

Selected differences between Articles 30, 31 and 44 of the WTO TRIPS Agreement as regards non-voluntary use of patented inventions

KEI Briefing Note 2022:3¹

October 12, 2022

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Introduction

Patents on inventions are typically thought of as a monopoly. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement), requires its members to grant the exclusive rights of “making, using, offering for sale, selling, or importing” a product or a product made by a patented process. (Article 28). But WTO members can also grant exceptions to those exclusive rights. These include both remunerative and non remunerative exceptions to rights, and importantly and consequently as regards the TRIPS, exceptions to the enforcement of the rights.

The distinction between exceptions to rights granted and the exceptions to the remedies to enforce those rights is somewhat arbitrary from the point of view of the right holder or the entity using an invention without consent from a right holder. A right without a remedy might not seem

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like much of a right, but it can make a big difference in terms of the way exceptions are regulated by the WTO.

The WTO TRIPS agreement includes an extensive set of exceptions to exclusive rights on patented inventions, including those relating to the exhaustion of rights (Article 6), exceptions to patentable subject matter (Article 27.2 and 27.3), a general reasonableness tested exceptions to rights clause (Article 30), a rules based exception for governments to authorize non-voluntary use of inventions (Article 31), possible exceptions to remedies to enforce patent rights,, including Article 44 on injunctions and Articles 45 on damages, measures to control anticompetitive practices (Articles 8, 31.k and 40), an exception for national security (Article 73), special rules for exporting certain medical products (Article 31bis and the June 17, 2022 TRIPS decision), and a time limited waiver for Least Developed Countries.

This note looks at three articles in the TRIPS Agreement regarding exceptions, Articles 30, 31 and 44. This is not an exhaustive review of the TRIPS rules, but rather a brief summary of the most important differences between the three articles. Among other things, the briefing note will highlight the advantages of Article 44 for permitting non voluntary uses of inventions, when remuneration is involved.

Part II, Section 5. Article 30 - Exceptions to Rights Conferred

Article 30 is a single sentence, some 49 words long. WTO members can provide exceptions to patent rights, so long as the exception satisfies three conditions. The exception to exclusive rights must (1) be limited, (2) not unreasonably conflict with a normal exploitation of a patent, and (3) not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Each of these conditions require some judgment calls regarding what is limited, reasonable, normal, prejudice or a legitimate interest.

In the one case testing Article 30 exceptions, the EU/Canada regarding patent protection of pharmaceuticals ([DS114](#)), a WTO panel found that Canadian's law permitting the nonvoluntary use of a patent to develop and test a generic drug, prior to the expiration of a patent, was allowed, as was the importing and exporting of a drug or its patented ingredients, in order to facilitate testing.

In arguing for the right to use the exception to important and export products based upon patented inventions, Canada made the following argument:

“Both the brand name and generic pharmaceutical industries were global in nature. Very few countries had fully integrated brand name or generic drug industries within their borders. Even in large countries, generic producers frequently had to obtain ingredients such as fine chemicals from producers in other countries. Many countries had no generic industries at all and had to obtain generic (as well as brand name) products from other countries. Smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on

an economic scale. Those industries had to export in order to be able to manufacture in sufficient quantities to achieve economies of scale, so that domestic consumers could receive the benefits of cost-effective generic products.”

WT/DS114/R, Page 79

On the other hand, the WTO ruled that the exception could not be used to manufacture and distribute drugs for storage in warehouses, until relevant patents expired. The EU/Canada DS114 decision came one year before the WTO Adopted the 2001 Doha Declaration on TRIPS and Public Health.

The take home message is that Article 30 exceptions are subject to scrutiny on several terms, including what constitutes a “limited” exception, what is the “normal exploitation” of a patent, what constitutes “unreasonable prejudice,” (reasonable prejudice is okay), even what constitutes prejudice (it is not the same as differentiation) what are the “legitimate” interests of the patent holder, and finally, what are the “legitimate interests of third parties.”

Typically Article 30 is used to justify exceptions that don’t involve payments to patent holders, such as the research exceptions in many national laws, or exceptions relating to aircraft or maritime vessels in transit, or the preparation of medicines carried out in pharmacies.

Some experts have argued that the exception can be used more broadly, to justify the export of medicines to countries without adequate access, to supply drugs for humanitarian purposes, or during health emergencies like the COVID 19 pandemic, or even to implement alternative reward mechanisms for drug development. There is a risk that a novel use of Article 30 to justify an exception can be subject to an adverse decision by a WTO dispute resolution panel, if challenged.

This risk of an Article 30 exception being rejected by the WTO was moderated by the 2001 Doha Declaration on TRIPS and Public Health. Paragraph 4 of that declaration states the TRIPS Agreement should be interpreted “in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” ([WT/MIN\(01\)/DEC/2](#)).

Part II, Section 5. Article 31 - Other Use Without Authorization of the Right Holder

Article 31 is an alternative to Article 30. Both address exceptions to patent rights.

In contrast to Article 30, which is short and provides a general framework, Article 31 is detailed and specific regarding its requirements and boundaries. In more than a dozen paragraphs and 643 words, Article 31 sets out restrictions and obligations. Among the more important conditions are the following:

- An authorization of such use shall be considered on its individual merits. (31.a)
- Before granting a nonvoluntary authorization, there has to be prior unsuccessful negotiation on “reasonable commercial terms and conditions,” a requirement that can be

waived in some (public noncommercial use, emergencies, remedies to anticompetitive practices) but not all cases. (31.b)

- The “scope and duration of such use shall be limited to the purpose for which it was authorized.” (31.c)
- The “authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances.” (31.g)
- The “use shall be authorized predominantly for the supply of the domestic market” (31.f) unless the authorization is “to remedy a practice determined after judicial or administrative process to be anti-competitive.” (31.k)
- There is a requirement for “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization,” (31.h) which can take into account the need to correct anti-competitive practices. (31.k)
- All of the decisions must be subject to “judicial review or other independent review by a distinct higher authority in that Member.” (31.i)

Some governments have struggled to enact and use exceptions within the Article 31 framework.

Particularly problematic is Article 31.f, which contains the restriction on exports. This provision is designed to limit the economies of scale available to a manufacturer, and, as noted by Canada in DS114, it has a significant negative impact in markets for biomedical products and particularly for WTO members with smaller domestic markets. The 31.f export restriction is both a barrier to reaching export markets and a problem for importers seeking a supplier.

The restriction on exports in 31.f are seen as so flawed that it has led to two different limited, complex, protectionist and widely criticized as inadequate overrides (Article 31bis and the June 17, 2022 decision on TRIPS). There are other workarounds in the TRIPS for exporting under a compulsory license, including using Articles 30 or 44 (see below), or declaring a compulsory license is a remedy to an excessive price or a failure to license, two grounds that meet the requirements of the Article 31.k exception to 31.f.

Some WTO members find the Article 31.k exception on exports daunting to use, in that it requires a “judicial or administrative process” to determine if a practice is anti-competitive. However, such processes, which can be purely administrative, including appeals, do not have to be complex or time consuming, at least as regards the WTO requirements. Countries should explore more manageable administrative processes to better exploit this provision.

Part III, Section 2, Article 44 - Injunctions

The TRIPS Agreement is divided into seven parts and several sections within those parts. Article 30 and 31 of the TRIPS are in PART II, Section 5: Patents. These are the two articles most patent experts study.

Often overlooked is Part III, the Enforcement of Intellectual Property Rights, Section 2: Civil and Administrative Procedures and Remedies. The provisions on remedies apply to all of the intellectual property rights described in Part II of the TRIPS, including but not limited to patents.

Article 44 concerning injunctions is of particular interest, because when compensation or remuneration is offered, denying or eliminating even the possibility of an injunction works the same as a compulsory license, but is regulated quite differently by the TRIPS than an exception under Part II.

Article 44.1

Article 44 includes two paragraphs. The first paragraph, 44.1, requires WTO members to provide judicial authorities with “the authority to order a party to desist from an infringement.” While injunctions are possible, they are not mandatory. When an injunction is rejected, the infringing party can continue to use a patented invention, without permission from the patent holder. In these cases, the judicial authority can effectively override the exclusive rights to make, sell, import or export an infringing product or service, often with an obligation to provide a royalty to the patent holder. This is exactly what happens in a growing number of jurisdictions for a variety of purposes.

U.S. Supreme Court decision in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)

The most influential court case in this respect is the U.S. Supreme Court case *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). According to the Court, the decision to grant or deny such relief is an act of equitable discretion by a district court, reviewable for abuse of discretion. A four-factor test must be applied when considering whether to award permanent injunctive relief in disputes arising under the Patent Act. The party seeking the injunction is required to demonstrate:

- (1) that it has suffered an irreparable injury;
- (2) that remedies available at law are inadequate to compensate for that injury;
- (3) that considering the balance of hardships between the plaintiff and defendant, remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction.

The eBay decision has turned countless patent infringement disputes into an effective compulsory licensing case, with courts ordering a “running royalty” for future nonvoluntary use of the patent, instead of granting the injunction. The court ordered compulsory licenses have been used in a wide range of cases, including for many medical devices, as well as for software, automobiles, LED manufacturing, and many other purposes.

Since the 2006 eBay decision there has been a decline in requests for permanent injunctions and also injunctions granted. According to [Josh Landau](#), much of the difference is associated with patent holders whose business is licensing or litigating infringement claims rather than

making things, so called non practicing entities (NPEs) or Patent Assertion Entities (PAEs). Research by [Christopher B. Seaman](#) noted that U.S. courts are particularly less likely to grant injunctions in cases involving electronics, software or medical devices, and more likely in cases involving drugs or vaccines.

- Josh Landau, “Much Ado About Injunctions,” *Patent Progress*, August 1, 2019. <https://www.patentprogress.org/2019/08/01/much-ado-about-injunctions/>
- Christopher B. Seaman, “Permanent Injunctions in Patent Litigation After eBay: An Empirical Study,” *Iowa Law Review*, Volume 101, Issue 5, July 2016. <https://ilr.law.uiowa.edu/assets/Uploads/ILR-101-5-Seaman.pdf>

In the COVID 19 pandemic, Genevant and Arbutus claimed that Moderna’s mRNA COVID 19 vaccine infringed on their patents, but did not ask for an injunction. Moderna subsequently sued Pfizer/BioNtech claiming the Comirnaty mRNA COVID 19 vaccine infringed Moderna patents. In an August 22, 2022 [press release](#) announcing the lawsuit, Moderna said it “is not seeking to remove Comirnaty® from the market and is not asking for an injunction to prevent its future sale.”

The possibility of a judicial order to deny an injunction and order the payment of royalties on an infringing good is an important flexibility in the TRIPS agreement, although rarely used by developing countries, despite its well known use in the United States, and the expanding interest in using this flexibility in other high income countries. Among the important characteristics is that the nonvoluntary use can be effectively authorized by a court, independent of any action by the government, and does not have restrictions on exports.

Innogenetics v. Abbott Laboratories, 512 F.3d 1363 (Fed. Cir. 2008)

For example, In a 2008 dispute over patents relating to the Hepatitis C virus, the U.S. Court of Appeals for the Federal Circuit found the lower court grant of an injunction to enforce a patent on an Abbott Laboratory diagnostic test was an abuse of discretion. The Federal Circuit Court ordered a compulsory license that would condition future sales of the infringing product on a running royalty. The suggested royalty was set in Euros. (After the decision the parties reached agreement on a licensing agreement).

From the decision in **Innogenetics v. Abbott Laboratories, 512 F.3d 1363 (Fed. Cir. 2008)**

“The technology in this case pertains to diagnostic tools that not only detect but also classify hepatitis C virus (HCV) genotypes in a biological sample, which facilitates tailoring the treatment of patients with different genotypes. . . .

. . . the district court's grant of an injunction prohibiting future sales of Abbott's genotyping assay kits was an abuse of discretion and must be vacated. While the market entry fee was based upon the projection that Abbott could sell its product through 2019, even Abbott acknowledges that such future sales would be subject to the running royalty, a compulsory license. We remand to the district court to delineate the terms of the compulsory license, such

as conditioning the future sales of the infringing products on payment of the running royalty, the 5-10 Euros per genotyping assay kit.”

See related commentary:

- Robert Dailey, Innogenetics Loses Injunction; Abbott HCV Genotyping Test to Remain on the Market, Patent Docs, January 17, 2008.
<https://www.patentdocs.org/2008/01/innogenetics-nv.html>
- Andrew Goldman. Innogenetics v. Abbott – 2008 compulsory license granted for HCV genotyping kits under eBay v. MercExchange. KEIOnline.Org. March 8, 2018.

United States: 19 USC § 1337 - Unfair practices in import trade

The United States International Trade Commission (ITC) provides a forum for patent holders to seek injunctions that block infringing goods from entering the U.S. [[19 USC § 1337](#)] The statute provides that such injunctions can be denied if the injunction has a negative impact on “the public health and welfare” and other factors and conditions in the United States economy:

19 USC § 1337 - Unfair practices in import trade

...

(d) Exclusion of articles from entry

(1) If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

Even if the ITC grants an injunction, the President, sometimes acting through the U.S. Trade Representative, may decide to block the injunction. For example, in an August 3, 2013 [letter](#), Ambassador Michael Froman, acting on behalf of President Obama, overruled an injunction the ITC had granted to Samsung regarding Apple mobile phones and tablets that infringed on Samsung owned patents, thereby allowing the infringing goods to enter the market in the U.S.

Germany: 2021 Patent Act Amendments

In 2021, the German Patent Act was amended, to provide a court with greater discretion so that injunctions are not automatically granted to the patent holder when there is an infringement of a patented invention.

One motivation for the change in the German law on injunctions is to provide more flexibility in cases where a product is complex and uses several patented inventions, although the discretion

provided by the new law is broader, particularly as regards the possible impact of an injunction on third parties, such as patients or consumers.

Section §139 of the German Patent Act now stipulates that:

“The injunction is excluded insofar as it would lead to disproportionate hardship for the infringer or third parties not justified by the exclusive right due to the special circumstances of the individual case and the requirements of good faith. In this case, the infringed party shall be granted appropriate compensation in money. The claim for damages according to paragraph 2 shall remain unaffected.”

A thoughtful analysis of the change is provided by Professors Martin Stierle and Fraz Hofmann, in an article titled “The Latest Amendment to the German Law on Patent Injunctions: The New Statutory Disproportionality Exception and Third-Party Interests,” published in GRUR International, Journal of European and International IP Law.

<https://doi.org/10.1093/grurint/ikac101>

Stierle and Hofmann write that third party interests could include residents in a foreign jurisdiction, and gives an example of “a certain infringing medical device which is produced within Germany to be exported to a country of the global south where patients share an urgent demand.”

“The legal obligation to consider third-party interests arises predominantly from the need to take fundamental rights into account.¹⁵⁸ The relevant fundamental rights, in particular the right to the integrity of the person (Art. 3 CFR), protect not only EU citizens or individuals living within the borders of the EU, but everyone affected by an act of an institution, body, office or agency bound by these rights. Hence, third-party interests arising from outside of Germany or the EU need to be at least considered if the interests fall within the scope of an applicable fundamental right that provides protection.” (Stierle and Hofmann, Page 11).

The new flexibility to deny an injunction in lieu of forward looking compensation is also described as an exception that can address situations where the German compulsory licensing procedures were too burdensome or otherwise not appropriate.

As an alternative to a compulsory license, the German law would fall under Article 44.1 of the TRIPS, rather than Article 31.

In one recent case involving a pharmaceutical product, a court in Düsseldorf was asked by Gilead to reject a request for an injunction related to an infringing product, the HCV drug sofosbuvir, that infringed a patent held by NuCana. Gilead cited the interests of HCV patients. The court ruled that Gilead would first have to seek a compulsory license on an expedited basis.

- Taylor Wessing, Pharma cases: No proportionality defence without (expedited) request for compulsory license, Lexology. September 14 2022.
<https://www.lexology.com/library/detail.aspx?q=f4dd6063-d7c8-4b7d-9606-8992ac2a416>
[c](#)

- Dr. Julia Traumann and Marc L. Holtorf. Patent injunction proportionality defence dismissed in German pharma ruling, Out-Law. Pinsent Masons. October 6, 2022. <https://www.pinsentmasons.com/out-law/news/patent-injunction-proportionality-defence-german-pharma-ruling>

SEP FRAND cases

A growing number of jurisdictions may deny injunctions in cases involving standards essential patents (SEP), when the court determines the patent holder has an obligation to license on faire, reasonable and non discriminatory (FRAND) terms. This remains an area of evolving jurisprudence and considerable lobbying by patent holders and infringing manufacturers, and the trend is for more discretion, not less, in granting or not granting injunctions.

Article 44.2

Even more significant that the flexibility found in Article 44.1 is the second sentence in the second paragraph of Article 44.2.

Article 44.2 is one paragraph with two sentences.

Article 44.

...

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization 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 judgments and adequate compensation shall be available.

The first sentence, relates to a nonvoluntary use "authorized by a government," and states that when this obligations in Part II of the TRIPS are complied with, injunctions can be eliminated and remedies can be limited to "to payment of remuneration in accordance with subparagraph (h) of Article 31." This sentence enhances the flexibility provided in Part II of the TRIPS, when remuneration is provided. But the second sentence goes further. The key language is:

In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

If the availability of a remedy under Part III of TRIPS, including the possibility of a court ordered injunction, is "inconsistent with a Member's Law, declaratory judgments and adequate compensation shall be available."

What this paragraph says is that a WTO Member law can eliminate even the possibility of an injunction, so long as “adequate compensation” is available for an infringing use.

Among the WTO member statutes that benefit from this provision are several exceptions in copyright laws that eliminate injunctions, but require compensation, for example, for cases where a building under construction infringes upon a copyrighted blueprint.

Canada: No injunction in case of a building

Canada: No injunction in case of a building

40 (1) Where the construction of a building or other structure that infringes or that, if completed, would infringe the copyright in some other work has been commenced, the owner of the copyright is not entitled to obtain an injunction in respect of the construction of that building or structure or to order its demolition.

<https://laws-lois.justice.gc.ca/eng/acts/c-42/fulltext.html>

In the United States, there are multiple statutes where injunctions are not available to patent holders.

U.S. non military use of nuclear energy

A U.S. statute dealing with a public interest declaration relating to the nonmilitary use of nuclear energy eliminates the availability of injunctions, but does provide for compensation.

- 42 U.S. Code § 2184 - Injunctions; measure of damages
- 42 U.S. Code § 2187 - Compensation, awards, and royalties

U.S. Non-disclosed biological product patents

A section of the U.S. Affordable Care Act (ACA) eliminates the possibility of an injunction when a manufacturer of a biologic drug does not provide timely access to the patent landscape of a biologic drug. Depending upon the degree of the failure, the manufacturer’s remedies for infringement are limited to a reasonable royalty, or no compensation at all. The section of the ACA is also referred to as the Biologics Price Competition and Innovation Act (BPCIA), and the dynamic it is associated with is often referred to as the “patent dance.” The sanction of a limitation on remedies, including specifically the elimination of injunctions, is designed to motivate a manufacturer to provide a biosimilar competitor with complete information on the patent landscape relating to the manufacturing and use of a product. This is effectively a mandatory compulsory license, one that is consistent with Article 44.2 of TRIPS.

- 35 USC 271(e)(6)(B-C) Non-disclosed biological product patents

“(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

“(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.”.

Use for or by the U.S. Government under 8 U.S. Code § 1498

The most frequently used U.S. statute that eliminates the availability of injunctions is [28 U.S. Code § 1498](#), which applies to the government’s use of a patent, copyright, designs or sui generis protections for plant varieties or semiconductor chip products.

Paragraph (a) of the statute deals with patented inventions, and states:

“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . .”

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.”

The government can authorize a third party to use patents without the consent of patent holders in a variety of ways. Authorization can be either explicit or implicit, and done in writing or orally. The most common use of this authority uses a standard clause in the Federal Acquisition Regulations (FAR) [52.227-1](#), titled Authorization and Consent, which states:

“The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent . . .”

A contract can provide a 28 U.S. Code § 1498 authorization by simply including language in a contract that the FAR 52.227-1 clause is incorporated by reference.

Earlier research by KEI has identified 59 contracts or amendments relating to COVID 19 products that included such an authorization ([KEI BN:2022:1](#)), and 166 contracts with a FAR

52.227-1 reference that have been disclosed through to the U.S. Securities and Exchange Commission EDGAR system. ([KEI BN:2022:2](#)).

The legal mechanism used in the U.S. government use cases under 28 U.S. Code § 1498 have several important features:

- The authorizations are simple, only requiring a few words in a contract to reference FAR 52.227-1.
- Authorizations are decentralized and can be made by thousands of federal employees with warrants to enter into contracts for the U.S. government.
- There is no requirement for prior negotiations with patent holders.
- There is no requirement to name the relevant patents or notify patent holders.
- There are no notifications to the WTO.
- The authorization covers current and future patent grants.
- The FAR 52.227-1 authorization has been used extensively for goods distributed to the general public through retail outlets, including commercial pharmacies.
- There are no restrictions on exports.

Concluding comments

Each of the three mechanisms to allow non voluntary use of patented inventions have their advantages. The exceptions under Article 30 of the TRIPS are the most flexible regarding the question of compensation or remuneration, but are subject to WTO review regarding the questions of what constitutes “unreasonable prejudice,” “normal exploitation” and “legitimate interests” of patent holders and third parties. Article 31 is a largely rules based regime that has some certainty regarding some issues, but also can be complex and problematic regarding exports, a topic addressed in an unsatisfactory way by the WTO TRIPS amendment 31bis and the WTO’s June 17, 2022 decision on TRIPS and vaccine exports, and other topics.

The flexibility to permit non-voluntary use, under a “running royalty” compensation or remuneration for forward looking non voluntary uses is the best option for WTO members, but also the least appreciated.

Table: Selected differences between Article 30, 31 and 44 for non voluntary use of patented inventions

	Article 30, Exceptions to Rights Conferred	Article 31, Other Use Without Authorization of the Right Holder	Article 44 (injunctions denied or not available under national law)
Exceptions must be :”limited.”	Yes	No	No
Exceptions do not unreasonably conflict with a	Yes	No	No

normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.			
Authorization of such use shall be considered on its individual merits	No	Yes	No
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	No	Yes, except for national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.	No
Use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;	No	Yes, except when remedy to anticompetitive practice or regulated under Article 31bis or the June 17, 2022 agreement on TRIPS	No
Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;	No	Yes	No
Compensation/remuneration required?	Not required but taken into consideration	Required	Required