

Chapter 15

Local Working of Patents: The Perspective of Developing Countries



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1 Introduction

A patent grants exclusive rights to a patentee enabling the exploitation of the underlying invention for a prescribed period of time—the usual being 20 years. This means that no one but the patentee, or a person authorized, will be entitled to produce the goods, or provide the services, to which a patented invention relates. Thus, a monopoly limited by time, over the manufacturing, production, sale, importation and distribution of the patented product is conferred to the patentee and no other. The purpose of this chapter is to investigate whether the imposition of a requirement which compels a patentee to set up a local industrial plant or factory to produce the patented product, or apply the patented process, in essence compelling the local working of a patent, as a condition for the maintenance of exclusive patent rights is compatible with the Agreement on the Trade Related Aspects of Intellectual Property (TRIPS), which forms one of the several covered agreements of the World Trade Organization (WTO). In particular, the analysis will deal with the principle of non-discrimination enshrined in Article 27:1 of TRIPS and its apparent inconsistency with Article 5A(2) of the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention), and then pose the question whether the imposition of a local working requirement would be compatible with the principle of non-discrimination enshrined in Article 27:1 of TRIPS. The last part of the chapter considers the approaches adopted in India and Sri Lanka in relation to the local working of patents, as these South Asian jurisdictions share similarities with many others that are both agricultural and developing economies, while also demonstrating a significant divergence in their domestic approaches towards local working.

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2 What Is ‘Local Working’?

The exclusive rights that emanate from the grant of a patent is territorial in nature. As such, an inventor is required to obtain patent protection in all countries in which the invention is to be exploited making use of national registration processes and the right to priority. From the point of view of a country granting such exclusive patent rights, a local working requirement would oblige the patent holder to ‘work’ the patent locally, as opposed to merely using the patent ‘as an exclusive right to prevent others from doing so *or to control importation*.’¹ Essentially, the local working of a patent entails that the ‘patentee must manufacture the patented product, or apply the patented process, within the patent granting country.’² The local working of a patent would bring about significant benefits to the country granting the patent, including but not limited to increased employment opportunities, transfer of technology and development of skills and expertise of human resources. Thus, in turn, and without doubt, working a patent locally will be useful for the dissemination of knowledge on the technology surrounding the patent, which would provide the know-how for the patent granting country to develop further and experiment on better uses of the technology involved. It has been suggested that the local working of patents is ‘desirable from the patent granting country’s point of view because they contribute to a variety of public policy goals such as employment creation, industrial and technology capacity building, national balance of payments, and economic independence.’³

On the other hand, requiring a patent owner to set up industrial plants in every country in which an invention is to be exploited would result in increased expenses, thus potentially reducing the yield of profit. Although through licensing arrangements, a patent owner could grant a local entity the right to produce a patented product, or apply a patented process, in local industrial plants or factories, this may still be less efficient than simply importing the patented product, manufactured in a single or multiple plants or factories elsewhere, into the patent granting country.⁴ This may also result in innovators distancing themselves from the patent system, while choosing to protect their inventions as trade secrets instead. Thus, any discussion as to the viability of imposing a local working requirement must consider these competing interests. Most importantly, however, one would have to consider whether a measure requiring the local working of a patent as a condition to maintain exclusive rights detracts from the cardinal rule against discrimination enshrined in Article 27:1 of TRIPS.

¹GHC Bodenhausen, *Guide to the application of the Paris Convention for the Protection of Industrial Property* (WIPO Publication 1969)71 (emphasis added).

²M Halewood, ‘Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law’ (1997) 35(2) *Osgoode Hall Law Journal* 243.

³*ibid* 246.

⁴GB Reddy and Harunrashid Kadri, ‘Local Working of Patents—Law and Implementation in India’ (2013) 18 *Journal of Intellectual Property Rights* 15.

This chapter by no means postulates a blanket requirement under national law that requires the local working of patents, as a precondition for the maintenance of patent rights. As is pointed out in this chapter, such an approach would be contrary to the non-discrimination obligations of WTO Members under Article 27:1 of TRIPS. Rather, what is required is a cautious exercise of TRIPS flexibilities towards a local working requirement that is case and context specific—thus, balancing the interests of patentees, as well as stakeholders in the patent granting country.

3 The Principle Against Discrimination and the Local Working Requirement

An important question that needs to be addressed is whether the imposition of a local working requirement conflicts with a WTO Member's obligations under TRIPS. In order to respond to this, it is necessary to consider the principle against discrimination set out in Article 27:1 of TRIPS. Article 27:1 reads as follows:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, *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* (emphasis added).

Accordingly, whether the patented product is imported or produced locally, patent protection must be available on equal terms so long as the other requirements set out in the first sentence of Article 27:1 are met. Thus, refusing the grant of patent protection or limiting the scope of protection available to a product solely produced abroad and imported into the patent granting country is a form of discrimination that is sought to be eliminated by Article 27:1. Further, engaging in such a practice may also conflict with a WTO Member's national treatment obligations enshrined in Article 3:1 of TRIPS.⁵

⁵The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art 3:1 provides that

[e]ach Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection (3) of intellectual property'. Thus, limiting the scope of protection in relation to products that are manufactured elsewhere and imported into the patent granting country (*vis-à-vis* patent owners who manufacture the patented products within the patent granting country) may amount to *de facto* discrimination against foreign patent owners, as it is they who in all probability would be manufacturing the patented product in their own countries, which are then imported into the patent granting country.

See, NP de Carvalho, *The TRIPS Regime and Patent Rights* (3rd edn, Kluwer Law International 2010) 289.

Yet, it must be noted that the principle against discrimination is at odds with a provision in the Paris Convention—i.e. Article 5A(2). The said provision reads as follows:

Each country of the Union shall have the right 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* (emphasis added).

Accordingly, Article 5A(2) of the Paris Convention recognizes that a failure to work a patent in a country in which protection is sought could amount to an abuse of monopoly rights conferred on the patent owner. If a country makes a determination that the failure to work a patent amounts to an abuse of patent rights, such a country has the ‘right’ to issue a compulsory license enabling the local production of the patented product as a form of response to the patent owner’s failure to work the patent. The only restriction under the Paris Convention is that such a:

...compulsory license may not be applied for [...] before 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; [and] it shall be refused if the patentee justifies his inaction by legitimate reasons...⁶

It is also important to note that what amounts to a ‘failure to work’ a patent is a matter for domestic interpretation and policy:

The member States are also free to define what they understand by ‘failure to work’. Normally, working a patent will be understood to mean working it industrially, namely, by manufacture of the patented product, or industrial application of a patented process. Thus, importation or sale of the patented article, or of the article manufactured by a patented process, will not normally be regarded as ‘working’ the patent.⁷

Therefore, a plain reading of Article 5A(2) of the Paris Convention suggests that where a patented product is solely imported into a patent granting country without being worked locally, a compulsory license may be issued provided that the requirements stipulated in Article 5A(4) are met. In other words, while a compulsory license can be issued for a patented product which is purely imported, such a license cannot be issued if the product is manufactured in the country concerned. Thus, locally produced patented products are favoured *vis à vis* purely imported patented products. As such, the result seems to contravene the fundamental policy against non-discrimination found in Article 27:1 of TRIPS which provides that equal treatment must be afforded to patents irrespective of whether the underlying product is imported or locally produced. Some countries have avoided grappling with this inconsistency by broadly defining the term ‘working’ to include the importation of the patented product.⁸ In fact, it has been suggested that only such an interpretation would be consistent with Article 27:1 of TRIPS:

⁶Paris Convention, art 5A(4).

⁷Bodenhausen (n 1) 71.

⁸M Trimble, ‘Patent Working Requirements: Historical and Comparative Perspectives’ (2016) 6 UC Irvine Law Review 483.

The trade-related context of TRIPS necessitates its own interpretation of the notion of domestic use or local working. While Members are, pursuant to adapted Art. 5A.2 PC, generally free to interpret domestic use, the wider context Arts 27.1 and 31 TRIPS implies that the patent holder exercises his property right when the product is provided on the domestic market, be it through local production or through importation.⁹

Not many have sought to discuss this apparent conflict between Article 27:1 of TRIPS and Article 5A(2) of the Paris Convention. A dispute in the WTO between the United States (US) and Brazil was the only instance when this issue was raised at the WTO level.¹⁰ However, the dispute was settled between the parties robbing the WTO of the opportunity to shed light on the controversial practice of imposing a local working requirement under domestic law. Nevertheless, the US's complaint and Brazil's defence were thought provoking. The primary contention of the US was that Article 68 of the Brazilian Industrial Property Law,¹¹ which enacted that inter alia the '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 in not economically feasible, when importation shall be permitted,'¹² and giving Brazil a right to impose a compulsory licence for failure to locally work a patent, was contrary to TRIPS. Essentially, the US contended that Brazil's law breached Article 27:1 of TRIPS by suggesting that a local working requirement for the enjoyment of exclusive patent rights that could only be satisfied by the local production, and not the importation, of the patented subject matter, was contrary to the policy of non-discrimination. The US Trade Representative (USTR) submitted that:

Brazil has asserted that the US case will threaten Brazil's widely-praised anti-AIDS program, and will prevent Brazil from addressing its national health crisis. Nothing could be further from the truth. For example, should Brazil choose to compulsory license anti-retroviral AIDS drugs, it could do so under Section 71 of its patent law, which authorizes compulsory licensing to address a national health emergency, consistent with TRIPS, and which the United States is not challenging. In contrast, Section 68 – the provision under dispute – may require the compulsory licensing of any patented product, from bicycles to automobile components to golf clubs. *Section 68 is unrelated to health or access to drugs, but instead is discriminating against all imported products in favour of locally produced products.* In short, Section 68 is a protectionist measure intended to create jobs for Brazilian nationals.¹³

If Brazil's 'access to medicine' justification was made in today's context, however, its weight would be significantly diluted. This is so, owing to the

⁹Brand, 'Article 2—Intellectual Property Conventions' in P-T Stoll, J Busche and K Arend (eds), *WTO—Trade-Related Aspects of Intellectual Property Rights* (Koninklijke Brill NV 2009) 140.

¹⁰*Brazil—Measures Affecting Patent Protection* (2001) World Trade Organization DS199.

¹¹Law No. 9.279 of 14 May 1996 (Law on Industrial Property (Brazil)).

¹²Law on Industrial Property (Brazil), art 68(1)I.

¹³Special 301 Report of the US Trade Representative dated 30 April 2001, 10 (emphasis added).

developments that led to the Doha Declaration¹⁴ which expressly recognized the ‘...gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.’¹⁵ As such, the provisions in TRIPS that permit WTO Members to implement compulsory licenses in cases of national emergency,¹⁶ would cast doubt on the justifiability of the use of compulsory licensing for failure to locally work a patent to achieve the same end of access to medicine.

At first blush, at least, the practice of issuing a compulsory license for failure to locally work a patent as permitted by the Paris Convention is a prohibited measure under TRIPS, as it directly conflicts with Article 27:1. How then could Article 5A(2), read with 5A(4), of the Paris Convention be reconciled with TRIPS, if at all?

4 Attempting to Reconcile the Conflict

The answer to the above question lies in the manner in which the two instruments, i.e. the Paris Convention and TRIPS, are interpreted. To begin with, it is necessary to consider whether there is in fact a conflict at all. In this regard, reference must be made to Article 2:1 of TRIPS, which provides that ‘[i]n respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention.’ Thus, every WTO Member must, in addition to TRIPS, comply with those provisions of the Paris Convention as set out in Article 2:1 of TRIPS. The use of the term ‘comply’ indicates that the reference is to provisions of the Paris Convention that imposes ‘obligations’ on Paris Union states. This is buttressed by Article 2:2 of TRIPS, which provides:

Nothing in Parts I to IV of this Agreement shall *derogate from existing obligations* that Members may have to each other *under the Paris Convention*, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits (emphasis added).

Hence, the question must be posed whether Article 5A(2), read with 5A(4), of the Paris Convention imposes any obligations on contracting states. If the answer to this is in the affirmative, then nothing in TRIPS (including Article 27:1) could derogate, or detract, from such an existing obligation. In this regard, it has been submitted that provisions of the Paris Convention (and no doubt also TRIPS) falls into two categories—the first being those that are binding on Member States and the

¹⁴Declaration on the TRIPS Agreement and Public Health (adopted by the WTO Ministerial Conference in Doha on 14 Nov 2001) WT/MIN(01)/DEC/2 (Doha Declaration).

¹⁵Doha Declaration, para 1.

¹⁶TRIPS, art 31.

second being provisions that allow Member States to limit the scope of a certain right.¹⁷ Commenting specifically on Article 5A(2) of the Paris Convention, it has been submitted:

It is indeed noteworthy that paragraph 2 [of TRIPS Article 2] states that nothing in parts I to IV ‘shall derogate from existing obligations’ under the Paris Convention. There is no mention of derogation of rights. This has not been an oversight of negotiators. One might think that, because any obligation corresponds to a right, paragraph 2 implicitly contains a mention of rights, but this is not so. The Paris Convention in some instances does grant rights to countries that the Paris Union Members, rather than to intellectual property owners, without imposing any corresponding obligations. For instance, it was understood that under Article 5A(2), Paris Union Members had the right (and not a mere faculty) to impose on patentees a local working requirement. Under the TRIPS Agreement, such right has been curtailed. The purpose of the last words of Article 27.1 is therefore to derogate from a right that governments of Paris Union Members had under the Paris Convention and that was deemed to diminish the substantive protection of patent owners’ rights and constitute therefore an unjustifiable barrier to international trade.¹⁸

If such an interpretation is adopted, any domestic legislative measure providing for a local working requirement would not derive from existing obligations between Members of the Paris Union. Accordingly, it must be concluded that the principle against discrimination in Article 27:1 of TRIPS is not subject to, or in any way limited by, Article 5A(2), read with 5A(4), of the Paris Convention—thus giving rise to a conflict between the principle of non-discrimination and requirement for local working of patents. Therefore, any domestic legislative measure adopted by a WTO Member that provides for a local working requirement can only be justified if it is compliant with TRIPS, albeit this would otherwise have been freely permitted under the Paris Convention. In particular, Articles 27:1, 30 and 31 of TRIPS must be considered in this regard.

The TRIPS framework provides for exceptions that permit WTO Members to deviate from the exclusive rights that they are mandated to confer to intellectual property owners—including exclusive patent rights conferred under TRIPS Article 28. A domestic legislative measure adopted by a WTO Member that confers its government or other national authority to issue a compulsory license in cases where a patent has not been worked locally no doubt would amount to a limitation on exclusive patent rights that TRIPS guarantees. As such, a key question that must be considered is whether the imposition of a local working requirement under domestic law could be regarded as a permitted exception under TRIPS Article 30. A WTO Dispute Settlement Panel in *Canada–Pharmaceutical Patents* interpreting Article 30 of TRIPS observed that:

Article 30 establishes three criteria that must be met in order to qualify for an exception: (1) the exception must be ‘limited’; (2) the exception must not ‘unreasonably conflict with normal exploitation of the patent’; (3) the exception must not ‘unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third

¹⁷Brand (n 9) 147.

¹⁸Carvalho (n 5) 139.

parties'. The three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed.¹⁹

Thus, any local working requirement that might be introduced into domestic law of a WTO Member must satisfy the cumulative 'three-step' test set out in Article 30 of TRIPS—the first of which requires a determination as to whether the legislative measure amounts to a 'limited' exception. In this regard, it was observed by the WTO Panel in *Canada–Pharmaceutical Patents* that:

Although the word ['limited'] itself can have both broad and narrow definitions, [...] the narrower definition is the more appropriate when the word 'limited' is used as part of the phrase 'limited exception'. The word 'exception' by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term 'limited exception', the word 'limited' must be given a meaning separate from the limitation implicit in the word 'exception' itself. The term 'limited exception' must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.²⁰

The Panel further observed that '[t]o determine whether a particular exception constitutes a limited exception, the extent to which the patent owner's rights have been curtailed must be measured.'²¹ Article 28 of TRIPS entitles a patent owner to prevent all third parties from 'making, using, offering for sale, selling or importing' a patented product. Whereas, a local working requirement that compels a patent owner to locally work a patent, and if not face the consequence of the patent becoming the subject of a compulsory license authorizing the local manufacture and sale of the patented product, would essentially entitle the licensee to make, use, offer for sale and sell the patented product—which affects four of the five acts that are exclusive to a patent owner. Arguably, such an encroachment into a patentee's domain of exclusivity cannot be described as a small diminution of the rights in question.²² Thus, it must be concluded that a domestic legislative measure providing for the issuance of a compulsory license for the failure to locally work a patent cannot be regarded as a 'limited' exception, hence failing to satisfy the first requirement of TRIPS Article 30.²³

This is, however, not the end of the discussion, as Article 31 of TRIPS dealing with 'Other use without authorization of the right holder'²⁴ must be considered. Article 31 provides that: 'Where the law of a Member State allows for other use of

¹⁹*Canada–Patent Protection of Pharmaceutical Products* (2000) World Trade Organization WT/DS114/R, para 7.23.

²⁰*ibid*, paras 7.30, 7.31.

²¹*ibid*, para 7.32.

²²Chia-Ling Lee, 'The Legality of Local Patent Working Requirements under the TRIPS Agreement' (2013) 2 NTUT Journal of Intellectual Property Law and Management 39, 47.

²³P Champ and A Attaran, 'Patent Rights and Local Working under WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute' (2002) 27 Yale Journal of International Law 365, 383; Lee (n 22) 47.

²⁴TRIPS, art 31.

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.’

Footnote (7) referenced in Article 31 of TRIPS provides that ‘... ‘Other use’ refers to use other than that allowed under Article 30.’ In other words, exceptions to patent rights imposed under Articles 30 and 31 are mutually exclusive. However, if a WTO Member seeks to justify a compulsory license for failure to locally work a patent under Article 31 of TRIPS, it must be done on an individual basis and after ensuring that all requirements set out from paragraph (a) to (l) of Article 31 are satisfied.

The fact that compulsory licensing under Article 31 can only be granted on ‘individual merits’²⁵ means that there is no room for domestic legislation that calls for the issuance of a compulsory license²⁶ solely because a patent was not worked locally, without there being other factors that warrant such an outcome. In the event a WTO Member decides to issue compulsory licenses for failure to locally work a patent on a case-by-case basis and after considering the individual merits of each case, such a measure may be successful under Article 31 provided that the other requirements contained therein are satisfied. The requirements that are most relevant to the context of failure to work are discussed below.

First, a compulsory license can only be issued after the proposed user (typically, the government or someone authorized by the government) ‘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.’²⁷ Thus, before a compulsory license is issued for failure to locally work a patent, the enabling domestic provision must require the government (or the authorized party) to have attempted to negotiate with the patent owner to secure authorization to work the patent locally on reasonable commercial terms and conditions. On the other hand, a related (yet important) question is whether compulsory licenses for failure to work should be refused if the patent owner justifies his inaction by legitimate grounds in view of the specific requirement to that effect under Article 5A(4) of the Paris Convention. In this regard, it is necessary to consider the relationship between TRIPS Article 31 and Article 5A of the Paris Convention. Article 5A(2) of the Paris Convention specifically deals with

²⁵TRIPS, art 31(a).

²⁶A Eikerman, ‘Article 31—Other Use Without Authorization of Right Holder’ in P-T Stoll, J Busche and K Arend (eds), *WTO—Trade-Related Aspects of Intellectual Property Rights* (Koninklijke Brill NV: 2009) 567.

²⁷TRIPS, art 31(b). It must be noted that 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.

compulsory licenses for 'abuse' of patent rights, including failure to work. Some have contended that Article 31 of TRIPS is dependent on Article 5A(2) of the Paris Convention and that 'prevention of abuse constitutes a fundamental requirement for the grant of compulsory licenses of any kind.'²⁸ Yet, the preferred view is that Article 31 of TRIPS 'places no restrictions on the list of grounds upon which compulsory licenses may be granted. This seems to support the view that these unwritten grounds are to be separate from the category of abuse.'²⁹ While this may be true in respect of the grounds upon which a compulsory license is based, the question that is posed here is whether the specific requirement under Article 5A(4) of the Paris Convention should curtail the grant of compulsory licenses under Article 31 of TRIPS, where the ground used to justify the compulsory license is a failure to locally work a patent. In this regard, suffice to note that Article 2:2 of TRIPS provides that nothing in TRIPS shall derogate or detract from 'existing obligations' between Paris Union states (who also happen to be WTO Members). While it was argued that a 'right' to issue compulsory licenses under Article 5A(2) of the Paris Convention does not constitute an existing obligation, the requirement that such a license must be refused in the event a patent owner's inaction is justified amounts to an obligation between Paris Union states. Accordingly, it may be persuasively argued, that the requirement set out in Article 5A(4) of the Paris Convention must be read into the context of TRIPS Article 31, where failure to work provides the basis of a compulsory license. A similar argument would apply to the other requirement stipulated in Article 5A(4) of the Paris Convention that prohibits the imposition of compulsory licenses for failure to work a patent before the expiration of four years from the filing date or three years from the date of grant, whichever expires last.

Secondly, 'the scope and duration of [the compulsory license] shall be limited to the purpose for which it was authorized'³⁰ and must be 'terminated if and when the circumstances which led to [the issuing of the compulsory license] cease to exist and are unlikely to recur.'³¹ When a patent is not locally worked, and the patentee has no valid reason or excuse for not doing so, the purpose of a compulsory license is arguably to enable the patent granting country to acquire the benefits of local working. As such, after a compulsory license on this basis is granted, where a patentee provides an assurance to work the patent locally (either by himself or through suitable licensing arrangements), the compulsory license should cease, unless there are grounds to believe that the circumstances upon which the compulsory license was granted (i.e. failure to locally work the patent) is likely to recur,

²⁸J Straus, 'Implications of the TRIPS Agreement in the Field of Patent Law' in F-K Beier and G Schricker (eds), *From GATT to TRIPS: the agreement on trade-related aspects of intellectual property rights* (Weinheim 1996) 204.

²⁹Eikerman (n 26) 564.

³⁰TRIPS, art 31(c).

³¹*ibid*, art 31(g).

as well as subject to the interests of the party in whose favour the compulsory license was granted.

Thirdly, compulsory licenses under TRIPS Article 31 have to be non-exclusive and non-assignable.³² This represents the same basis upon which compulsory licenses are permitted under Article 5A(2) of the Paris Convention, and should raise no concern in practice.³³

Notably, however, compulsory licenses under TRIPS Article 31 are subject to a significant limitation. That is, the compulsory license ‘shall be authorized predominantly for the supply of the domestic market of the Member.’³⁴ Although this provision does not fully prohibit the exportation of products manufactured under a compulsory license, as it does allow the export of the ‘non-predominant’ part of the production,³⁵ the fact that the products must be supplied ‘predominantly’ to the local market may become a disincentive to licensees. The term ‘predominantly’ attracts a number of possible interpretations. Some suggest that where the domestic market of the Member granting the compulsory licence takes the greatest share of supply among all Members receiving products produced under the licence, then the product manufactured under a compulsory license is supplied ‘predominantly’ to the domestic market.³⁶ Others argue that a quantitative approach should be adopted in determining whether a product is supplied predominantly to the domestic market³⁷—e.g. ‘49.9% of the production under a compulsory licence could be exported.’³⁸ Another possible interpretation is that ‘the intentions of Members should be decisive in determining what constitutes a ‘predominant’ use of the compulsory licence’³⁹ according to which WTO Members would not violate their obligation under Article 31(f) if the granting of a compulsory licence is primarily aimed at supplying the domestic market.⁴⁰ It has been suggested that unless the last of these interpretations is adopted, WTO Members ‘with a small market would possibly be obliged either to allow for only uneconomical production or not to issue

³²*ibid*, arts 31(d), (e).

³³Paris Convention, art 5A(4).

³⁴TRIPS, art 31(f). However, it must be noted that this restriction does not apply to the export of ‘pharmaceutical products’ under a compulsory license to an ‘eligible importing Member’ (TRIPS, art 31bis).

³⁵Eikerman (n 26) 573.

³⁶FM Abbott, ‘Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health’ (2002) Quaker United Nations Office, Occasional Paper No 9 26 <<https://ssrn.com/abstract=1977304>>.

³⁷Carlos Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007) 321.

³⁸Jerome Reichmann and Catherine Hasenzahl, ‘Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America’ (2005) ICTSD Issue Paper No 5, 16 <https://www.ictsd.org/downloads/2008/06/cs_reichman.hasenzahl.pdf> accessed 1 January 2018.

³⁹Carvalho (n 5) 241.

⁴⁰Eikerman (n 26) 574.

compulsory licences at all⁴¹—which arguably defeats the very objectives of Article 31 of TRIPS. Accordingly, any domestic legislative measure providing for a compulsory license for failure to locally work a patent must provide that the licensee must primarily aim to supply the domestic market, which would not preclude the possibility of export.

Based on the foregoing discussion, any domestic legislation that provides for a local working requirement, through the vessel of a compulsory license for failure to work, would arguably be compliant with the TRIPS framework provided that it subscribes to the conditions expressly set out in Article 31, and those set out in Article 5A(4) of the Paris Convention made applicable by TRIPS Article 2:2.

There is, however, one other issue that must be considered, which potentially stands as a significant obstacle to local working requirements—i.e. TRIPS Article 27:1 which imposes an obligation against discrimination. Thus, it is necessary to consider the relationship between Articles 27:1 and 31 of TRIPS. In *Canada–Pharmaceutical Patents* the WTO Panel had to consider precisely that, but in the context of Article 30 of TRIPS. Accordingly, the Panel concluded that ‘the anti-discrimination rule of Article 27.1 does apply to *exceptions of the kind authorized by Article 30*.’⁴²

The dispute before the WTO Panel was whether discrimination as to the field of technology arose in the implementation of Section 55.2(1) of Canada’s Patent Act. The said provision, which created a regulatory review exception, provided as follows:

It is not an infringement of a patent for any person to make, construct, use or sell the patented invention *solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product* (emphasis added).

Thus, where a law requires approval to be granted by any authority before a product could be placed on the market, notwithstanding the existence of a patent, any third party which is planning to enter the market after the patent expires could use the patented product for the limited purposes of supplying information to the relevant authority in order to obtain approval. The rationale for this mechanism is to eliminate any delays that may be faced by third parties as a result of having to obtain regulatory approval prior to entering the market, especially in the pharmaceutical industry. While arguing that Section 55.2(1) was consistent with Article 30 of TRIPS, Canada sought to draw a distinction between TRIPS Articles 30 and 31 to suggest that the norms against discrimination enshrined in Article 27:1 do not apply to Article 30. In the process, however, Canada admitted that the non-discrimination principles did apply to Article 31 of TRIPS. The Panel accordingly concluded:

⁴¹ibid.

⁴²*Canada–Pharmaceutical Patents* (n 19), para 7.93 (emphasis added).

The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27:1, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30.⁴³

Such a conclusion renders the imposition of a compulsory license for failure to locally work a patent more difficult to justify—as even if a domestic measure permitting such compulsory licenses complies with all the requirements of Article 31, it still has to withstand the policy against discrimination set out in Article 27:1.⁴⁴

In view of the conclusion on the interaction between TRIPS Articles 31 and 27:1, it is necessary to determine whether there could ever be a TRIPS compliant local working requirement. In this regard there are two matters that merit attention. The first concerns the meaning of ‘discrimination’ in Article 27:1 of TRIPS. The second concerns the context in which the obligation not to discriminate arises.

The term ‘discrimination’ is perhaps one of the most difficult terms to define. The WTO Panel in the *Canada–Pharmaceutical Patents* dispute considered to great detail the meaning of discrimination in relation to Article 27:1 of TRIPS. The Panel observed in this context that:

The primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term ‘discrimination’. They speak in more precise terms. The ordinary meaning of the word ‘discriminate’ is potentially broader than these more specific definitions. It certainly extends beyond the concept of differential treatment. *It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment.* Discrimination may arise from explicitly different treatment, sometimes called ‘de jure discrimination’, but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called ‘de facto discrimination’....Discrimination’ is a term to be avoided whenever more precise standards are available, and, when employed, it is a term to be interpreted with caution, and with care to add no more precision than the concept contains.⁴⁵

The Panel concluded that Section 55.2(1) did not amount to *de jure* discrimination in that a plain reading of the said provision did not discriminate one field of technology over another. The European Commission (which was the complainant) argued that the Canadian provision resulted in *de facto* discrimination as well, since it was predominantly in the pharmaceutical industry that regulatory approval was required before a product can be placed in the market. As regards this, the Panel observed that:

⁴³ibid, para 7.91.

⁴⁴KJ Nowak, ‘Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in TRIPS Article 27’ (2005) 26 Michigan Journal of International Law 899. Scholars are divided on this point. Some scholars have argued that the WTO Panel was wrong in holding that the non-discrimination rule in art 27:1 applies to exceptions.

⁴⁵*Canada–Pharmaceutical Patents* (n 19), para 7.94 (emphasis added).

.. de facto discrimination is a general term describing the legal conclusion that an ostensibly neutral measure transgresses a non-discrimination norm because its actual effect is to impose differentially disadvantageous consequences on certain parties, and because those differential effects are found to be wrong or unjustifiable.⁴⁶

Thus, in simple terms discrimination arises from subjecting persons who are similarly situated or circumstanced, to differential treatment. In the case of Article 27:1 of TRIPS, whatever the field of technology, wherever the product is manufactured (i.e. whether locally produced or imported), or wherever the product was first invented, all patentable inventions are deemed to form one single class to which equal treatment must be afforded. Of course, in the event certain persons within that single class are discriminated, so long as the differential effects are not found to be wrong or unjustified, it may nonetheless be consistent with TRIPS. It is in this background that one must assess the possibility of imposing compulsory licenses in relation to products solely produced abroad and imported into a patent granting country. Thus, the question that must be posed is whether the issuance of a compulsory license that discriminates against a patent owner who solely imports the patented product into the country concerned *vis-à-vis* patent owners who produce the patented products locally, is a form of discrimination that is wrong or unjustified so as to violate TRIPS Article 27:1.

It has been submitted that the context in which the term ‘discrimination’ in Article 27:1 of TRIPS is used does not create an absolute bar against the forms of discrimination specified therein.⁴⁷ It was observed in *Canada–Pharmaceutical products* that:

[T]he context to which the Panel may have recourse for purposes of interpretation of specific TRIPS provisions, in this case Articles 27 and 28, is not restricted to the text, Preamble and Annexes of the TRIPS Agreement itself, but also includes the *provisions of the international instruments on intellectual property incorporated into the TRIPS Agreement*, as well as any agreement between the parties relating to these agreements within the meaning of Article 31(2) of the Vienna Convention on the Law of Treaties.⁴⁸

Accordingly, even though Article 5A(2), read with 5A(4), of the Paris Convention are not provisions that cannot be overridden by TRIPS (in view of the arguments made before concerning the effect of Article 2:1 and 2:2 of TRIPS), these provisions in the Paris Convention, being an international instrument on intellectual property ‘incorporated into TRIPS’, could still provide useful context for the interpretation of TRIPS Article 27:1. In light of this, it is necessary to consider the purpose for which Article 5A(2), read with 5A(4), was introduced to the Paris Convention, and whether a blanket prohibition on the imposition of compulsory licenses for failure to locally work a patent disregards that purpose.

⁴⁶*ibid*, para 7.101 (emphasis added).

⁴⁷Bryan Mercurio, and Mitali Tyagi, ‘Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements’ (2010) 19 *Minnesota Journal of International Law* 275.

⁴⁸*Canada–Pharmaceutical* (n 19), para 7.14 (emphasis added).

From a historical point of view, it must be noted that it was common practice for states to forfeit patents that were not worked in the territory in which patent rights were granted. One of the earliest known patent legislation, the Venetian Patent Act 1474, required the active exploitation of patents, the failure of which resulted in the patent being cancelled.⁴⁹ In other words, if a patent owner resorted to the practice of solely importing the patented product, the country of importation was permitted to forfeit the patent resulting in the complete extinguishment of the rights of a patent owner in that territory. Forfeiture was regarded as too harsh a punishment, and it was in this regard that Article 5A(1) of the Paris Convention was put into place. Article 5A(1) of the Paris Convention provides that '[i]mportation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent', thus, prohibiting forfeiture as a consequence of failing to locally produce a patented product. Therefore, the purpose of Article 5A(2) of the Paris Convention is to maintain the interests of the country granting patent protection, while also taking into account the interests of the patent owner. It was an important balancing act to mitigate the harshness of forfeiture and to address the abuse of patent rights that failure to locally work a patent could give rise to. As such, in interpreting TRIPS Article 27:1, the objectives of Article 5A(2), read with 5A(4), of the Paris Convention provides an important context, which cannot be disregarded.

Furthermore, the context for the purpose of interpreting a treaty shall also include its preamble.⁵⁰ In this case, the relevant instrument being the TRIPS Agreement, one may consider the preamble to TRIPS in an attempt to make sense of the intention of the contracting parties, when they negotiated Article 27:1. Since the preamble to TRIPS recognizes *inter alia* '...the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives...' one could argue that a blanket prohibition on the imposition of a local working requirement for the maintenance of exclusive patent rights would defeat the aims expressly recognized in the preamble to TRIPS. As stated earlier, imposing a local working requirement is a useful mode of achieving some of the 'developmental' and 'technological' objectives envisaged by TRIPS. Moreover, Article 31(3) of the Vienna Convention on the Law of Treaties provides that '[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.'

The objectives of TRIPS have been clearly laid down in Articles 7 therein, which provides that:

⁴⁹Christine MacLeod, *Inventing the Industrial Revolution: The English Patent System, 1660–1800* (Cambridge University Press 1988) 11.

⁵⁰Vienna Convention on the Law of Treaties (adopted on 23 May 1969, entered into force on 27 January 1980), art 31 (2).

The protection and enforcement of intellectual property rights should contribute to the *promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations* (emphasis added).

Thus, given that locally working a patent would no doubt carry out the objectives stated in Article 7 of TRIPS, the rules of interpretation require that the provisions of TRIPS including Article 27:1 be interpreted in a manner that gives effect to these objectives. This approach too demonstrates that TRIPS as a whole does not condemn the imposition of a local working requirement.

Also noteworthy are the principles laid down in Article 8 of TRIPS which reads as follows:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

This stresses the need for ‘socio-economic’ and ‘technological’ development and the need to prevent practices which ‘adversely affect the international transfer of technology.’ Accordingly, it may be persuasively argued that on an overall reading of TRIPS, the imposition of a local working requirement in a Member’s domestic law does not fall afoul of TRIPS Article 27:1 if such a measure can be justified on valid grounds. In particular, where the domestic legislative measure is grounded on TRIPS Article 31 and compulsory licenses for failure to work are granted on a case-by-case basis, the chances of it being compliant with TRIPS is much greater.

5 The Approaches in India and Sri Lanka

The discussion hitherto established that a local working requirement that utilizes the compulsory licensing mechanism envisaged under TRIPS Article 31, read with Article 5A(2) and (4) of the Paris Convention, might be compatible with the TRIPS framework provided that any discrimination that this might give rise to is justifiable and not wrong. In this part of the chapter, the approach adopted in India in respect of failure to locally work patents is considered in order to inspire legal reform in a jurisdiction further south, i.e. Sri Lanka.

5.1 The Law in India

Section 83 of the Indian Patents Act 1970 (PA 1970),⁵¹ provides as follows:

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 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;*
- (b) that they are not granted *merely to enable patentees to enjoy a monopoly for the importation of the patented article* (emphasis added).

Thus, sub-section (b) of Section 83 makes it patently clear that patents are not granted in India to merely allow patentees to exclusively import the patented product into the country, whereas Sub-section (a) sets out that patents must be worked in India to the extent reasonably practicable. This, arguably, establishes a local working requirement in India. Section 146(1) of the PA 1970 facilitates this by providing as follows:

The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

Section 146(2) of the PA 1970, read with Rule 131 of the Patents Rules 2003, requires patentees and licensees to provide an annual statement of commercial working. The statement must comply with Form 27 (as indicated in the Second Schedule to the Patent Rules 2003), and must include the following:

1. Whether the patent has been worked.
2. Justifications if the patent has not been worked.
3. If it had been worked, the quantum and value (in Indian Rupees) of the patented product locally manufactured and imported from other countries including details of those countries.
4. Details of licenses and sub-licenses granted during the year.
5. Whether the requirement to promote the public interest has been met partially, adequately or to the fullest extent possible at a reasonable price.

Thus, while there is a possibility for a patent to be regarded as sufficiently worked locally even though the patented product is solely imported, this seems to be the exception rather than the norm. Unless the patentee is able to provide

⁵¹T Kongolo, 'Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS): New Strategies for Developing Countries' (2000) International Business Law Journal 345. Apart from India, countries such as Congo, Kenya, Tanzania and Nigeria have provisions relating to local working of patents in their domestic laws.

justifications as to why the patented product cannot be manufactured locally, or where the requirement to promote the public interest is met by the importation of the patented product, it appears that a patent must be locally worked—i.e. by the local manufacture of the patented product or application of the patented process. This view is consistent with the decision of the High Court of Bombay in *Bayer Corporation v Union of India*,⁵² where the court held that although the local manufacture of the patented product is not a prerequisite for a patent to be considered as being worked in India, the patentee must establish why it is not possible to manufacture the patented product locally.

While the failure to submit statements of commercial working as required under the law could lead to substantial fines (up to ₹ one million),⁵³ what is notable is that the failure to locally work a patent could also become a ground upon which a compulsory license may be granted. This is possible in view of Section 84(1) of the PA 1970, read with Section 90. Section 84(1) permits the grant of compulsory licenses in the following terms:

At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of 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* (emphasis added).

Thus, while Section 84(1) itself expressly specifies that a compulsory license may be issued on the ground that a patent is not worked in India, Section 84(7) sets out instances when ‘the reasonable requirements of the public’ is deemed not to have been met. This includes the failure of the patentee ‘to work the patent in the territory of India on a commercial scale to an adequate extent or to work the patent to the fullest extent that is reasonably practicable.’⁵⁴ More importantly, the reasonable requirements of the public will be deemed not to have been satisfied where the ‘working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article.’ Notably, the general purposes for granting compulsory licenses include the objective of ensuring that ‘patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable.’⁵⁵

⁵²*Bayer Corporation v Union of India* (2013) Bombay High Court, WP No 1323 of 2013.

⁵³Patent Act 1970, s 122.

⁵⁴*ibid*, s 84(7) (d).

⁵⁵*ibid*, s 89(a).

On a reading of the aforesaid provisions that exist in the PA 1970, it is clear that the Indian approach requires the local working of patents, leading to the grant of compulsory licenses in cases where the requirement is not met. Arguably, the grant of compulsory licenses for failure to work complies with TRIPS Article 31, read with Article 5A(2) and (4) of the Paris Convention. If at all, there could be some controversy in respect of the requirement set out in TRIPS Article 31(f)—which requires licenses to be granted ‘predominantly for the supply of the domestic market.’ This is because although the grant of compulsory licenses in India are for the predominant ‘purpose’ of supplying to the Indian market, licensees ‘may also export the patented product, if need be.’⁵⁶ However, it may be argued that this approach is still compliant with TRIPS Article 31(f) in view of the broader, and more flexible, interpretation that may be afforded to that provision.⁵⁷ The Indian approach would arguably also satisfy the norms on non-discrimination enshrined in TRIPS Article 27:1, which are made relevant to the context of Article 31, since the approach to local working under the PA 1970 is not a generalized one, and instead adopts a case-by-case assessment in the public interest.⁵⁸

5.2 *The Law in Sri Lanka*

Unlike India, the approach adopted in Sri Lanka in relation to local working of patents is strikingly less specific, if not far less progressive. The law that regulates patents in Sri Lanka is contained in Part IV of the Intellectual Property Act 2003 (IP Act 2003). In particular Section 84(1) under the heading ‘Rights of owner of Patent’ provides that a patentee shall have inter alia the exclusive right to exploit the patented invention, while also empowering the patentee to exclude the unauthorized exploitation of the patent by third parties.⁵⁹ It is noteworthy that ‘exploitation’ of a patent is defined as ‘... the making, *importing*, offering for sale, selling, exporting or using the [patented] product.’⁶⁰ Whereas, the IP Act 2003 does not contain a single provision that expressly deals with failure to locally work patents. This is a significant disadvantage to Sri Lanka, as it could discourage the

⁵⁶ibid, s 90(1) (vii).

⁵⁷Eikerman (n 26).

⁵⁸Reddy and Kadri (n 4); Jorge Contreras, Rohini Laksharje and Paxton Lewis, ‘Patent Working Requirements and Complex Products’ (2017) 7 New York University Journal of Intellectual Property & Entertainment Law 1.

In *Bayer Corporation v Union of India*, the High Court of Bombay considered the ‘failure to work’ provisions of the Patent Act 1970 in light of TRIPS, art 27, 30 and 31. It seems that the High Court was of the view, albeit tacitly, that the provisions in the Patent Act 1970 permitting compulsory licenses for failure to locally work a patent is not inconsistent with TRIPS. For a more comprehensive discussion of the Indian approach.

⁵⁹Intellectual Property Act 2003, s 84(2)..

⁶⁰ibid, s 84(3) (emphasis added).

transfer of technology (being an important objective that developing countries strive to achieve through the patent system) in fields of technology that remain underdeveloped in Sri Lanka, while also being detrimental towards generating employment opportunities through the setting up of local industrial plants and factories.

However, Section 86(2) of the IP Act 2003, which replicates TRIPS Article 31, provides for the grant of compulsory licenses, and there is a possibility that compulsory licenses can be issued in cases of failure to work, albeit this has never happened so far. Unlike in India, where compulsory licenses may be granted on inter alia the ground that a patent has not been locally worked, the corresponding Sri Lankan provision does not specify any grounds upon which such licenses may be issued. In exercising his discretion, the Director General of Intellectual Property, must only be satisfied that 'the applicant has made efforts to obtain approval from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.'⁶¹ Unlike in the case of the Indian provision, where a compulsory license may be granted only after the expiration of three years from the date of grant of a patent, the corresponding Sri Lankan provision does not contain such a restriction. While TRIPS Article 31 does not itself impose such a requirement, in cases of failure to work, it must be recalled that Article 5A(4) of the Paris Convention imposes this requirement. As such, in the case of Sri Lanka, the competent authority in issuing compulsory licenses on the ground of failure to work must comply with Article 5A(4) of the Paris Convention, in addition to the requirements set out in TRIPS Article 31. Most significantly, Section 86(2)(d) provides that the exploitation of a patent under a compulsory license 'shall be predominantly for the purpose of supply to the domestic market,' which is included to comply with TRIPS Article 31(f). The wording of this provision is much narrower in comparison to the corresponding Indian provision (which requires licenses to be granted for the 'predominant purpose of supply in the Indian market'). While the Sri Lankan provision has literally reproduced TRIPS Article 31(f), the Indian provision has adopted a style that corresponds to a broader interpretation of the same TRIPS provision. Thus, unless the Sri Lankan competent authority adopts a broader and more flexible approach in interpreting Section 86(2)(d) when imposing conditions on a licensee under a compulsory license, the requirement to supply predominantly to the domestic market may stand as a disincentive to licensees in Sri Lanka. This is particularly because the Sri Lanka market is small (in comparison to India) and unless licensees are able to engage in exportation, their operations may become uneconomical.

Thus, it would not be all that inaccurate to suggest that the Sri Lankan position in relation to local working is far less progressive than that of its neighbour's. In fact, when the Intellectual Property Bill 2003 (IP Bill) was originally introduced in Parliament, the draft did not even contain a clause that was equivalent to Section 86

⁶¹*ibid*, s 86(2)(b); This requirement may be waived in cases of national emergency of public non-commercial use (s 86(2)(c)). This complies with TRIPS, art 31(b).

in the IP Act 2003 that provides for limited exceptions and compulsory licenses. Yet, in view of the IP Bill's constitutionality being challenged, the Supreme Court made a determination that without provisions capable of providing for exceptions to the exclusive rights conferred on patent owners for a period of 20 years under clauses 83 and 84 of the IP Bill (the equivalent of Sections 83 and 84 of the IP Act 2003), both those clauses would be contrary to Article 12 of the Sri Lankan Constitution, which guarantees all persons the equal protection of the law. The Supreme Court in the course of its determination observed as follows:

None of these measures⁶² have been incorporated in the Bill on Intellectual Property. The provisions of the TRIPS Agreement clearly specify that it has incorporated mitigatory provisions, as the Agreement would be applicable for developed countries as well as to the less developed nations. In fact, World Trade Organization (WTO) has recognized the inequality of nations in respect of the TRIPS Agreement by prescribing a staggered time frame for the implementation of the Agreement among countries of different economic levels. Therefore it is an accepted fact that the provisions of the TRIPS Agreement would be applicable to countries developed as well as developing, which cannot be treated as equals. Article 12(1) of the Sri Lanka Constitution not only guarantees equality before the law, but also provides for the equal protection of the law. It is well settled law that just as much as equals should not be placed unequally, at the same time unequals should not be treated as equals.⁶³

Section 86 of the IP Act 2003 was a result of the Supreme Court's intervention and clearly intended to bring greater equality between Sri Lanka, as a nation that was (and still is) burdened with economic difficulties, and other more developed nations that were the proponents of the intellectual property system. Despite the intervention, however, it is unfortunate that, in formulating Section 86 of the IP Act 2003, the drafters have not been forward thinking in their approach, and instead thought it fit to simply reproduce TRIPS Article 30 and 31 verbatim. Thus, to overcome the potential disadvantages of the lack of a coherent legislative framework to facilitate the local working of patents, Sri Lanka would benefit by modifying its current approach to compulsory licensing. In particular, the following key points must be noted in making these modifications:

1. A list of grounds upon which compulsory licenses may be granted must be specified in the legislation. Such a list must be sufficiently open and wide, and must be non-exhaustive, while specifically stating that failure to locally work a patent is one of the grounds upon which a compulsory license can be granted.
2. In cases where a compulsory license is being granted on the ground of failure to work, in addition to the requirements set out in Article 31 of TRIPS, the legislative provision must also enshrine the requirements set out in Article 5A(4) of the Paris Convention.
3. In order to incentivize potential licensees that obtain licenses under compulsory licensing schemes, the legislation must adopt a flexible approach to

⁶²Here, the Supreme Court was referring to the exceptions to patent rights made available under TRIPS, arts 30, 31.

⁶³SC Special Determination No 14/2003 (SN Silva CJ).

- implementing the requirement in TRIPS Article 31(f)—i.e. the requirement that licenses must be issued ‘predominantly for the supply of the domestic market’.
4. The determination of the Director General of Intellectual Property to grant a compulsory license for failure to work must be based on rational and valid grounds and must be made on a clear case-by-case basis in order to prevent a violation of TRIPS Article 27:1.

6 Conclusion

Patents are aimed at encouraging innovation. However, abuse of patent rights can lead to tremendous hardships especially in developing countries. The patent system must attempt to draw a balance between the rights of the inventor, and others who seek to benefit from the invention. In this regard, the interests of the patent granting country must be taken into consideration. This would include the opportunities available for the transfer of technology, infrastructure development and the generation of employment opportunities in the fields in which patents are granted. These aims could not be achieved unless patents are locally worked—i.e. the patented product is manufactured or the patented processes are applied locally. The mere importation of a finished patented product, without any further processing in the patent granting country, would be of no benefit and the only outcome would be the sale of patented products at prices determined by patentees. Therefore, the imposition of a local working requirement is a measure by which a balance could be reached between the patent owner’s interests on the one hand, and the interests of the patent granting country, its government and citizens. What has been suggested in this chapter is that utilising compulsory licensing schemes permitted under TRIPS Article 31 to implement a local working requirement could achieve that fine balance, without unreasonably interfering with the rights and interests of patent owners, while also ensuring compliance with the non-discrimination policy of TRIPS Article 27:1. This chapter considered the approach to local working adopted in India and compared it with Sri Lanka’s approach, which unfortunately is much less developed and forward thinking. The chapter concluded by suggesting ways by which Sri Lanka’s legislative framework could be improved to facilitate and apply a local working requirement through the vessel of compulsory licenses permitted under TRIPS Article 31. It is only with a coherent policy and legislative framework on local working of patents that developing countries such as Sri Lanka could strive to achieve socio-economic prosperity and technological advancements within the WTO’s TRIPS framework.

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