eBay Compulsory Licenses

Judicially Mandated Licenses of Medical Technology Patents Post-*eBay v. MercExchange*

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Pre-*eBay*:

General rule for patent infringement 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
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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)

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

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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)

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Why is this significant?

-Injunction no longer the default remedy for patent infringement; a denied injunction will allow the continued infringing use of the patent in exchange for a running royalty

- Many cases post-*eBay* where courts deny injunction and grant compulsory license for the patent(s) at issue.

eBay CLs and TRIPS

eBay compulsory licenses fall under TRIPS **Article 44** on injunctions, under Part III (Enforcement of Intellectual Property Rights):

1. The judicial authorities shall have the authority to order a party to desist from an infringement…
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**. …

TRIPS Article 45 on damages is also relevant.

Ebay CLs - examples

In the field of medical technologies, there have been *eBay* compulsory licenses for, 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

eBay CLs - examples

***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] f**air 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 consequence**s—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."**

eBay CLs - examples

***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 $1.3 reasonable royalty. 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."

eBay CLs - examples

***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**.

eBay CLs - examples

***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 r**easonable 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."**

eBay CLs - examples

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.**

eBay CLs - examples

Trade Secrets

***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 denied the injunction as far as CardiAQ's request that Neovasc suspend its TMVI program for 18 months.

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."**

Questions/Comments

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