an important impact on FDI incentives and losses.[29] Ho's study on Thailand points to similar conclusions: after Thailand's grant of a compulsory license over Kaletra, Abbott's HIV drug, the pharmaceutical company withdrew its applications to sell several other drugs in Thailand (Ho, 2009, p. 444). It remains to be seen whether India's market size and other 'location advantages' will spare her from pharmaceutical industry FDI losses despite suggestions to the contrary in light of the decision in *Natco/Bayer* (Chopra and Muthappa 2012, p. 39).

C. Local Working Requirements and Different Technologies

The strength of IPRs plays an important role in technology transfer not only through FDI (Fink and Braga, 2005), but also through trade and licensing (Co, 2007; Wakasugi, 2007; Yang and Maskus, 2005) and the importance has been found to vary by industry and market structure (Maskus, 1998, p. 111). With respect to trade, patent strength has been found to positively and significantly affect trade with impact varying across sectors (Maskus and Penubarty, 1997; Park and Lippoldt, 2007). With respect to licensing, markets for patent licensing have been found to be more likely to develop in some industries rather than others (Arora *et al.*, 2001).

With respect to FDI, trade reductions through the exercise of market power have been found to be more prominent in patent-sensitive sectors and FDI potentially more prevalent in these sectors (Maskus and Penubarti, 1997, p. 109). Weak protection of IPRs has been found to impact the composition of FDI inflows, deterring investment in IPR-sensitive-sectors and encouraging

[29] This is consistent with the findings of Attaran (2004), Lybecker and Fowler (2009), Trouiller *et al.* (2002), and Watal (2000).

distribution rather than local production (Javorcik, 2004, p. 40). It is not surprising then that patent strength has been found to be positively associated with United States FDI expansion in the chemical industry (Park and Lippoldt, 2007, p. 23), a patent-sensitive sector.[30]

The industrial chemical industry almost tops the list of sectors in which FDI is most prevalent, but this industry, along with the steel and energy industries where fixed costs and first-copy costs are high, are prime targets for local working requirements that theoretically weaken IPRs (David, 2005; De Carvalho, 2010, p. 292; Bouchard and Koch, 2009). With respect to pharmaceuticals, although considered patent-sensitive, demand for these technologies is generally met through importation (De Carvalho, 2010, p. 292; Seiter, 2005; Maskus, 1998). While there may soon be a mechanism under Article 31*bis* of the TRIPS Agreement that allows DCs and LDCs in a health crisis to request the issuance of a compulsory license for a needed drug, it remains to be seen whether this mechanism will be sufficient to fully meet the demands of DCs and LDCs lacking the infrastructure required to manufacture the pharmaceutical technology locally (Seiter, 2005, p. 3-4; Sykes, 2002).[31]

D. Conclusion

General infrastructure, tax incentives, present labour skills, legal security, as well as market size and shape are but a few elements factored into the decision as to whether or not to transfer technology to a particular region through market channels. In addition, since technology that is easy to copy will create more transaction costs when being transferred, there will be more reluctance to transferring these technologies. In light of these variables, it is difficult to assess the impact on technology transfer of one element within patent law, such as a local working requirement. Nevertheless, in this part of our paper we have attempted to do precisely that on the basis of the existing economic literature.

We have found that there is a fine line between the promotion of FDI incentives and a local working requirement and that the matter is sensitive to a large set of factors. We try to summarise these factors in the rubric/checklist below in order to allow for an informed analysis, as well as an evaluation of the welfare effects of local production in a more systematic way. The elements

[30] Maskus and Penubarty (1997) categorise the following as patent-sensitive: petroleum and coal products, food products, professional goods, metal products, electrical machinery, plastic products, other chemical products, pharmaceuticals, machinery, and industrial chemicals. The same authors categorise the following as least patent-sensitive sectors: leather products, wearing apparel, footwear, rubber products, printing and publishing, transport equipment, nonferrous metals, beverages, and iron and steel.

[31] Local manufacturing of pharmaceuticals in developing countries besides India, China and other MDCs, usually does not include chemical synthesis: even if the requisite infrastructure exists in a country, it is unlikely to include "the most technical and value-adding" stage of pharmaceutical manufacturing, *i.e.* chemical synthesis.

listed in the rubric/checklist are, however, not exhaustive and the importance of many of these elements has already been highlighted in studies by Maskus (1998) and Dunning (1977) among others.

LOCATION ADVANTAGES	PATENT-SENSITIVE TECHNOLOGIES	PHARMACEUTICAL TECHNOLOGIES
Large market size		
High local demand		
High trade and transport costs		
Short distances from markets		
Abundant natural resources		
Low fixed costs for building		
Transparent government procedures		
Highly-skilled labour force		
Low wages		
Proximity to customers		
Modern infrastructure		
Weak IPRs and Strong competition		
Infrastructure for chemical synthesis		
Effective control agency to enforce GMP[32]		
Compulsory license through Article 31*bis* unlikely		
Weak IPRs and strong competition		

V. Which Way Forward?

We must allow those who are unable to play on level terrain to benefit from a "modulation" of the rules, or – in this case – of their obligations under the TRIPs Agreement. This is not a new idea; many scholars have suggested that such obligations be modulated under the tenets of Special and Differential

[32] As stated by the World Bank, "pharmaceutical manufacturing should only be encouraged in countries that have an effective control agency to enforce GMP [Good Manufacturing Practice]".

Treatment (Cottier, 2006; Hoekman *et al.,* 2003; Kleck and Low, 2004; Michalopoulos, 2000). According to many scholars, adhesion to particular WTO Agreements should be contingent "on a set of observable and common analytical criteria" (Lopez Gonzalez *et al.,* 2011). Cottier (2006), in particular, argues that it should be possible to identify such analytical criteria, as they are closely related to identified constraints; the identification of such criteria might then allow for an "implicit threshold approach malleable to the principle of graduation" (Lopez Gonzalez *et al.,* 2011) and can be taken to exempt some, rather than others, from their obligations under the TRIPS Agreement. It is argued here that this could also be taken into account in the legal interpretation of the relevant agreement, especially when two apparently conflicting provisions are to be reconciled.

The observable criteria enumerated in the rubric/checklist at the end of Part I might allow for an assessment of competitiveness and following Cottier's reasoning, it should be possible, on the basis of econometric data, to assess whether particular technologies manufactured in certain countries are, or will be, below a certain level of competitiveness. A lack of competitiveness of certain sectors alone may, however, not suffice to justify a compulsory license for local production, but it may set the stage; it may be a requirement on top of which an 'abusive' failure to work has to be proven on a case-by-case basis. A two-step test would thus be advanced: lack of competitiveness justifies differential treatment under Article 27.1 of the TRIPS Agreement, and proof of an abusive 'failure to work' serves as a second step under Article 5(A)(2) of the Paris Convention. Both must be present to justify a compulsory license for lack of local production under international law.

The question of how to measure competitiveness and the thresholds for differentiated levels of competitiveness are questions that deserve further attention and research. In their paper on "TRIPS and Special and & Differential Treatment", Lopez Gonzalez *et al.* revisit the case for derogations to TRIPS obligations for pharmaceuticals in DCs. The study identifies countries that should benefit from such derogations, but the identification of countries is only possible because of the limited scope of the study, which examines international competitiveness of pharmaceutical technologies. With the rubric at the end of Part I of our study, as well as country-specific data, economists could create a composite index specific to individual patented technologies and similar to that created in the study by Lopez Gonzalez *et al.* The purpose of such a study would be to distinguish among countries in a manner than maximises welfare with the lowest negative impact on FDI incentives.

VI. Conclusions

Patent law has been challenged, re-challenged and then challenged again in the past decades. One of the main debates in the international context relates to the question of whether international minimum standards – as imbedded in the TRIPS Agreement – are (in)adequate for developing countries and (counter)productive to their growth. To what extent should countries with different levels of (economic and social) development be treated differently; to what extent are existing international standards too high for DCs and LDCs?

The tenets of international trade law require equal conditions for trade, and many DCs already find themselves in a competitive relationship with 'northern' countries and their companies – at least in certain sectors. Under these circumstances, differential treatment seems unjustified. However, other countries need transition periods and assistance before being able to fully open their markets and play the game of international free trade. The question then arises as to where a balance is to be achieved and how it can be optimised within the existing framework.

In this paper, we have attempted to give context to the local working requirements of many DCs and LDCs. Through a review of relevant economic literature, we have studied the impact on technology transfer of such requirements and generally conclude that local working requirements weaken IPRs, the strength of which is ironically associated with technology transfer through FDI. FDI levels in some DCs may be high due to the 'location' advantages for particular technologies in these countries, but the ability of LDCs to attract investment remains comparatively limited due to the lack of such 'location' advantages in these countries.

The contemplation of these economic issues emerges from a legal dichotomy, namely the seeming contradiction between Article 5(A)(2) of the Paris Convention, which allows the granting of compulsory licenses to sanction the failure to work a patent, and Article 27.1 of the TRIPS Agreement, which explicitly precludes discrimination based on whether patented products are imported or locally produced. Based on our analysis of relevant provisions of both legal instruments through the lens of the Vienna Convention, we conclude that there is no discrimination within the meaning of Article 27.1 of the TRIPS Agreement where differentiation between products that are locally produced and products that are imported, is justified.

In order to justify such differentiation, we turn to the economic literature on graduation, which recognises the heterogeneity in capacity across DCs and LDCs and the need for Special and Differential Treatment contingent on competitive shortfalls. We recommend the use of graduating thresholds based on international competitiveness to determine when exemptions to TRIPS obligations no longer constitute justified differentiation, but we leave it to economists to create a composite index for measuring competitiveness for

individual patented technologies – an index similar to that created in the study by Lopez Gonzalez *et al.,* but one that doesn't 'discriminate' in favour of pharmaceutical technologies.

Appendix:

COUNTRY (GINARTE-)PARK INDEX NUMBER	LEGISLATED LOCAL WORKING REQUIREMENTS
Argentina **3.98**	LEY DE PATENTES DE INVENCION Y MODELOS DE UTILIDAD (Ley 24.481 modificada por la Ley 24.572 T.O. 1996 - B.O. 22/3/96-) Modificada por la Ley 25.859 Art. 43: "Transcurridos TRES (3) años desde la concesión de la patente, o CUATRO (4) desde la presentación de la solicitud, si la invención no ha sido explotada, salvo fuerza mayor o no se hayan realizado preparativos efectivos y serios para explotar la invención objeto de la patente o cuando la explotación de ésta haya sido interrumpida durante más de UN (1) año, cualquier persona podrá solicitar autorización para usar la invención sin autorización de su titular. Se considerarán como fuerza mayor, además de las legalmente reconocidas como tales, las dificultades objetivas de carácter técnico legal, tales como la demora en obtener el registro en Organismos Públicos para la autorización para la comercialización, ajenas a la voluntad del titular de la patente, que hagan imposible la explotación del invento. **La falta de recursos económicos o la falta de viabilidad económica de la explotación no constituirán por sí solos circunstancias justificativas**."
Algeria **3.07**	Ordonnance n° 03-07 du 19 Joumada El Oula 1424 correspondant au 19 juillet 2003 relative aux brevets d'invention. Art. 38. « Toute personne peut, à tout moment après l'expiration d'un délai de quatre (4) années à compter de la date de dépôt de la demande d'un brevet ou de trois (3) années à compter de la date de délivrance du brevet d'invention, obtenir auprès du service compétent, une licence d'exploitation pour cause de défaut ou d'insuffisance d'exploitation. Pour l'appréciation du délai cité à l'alinéa ci-dessus, le service compétent appliquera celui qui expire le plus tard. La licence obligatoire ne peut être accordée par le service compétent, qu'après vérification de la réalité du défaut ou de l'insuffisance d'exploitation et s'il n'existe pas de circonstances qui justifient ce défaut ou cette insuffisance d'exploitation de l'invention brevetée. »
***Bangladesh**	Patents and Designs Act, 1911 (Act NO. II of 1911), s. 22:

1.87	"Any person interested may present a petition to the Government which shall be left at the Department of Patents, Designs and Trade Marks, together with the prescribed fee, alleging that **the demand for a patented article in Bangladesh is not being met to an adequate extent and on reasonable terms** and praying for the grant of a compulsory license, **or, in the alternative, for the revocation of the patent**."
Brazil **3.59**	*Ley N° 9.279, del 14 de mayo de 1996, que regula los derechos y obligaciones relativos a la propiedad industrial*, Art. 68(1): "The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision. (1) The following also occasion a compulsory license: **I. non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted;** or II. commercialization that does not satisfy the needs of the market."
Canada **4.67**	Patent Act (R.S., 1985, c. P-4) S. 65: "(1) The Attorney General of Canada or any person interested may, at any time after the expiration of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act. What amounts to abuse (2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances: (*a*) and (*b*) [Repealed, 1993, c. 44, s. 196] (*c*) **if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;** (*d*) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be

	granted; (*e*) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or (*f*) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials. (3) and (4) [Repealed, 1993, c. 44, s. 196] Definition of "patented article" (5) For the purposes of this section, the expression "patented article" includes articles made by a patented process.
Egypt **2.77**	Law No. 82 of 2002 Pertaining to the Protection of Intellectual Property Rights, Art. 23(4): "The Patent Office - after the approval of a Ministerial Committee established by a decree from the Prime Minister - shall grant compulsory licenses for the exploitation of the invention. The committee shall determine the financial rights of the patentee upon the issuance of such licenses, in the following circumstances: […] Fourth- If the patentee does not exploit the patent in the Arab Republic of Egypt by himself or upon his approval, or it has not been sufficiently exploited, in spite of the lapse of four years from the date of submitting the patent application, or three years from the date of the grant thereof - whichever is longer - and also if the patentee ceases the exploitation of the invention **without an acceptable reason** for a period exceeding one year. **The exploitation may be achieved by the production of the protected product in the Arab Republic of Egypt, or by the utilization of the method of manufacture protected by a patent of invention therein.**"
Ethiopia **2.13**	Proclamation No. 123/1995 Concerning Inventions, Minor Inventions and Industrial Designs, Art. 29(3): "Any person who is capable of working a patented invention may apply for a compulsory license, where the patentee fails, **without legitimate reason** to justify his inaction, to work his invention **in Ethiopia**, after the expiration of a

	period of three years from the date of grant of the patent or four years from the date of filing of the patent application which ever expires last."
Ghana **3.35**	Patents Act, 2003 (Act 657), s. 14(1): "On a request, made to the court after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the court may issue a non-voluntary licence **if the court is satisfied that the patented invention is not exploited or is insufficiently exploited, by working the invention locally or by importation, in the country.**"
India **3.76**	Patents Act, 1970, s. 84(1): "At any time after the expiration of three years from the date of the sealing of a patent, any person interested may make an application to the Controller for grant of a compulsory licence on patent on any of the following grounds, namely: – ***(a)*** **that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or** ***(b)*** **that the patented invention is not available to the public at a reasonably affordable price, or** *(c)* that the patented invention is not worked in the territory of India."
Indonesia **2.77**	Law No. 14 of 1 August 2001 Regarding Patents, Art. 76(3): "A request for a Compulsory License as referred to in paragraph (1) shall only be made on the grounds that the relevant patent has not been implemented or only partially implemented by the Patent holder."
Jordan **3.43**	Patents of Invention Law No. 32 of 1999, as amended by Law No. 28 of 2007, Art. 22B: "The Minister may grant a license to use a patent to third parties without obtaining the patentee's consent in any of the following cases exclusively: […] B.1. If the patentee doesn't exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapses later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation. 2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, **the importation of the subject goods of the patent to the kingdom shall be deemed**

	utilization of the patent.
Kenya **3.22**	Industrial Property Act, 2001, s. 72(1): "At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may apply to the Tribunal for a licence to exploit the patented invention **on the grounds that a market for the patented invention is not being supplied on reasonable terms in Kenya.**"
Malaysia **3.48**	Patents Act No. 291 of 1983, as amended, s. 49(1): "(1) At any time after the expiration of three years from the grant of a patent, or four years from the filing date of the patent application, whichever is the later, any person may apply to the Registrar for a compulsory licence under any of the following circumstances: *(a)* where there is no production of the patented product or application of the patented process **in Malaysia** without any legitimate reason; *(b)* where there is no product **produced in Malaysia** under the patent for sale in any domestic market, or **there are some** but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason."
Mexico **3.88**	Ley de la Propiedad Industrial del 25 de junio de 1991 con las ultimas enmiendas del 17 de mayo de 1999, Art. 70: "Tratándose de invenciones, después de tres años contados a partir de la fecha del otorgamiento de la patente, o de cuatro años de la presentación de la solicitud, según lo que ocurra más tarde, cualquier persona podrá solicitar al Instituto la concesión de una licencia obligatoria para explotarla, cuando la explotación no se haya realizado, salvo que existan causas debidamente justificadas. Párrafo reformado DOF 02-08-1994 **No procederá el otorgamiento de una licencia obligatoria, cuando el titular de la patente o quien tenga concedida licencia contractual, hayan estado realizando la importación del producto patentado u obtenido por el proceso patentado.**"
Morocco **3.52**	Dahir No. 1-00-91 of 9 Kaada 1420 (February 15, 2000) on the Enactment of Law No. 17-97 on the Protection of Industrial Property, Art. 60: "Any person or entity under public or private law may, three years after the patent is granted or four years after the date on which the patent is applied for, obtain from the court a compulsory license

	for such patent, on the conditions provided for in Articles 61 and 62 below, if at the time of the request, and **failing legitimate reasons**, neither the owner of the patent or his successor in title: *(a)* has begun to work or has made real and effective preparations for working the invention that is the subject matter of the patent on the territory of the Kingdom of Morocco; ***(b)* has marketed the product that is the subject matter of the patent in a quantity sufficient to meet the needs of the Moroccan market; or** *(c)* where the working or marketing of the patent in Morocco has been abandoned for more than three years."
Mozambique **2.52**	Industrial Property Code (Approved by Decree No. 04/2006 of 12th April 2006), Art. 83: 1. "The proprietor of a patent shall be required to work the patented invention, either directly or indirectly. 2. Working shall commence within three years after the date on which the patent was granted, or within four years after the application was filed, whichever period is longer. 3. If the proprietor fails to work the invention within the stipulated periods, he may be compelled to grant a licence to a third party. 4. The proprietor of the patent may also be compelled to grant a licence to a third party to work the patent if the use of another patent depends on it. 5. A compulsory licence will only be granted, as envisaged in the preceding paragraphs, when the potential user has made efforts to obtain the patent proprietor's agreement on reasonable conditions and the negotiations have not been successful."
Nigeria **2.50**	Patents and Designs Act, Chapter 344, 1990, Schedule 1, paras. 1-4: "**1.** Subject to this Part, at any time after the expiration of a period of four years after the filing of a patent application or three years after the grant of a patent, whichever period last expires, a person may apply to the Court for the grant of a compulsory licence on one or more of the following grounds- (a) that the patented invention, being capable of being worked in Nigeria, has not been so worked; (b) that the existing degree of. working, of the patented invention in Nigeria does not meet on reasonable terms the demand for the product; (c) that the working of the patented invention in Nigeria is being hindered or prevented by the importation of the

	patented article; and (d) that, by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced. **2.** If an invention protected by a patent in Nigeria cannot be worked without infringing rights derived from a patent granted on an earlier application or benefiting from an earlier foreign priority, a compulsory licence may be granted to the patentee of the later patent to the extent necessary for the working of his invention if the invention- (a) Serves industrial purposes different from those served by the it, invention which is the subject of the earlier patent; or (b) constitutes substantial technical progress in relation to that last mentioned invention. **3.** If the two inventions mentioned in paragraph 2 of this Schedule serve the same industrial purposes, a compulsory licence may be granted under that paragraph only on condition that a compulsory licence shall also be granted in respect of the later patent to the patentee of the earlier patent, if he so requests. **4.** A compulsory licence shall not be granted in respect of a patent if the patentee satisfies the court that **his actions in relation to the patented invention are justifiable in the circumstances, but he shall not be held to have so satisfied the court if he merely shows that the patented article is freely available for importation.**"
Philippines **4.18**	Intellectual Property Code, s. 93(5): "The Director of Legal Affairs may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances: […] If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: ***Provided*, That the importation of the patented article shall constitute working or using the patent.**"
Saudi Arabia **2.98**	Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs, 2004, Art. 24(a):

	"The City may grant a compulsory license to a third party to exploit an invention covered by the patent or a layout design of an integrated circuit covered by a certificate of design upon an application submitted to it, according to the following: (1) The application shall be submitted after the elapse of four years from the date of filing the patent application or three years from the date of granting the patent, whichever expires later, without the owner of the protection document exploiting his invention or having exploited it in an inadequate fashion, unless he justifies that with a legitimate excuse. […] (3) The compulsory license is basically granted to make the invention or design available in the local markets. But this provision does not apply where the aim of the license is to prevent or restrict practices against which a decision or judgment is issued declaring them to be acts of unlawful competition."
South Africa **4.25**	Patents Act No. 57 of 1978, s. 56(2): "The rights in a patent shall be deemed to be abused if—(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working; […] (c) **the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms**; (d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; **or** (e) **the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title**."

Thailand **2.66**	Patent Act B.E. 2522 (1979), s. 46(1)-(2): "At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee **unjustifiably** fails to exercise his legitimate rights as follows: (1) **that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or (2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.**"
Tunisia **3.25**	Loi n_2000-84 du 24 août 2000, relative aux brevets d'invention, Art. 69: "Any interested party may, after the expiry of the period provided for in Article 51 of this Law, obtain a compulsory license at any time in any of the following cases: — where the invention to which the patent relates has not started to be worked industrially in Tunisia, or where no real and effective preparations have been made for such working, within the period provided for in Article 51 of this Law; — **where the product which is the subject matter of the invention has not been marketed in sufficient quantities to meet the needs of the Tunisian market**; — where the industrial or commercial exploitation of the invention to which the patent relates has been abandoned for more than three years in Tunisia."
Uruguay **3.39**	*Ley N° 17.164 del 2 de septiembre de 1999 - Regúlanse los derechos y obligaciones relativos a las patentes de invencíon, los modelos de utilidad y los diseños industriales (1.827*R)*, Art. 54: "Any interested party may request a compulsory license after three years have elapsed since the grant of the patent or four years since the date of application, whichever expires last, if the invention has not been exploited or if serious and effective preparations have not been made for its exploitation or if exploitation has been suspended for more than one year, provided that there are no reasons of *force majeure*. In addition to the reasons recognized in the legislation, insurmountable objective problems of a technical or legal nature such as delays in the granting of authorizations by government bodies,

	independent of the will of the owner of the patent, which make working the patent impossible, shall be considered reasons of *force majeure*. **The exploitation of a patent shall include its production, use, import or any other commercial activity undertaken and related to its subject matter. In this respect, the working of the patent by a representative or licensee shall be considered carried out by the owner of the patent.**"
***Zambia** **1.94**	Patents Act, Chapter 400 of the Laws of Zambia, s. 37: "(1) Subject to the provisions of subsection (14), any person interested who can show that he has been unable to obtain a licence under a patent on reasonable terms may, after the expiration of a period of three years subsequent to the date on which that patent was sealed or four years subsequent to the date on which the application in respect thereof was lodged, whichever period last expires, apply to the Registrar in the prescribed manner for a compulsory licence on the ground that the reasonable requirements of the public with respect to the invention in question have not been or will not be satisfied. […] (6) The reasonable requirements of the public referred to in subsection (1) shall be deemed not to have been satisfied in any of the following circumstances, namely: *(a)* if the patented invention, being an invention capable of being worked in Zambia. is not being worked therein on a commercial scale and there is **no satisfactory reason for such non-working** […] *(b)* if the working of the invention within Zambia on a commercial scale is being prevented or hindered by the importation of the patented article by the patentee or persons claiming under him, or by persons directly or indirectly purchasing from him or by persons against whom the patentee is not taking or has not taken proceedings for infringement; *(c)* **if the demand for the patented article in Zambia is not being met to an adequate extent and on reasonable terms**; *(d)* if by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry of Zambia or the trade of any person or class of persons trading in Zambia, or the establishment of any new trade or industry in Zambia, is being prejudiced, and it is in the public interest that a licence or licences should be granted; *(e)* if any trade or

	industry in Zambia, or any person or class of persons engaged therein, is being prejudiced by unfair conditions attached by the patentee, whether before or after the commencement of this Act, to the purchase, hire, licence or use of the patented article, or the using or working of the patented process; (*f)* if any condition which under the provisions of section *forty-nine* is null and void as being in restraint of trade and contrary to public policy, has been inserted in any contract made in relation to the sale or lease of or any licence to use or work any article or process protected by the patent: Provided that, for the purpose of determining whether there has been any abuse of the monopoly rights under a patent, due regard shall be had to the fact that patents are granted not only to encourage invention but also to secure that inventions shall so far as possible be worked on a commercial scale in Zambia without undue delay."
Zimbabwe **2.60**	Patents Act (Chapter 26:03) (as last amended by Act 9 of 2002), s. 31: "(1) Subject to subsection (15), any person interested who can show that he has been unable to obtain a licence under a patent on reasonable terms may, within a period of six months from the initial request for a voluntary licence, apply to the Registrar in the prescribed manner for a compulsory licence on the ground that the reasonable requirements of the public with respect to the invention in question have not been or will not be satisfied. […] (6) The reasonable requirements of the public referred to in subsection (1) shall be considered not to have been satisfied in any of the following circumstances— (a) if the patented invention, being an invention capable of being worked in Zimbabwe, is not being worked therein on a commercial scale and there is **no satisfactory reason for such non-working**: […] (b) if the working of the invention within Zimbabwe on a commercial scale is being prevented or hindered by the importation of the patented article by— (i) the patentee or persons claiming under him; or (ii) persons directly or indirectly purchasing from the patentee; or (iii) persons against whom the patentee is not taking or has not taken proceedings for infringement; (c) **if the demand for the patented article in Zimbabwe is not being met to an adequate extent and on reasonable**

	terms; (d) if, by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry of Zimbabwe or the trade of any person or class of persons trading in Zimbabwe or the establishment of any new trade or industry in Zimbabwe is being prejudiced, and it is in the public interest that a licence or licences should be granted; (e) if any trade or industry in Zimbabwe or any person or class of persons engaged therein is being prejudiced by unfair conditions attached by the patentee, whether before or after the appointed day, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; (f) if any condition, which under section forty-four is null and void as being in restraint of trade and contrary to public policy, has been inserted in any contract made in relation to the sale or lease of or any licence to use or work any article or process protected by the patent: Provided that, for the purpose of determining whether there has been any abuse of the monopoly rights under a patent, due regard shall be had to the fact that patents are granted not only to encourage invention but also to secure that inventions shall so far as possible be worked on a commercial scale in Zimbabwe without undue delay.