



KEI TPP Briefing note 2015:1 Compulsory licenses and the 3-step test¹

May 14, 2015

Main point: The TPP IP Chapter will limit the allowable exceptions to a patent holder's exclusive rights, as they relate to compulsory licenses and other non-voluntary authorizations to use patents. At risk are the flexibilities in Article 31 of the TRIPS. This can and should be fixed.

The World Trade Organization (WTO) TRIPS agreement creates obligations to grant patents, and creates a set of exclusive rights associated with those patents.

The TPP proposes to expand the obligation to grant patents, requires extensions of patent terms beyond 20 years, expands the rights associated with a patent, and creates stricter obligations to enforce those rights.

Like TRIPS, the TPP also provides for exceptions to the exclusive rights of a patent. But some versions of the TPP IP Chapter text propose to limit the space for exceptions. In particular, the May 16, 2014 version of the TPP IP Chapter proposed significant and perhaps radical restrictions on the use of compulsory licensing of patents. In this version of the negotiating text, the TPP would limit compulsory licenses to cases where the compulsory license does not “unreasonably conflict with a normal exploitation of the patent,” a standard not used in the TRIPS for compulsory licenses.

The WTO TRIPS agreement is the current global standard for patent exceptions. The core approach to exceptions in the TRIPS are two articles that can be used to justify a national exception -- TRIPS Articles 30 and 31.

In TRIPS, Article 30 has the title “Exceptions to Rights Conferred,” and it sets out in a single sentence of 49 words, three separate tests for an exception to patent rights.

Article 30 Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation

¹ Prepared by Andrew Goldman and James Love

of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 30 thus provides that exceptions must (1) be “limited,” and (2) “not unreasonably conflict with a normal exploitation of the patent,” and also (3) “not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” In the leading WTO dispute on patent exceptions, DS 114, failing *any* of the three are fatal for an exception.² According to the WTO, “They apply cumulatively, each being a separate and independent requirement that must be satisfied.”³

Except for a minor change in the proposed title and changing “Members” to “Each Party,” TRIPS Article 30 has been copied verbatim in Article QQ.E.4 in the TPP. The May 16, 2014 version of the TPP IP chapter reads as follows:

Article QQ.E.4: {Exceptions}

Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

TRIPS Article 31 is much different than TRIPS Article 30, in both style and substance. The title of Article 31 is “Other Use Without Authorization of the Right Holder,” and it applies “where the law of a Member allows for other use {footnote 7} of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government.” Footnote 7 says “‘Other use’ refers to use other than that allowed under Article 30.”

While Article 30 included a single sentence and 49 words of text, Article 31 includes 633 words, in paragraphs (a) through (l)(iii).

As discussed below, Article 30 of the TRIPS is described by the WTO as applying to “limited exceptions,” normally not involving remuneration to the patent holder or any type of case by case formal authorization by governments.

The WTO describes Article 31 as the provision for “Compulsory Licenses,” which typically involve both remuneration and more formal terms and conditions for which a government or a court authorizes a non-voluntary use.

The November 2013 version of the TPP IP Chapter included an Article QQ.E.5*quater*, which provided that the exceptions under Article 31 of the TRIPS were allowed.

² DISPUTE SETTLEMENT: DISPUTE DS114, Canada — Patent Protection of Pharmaceutical Products.

³ Guide to the TRIPS Agreement, Module V, page 10.

Article QQ.E.5quater

“Nothing in this Chapter shall limit a Party's rights and obligations under Article 31 of the TRIPS Agreement or any amendment thereto.”

In the May 12, 2014 version of the TPP IP Chapter, Article QQ.E.5quater had disappeared, leaving only the 3 step test as the standard for exceptions. The elimination of Article QQ.E.5quater has been harshly criticized by KEI.

New leak of TPP consolidated text on intellectual property provides details of pandering to drug companies and publishers

November 16, 2014 <http://keionline.org/node/2108>

Among the most significant changes from the August 30, 2013 version of the text (the last version leaked) are the modifications to the articles in the TPP that regulate exceptions to the exclusive rights in patents. In the August 2013 version of the TPP IP Chapter, there were four articles setting out the standards for exceptions to patent rights . This included (1) a general 3-step test based upon Article 30 of the TRIPS agreement, (2) a Regulatory Review Exception, sometimes referred to as the “Bolar” provision, (3) an experimental use exception, and (4) a provision on “Other Use Without Authorisation of the Right Holder,” which referenced Article 31 of the TRIPS. In the August 30, 2013 version only (1), the 3 step test, was out of brackets. See: August 30, 2013 text: Page 30-31

Article QQ.E.5: {Exceptions}

Article QQ.E.5bis: {Regulatory Review Exception}

Article QQ.E.5ter: {Experimental Use of a Patent}

Article QQ.E.5quater: {Other Use Without Authorisation of the Right Holder}

In the May 16, 2013 version of the text, there are now just two articles on exceptions.

See: May 16, 2013 text: Page 25.

Article QQ.E.4: {Exceptions}

Article QQ.E.1362 63: {Exceptions / Regulatory Review Exception}

The most shocking change in the text is the elimination of this article from the August 30, 2013 text:

Article QQ.E.5quater: {Other Use Without Authorisation of the Right Holder}

Why was this important? Because QQ.E.5quater, on "Other Use Without Authorisation of the Right Holder" provided that "Nothing in this Chapter shall limit a Party's rights and obligations under Article 31 of the TRIPS Agreement or any

amendment thereto."

Article 31 of the TRIPS is the provision under which all developing country compulsory licenses have been issued on drug patents.

By eliminating QQ.E.5quater, Ambassador Froman has created a new legal framework that will require that all compulsory licenses on patents will be subject to the restrictive language of TPP Article QQ.E.5: {Exceptions}. This QQ.E.5 language (familiar to many as taken from Article 30 of the TRIPS agreement) . . .

How does this change things? At present, a WTO member that wants to justify an exception or limitation on the exclusive rights of a patent will often justify that limitation under Article 30 OR Article 31 of the TRIPS. These are two separate paths for exceptions. How do they differ? Article 30 has the nice feature that there are no rules on procedures, and no requirement to pay money to right holders. For this reason, Article 30 is typically used to justify the exceptions that involve no money going to the right holder, such as the personal use exception, or the research or reverse engineering exceptions. But Article 30 is also restrictive, and risky, because the exception cannot "unreasonably conflict with a normal exploitation of the patent" or "unreasonably prejudice the legitimate interests of the patent owner."

For compulsory licensing, governments typically rely upon Article 31 of the TRIPS, which sets out in 642 words, a set of procedures that must be followed, limitations on the uses of compulsory licenses, and standards for remuneration of patent holders. Article 31 is seen as more complex, and less risky, because if you follow the rules in Article 31, the compulsory license cannot be challenged.

What Ambassador Froman is proposing in the TPP, and other TPP negotiators have agreed to, is to require that all compulsory licenses be subject to the so called 3-step test, which is risky and restrictive. This is a huge change in global norms on compulsory licensing of patents, and perhaps the single most consequential proposal in the TPP as regards patent rights.

. . .

For more context, and to better understand the significance of the elimination of TRIPS Article 31 exceptions, it is helpful to read the WTO's *Guide to the TRIPS Agreement*, which provides an extended discussion of exceptions under Articles 30 and 31, on pages 10-14 of its module V, on Patents. Among other things, the WTO guide gives examples of which exceptions are typically used, and whether they fit under Article 30 or 31.

- https://www.wto.org/english/tratop_e/trips_e/ta_modules_e.htm),
- https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules5_e.pdf

The WTO Guide describes the exceptions under Article 30 as “Limited Exceptions,” and those under Article 31 as involving “Compulsory Licenses”:

Other than the question of exhaustion of intellectual property rights dealt with in Module I, there are two types of permissible exceptions to the exclusive rights conferred on patent owners: (1) limited exceptions and (2) compulsory licences. These are explained in detail below.

(a) Limited Exceptions

TRIPS negotiators adopted the approach of establishing general principles rather than an exhaustive list. Many countries use this provision to provide that certain uses shall not infringe the patent rights. Often, limited exceptions to patent rights cover the use of the patented invention by third parties for:

- private, non-commercial purposes;
- research or experimental purposes (to varying degrees according to national legislation and jurisprudence);
- "early working" of patented pharmaceuticals for the purposes of obtaining marketing approval or the so-called "Bolar" provision;⁵
- prior use i.e. continuing use of the invention initiated secretly prior to the priority date/filing date;
- temporary use on vessels, aircraft or land vehicles temporarily or accidentally entering the waters, airspace or land. This exception is expressed as an explicit obligation in Article 5ter of the Paris Convention

Such uses, while taking into account the interests of the society and third parties, have not been considered to be unreasonably prejudicial to the interests of patent owners.

...

(b) Compulsory licences

The TRIPS Agreement does not use the term "compulsory licences" but rather "use without authorization of the right holder". Article 31 covers both compulsory licences granted to third parties for their own use and use by or on behalf of governments without the authorization of the right holder. A compulsory licence can be said to be a licence given by a government authority to a person other than the patent owner which authorizes the production, importation, sale or use of the patent-protected product without the consent of the patent owner. The TRIPS Agreement builds upon

the provision in Article 5A of the Paris Convention⁷, and recognizes the right of Members to authorize compulsory licences subject to conditions aimed at protecting the legitimate interests of the right holder that are detailed in Article 31. This was reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health (see details in Module IX). While setting out certain conditions, the TRIPS Agreement does not limit the grounds or underlying reasons that might be used to justify the grant of compulsory licences (except in the 7 Article 5A recognizes the right of Members 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 conferred by the patent, for example failure to work. A compulsory licence may not be applied for on the ground of failure to work or insufficient working before four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. It must be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence must be non-exclusive and not 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. 13 case of semi-conductor technology⁸). Article 31 does mention (1) national emergencies, (2) other circumstances of extreme urgency and (3) anti-competitive practices — but only as grounds when some of the normal requirements for compulsory licensing do not apply, such as the need to try for a voluntary licence first.

...

Some negotiators now recognize that it was a mistake to eliminate the references to Article 31 of the TRIPS, but the one proposal in 2015 to “fix” the omission of Article QQ.E.5quater is flawed.

In 2015, a version of the consolidated text of the IP Chapter was amended, by adding a footnote to Article QQ.E.4. This proposal, by Australia, reads:

“For greater certainty, nothing in this Chapter shall prevent a Party from taking measures pursuant to Article 31 of the TRIPS Agreement, including any waivers or amendments thereto.”

This language was similar to the proposed language in Article QQ.E.5quater that was present as recently as the November 2013 draft, but different in ways that were important, making the footnote weaker than the earlier article.

2015 Australia proposal: “Nothing in this Chapter shall prevent a Party from taking measures pursuant to Article 31

November 2013 language: “Nothing in this Chapter shall limit a Party's rights and obligations under Article 31”

“Shall prevent a Party from taking measures pursuant to” has a different meaning that “shall limit a Party's rights and obligations under.”

The problem with the Australia footnote is that it can be interpreted to mean that exceptions can use the procedures set out in Article 31 of the TRIPS, but they would still have to be consistent with the 3-step test -- meaning the footnote in the present form would solve nothing. Keep in mind that step 2 in the 3 step test is “not unreasonably conflict with a normal exploitation of the patent.” There is a risk that a compulsory license designed to expand access to a drug or a patented invention embedded in a standard would fail this test, in some fora.

The potential for a significant reduction in the Article 31 flexibility is illustrated by Figure 1.

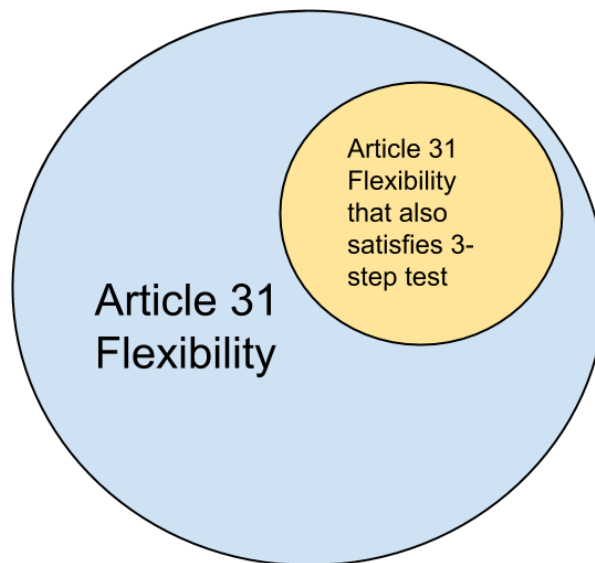


Figure: 1: Only a subset of Article 31 actions also satisfy the 3-step test.

Article 31 in the TRIPS is a stand-alone area for exceptions to exclusive rights. But in the TPP, the additional requirement that Article 31 actions be subject to the 3-step test would shrink the space for compulsory licenses. It is entirely inappropriate for a trade agreement,

negotiated in secret, to impose such a radical change in global standards for compulsory licensing of patents.

Potential Liability Under the Investment Chapter for Compulsory Licenses

As currently worded, the TPP's Investment Chapter⁴, Article II.7.5 (Expropriation and Compensation), makes the danger of the absence of Article 31 provisions all the more stark. Article II.7 establishes prohibitions against the direct and indirect expropriation or nationalization of a covered investment, and establishes the level of compensation owed for violation at fair market value of the expropriated investment as of the date of expropriation.

Article II.7: Expropriation and Compensation[15]

1. No Party may expropriate or nationalize a covered investment either directly or indirectly through measures equivalent to expropriation or nationalization ("expropriation"), except: (a) for a public purpose[16,17]; (b) in a non-discriminatory manner; (c) on payment of prompt, adequate, and effective compensation in accordance with paragraphs 2 through 4; and (d) in accordance with due process of law.
2. Compensation shall: (a) be paid without delay; (b) be equivalent to the fair market value of the expropriated investment immediately before the expropriation took place ("the date of expropriation"); (c) not reflect any change in value occurring because the intended expropriation had become known earlier; and (d) be fully realizable and freely transferable.
3. If the fair market value is denominated in a freely usable currency, the compensation paid shall be no less than the fair market value on the date of expropriation, plus interest at a commercially reasonable rate for that currency, accrued from the date of expropriation until the date of payment.
4. If the fair market value is denominated in a currency that is not freely usable, the compensation paid – converted into the currency of payment at the market rate of exchange prevailing on the date of payment – shall be no less than: (a) the fair market value on the date of expropriation, converted into a freely usable currency at the market rate of exchange prevailing on that date; plus (b) interest, at a commercially reasonable rate for the freely usable currency, accrued from the date of expropriation until the date of payment.
5. The Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter QQ._ (Intellectual Property

⁴ <https://wikileaks.org/tpp-investment/WikiLeaks-TPP-Investment-Chapter.pdf>

Rights) and the TRIPS Agreement.[18]

6. For greater certainty, a Party's decision not to issue, renew, or maintain a subsidy or grant, (a) in the absence of any specific commitment under law or contract to issue, renew, or maintain that subsidy or grant; or (b) in accordance with any terms or conditions attached to the issuance, renewal or maintenance of that subsidy or grant, standing alone, does not constitute an expropriation. <>

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[15] - Article II.7 (Expropriation and Compensation) shall be interpreted in accordance with Annex II-B and is subject to Annex II-C.

[16] - For greater certainty, for purposes of this Article the term "public purpose" refers to a concept in customary international law. Domestic law may express this or a similar concept using different terms, such as "public necessity," "public interest," or "public use."

[17] - For the avoidance of doubt: (i) where Brunei Darussalam is the expropriating Party, any measure of direct expropriation relating to land shall be for the purposes as set out in the Land Code (Cap. 40) and the Land Acquisition Act (Cap. 41), as at the date of entry into force of the Agreement; and (ii) where Malaysia is the expropriating Party, any measure of direct expropriation relating to land shall be for the purposes as set out in the Land Acquisition Act 1960, Land Acquisition Ordinance 1950 of the State of Sabah and the Land Code 11958 of the State of Sarawak, as at the date of entry into force of the Agreement.

[18] - For greater certainty, the Parties recognize that, for the purposes of this Article, the term "revocation" of intellectual property rights includes the cancellation or nullification of such rights, and the term "limitation" of intellectual property rights includes exceptions to such rights.

Article II.7.5 exempts compulsory licenses on intellectual property from the Expropriation article, but only "to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter QQ. (Intellectual Property Rights) and the TRIPS Agreement." The use of the conjunction "and" is potentially quite significant, as no matter what flexibilities the TRIPS Agreement provides, one plausible interpretation of this provision would be that because the independent availability of Article 31 is omitted from the TPP IP Chapter, a country that seeks to issue a compulsory license under Article 31 could be liable for expropriation, if the compulsory license did not also satisfy the 3-step test.

Such an interpretation would find support in Annex II-B, which, per footnote 15, guides interpretation of the Expropriation Article; Annex II-B paragraph 3(b), which says that there may be circumstances in which even acts "to protect legitimate public welfare objectives," such as public health, may constitute indirect expropriation. The fact that this footnote refers to "in rare circumstances," is helpful, but not that comforting, because for all TPP members, compulsory licenses represent only a tiny fraction of the patents granted, for any field of technology.

Annex II-B Expropriation

The Parties confirm their shared understanding that:

...

3. The second situation addressed by Article II.7(1) is indirect expropriation, where an action or series of actions by a Party has an effect equivalent to direct expropriation without formal transfer of title or outright seizure.

...

(b) Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, and the environment, do not constitute indirect expropriations, except in rare circumstances.

This potential for liability under the Expropriation Article magnifies the risks of creating a new standard in the TPP for compulsory licensing.

The IP Chapter's vague overtures to the Doha Declaration on TRIPS and Public Health have also been held out to defend change in the standards for compulsory licenses in the TPP. However, in the May 16, 2014 draft of the IP Chapter, the Doha Declaration is only referred to once, in the context of Article QQ.A.7, and in this Article, the reference is limited to "the effective utilization of the TRIPS/health solution," which appears to be a reference to the implementation paragraph 6 of the 2001 Doha Declaration. Paragraph 5 of the 2001 Doha Declaration, which provides an understanding of the grounds under which a compulsory license can be issued, is not referenced.

In Article QQ.A.7(a), the TPP proposes to mix different elements of the 2001 Doha Declaration on TRIPS and Public Health, losing the clarity and power of paragraph 4 in the 2001 version.

The insertion of confusing references to "HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency" have been proposed, to attempt to narrow the scope of the safeguards -- if not legally, at least in the minds of policymakers and the public. If these references are eliminated, the text would read:

The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. . . Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.

While the safeguard language in Article QQ.A.7(a) is helpful, it does not change the plain language of other binding provisions in the TPP IP text. For example, the TPP will require wider patenting of new uses of older drugs, patent extensions and exclusive rights in test data. Article QQ.A.7(a) does not eliminate these obligations, even though they frustrate the objective of "access to medicine for all."

Fixing the TPP on this issue

Negotiators could reinsert the disappeared proposed language of Article QQ.E.5^{quater} from the November 2013 draft as a standalone provision:

“Nothing in this Chapter shall limit a Party's rights and obligations under Article 31 of the TRIPS Agreement or any amendment thereto.”

Alternatively, Article QQ.E.4 could be modified.

Article QQ.E.4: {Exceptions} Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties, or alternatively that the exceptions comply with Article 31 of the TRIPS Agreement.

Our preferred option would be to replace the current language in Article QQ.E.4 with the following:

Article QQ.E.4:

Each Party may provide limitations and exceptions to the exclusive rights conferred by a patent that are consistent with the excetions allowed by the TRIPS Agreement, including but not limited to Article 30, 31 and 40.

Conclusion

The ability to grant a compulsory license on a patent is an important safeguard, and one that all TPP members will want to use, or threaten to use, in order to address abuses of patent rights or outcomes that are contrary to public policy goals. If the negotiators don't fix the problems in the current text, the space for compulsory licensing will be much smaller, and it will be far more risky to issue compulsory licenses, and the threats to grant compulsory licensing will be much less effective.

It is irresponsible, and truly astounding, that TPP negotiators would introduce new standards for the use of compulsory licensing of patents in a secret negotiation, without a public debate or any effort to consider the impact of such a move, not only on the health sector, where the risks are obvious, but on the economy as a whole, which is dealing with the consequences of patent thickets in many different areas.