COMPULSORY LICENSING AND DATA PROTECTION

At the 6 November 2000 meeting of the Issue Group on Access to Medicines, the Commission services announced that an EU position on compulsory licensing and on data protection would be made public in early 2001. These documents, entitled respectively “Legal Issues Related to Compulsory Licensing” and “Questions on TRIPs and Data Exclusivity” reflect the current assessment by the EU and its Member States, of some aspects relating to Articles 31 and 39.3 of the TRIPs Agreement. The EU reserves the right to re-assess some of these issues in the light of possible future developments. It should also be borne in mind that no WTO Member can give by itself an authoritative interpretation of provisions of the TRIPs Agreement.

LEGAL ISSUES RELATED TO COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT

AN EU CONTRIBUTION

I. EXECUTIVE SUMMARY

1. Compulsory licensing under TRIPs is a complex matter. Though allowing compulsory licensing under certain conditions, Article 31 TRIPS does not contain tailor-made solutions to problems raised by developing countries and NGO’s in the debate on access to health. Situations in which some WTO Members or civil society actors today envisage the use of compulsory licenses were not envisaged by the TRIPs negotiators. The assumption had always been that compulsory licensing was a tool of industrial policy and competition policy. To some extent, Articles 7, 8, 30 and 31 of the TRIPs Agreement could be envisaged to address some specific problems, but they would not offer a very high degree of legal certainty and could create huge risks of resort to dispute settlement by WTO Members. The wider policy debate underlying compulsory licensing would not be well served by legal battles and resort to dispute settlement. WTO dispute settlement on these matters will remain risky as long as there is no consensus on such interpretations among all signatories of the TRIPs Agreement.

2. The Paris Convention on the Protection of Industrial Property formally recognises Members’ rights to grant compulsory licences in cases of abuse of patent rights including “failure to work”.

3. Article 31 of the TRIPs Agreement leaves Members the freedom to determine grounds for granting compulsory licences, provided that the conditions and procedures imposed by Article 31 are met, and taking into account the other provisions of TRIPs.
4. Article 27.1 of TRIPs prohibits WTO Members to issue compulsory licences for lack of local manufacturing, i.e. for the sole reason that the domestic market is supplied, in all or in part, by imports and not exclusively by local manufacturing. It does not preclude Members from granting compulsory licences in cases where imports and/or local manufacturing of the patent protected products are insufficient to meet market demand or where the products are marketed on manifestly unreasonable terms.

5. It is not permitted under TRIPs to issue a compulsory licence with a view to supplying a third market (unless in case of anti-competitive practices).

6. The *chapeau* of Article 31 does not specify whether “third parties” authorised by government should be local or foreign manufacturers. Arguments by smaller developing countries that their right to issue compulsory licences would be meaningless if they could not grant a licence to a foreign manufacturer should be taken seriously, but TRIPs does not seem to give any legal certainty on this issue.

On the one hand, the TRIPs Agreement does not expressly preclude Members to grant third country manufacturers a compulsory licence for the supply of its territory. On the other hand, the TRIPs Agreement recognises the territoriality of patents and does not oblige WTO Members to recognise the effect, on their territory, of a compulsory licence issued by another WTO Member. Therefore, EU Member States do not recognise the effects, on their territory, of compulsory licences issued by other countries.

It might be possible to construct a reading of the TRIPs Agreement allowing (but certainly not obliging) a WTO Member to “recognise” a compulsory licence issued by a third country (in particular by invoking Article 30 in conjunction with Article 8 of the TRIPs Agreement), but it is not certain whether such reading would stand scrutiny by a panel or the Appellate Body.

Assuming a consensus on this issue would emerge among WTO Members, it would take considerable time before such a legislative basis would be in place. There is no quick solution to the question of foreign compulsory licensing.

7. With regard to transit of products under compulsory licence the legal problems are, *mutatis mutandis*, the same as for foreign manufacturing.

8. “Fast track” compulsory licensing is allowed under TRIPs, but only in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when a licence is issued as a remedy to practices determined by competition authorities to be anti-competitive.

The relevant legal provisions are set out in the annex.
II. ANALYSIS

A compulsory licence is an authorisation given by a national authority (Minister, National Patent Office etc.) to a person for the use and exploitation of a patented product or process without the consent of the patent holder. Compulsory licensing is an exception to the main principle of patent law, namely that the patent holder enjoys the exclusive right to authorise the use of its patented invention.

The emergence of compulsory licences is linked to historical obligations in patent laws to “work” (i.e. manufacture and market) locally a patented invention. Compulsory licences were gradually applied in other cases. Other typical grounds for compulsory licensing relate to circumstances of exceptional nature such as abuse of patent rights, emergency, public interest (e.g. public health), dependent\(^1\) patents, or anti-competitive practices.

A. Compulsory licensing under the Paris Convention

The Paris Convention on the Protection of Industrial Property formally recognises Members’ rights to grant compulsory licences. Under its Article 5A, Members can grant compulsory licences to prevent abuses of patent rights, expressly mentioning as an example “failure to work”\(^2\), provided that:

- a compulsory licence may not be applied for on the ground of failure to work or insufficient working 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;

- such licence must be refused if the patentee justifies his inaction by legitimate reasons;

- it must be non-exclusive; non-transferable, even in the form of the grant of a sub-licence, except with that part of the enterprise or goodwill which exploits such licence.

Apart from abuse of patent rights in general and failure to work, which is only mentioned by way of example, the Paris Convention does not mention other grounds for the granting of compulsory licences. Members remain free in this respect.

B. Compulsory licensing under the TRIPs Agreement

Compulsory licensing is dealt with under Article 31 of the TRIPs Agreement, where the practice is referred to as “use without authorisation of the right holder”.

\(^1\) A dependent patent is a patent which cannot be exploited without infringing another patent.

\(^2\) On the other hand, the possibility to forfeit a patent is not allowed unless in cases where compulsory licensing would prove ineffective to solve the problem created by the abuse of a patent right.
1. **On the basis of which grounds can compulsory licences be issued?**

Article 5A of the Paris Convention is part and parcel of the TRIPs Agreement: each WTO Member still has the right “to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights”. This is echoed by Article 8.2 of TRIPs: “Appropriate measures ... may be needed to prevent abuse of intellectual property rights by right holders”.

Article 31 TRIPs does not specifically pursue grounds on the basis of which compulsory licences can be issued, but rather conditions and procedures that have to be respected when issuing them. Earlier drafts (in particular the draft of 23 July 1990) did contain a limitative list of cases where compulsory licences could be granted, but there was disagreement among the negotiators. Finally, instead of defining specific grounds, it was preferred to impose strict procedural safeguards on the granting of compulsory licences.

Some grounds are however expressly mentioned in Article 31 (emergency and extreme urgency, public non-commercial use by government or third parties, dependent patents and anti-competitive practices) though without limiting the Member’s possibility to grant compulsory licences on other grounds. Other possible grounds could be deducted from other TRIPs provisions, such as for instance Article 8.2 allowing Members to take measures necessary to protect, inter alia, public health and nutrition or to prevent abuses, provided that such measures are consistent with the Agreement.

**Conclusion**: Article 31 of the TRIPs Agreement leaves Members some discretion in granting compulsory licences, provided that the conditions and procedures imposed by Article 31 are met, and taking into account the other provisions of TRIPs.

2. **Is lack of local working an acceptable ground under TRIPs for the granting of compulsory licences?**

Local working is traditionally understood to mean manufacturing and marketing of patent protected products within the territory of the country where the patent is registered. The term encompasses two notions:

- industrial use (local manufacturing)
- commercial use (sale of locally manufactured and/or imported patent protected products).

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3 Articles 1 through 12 of the Paris Convention are incorporated by reference into TRIPs, through Article 2.1.

4 *i.e.* to remedy an adjudicated violation of competition laws; to address national emergency; public interest concerning national security or critical peril to life of the general public; when the needs of the local market where insufficiently met.

5 The only case in which Members’ freedom to determine grounds for compulsory licences is restricted is on semi-conductor technology, which can only be subject to compulsory licenses for public non-commercial use and to remedy anti-competitive practices.
Under Article 5B of the Paris Convention, lack of local working is expressly allowed as ground for issuing compulsory licences. Article 31 nor mentions neither specifically excludes it. On this basis, one could argue *prima facie* that TRIPs allows granting of compulsory licences for lack of local working.

In fact, local working was one of the most controversial issues during the Uruguay Round negotiations. Developing country Members heavily insisted on a provision specifying that local working was one of the obligations of the patentee and pushed for an express recognition of compulsory licensing for lack of local working, while mainly the US was rather seeking for a narrowing of the scope of Article 5A.6

Chairman Annel’s draft of 23 July 1990 expressly limited (though in brackets) the grounds of compulsory licensing to inter alia “in the event [of failure to exploit the patented invention or that its exploitation][that the acts of manufacturing selling or importing the patented product or using the patented process ...] does not satisfy the [basic] needs of the local market before the expiration of a period of four years ...”.

The draft submitted to the Brussels Ministerial Conference of December 1990, also contained a paragraph on compulsory licensing in cases of failure to work, under conditions inspired by Article 5A of the Paris Convention, *i.e.* allowing compulsory licensing for failure to work after a certain period. But the bracketing in the final sentence shows again that negotiators were far from agreeing on this issue: “Such authorisation shall not be granted [where importation is adequate to supply the local market or] if the right holder can justify failure to work ...by legitimate reasons”.

Above drafts show the clear willingness of part of the negotiators to exclude compulsory licences based on lack of local manufacturing in cases where imports are sufficient to meet local market demand. Also, in both drafts the general non-discrimination clause on patents (later last sentence of future Article 27.1) did not prohibit discrimination between imported and locally produced goods.

As said above, Article 31 finally leaves open the cases in which compulsory licences can be granted. However, it can be inferred from the negotiation history of TRIPs that the stipulation that “patents shall be available and patent rights enjoyable without discrimination as to ...whether products are imported or locally produced” under Article 27.1 of TRIPs was introduced to cover local working requirements7. The applicability of this clause to Article 30 was confirmed by the WTO Panel in *Canada – Patent Protection for Pharmaceutical Products* (examining Article 30 TRIPs).8

On the basis of the above, it appears that a distinction should be made between:

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7 The link between Article 27.1 and Article 31 is confirmed by Article 70.6 of TRIPs: *Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorisation of the right holder where authorisation for such use was granted by the government before the date this Agreement became known*.
8 “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”.
i. a **local manufacturing requirement** allowing authorities to grant compulsory licence for the sole reason that no local manufacturing takes place, without regard to whether the patent protected products are imported in sufficient quantities to meet market demand and offered for sale on reasonable commercial terms.

ii. a **local marketing requirement** allowing authorities to grant compulsory licences in cases where imports and/or local manufacturing of the patent protected products are insufficient to meet market demand or, where the products are marketed on unreasonable terms

A local manufacturing requirement as described under i. would be incompatible with TRIPs. In such case, a licence could be granted for the mere reason that a patented product is imported. Only those types of patent protected products whose supply to the country issuing the licence is done, *in all or in part*, through import can be the subject of compulsory licensing on the basis of a local manufacturing requirement, while those type of patent protected products whose supply occurs exclusively through domestic production can never be subject to compulsory licensing on the basis of a local manufacturing requirement. Therefore, it discriminates against imported products, constituting a breach of Article 27.1 of the TRIPs Agreement. Also, it would be at odds with the general free trade and non-discrimination principles underlying the WTO Agreement.

This point of view remains contested by developing countries and some commentators, arguing that Article 27.1 would be met if, for instance a compulsory licence for lack of local manufacturing would put production and importation on an equal footing or that Article 27.1 only refers to discrimination in the exercise of rights against infringing goods, whether imported or locally produced. These arguments are not convincing, especially in the light of the negotiating history of the TRIPs Agreement.

A local marketing requirement which as described under (ii) is perfectly compatible with TRIPs, because it is not discriminatory, but is rather aimed at addressing abuse by the patent holder of its patent right within the meaning of Article 5A of the Paris Convention, as incorporated in TRIPs and Article 8.2 of TRIPs. This kind of requirements are common in industrialised countries' patent laws.

**Conclusion**: Article 27.1 of TRIPs prohibits WTO Members to issue compulsory licences for lack of local manufacturing, *i.e.* for the sole reason that the domestic market is supplied, in all or in part, by imports and not exclusively by local manufacturing.

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9. It has been argued that it should be possible to provide, in line with Article 8.1 TRIPs for the granting of compulsory licenses in qualified cases for lack of industrial working when such a lack would affect the commercial or industrial development of the country of sectors of vital interest.

10. Section 48 of the UK Patent Law for instance, which was recently amended to bring it into compliance with TRIPs, allows the grant of a compulsory license with regard to patents “whose proprietor is a WTO proprietor”, in cases where the demand in the UK is not being met on reasonable terms (while with regard to “non WTO proprietors” industrial local working still applies).
It does not preclude Members from granting compulsory licences in cases where imports and/or local manufacturing of the patent protected products are insufficient to meet market demand or where the products are marketed on unreasonable terms.

3. **Is it permitted to a WTO Member to issue a compulsory licence with a view to supplying a third market?**

Article 31(f) TRIPs specifies that when national authorities issue compulsory licences, this must be “predominantly to supply their domestic market”. Export considerations may not be a factor in considering the grant of compulsory licences, and it flows from this, following the wording of Art 31(c), that the terms of a compulsory licence should not explicitly permit exportation.

There is always an inherent risk that the products manufactured under compulsory licence will find their way to third country markets where they might come into competition with identical products put on the market with the consent of the patent holder. If the product in question is patent-protected in the third country market, these imports would be considered illegal.

There is one exception to the not-for-export rule: Article 31(k) TRIPs stipulates that when a WTO Member issues a compulsory licence as a remedy to practices determined, after judicial or administrative process (i.e. by duly appointed competition authorities and with respect of basic procedural rules) to be anti-competitive, such licence may be for export purposes.

**Conclusion**: it is not permitted under TRIPs to issue a compulsory licence with a view to supplying a third country market (unless in case of anti-competitive practices), but export is possible as long as local supply remains predominant.

4. **Is it required that manufacturing of products covered by the compulsory licence takes place in the country issuing the licence?**

This question is of particular concern to smaller developing countries. If such countries were to issue compulsory licences (on justified grounds and in line with Article 31 TRIPs), e.g. when a certain -patent protected- essential medicine does not meet market demand in that country or at least not on reasonable terms, it is very likely that no local manufacturer (if any) would have the capacity to produce that medicine within a reasonable time-frame, in sufficient quantities, not to speak of the quality it could offer. In such case, the right provided to that country under Article 31 would have no effect in practice, unless it were possible to entrust production to a foreign manufacturer.

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11 In principle, exhaustion should not apply to goods put on a market through compulsory licensing. Traditionally, the principle of exhaustion requires that the goods concerned have been put on the market in country B with the consent of the right holder. When goods have been put on the market in country B under compulsory licence, there is no consent by the right holder, and exhaustion should not apply. In the context of intra-EC trade, for instance, the ECJ held that the holder of a patent can oppose importation of a product produced in another Member State under compulsory licence (Case 19/84, Pharmon, ECR 2281).
The *chapeau* of Article 31 does not specify whether “third parties” authorised by government should be local or foreign manufacturers. Article 31(f) only stipulates that such use shall be predominantly for the supply of the domestic market (of the country issuing the licence), and remains silent on the locality of production. This also the case for Article 44.2 (on injunctions), which refers to third parties authorised by “*a government*”.

There is nothing in Article 31 itself which appears to prevent a Member from issuing a licence, for the use of its own domestic market, to a foreign manufacturer, although such situation had not really been envisaged by the TRIPs negotiators. The assumption had always been that compulsory licensing was a tool of industrial policy (to create a local technology-based industry) and competition policy (to correct abuse of monopoly). It is only very recently that compulsory licensing became an issue in the debate on access to health.

Other TRIPs Articles provide little guidance, except for Article 4bis(1) of the Paris Convention, as incorporated into TRIPs, which provides that “*patents applied in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries ...*” This principle of territoriality of patents means that patents granted in one country are independent from countries granted in another one. If patents are territorially independent, the same would apply to compulsory licences on patents. No country is obliged by TRIPs to accept the effect, on its territory, of compulsory licenses issued by a foreign authority. Therefore, the effective possibility for a foreign manufacturer to effectively engage into production will depend on the law of the country of production (COP).

- Of course, if the product under licence is not patent-protected in the COP because the COP is no WTO member or is not yet obliged by TRIPs to provide patent protection to the product under licence or simply because no patent has been applied for in the COP, there will be no patent holder in the COP to oppose manufacturing.

- If the products is patent protected in the COP and the latter is obliged to give full effect to TRIPs, it must, by virtue of Article 28 of TRIPs, guarantee to the patent holder, on its territory, the exercise of his exclusive right to prevent third parties not having his consent to manufacture the product under licence. Logically, the patent holder will seek to enforce this right through judicial or administrative proceedings. Two scenarios can be envisaged:

  i) If the COP’s patent legislation does not provide for an exception to the patent holder’s rights in case of production under a foreign compulsory licence, the COP’s judicial or administrative authorities will enforce the patent holder’s right, and prohibit production by the compulsory licensee. Article 31 does not oblige any WTO Member to accept the manufacturing, under foreign compulsory licensing, on its territory of a product that is patent protected on its territory. This is the case in the EU, where no Member State recognises compulsory licences issued by other countries.
No EU Member State patent law contains any provision exempting manufacturing under foreign compulsory licence from opposition by the patent holder for unauthorised use. This is perfectly in line with TRIPs: Article 31 TRIPs does not provide for this and Article 4bis(1) of the Paris Convention rather suggests the opposite.

ii) The COP could voluntarily accept that a compulsory licence issued by a third country can have effect on its territory. Such country may take the view that TRIPs allows limitations on the patent holder’s right in the COP’s territory and, on this basis, introduce legislation providing for an exception to the patent holder’s rights in case of manufacturing under a foreign compulsory licence. In such case the patent holder will not be able to prevent manufacturing, and the CIL will be supplied.

Under this scenario there is an apparent conflict between Article 31 and Article 28 of TRIPs: the CIL’s right under Article 31 would indeed be given full effect, but a third country (e.g. the country of origin of the patent holder or the country where the patent holder manufactures the products in question) could start a dispute settlement procedure against the COP for not having respected its obligations under Article 28 TRIPs.

On the basis of which TRIPs-provision could the COP justify this non respect?

i) Article 31? Article 31 authorises a Member to have legislation on compulsory licensing, and imposes a number of requirements in this respect, but Article 31, in itself, does not oblige, or even allow the COP to put aside its obligations under Article 28 TRIPs.

ii) Article 30? Maybe Article 30, allowing for limited exceptions under certain conditions\(^\text{13}\) would provide such basis to the COP. It allows taking into account the “legitimate interests” of parties other than the patent holder. But Article 30 grants Members a right, and does not impose any obligation. It is important to note that the footnote to Article 31 (“other use refers to use other than allowed under Article 30”) indicates that Articles 31 and 30 are mutually exclusive: a WTO Member can not invoke both Article 31 and Article 30 to justify the same practice. This does not necessarily exclude that a panel would find that two different WTO Members can each invoke one of these Articles, respectively the CIL, for issuing the compulsory license, and the COP for maintaining a limited exception for production under foreign compulsory licence. But it remains perfectly possible that a panel would find that this could not be the case.

\(^{12}\) Non-violation complaint might be an issue here, but not yet possible under TRIPs (see Article 64).

\(^{13}\) These conditions are that the exception:

a) is limited;
b) does not unreasonably conflict with a normal exploitation of the patent; and
c) does not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.
iii) Article 8. Article 8.1 authorises Members to take measures to protect public health (on their territory?) while Article 8.2. recognises the need to take appropriate measures, if consistent with the Agreement, to prevent abuse of intellectual property rights by right holders (without specifying whether this abuse has to occur on the territory of the Member taking such measure) or the resort to practices which unreasonably restrain trade. However, it is contested that Article 8 can be invoked on its own, let alone whether it would be sufficient ground by itself, to justify exceptions to the exclusive rights of the patent holder under Article 28 TRIPs, because it is conditional upon compliance with other provisions of TRIPs. It should be noted that the panel on *Canada – Patent Protection for Pharmaceutical Products* held that “Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments” and that “both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind [when interpreting Article 30] as well as those of other TRIPs-provisions which indicate its object and purposes”.

It follows from this that an extensive interpretation of Articles 30 and 8 of TRIPs may provide a ground for a WTO Member to justify an exception to Article 28 (such as recognition of a foreign compulsory licence) but this should be assessed on a case-by-case basis.

It is not certain whether a panel or the Appellate Body would accept justification of recognition by one WTO Member of a compulsory licence issued by another based on Articles 30 and 8 of the TRIPs Agreement. The panel could for example find that the COP, when recognising a foreign compulsory license, would in fact grant a compulsory licence itself, in which case such licence would have to meet all the disciplines of Article 31, including supply of its own domestic market (thus making supply of the CIL’s market impossible) The outcome of a WTO dispute settlement procedure is therefore, at best, uncertain.14

**Conclusion:**

Arguments by smaller developing countries that their right to issue compulsory licences would be meaningless if they could not grant a licence to a foreign manufacturer, should be taken seriously, but TRIPs does not seem to give any legal certainty on this issue.

On the one hand, the TRIPs Agreement does not explicitly preclude Members from granting third country manufacturers a compulsory licence for the supply of its territory. On the other hand, the TRIPs Agreement recognises the territoriality of patents and does not appear to oblige WTO Members to recognise the effect, on their territory, of a compulsory licence issued by another WTO Member.

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14 Another problem that may arise in the context of third country compulsory licensing is that of exports of products under licence to third markets. Article 31(f) TRIPs stipulates that a compulsory licensee shall be authorised predominantly for the supply of the domestic market of the Member authorising such use. This requirement would also apply in case of third country manufacturing. Could this be taken to mean that the third country licensee (if not prevented from production in the COP) would be entitled to directly export a “non predominant” part of its production under licence to other countries than the CIL or would such export only be possible via the CIL? No doubt that third country manufacturing may increase the risk of parallel imports.
It might be possible to construct a reading of the TRIPs Agreement allowing (but certainly not obliging) a WTO Member to “recognise” a compulsory licence issued by a third country (in particular by invoking Article 30 in conjunction with Article 8 of the TRIPs Agreement), but it is not certain whether such reading would stand scrutiny by a panel or the Appellate Body.

Even assuming a consensus on this issue would emerge among WTO Members, it would take considerable time before such a legislative basis would be in place. There is no quick solution to the question of foreign compulsory licensing.

5. **Transit of products manufactured under a compulsory licence?**

A further problem is the case where, for reasons of logistics, products manufactured in the COP on their way to the CIL transit through a third country, or in case of transit of products produced in the CIL itself under compulsory licence on their way to a country where the products are not patent protected or a country which accepts parallel imports of such products.

The legal problems and conclusion are, *mutatis mutandis*, the same as under point 4.

6. **Is fast track compulsory licensing allowed under TRIPs?**

The general principle is that there is no “fast track” compulsory licensing. Article 31(b) provides that compulsory licenses can only be issued if the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions, and that these efforts have not been successful within “a reasonable period of time”.

Nevertheless, this “prior attempt” 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 cases of national emergency or extreme urgency, the patent holder must only be notified of the issuing of the compulsory licence as soon as reasonably practicable. In the case of public non-commercial use, where the government (or its 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 patent holder must be informed promptly (Article 31[b]). Another case where “prior attempt” is not obligatory is when a compulsory licence is issued as a remedy to practices determined by competition authorities to be anti-competitive (Article 31[k]).

**Conclusion**: Fast track compulsory licensing is allowed under TRIPs, but only in cases of national emergency or other circumstances of extreme urgency, in cases of public non-commercial use or when a licence is issued as a remedy to practices determined by competition authorities to be anti-competitive.
III  **GENERAL CONCLUSION**

Compulsory licensing under TRIPs is a complex matter. Though allowing compulsory licensing under certain conditions, Article 31 TRIPs does not contain tailor-made solutions to problems raised by developing countries and NGO’s in the debate on access to health. Situations in which some WTO Members or civil society actors today envisage the use of compulsory licenses were not envisaged by the TRIPs negotiators. The assumption had always been that compulsory licensing was a tool of industrial policy and competition policy. To some extent, Articles 7, 8, 30 and 31 of the TRIPs Agreement could be envisaged to address some specific problems, but they would not offer a very high degree of legal certainty and could create huge risks of resort to dispute settlement by WTO Members.

The wider policy debate underlying compulsory licensing would not be well served by legal battles and resort to dispute settlement. WTO dispute settlement on these matters will remain risky as long as there is no consensus on such interpretations among all signatories of TRIPs.

The above interpretation reflects the current assessment of some aspects relating to Article 31 of the TRIPs Agreement. The EU reserves the right to re-assess some of these issues in the light of possible future developments. It should also be borne in mind that no WTO Member can give an authoritative interpretation of provisions of the TRIPs Agreement. Article 68 of the TRIPs Agreement entrusts the task of monitoring Members’ compliance with the TRIPs Agreement to the TRIPs Council.
Annex: Relevant provisions

Article 5A Paris Convention

Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licences.

(1) Importation 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.

(2) 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.

(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working 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; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

Article 7 TRIPs

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.

Article 8 TRIPs

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.

Article 27.1 TRIPs

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.

Article 31 TRIPs

Where the law of a Member allows for other use* of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:

(a) authorisation 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 authorisation 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 authorised, 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 authorised predominantly for the supply of the domestic market of the Member authorising such use;
g) authorisation for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorised, 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 authorisation;

(i) the legal validity of any decision relating to the authorisation 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 authorisation if and when the conditions which led to such authorisation are likely to recur;

(l) where such use is authorised 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 authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.

* "Other use" refers to use other than that allowed under Article 30
Article 44.2 TRIPs

Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorised by a government, without the authorisation of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgements and adequate compensation shall be available.
Before being marketed, new pharmaceutical products need to undergo a series of safety tests. It is on the basis of the results of these tests, made by the applicant and submitted to the regulatory authorities, that the latter may grant authorisation to market new pharmaceuticals.

The question of the protection of such test data arises when a request for market approval is filed for a product which is similar to an already approved product. Should the new applicant submit its own tests, or should he only show that his product is similar (“bio-equivalent”) to an already approved one, and let the regulatory authority rely on the test data of the original product? Data exclusivity prevents the regulatory authority from relying on these original data for a set period, during which no authorisation of medicines similar to those of the original applicant may take place on the basis of the original tests. The “copier” (usually a generic drug manufacturer) is then obliged either to produce its own tests or to wait until the exclusivity period has expired.

Data exclusivity is different from patent protection. Data exclusivity applies even for products which, although being new on the market, are not the subject of an application for patent protection. Where patent protection is sought, inter alia, as a way to compensate the inventor for its R&D efforts, the objective of data exclusivity is to compensate the manufacturer of a new product for time and money invested in running approval tests.

In the EC, data exclusivity is regulated by Article 4.8 of Directive 65/65 as amended by Directive 21/87, which grants Member States latitude to provide for data exclusivity periods from 6 to 10 years from the first marketing of the protect, or of 6 years maximum dependant on the term of patent protection of the relevant product. After completion of the exclusivity term, test data can be relied upon by new applicants (“abbreviated applications”). This regime is meant to strike a balance between the economic interests of the R&D based pharmaceutical industry on the one hand, and ethical considerations and the interests of the generic producers on the other hand. Switzerland grants 10 of data exclusivity and Australia, New Zealand and the USA grant 5 years.

The object of this note is to explore some issues related to data exclusivity which have recently been the object of controversy:

1. The exact meaning and scope of the obligation contained in Article 39.3. Does it oblige WTO Members to grant data exclusivity over a certain period of time?

2. Linkage of data exclusivity protection term to patent protection term.

16 OJ L 15, 17.01.1987, pp. 36-37
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3. Other issues raised by the pharmaceutical industry.

1. **Meaning and scope of Article 39.3 TRIPs**

The TRIPs Agreement requires Members to protect against “unfair commercial use” certain test data[^17] submitted to the government as part of the regulatory approval process. Article 39.3 of TRIPs reads:

“Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed tests or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use”.

Thus, Article 39.3 contains two obligations:

1. protect data against “unfair commercial use”; and
2. protect data against disclosure, unless it is necessary to protect the public or unless steps are taken to protect against unfair commercial use.

Proponents of data exclusivity, as it exists in the EC or the US, defending the interests of the R&D based pharmaceutical industry, argue that Article 39.3 was intended to prevent generic manufacturers from relying upon the originator's data as a “shortcut” to marketing approval, by giving the originator exclusive use of its data for a period of time sufficient for it to recoup the costs incurred in running trial tests and producing and compiling data for submission to regulatory authorities. According to the proponents, this is the only logical way in which Article 39.3 could be interpreted. They point out that non-disclosure is not an issue here, because generic manufacturers do not care about data to be publicly available or not, as long as regulatory authorities can rely on them for the benefit of their competitors. Finally, they also insist that data exclusivity does not prevent manufacturers of similar products from running their own tests and submitting the results to the regulatory authorities and obtaining authorisation on the basis of these own tests.

Opponents of data exclusivity claim that “data exclusivity” and “protection against acts of unfair competition” are different concepts which should not be confused. In their view, Article 39.3 only requires a form of data protection so as to prevent unfair commercial use of the data by competitors. The reason that certain companies are seeking an interpretation of Article 39.3 as meaning “data exclusivity” is to gain market protection for pharmaceutical products that are not covered by product patents. Since Article 39.3 has no time limitation, the effect of such an interpretation would be to provide an unlimited market protection against generic applications for an unpatented product.

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[^17]: Test data is not stricto sensu “undisclosed information” (as indicated in the title of Article 39.3) but rather information disclosed selectively and under precise conditions to regulatory authorities.
The question is thus whether article 39.3 obliges Members to prevent their regulatory authorities from using and relying on the data of a registered patent or non-patent protected product in examining similar products from generic manufacturers during a certain period of time.

It must be admitted that the wording of Article 39.3 does not, from a prima facie reading, appear to impose data exclusivity during a certain period of time. This lack of clarity is the obvious result of a difficult negotiation process where divergences of views arose between developing and industrialised countries as to the necessity of EC/US like type of data protection as well as among industrialised countries on the length of the data exclusivity period.

The main question of interpretation is what is meant by “unfair commercial use”. Clearly, this concept is different from the concept of “unfair competition”, as used in Article 39.1 with a reference to Article 10bis of the Paris Convention on the Protection of Industrial Property, and which relates to behaviour among competitors. Protection of registration data is a governmental function. Article 39.3 does not indicate whether the notion of “unfair commercial use” refers to unfair commercial use by generic manufacturers to those who have submitted the data (usually research-based pharmaceutical industry) or to use by regulatory authorities of these data to the benefit of competitors. Protecting data against “unfair commercial use” is also different from protecting them from disclosure, since the latter is a separate and distinct obligation under Article 39.3.

The office of the United States Trade Representative has defined “unfair commercial use” in Article 39.3 to mean that “the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorised by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision.”

Similarly, New Zealand stated that “we interpreted Article 39.3 as meaning that there is a restriction on the use which regulatory authorities can make of original data they hold in order to approve subsequent applications for approval of generic medicines, animal remedies or pesticides.”

According to the above statements, the only way to guarantee that no “unfair commercial use” within the meaning of Article 39.3 shall be made is to provide that regulatory authorities should not rely on these data for a reasonable period of time, the determination of what is a reasonable period of time being left to the discretion of the Members.

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18 Article 10bis of the Paris Convention defines unfair competition “any act of competition contrary to honest practices in industrial or commercial matters”. It refers to practices such as false allegations on competitors’ products or services, acts which may cause confusion about the origin and nature of products or services, undue advantage of the goodwill of another’s enterprise, parasitism, etc. as regulated in the EC’s member States’ national laws.

19 Office of the General Counsel, U.S. Trade Representative, The Protection of Undisclosed Test Data in Accordance with TRIPs Article 39.3, unattributed paper for submission in bilateral discussions with Australia (May 1995)

Earlier drafts of Article 39.3 made this purpose more explicit, by requiring governments to protect data not only against the “unfair exploitation by competitors” but also expressly providing that the data may not be relied upon for the approval of competing products. Chairman Annel’s draft of 23 July 1990 proposed:

“Parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right holder except with the right holder’s consent (...) Proprietary information submitted to a government agency for purposes of regulatory approval procedures such as clinical or safety tests, shall not be disclosed ....”

In the draft submitted to the Brussels Ministerial Conference of December 1990 this became:

“Parties, when requiring as a condition of approving the marketing of pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed tests or other data, the origination of which involves a considerable effort shall protect such data against unfair commercial use. Unless the person submitting this information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature and the expenditure involved in their preparation. In addition parties shall protect such data against disclosure, except where necessary to protect the public”.

According to one commentator, the US negotiators finally decided to drop the more explicit language of above drafts because they did not view such wording as essential because, in any event, “the accepted definition at the time of protection against unfair commercial use included non-reliance for a fixed period of time for new chemical entities”.

Article 39.3 of TRIPs, as it now stands, is not as explicit as the above drafts. However, both the logic and the negotiation history of Article 39.3 of TRIPs leave no doubt that providing data exclusivity for a certain period of time was the envisaged way to protect data against unfair use as prescribed by Article 39.3.

In theory, Article 39.3 appears to give Members the discretion to provide for different means of data protection, although it is very difficult to imagine other ways than non-reliance over a certain period of time, except for a (temporary) refusal to grant any second market approval to similar products (even if the second applicant submits its own data), as is the case in at least one WTO Member and maybe for an obligation to pay as a compensation for reliance on proprietary data without having to obtain consent from the first applicant. The question remains whether such payment would indeed be sufficient to guarantee that any “unfair commercial use” of test data takes place. For instance, it would be essential that such payment reflects the investments made by the original applicant – which may not always be easy to establish.
In theory, any country maintaining an effective system to implement obligations under 39.3, even if different from non-reliance over time, would not be in breach of its TRIPs obligations, but we are not aware of many alternatives and it is clear that what the TRIPs-negotiators had in mind was data exclusivity over a certain period of time. On the other hand, as it does not set any time limit, Article 39.3 would not prevent a country from providing for data exclusivity for an unlimited period of time.

Conclusion:

On its face, Article 39.3 of TRIPs contains an obligation to protect test data against “unfair commercial use”, and it seems that the most effective way to fulfil that objective, as envisaged by the TRIPs negotiators, is to provide for data exclusivity over a reasonable period of time. Whether any system other than data exclusivity over a reasonable period of time would meet the requirements of Article 39.3 of the TRIPs Agreement is to be assessed on a case-by-case basis, but examples of actual application by WTO Members of alternative -and TRIPs compliant- systems to non-reliance over a reasonable period do not appear to exist.

2. Link with patent protection period

Data protection is an obligation under TRIPs, whether or not the product whose test data are subject to data protection is patent protected or not. Data protection must be conferred on non-patent protected products.

The question is more delicate when it comes to products which are patent protected but whose “effective” patent protection, i.e. protection term remaining after marketing approval (which for pharmaceutical products can sometimes intervene up to 12 years, although on average only around 8 years after patent application) is very short. This depends on what should be considered the minimum reasonable term of data exclusivity for a country to meet its obligations under Article 39.3. Would this be 5 years (as is the case in inter alia the US), 4 years, or 3 years etc.? This remains an open question.

Conclusion:

WTO members must provide protection against unfair commercial use to all pharmaceutical or of agricultural chemical products which utilise new chemical entities for which the submission of data for marketing approval is required, whatever their patent-status.

3. Other issues

Recently, the TRIPs-compatibility of a number of data protection related practices has been put into question:

- The starting point for data exclusivity periods. Should this be as from the date of filing the market approval request or as from the date of market approval? Article 39.3 remains mute on this issue.
The starting point of data exclusivity as such cannot be the only relevant criterion to determine the TRIPs compatibility of a WTO Member’s data protection law. A protection period of 12 years as from the filing of a market approval request may be more effective than a 4-year period as from marketing approval. The question is whether the effective data exclusivity period is long enough to be considered as providing sufficient protection against unfair commercial use.

- Springboarding is a practice where review of applications by second applicants, relying on the original data, occurs during the period of data exclusivity, but marketing approval is only granted when the period of data exclusivity has expired. Again, such practice cannot, on its own, be considered as being non-compliant with Article 39.3 of TRIPs.

Conclusion:

Above two practices do not appear by themselves inconsistent with TRIPs. However, any such practice is to be assessed on a case-by-case basis, the main question being whether effective protection against “unfair commercial use” is granted. If such is not the case, the measure would in any event be in breach of TRIPs.

The above analysis reflects the current assessment of some aspects relating to Article 39.3 of the TRIPs Agreement. The EU reserves the right to re-assess some of these issues in the light of possible future developments. It should also be borne in mind that no WTO Member can give an authoritative interpretation of provisions of the TRIPs Agreement. Article 68 of the TRIPs Agreement entrusts the task of monitoring Members’ compliance with the TRIPs Agreement to the TRIPs Council.
Annex: relevant provisions

Article 4.8 of Directive 65/65 as amended by Directive 21/87:

“...without prejudice to the law relating to the protection of industrial and commercial property:
(a) The applicant shall not be required to provide the results of pharmacological and toxicological tests or the results of clinical trials if he can demonstrate:
(…)
(iii) or that the proprietary medicinal product is essentially similar to a product which has been authorised within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products within the meaning of Part A in the Annex to Directive 87/22/EEC (1) or of a medicinal product within the meaning of Part B in the Annex to that Directive for which the procedure laid down in Article 2 thereof has been followed; furthermore, a Member State may also extend this period to 10 years by a single Decision covering all the products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the above mentioned six-year period beyond the date of expiry of a patent protecting the original product.”

Article 39.3 of the TRIPs Agreement:

“Section 7: Protection of Undisclosed Information

1. In the course of ensuring effective protection against unfair competition as provided for in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly, of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question
(b) has commercial value because it is secret; and
(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret
3. Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed tests or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.