

# Limitations on remedies as a TRIPS flexibility

James Love

Knowledge Ecology International

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# TRIPS - Article 44 - 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.
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.

# U.S. practice under Article 44.1

# eBay Inc v. MercExchange, L.L.C., 547 U.S. 388 (2006)

The Supreme Court of the United States unanimously determined that an injunction should not automatically be available merely because of a finding of patent infringement. Instead, courts are required to weigh four factors to determine if an injunction should be issued. Quoting from the opinion:

"That test requires a plaintiff 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, a remedy in equity is warranted; and

(4) that the public interest would not be disserved by a permanent injunction.

The decision to grant or deny such relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion."

# Examples of non-voluntary use of medical patents under eBay precedent

# 2006: Voda v. Cordis Corporation

In a 2006 case, Dr. Jan K. Voda alleged that three patents concerning an angioplasty guide catheter were infringed by Cordis (a Johnson and Johnson company). A jury found for Dr. Voda on infringement (though it did not find willfulness), and determined that he was entitled to a reasonable royalty of 7.5% of Cordis' gross sales of the infringing catheters. Finding that Dr. Voda failed to demonstrate either irreparable injury or that monetary damages would be inadequate, the court denied his request for a permanent injunction. The denial of the injunction was affirmed on appeal (536 F.3d 1311).

# 2007: Innogenetics, N.V. v. Abbott Labs

In 2007, Innogenetics brought suit in Wisconsin against Abbott Laboratories alleging that Abbott had infringed its patent for a method of genotyping the hepatitis C virus, marketed in the form of diagnostic test kits. The jury found that the patent had indeed been infringed, and, based on a consideration of a hypothetical negotiation for a license, it determined that Abbott should pay \$7 million, which included a running royalty of 5 to 10 euros per test sold up until that time. The court evaluated Innogenetic's motion for injunctive relief by evaluating the eBay factors, finding that the public interest favored the denial of a permanent injunction, but that all other factors cut in favor of granting it. The court therefore granted the injunction. On appeal in 2008, however, the Federal Circuit vacated this injunction. Additionally, it found that the \$7 million verdict was not a royalty limited only to Abbott's past infringement, saying: "The reasonable royalties awarded to Innogenetics include an upfront entry fee that contemplates or is based upon future sales by Abbott in a long term market. When a patentee requests and receives such compensation, it cannot be heard to complain that it will be irreparably harmed by future sales."

# 2009: Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates

In a 2009 case, patentee Bard Peripheral Vascular, Inc. sued W.L. Gore & Associates in Arizona for infringement of a patent for a prosthetic vascular graft. Finding infringement, the jury awarded Bard \$185,589,871.02, accounting for both lost profits and including a 10% reasonable royalty rate. The court denied Bard's motion for a permanent injunction, holding that a compulsory license was appropriate compensation; it wrote: "The Court is satisfied that 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."

# 2009: Medtronic Sofamor Danek USA, Inc. v. Globus Med., Inc.

In a 2009 Pennsylvania infringement action between patentee Medtronic Sofamor Danek USA, Inc. and Globus Medical, Inc. concerning a dispute over patents pertaining to devices and methods used by spinal surgeons to stabilize bony structures, manufactured and marketed by Medtronic in a commercial embodiment called the “Sextant System,” and by Globus as the “Pivot System.” A jury found the patents infringed. Following unsuccessful settlement discussions, the parties agreed to a bench trial on the matter of damages and injunctive relief. The court refused to grant an injunction, and determined that a royalty rate of 15% of Globus’ sales would be applied to a royalty base of \$13,901,795, resulting in a reasonable royalty of \$2,085,269.20, plus prejudgment interest.

# U.S. practice under Article 44.2

- 28 USC 1498 - injunctions not available, but patent owners can make claims for compensation for the use of the patent, by or for the U.S. government.
- 35 USC 271(e)(6)(B-C).
  - In cases involving a biologic drug, there are severe limits on remedies for infringement, when the patents are not timely disclosed to potential biogeneric competitors. These include the elimination of injunctions, and non-voluntary use subject to “reasonable royalty” or no royalty, depending upon the nature of the failure to disclose.