

Running royalties as remedy to continued infringement of patents, with an emphasis on United States legal practice under the eBay legal doctrine

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WTO rules on injunctions and damages

Where in TRIPS

Standards for injunctions and damages in cases of infringement are set out in Part III of the TRIPS on the Enforcement of Rights, Articles 44 and 45.

Obligations on injunctions

Governments are required to (44.1) give judicial authorities the discretion to grant *or not grant* injunctions, or (44.2) to create a system to compensation for infringing use when injunctions are never available.

Obligations on damages

Article 45 gives judicial authorities the authority to grant "damages adequate to compensate for the injury the right holder has suffered because of an infringement." The standards for compensation or remuneration in cases where injunctions are not possible are provided in Article 44.2.



The general rule for injunctions is found in TRIPS Article 44.1 - Injunctions

1. The judicial authorities **shall have the authority** to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.



Exception: WTO members can eliminate the possibility of injunctions, under Article 44.2.

TRIPS Article 44.2 - Injunctions

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.

Examples of 44.2 in the United States include 28 USC § 1498 (use by or for the government) and the Biologics Price Competition and Innovation Act (when patents are not timely disclosed to biosimilar competitors).



Running royalties as an alternative to an injunction are a non-voluntary authorization to use a patent, and have some important features

- 1. Limitations on remedies in Part 3 of TRIPS can be used to allow non-voluntary use of a patent, independent of and without regard to the requirements of non-voluntary uses in Part 2 of the TRIPS, such as Articles 30, 31 or 31.bis.
- 2. Most consequential, there are no requirements in Part 3 of the TRIPS to have prior negotiation on reasonable commercial terms (Article 31.b), or to limit exports to 49 percent of production (Article 31.f) or the complex procedures in Article 31.bis.
- 3. Article 44.2 of TRIPS permits governments to create liability rules for non-voluntary use of patents.



Implementation of TRIPS 44.1 in the United States



35 U.S. Code Chapter 29 - REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

35 U.S.C. § 283 - Injunctions

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.



Pre-*eBay*:

Common practice for patent infringement cases (not involving the federal or state governments) remedy was **monetary damages for past harm, plus permanent injunction absent exceptional circumstances.**

eBay Inc. v. MercExchange, LLC., 547 U.S. 388 (2006)

*MercExchange held a business method patent for "an electronic market designed to facilitate the sale of goods between private individuals by establishing a central authority to promote trust among participants."

*MercExchange sought to license its patent to Ebay, failed to reach agreement; filed patent infringement suit in E.D.Va.

*District Court found infringement, awarded damages but no permanent injunction. 275 F.Supp.2d 695 (E.D.Va 2003).



eBay Inc. v. MercExchange, LLC 547 U.S. 388 (2006)

On appeal, the Court of Appeals for Federal Circuit reversed, applying the general rule for permanent injunctions in patent infringement. 401 F.3d 1323 (2005). "...the district court did not provide any persuasive reason to believe this case is sufficiently exceptional to justify the denial of a permanent injunction."

On cert, the question for the Supreme Court was the "appropriateness" of this rule for patent infringement.



eBay Inc. v. MercExchange, LLC 547 U.S. 388 (2006)

eBay sought to have SCOTUS extend traditional 4-factor test for permanent injunctions using principles of equity to patent infringement.

For permanent injunction, plaintiff must demonstrate:

- 1) Irreparable injury
- 2) Remedies available at law (e.g. \$) are inadequate to compensate for the injury
- 3) Remedy in equity is warranted after balance of hardships (plaintiff/defendant)
- 4) Public interest would not be disserved by permanent injunction

The Court ruled for *eBay*, holding that the traditional 4-factor test applies to Patent Act disputes. (J.Thomas; unanimous)



eBay Inc. v. MercExchange, LLC 547 U.S. 388 (2006)

Justice Kennedy concurring opinion at 396:

"In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases. An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees. See FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3, pp. 38–39 (Oct.2003), available at http://www.ftc.gov/os/2003/ 10/innovationrpt.pdf (as visited May 11, 2006, and available in Clerk of Court's case file). For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. See *ibid*. When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement *397 and an injunction may not serve the public interest. In addition injunctive relief may have different consequences for the burgeoning number of patents over business methods, which were not of much economic and legal significance in earlier times. The potential vagueness and suspect validity of some of these patents may affect the calculus under the four-factor test."



Ebay Inc. v. MercExchange, LLC 547 U.S. 388 (2006)

Why is this significant?

-Injunction not the default remedy for patent infringement; a denied injunction will allow the continued infringing use of the patent in exchange for a running royalty

- There are many cases post-*eBay* where courts have denied injunctions but ordered the payment of a reasonable royalty for the continued infringement of the patents. These are sometimes called a "compulsory license" and the compensation a "running royalty" by the Judge.



WTO 2012 Trade Policy Review https://www.keionline.org/node/1712

Brazil:

Regarding the enforcement of IP rights, recent court decisions in the United States have allegedly responded to instances of infringement of medical patents by denying injunctive relief, instead granting monetary damages, often in the form of royalty payments, what would in effect provide for a compulsory licensing. Four examples of such cases are: Voda v. Cordis Corp., Innogenetics, N.V. v. Abbott Labs, Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, and Medtronic Somafor Danek USA, Inc. v. Globus Med., Inc.

Could the United States please confirm and elaborate on the decision of such cases? Are the monetary damages allegedly issued a type of compulsory licensing?

USTR:

The United States does not agree with the interpretation of such cases suggested by the question. The remedies in these cases reflect judicial determinations of the most appropriate form of relief in particular cases based on the application by those courts of relevant legal standards to the facts of those cases, not a form of compulsory licensing. The U.S. patent law (Title 35 of the U.S. Code) does not contain any compulsory licensing provisions.



The term "compulsory license" is frequently used by the courts in the context of denying permanent injunctions under *eBay*.

Judge Richard Posner uses the phrase six times in *Apple v. Motorola*, for example:

"A compulsory license with ongoing royalty is likely to be a superior remedy in a case like this because of the frequent disproportion between harm to the patentee from infringement and harm to the infringer and to the public from an injunction, a factor emphasized in Justice Kennedy's concurring opinion in *eBay*..."

Apple v. Motorola, 869 F.Supp.2d 901, 918 (N.D. Ill. June 22, 2012), *aff'd in part, rev'd in part and remanded*, 757 F.3d 1286 (Fed. Cir. 2014)



Post-eBay examples of denied injunctions in the US

In the field of medical technologies, the United States has rejected injunction and ordered running royalties in several cases, among others:

Oral contraceptives Arthroscopic surgical instruments Transcervical contraceptive devices Transcatheter heart valves Contact lenses Surgical Spine-Stabilizing Devices Grafts, stents and cardiovascular patches Hepatitis C Virus diagnostic tests Angioplasty guide catheters



Bard Peripheral Vascular v. W.L. Gore

Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., No. CV-03-0597-PHX-MHM, 2009 WL 920300 (D. Ariz. Mar. 31, 2009), aff'd, 670 F.3d 1171 (Fed. Cir. 2012), opinion vacated in part on reconsideration, 682 F.3d 1003 (Fed. Cir. 2012), and vacated in part on reh'g en banc, 476 F. App'x 747 (Fed. Cir. 2012)

Patent infringement case involving patents on **grafts, cardiovascular patches, stent-grafts** and related products. Injunction denied, particular emphasis on inadequate remedy at law and public interest.

Inadequate Remedy at Law. Plaintiff had already received lost profits and a 10% reasonable royalty rate totaling more than \$185 million at the time of the opinion. "… [A] fair and full amount of compensatory money damages, when combined with a progressive compulsory license, will adequately compensate Plaintiffs' injuries, such that the harsh and extraordinary remedy of injunction—with its potentially devastating public health consequences—can be avoided."

Public Interest. The District Court said that the potential disruption in product availability for thousands of cardiovascular patients was of great concern:

"... [T]he values of the Patent Act and the protections that it offers to the patentee are sometimes outweighed by the Court's equitable concern for the greater public good, particularly in the realm of vascular surgery and other potentially life saving technologies.... Given the utility of Gore's infringing products ... the important role that these products play in aiding vascular surgeons who perform life saving medical treatments, sound public policy does not favor removing Gore's items from the market. The risk is too great. Placing Gore's infringing products out of reach of the surgeons who rely on them would only work to deny many sick patients a full range of clinically effective and potentially life saving treatments."



Edwards Lifesciences AG v. Corevalve

Edwards Lifesciences AG v. Corevalve, Inc., 2011 WL 446203, No. 08-91-GMS (D. Del. Feb 7, 2011)

Patent infringement case involving patents on **transcatheter heart valves** used to treat heart disease and the narrowing of aortic valves. Corevalve found to have infringed; Edwards awarded \$72M in lost profits and \$1.3M in reasonable royalties. Injunction denied, **concern of likelihood of injunction causing Corevalve to move to MX**.

Irreparable Harm. Noting that injunction is a prospective remedy and the "irreparable" component of the injury was past conduct. Edwards did not allege prospective lost customers, and the Court noted that Edwards' own briefs focused on past conduct.

Inadequate Remedy at Law. Edwards failed to produce any evidence or testimony in the record in support of its assertion that monetary damages would be insufficient to compensate prospectively. Edwards did not dispute that in the event of an injunction on U.S. manufacturing, Corevalve could move operations to Mexico and remain on the U.S. market with little to no interruption. The Court additionally noted that Edwards had already licensed its patent to a competitor and that such licensing was evidence that monetary damages could compensate for future infringement by Corevalve.

Balance of Hardships. "[T]he only practical effect of a permanent injunction would be that CoreValve would be forced to move its United States manufacturing operations for the accused product to Mexico," with little impact on Edwards' market position or ability to sell its products.

Public Interest. "The public interest would not be substantially advanced or harmed by the issuance of an injunction, since **CoreValve would be able to continue manufacturing accused product abroad without seriously affecting the supply** of the product available to the public."



TRIPS Article 31(f) ("any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use") and the Para 6 mechanism does not apply to these types of judicial compulsory licenses.



Conceptus, Inc. v. Hologic

Conceptus, Inc. v. Hologic, Inc., No. C 09-02280 WHA, 2012 WL 44064 (N.D. Cal. Jan. 9, 2012)

Patent infringement case involving patents on a **transcervically introduced permanent contraception system**. Hologic's system, "Adiana," found to have infringed Conceptus's "Essure," Conceptus awarded lost profits and 20% royalty. Injunction denied. (Factors 2, 3, 4)

Irreparable Harm. In favor of injunction. **Two-product market** for transcervical hysteroscopic sterilization, and Hologic took market share away from Conceptus. Essure is Conceptus's sole product, and "**Harm to the core of a patentee's business also supports a finding of irreparable harm.**"

Inadequate Remedy at Law. Conceptus **could be adequately compensated for its harm**, in spite of Conceptus's arguments that it had suffered and would continue to suffer non-financial harms (including, *e.g.*, abillity to attract and retain talented employees) and that it had never licensed the relevant patent and had not intention of doing so. The **Court noted that Conceptus did not argue that the damages award and royalty rate was incorrect, and that in fact Conceptus's own expert had argued for both.**

Balance of Hardships. Hologic **would be forced to lay off nearly 300 employees** directly related to the manufacture and research of Adiana, and **would lose \$215 million invested** in the development of the product.

Public Interest. The Court found that "the public interest would undoubtedly be harmed by an injunction," noting that enjoining Adiana would leave only one product for transcervical hysteroscopic sterilization. Clear public health benefits from having a choice of different products with different qualities.



Smith & Nephew v. Interlace Med

Smith & Nephew, Inc. v. Interlace Med., Inc., 955 F. Supp. 2d 69 (D. Mass. 2013)

Patent infringement case involving patents on an **arthroscopic surgical instrument**, a **surgical endoscopic cutting device** and method for its use. Irrep harm and inadequate remedy weighed slightly in favor of injunction; balance of hardships and public interest against.

Irreparable Harm. Defendant was a **direct competitor** (even in the absence of a two-player market), and evidence produced of S&N's **lost market share, increased sales costs and interference with S&N's customers**.

Inadequate Remedy at Law. Monetary damages inadequate to fully compensate for lost market share, lost business opportunities, and "intangible harm associated with the violation of its right to exclusivity." However, those damages could "nevertheless substantially mitigate S&N's losses," and furthermore found that a reasonable royalty would be easily calculable because defendant tracked sales of the infringing products.

Balance of Hardships. Potential hardships to defendant including the **loss of \$266 million investment** and over **150 jobs** far outweighing hardship to S&N (and noting that S&N's hardship could be at least partially remedied by monetary damages). Because USPTO reexamination proceedings were ongoing, a permanent injunction might later be invalidated if patents are voided, in which case defendant would face costs of \$38 million to restart its product line.

Public Interest. Defendant's evidence of the negative impact to doctors and patients outweighed S&N's evidence that there were no clinical studies showing any advantage of the Hologic device over S&N's. The Court stated that "Because different doctors may find one device or the other more suitable for particular intrauterine tissue procedures, health providers and patients benefit substantially from having both products available in the market."



Bayer Pharma AG v. Watson Laboratories

Bayer Pharma AG v. Watson Laboratories, Inc., No. 12-1726-LPS, 2016 WL 7468172 (D. Del., Dec. 28, 2016)

Watson's proposed generic found to have infringed Bayer's patents in **Natizia, an oral contraceptive**. Motion for permanent injunction denied. (Main factors: irreparable harm, inadequate remedy at law.)

Irreparable Harm. Bayer - speculative arguments re potential losses, had not submitted any data to explain the general magnitude of potential losses, nor proven how Watson's ANDA filing caused Bayer to change its marketing plans. Only slight possible necessity of future litigation with Watson, the relatively small sales of Natizia, and the "seemingly close-to-inconsequential" place that Natizia holds in Bayer's portfolio.

Inadequate Remedy at Law. Costs of litigation (including future litigation) could be compensated by damages, possibility of Watson prematurely and unlawfully launching a generic version without FDA approval would be unlikely to be deterred by an additional order by the Court where penalties for such behavior would already be subject to civil and criminal penalty.

Balance of Hardships. In favor of Bayer. Bayer stood to lose some value of its patent if infringing activity were to occur but there would be little, if any, harm to Watson in the event of injunction. The Court noted that there was **no** evidence in the record as to how much more quickly Watson could launch its proposed generic product without the injunction as compared to with the injunction in place.

Public Interest. Slightly weighed in favor of Bayer. While the Court acknowledged that the public has an interest in having an earlier launch of a generic, this was **slightly outweighed by the public interest in protecting valid patents and encouraging investment in new products**. The Court noted that **neither side presented evidence on these points**.



Trade Secrets: CardiAQ Valve Techs., Inc. v. Neovasc

CardiAQ Valve Techs., Inc. v. Neovasc Inc., No. 14-CV-12405-ADB, 2016 WL 6465411 (D. Mass. Oct. 31, 2016)

CardiAQ Valve Technologies ("CardiAQ") sued Neovasc for misappropriating CardiAQ's trade secrets related to CardiAQ's **transcatheter mitral valve** ("TMVI") device to develop its own competing device. After a jury returned a verdict that Neovasc had misappropriated CardiAQ's trade secrets, and awarded \$70,000,000 in damages, the Court heard post-trial motions including CardiAQ's motion for permanent injunction, and <mark>denied the injunction as far as CardiAQ's request that Neovasc suspend its TMVI program for 18 months</mark>.

Irreparable Harm and Inadequate Remedy at Law. CardiAQ's expert testified that Neovasc would have agreed to pay CardiAQ **\$90 million following a hypothetical negotiation** between the parties; among the assumptions made was that Neovasc had, through misappropriation of trade secrets, gained an **18-month head start** on its TVMI project. **"By now asking for Neovasc's project to be suspended for 18 months, CardiAQ is trying to have it both ways — it has already received damages that approximate the value of the 18-month head start to Neovasc, and now it seeks an injunction that would eliminate the 18-month head start."**

Balance of Hardships. CardiAQ's alleged hardship of having to compete with Neovasc at hospitals and for the attention of prominent surgeons is far less severe than that which Neovasc would face, including the **layoff of dozens** of employees dedicated to the TMVI program at issue, and the threat to Neovasc's existence given the size of the company and the centrality of the TMVI program to its business.

Public Interest. Both companies' prototypes differed in several respects and it was unknown which would be most effective at treating malfunctioning mitral valves. **"By imposing the 18-month injunction, the Court could potentially** delay the progress of the one TMVI device that works, and thereby keep a lifesaving device off the market for an additional year-and-a-half."



Wisconsin Alumni Research Foundation v. Apple, Inc., Case: 3:14-cv-00062-wmc, (W.D. Wis., June 6, 2017)

WARF filed suit alleging that Apple infringed on its computer processor patent, and requested permanent injunction, and a jury returned a verdict finding for WARF and awarding \$234M in damages. On post-trial motion, WARF sought permanent injunction. The Court denied the motion, and awarded WARF an ongoing royalty of \$2.74 per unit, backdated to the date of the judgment (October 2015).

Irreparable Harm. The Court was unconvinced by WARF's argument that the possibility of WARF having to engage in future litigation against Apple causes significant and unquantifiable harm. The Court also cited a passage from Justice Anthony Kennedy's concurring opinion in *ebay*.

https://www.keionline.org/node/2803



Patents - semiconductor patents for LED devices

Nichia Corp. v. Everlight Americas, Inc., 855 F.3d 1328 (Fed. Cir. 2017)

Everlight found to have infringed patents for Nichia's LED devices, but trial court denied motion for permanent injunction, finding no irreparable harm to Nichia and that monetary damages would be sufficient to compensate.

Federal Circuit affirmed, finding that Nichia failed to show irreparable harm:

In any event, regardless of the court's analysis of the licenses, we note that the court treated Nichia's licenses as an independent ground for denying the injunction. *Id.* It did not rely on Nichia's licenses in its earlier analysis of irreparable harm, but rather found the licenses to further bolster its prior finding. *Id.* The court's licensing analysis thus does not undermine its separate findings that Nichia failed to establish market competition, lost sales, and price erosion, and that these failures all weigh against a conclusion that Nichia would suffer irreparable harm absent an injunction. *Id.*

We discern no clear error in the district court's finding that Nichia failed to prove that it would suffer irreparable harm absent the injunction. On that traditional equitable factor, Nichia did not bear its burden. See W. T. Grant Co., 345 U.S. at 633, 73 S.Ct. 894. Because Nichia failed to establish one of the four equitable factors, the court did not abuse its discretion in denying Nichia's request for an injunction.

http://www.cafc.uscourts.gov/node/21867



Among the many other examples are cases involving Standards Essential Patents (SEP)

On January 8, 2013, the United States Department of Justice and the United States Patent & Trademark Office issued a **"Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments,"** which addressed the limitations on obtaining injunctions.

"By participating in the standards-setting activities at the [standards developing organization] SDO and by voluntarily making a F/RAND licensing commitment under the SDO's policies, the patent holder may be implicitly acknowledging that money damages, rather than injunctive or exclusionary relief, is the appropriate remedy for infringement in certain circumstances, as discussed below."

There are significant efforts to develop new policies on injunctions in the European Court of Justice (ECJ) and in several member states of the European Union, and in China, India and other countries.



2014: European Commission press release

Antitrust: Commission finds that Motorola Mobility infringed EU competition rules by misusing standard essential patents, April 29, 2014

"The so-called smartphone patent wars should not occur at the expense of consumers. This is why all industry players must comply with the competition rules. Our decision on Motorola, together with today's decision to accept Samsung's commitments, provides legal clarity on the circumstances in which injunctions to enforce standard essential patents can be anti-competitive. This will also contribute to ensuring the proper functioning of standard-setting in Europe. While patent holders should be fairly remunerated for the use of their intellectual property, implementers of such standards should also get access to standardised technology on fair, reasonable and non-discriminatory terms. It is by preserving this balance that consumers will continue to have access to a wide choice of interoperable products."

-Commission Vice President in charge of competition policy Joaquín Almunia

2015: European Court of Justice in Huawei v ZTE

In 2015, in a dispute between Huawei and ZTE*, the ECJ set out a procedure for patent holders and third parties to follow in cases involving requests for injunctions on standards essential patents:

- 1. Before bringing an action for injunctive relief, the SEP owner must notify the alleged infringer of the alleged infringement by designating the SEP(s) at issue and specifying the way in which it has been infringed;
- 2. The alleged infringer then must express its willingness to take a license on FRAND terms or else the SEP owner may pursue an injunction;
- 3. If the alleged infringer has expressed its willingness to take a license on FRAND terms, the SEP owner must make a specific, written offer for a license on FRAND terms specifying, in particular, the royalty and the way in which it is to be calculated;
- 4. The alleged infringer (if it continues to use the patent in question) then must diligently respond to that offer in accordance with recognized commercial practices in the field and in good faith, and without delaying tactics;
- 5. If the alleged infringer rejects the SEP owner's offer, it must make a specific, written counteroffer on FRAND terms; and
- 6. If the alleged infringer's counteroffer is rejected, the alleged infringer must, as of that time, provide appropriate security (including for past use) and be able to render an account of its acts of use.

Limin CHEN, Will Wang and Jimmy Chen, Zhong Lun Law Firm, Seeking Injunctions for Standard Essential Patents in China, Lexology, March 3, 2016

Generally under Chinese practice, SEP holders may obtain an injunction if the following conditions are met:

- 1. Licensor provides its licensees with a FRAND offer and acts in good faith in the negotiation.
- 2. Licensee engages in bad-faith behavior, specifically:
 - a. Engages in negligent or willful misconduct in the negotiation of the license agreement with the SEP holder, such as willfully delaying negotiations, which is known as "reverse patent hold-up."
 - b. Proposes unreasonable license terms. SEP holders cannot accept unreasonable licensing conditions not only because it would be inequitable but also because it would upset the public interest by creating a competitive disadvantage for all other SEP licensees.
- 3. The injunction does not harm the public interest. SEPs are usually part of a larger patent portfolio, which means preventing the implementation of an SEP can significantly impair a product or an entire industry. This will ultimately harm consumers. Therefore, courts and authorities consider the impact of injunctions on larger public interests. Claims to prevent ordinary consumers from using related products are generally not supported for this reason.

Recommendations

For WIPO SCP

Request a study providing information about the cases where non-voluntary use has been allowed as a limitation on remedies, perhaps with a focus on cases involving medical technologies and standards essential patents.

For governments

Consider mechanisms to implement compulsory license as a limitation on remedies, including cases where exports are involved.



Questions/Comments

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