September 11, 2019

The Honorable Senator Christopher Coons
218 Russell Senate Office Building
Washington, DC 20510

Dear Senator Coons:

Knowledge Ecology International (KEI) is a public interest group based in Washington, DC. KEI focuses on policies relating to the production and management of and access to knowledge goods. This includes policies regarding patents, as well as the affordability and pricing of medical inventions, among other topics. More about KEI's work is available here: https://www.keionline.org/ourwork.

We are concerned that the STRONGER Patents Act[1] and other proposals by Senator Coons would change current U.S. law regarding the granting of injunctions, effectively overturning the standard now established by the U.S. Supreme Court in *eBay v. MercExchange.* As you know, that standard requires a patent holder to prove:

1. that it has suffered an irreparable injury;
2. that the law does not provide other adequate ways to compensate it;
3. that considering the balance of hardships between the plaintiff and defendant, an injunction is warranted; and
4. that the public interest would not be harmed by a permanent injunction.

If enacted, the STRONGER Patents Act would create a presumption of irreparable injury and inadequacy of the remedies available, two of the four factors that a court must consider when a party seeks an injunction, according to the 2006 Supreme Court opinion in *eBay v. MercExchange*.

The current statute on injunctions as a remedy for patent infringement is found in Section 283 of title 35, which is one 38-word sentence:

[1] https://www.congress.gov/bill/116th-congress/senate-bill/2082/text

§283. Injunction

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.

The STRONGER Patents Act seeks to add the following language to §283:

(b) Injunction.—Upon a finding by a court of infringement of a patent not proven invalid or unenforceable, the court shall presume that—

(1) further infringement of the patent would cause irreparable injury; and

(2) remedies available at law are inadequate to compensate for that injury.

This is an attempt to make such injunctions more automatic, even when the party seeking the injunction provides no evidence to support such claims, and the contrary is readily apparent.

While unpopular with some patent holders (particularly those who do not themselves make or provide goods or services), the *eBay* standard for injunctions has had a very important procompetitive impact in many cases, while providing income to inventors though reasonable royalty payments.

In the healthcare arena, there are several cases where permanent injunctions were denied for medical devices or diagnostic tests. KEI has researched some of these cases, and we have published a list of examples available here: https://www.keionline.org/us-injunction-medical.

In these cases, including the ones described below, the courts have examined the facts and found that a reasonable royalty was a more equitable remedy than an injunction.

In our view, it is very important that a federal judge has the discretion to deny a request for an injunction when the injunction would have a harmful impact on the public's health, particularly in cases involving complex medical technologies, where a single patent claim can be asserted to take an important medical product off the market, denying patients access and/or driving up the prices.

It is our view that the current statutory standard is appropriate,and should not be modified, particularly concerning the two factors that the STRONGER Patents Act seeks to modify, which will be particularly harmful changes to the law.

These are a few of the cases involving medical devices and diagnostic tests:

- Jan K. Voda, M.d., V Cordis Corporation, Case: 5:03-cv-01512-L, September 5, 2006. Cordis manufactures an angioplasty guide catheter.

  > "plaintiff has failed to demonstrate either irreparable injury or that monetary damages are inadequate, the court denies his request for a permanent injunction."

- Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, January 17, 2008. Abbott manufactured a device for genotyping hepatitis C virus, which, among other things, is used to ensure blood banks do not sell blood infected with the hepatitis C virus. From the opinion:

  > "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."

- Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., No. CV-03-0597-PHX-MHM, March 31, 2009. Medical technology: prosthetic vascular graft.

  > "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.
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  > . . . the 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. The Court therefore declines to enjoin Gore from the continued production and sales of its Counterpart Products, finding that Plaintiffs' remedy at law provides adequate compensation under the meaning of the Patent Act, particularly when viewed in light of the public interest served by Gore's continued infringement—for which Plaintiffs are to receive a compulsory license."

- Johnson & Johnson Vision Care, Inc., v. CIBA Vision Corp., 712 F. Supp. 2d 1285, April 27, 2010, involving extended-wear contact lenses.

  > . . . evidence convinces the Court that millions of innocent contact lens wearers will suffer real adverse consequences if sale of ACUVUE OASYS is enjoined. These are not just issues of comfort or cosmetics, as CIBA argues, but rather deal with the more substantive concerns of proper vision and eye care. There will

also be significant disruption, confusion and cost (estimated to be in the hundreds of millions of dollars) caused by ACUVUE OASYS patients being abruptly told that the contact lens for which they have been fitted and with which they are satisfied, is no longer available. Choosing a new lens will at minimum require refitting and the new lens may not prove as efficacious as the ACUVUE OASYS lens. Moreover, patients may have to be refitted more than once until an appropriate lens is found. An undefined number will not be able to be refitted appropriately at all. CIBA's answer that ''they can just wear glasses'' is no answer, in this Court's view.

The preponderance of the evidence convinces the Court that an injunction will create consequential medical, practical and economic issues for large numbers of ACUVUE OASYS users. The deleterious effects of the injunction on the general public would simply be too great to permit. Thus, CIBA has failed to carry its burden of proving that the public interest would not disserved by the entry of a permanent injunction.

- Edwards Lifesciences AG v. CoreValve, Inc., et al., No. C.A. 08-91-GMS, February 7, 2011, a case involving a valve prosthesis that can be implanted in the body without the need for surgical intervention, but rather through the use of a catheter.

  The object of the invention, and the key innovation upon which the parties focused at trial, is to provide a valve prosthesis that can be implanted in the body without the need for surgical intervention, but rather through use of a catheter. With respect to cardiac valves, the invention thus permits a valve to be implanted without the need for open heart surgery and the risks that come with such surgery.

  . . . CoreValve's infringement stems not from sales of the accused product, all of which occurred outside the United States, but rather from the manufacturing of the accused product in the United States. 13 Thus, Edwards must establish that CoreValve's manufacturing operations in the United States are continuing and will continue to cause irreparable harm if not enjoined. Edwards, however, does not appear to dispute that CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately if the court enjoined it from continuing to manufacture its products in the United States. . .

  The court fails to see what hardship Edwards would suffer if CoreValve were permitted to continue manufacturing its product in the United States, as opposed to in Mexico, that could not be compensated through remedies at law. The public interest would not be substantially advanced or harmed by the issuance of an injunction, since Core Valve would be able to continue manufacturing accused

product abroad without seriously affecting the supply of the product available to the public. Consequently, the court will deny Edwards' motion for a permanent injunction.

- Conceptus, Inc. v. Hologic, Inc., No. C 09-02280 WHA, January 9, 2012, a case involving intrafallopian contraceptives.

  Defendant Hologic owns and markets the infringing Adiana contraceptive system. The Adiana system, like the Essure system, involves the minimally invasive transcervical placement of a contraceptive device (referred to by Hologic as a "matrix") into a woman's fallopian tubes. Combined with the use of radiofrequency energy, the Adiana matrix — much like the Essure system — is intended to produce intrafallopian occlusion, which either prevents conception from occurring or blocks the passage of a fertilized ovum to the uterus. Adiana received FDA approval in July 2009. This is a two-product market: Essure and Adiana are the only two products available for transcervical hysteroscopic sterilization.

  The public interest would undoubtedly be harmed by an injunction. Enjoining the sale of Adiana would leave only one product for transcervical hysteroscopic sterilization. Public health has benefitted, and will continue to benefit, from having a choice of products for transcervical hysteroscopic sterilization. This is especially important because the products are different. Removing Adiana from the market would have eliminated an important alternative for patients.

  Essure and Adiana are not interchangeable products and procedures. With Essure, there is a risk of perforations because of its long corkscrew-like tail. Evidence at trial also showed that some patients do not want Essure because it is metallic. For example, Essure is not available to patients who have nickel allergies. With Essure, there is a concern that the trailing coils could interfere with certain types of endometrial ablation procedures. There is also the possibility of pain after placement of Essure coils (TX 137 at 9976–78).

  On the other hand, Adiana is not a metallic coil but is a small foam cylinder. It is not screwed into the fallopian tube. Instead, the fallopian tube is "burned" slightly by radiofrequency energy. As the tube heals, the healing tissue grows into the foam insert. . . . the precise mechanism of action has important advantages over Essure, such as a non-metalic body, no risk of perforation, and use of radiofrequency energy.

  In this action, the public benefit of having two products with different qualities in the transcervical hysteroscopic sterilization market militates strongly against an injunction.

- Tyco Healthcare Grp. L, et al., v. Ethicon Endo-Surgery, Inc., 3:10-cv-00060-JBA, March 28, 2013, involving ultrasonic surgical devices.

> The three patents at issue in this lawsuit are directed to ultrasonic surgical devices, which employ ultrasonic energy to cut and coagulate vessels in surgery. . . .
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> The devices at issue are commonly used in laparoscopic surgery in which trocars are used to pierce a patient's body and a narrow hollow tube, or "cannula," is used to provide a "working pathway" to the target surgical site.
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> . . . "remedies available at law, such a monetary damages," are fully adequate to compensate for Tyco's injury.
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> The Court finds that the public interest prong cuts both ways, as there is certainly an interest in "protecting the rights of patent owners," see Smith & Nephew, Inc. v. Synthes (U.S.A.), 466 F. Supp. 2d 978, 985 (W.D. Tenn. 2006), as well as an important consideration that a permanent injunction would pull many devices that are presently used in surgery off the market.

- Verinata Health, Inc., et al., v. Ariosa Diagnostics, Inc., et al., 329 F. Supp. 3d 1070, July 19, 2018. This suit involves the Harmony test, a non-invasive prenatal screening of fetal chromosomal abnormalities, sold by Ariosa, a company acquired by Roche in 2014.

> Defendant Ariosa is a molecular diagnostics company that researches, evaluates, and develops non-invasive prenatal tests for chromosomal abnormalities in a fetus. . .
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> This Court is unconvinced by Illumina's argument that the harm resulting from competing against Roche is not compensable by monetary damages.

Even when an injunction is granted, such as in the Braun/Terumo case below, the court now can narrow the injunction in ways that protect competition, and protect access to an important medical technology.

- B. Braun Melsungen AG, et al., v. Terumo Med. Corp., et al., 778 F. Supp. 2d 506, April 21, 2011, involving intravenous catheters.

> The Court finds that [the balance of hardships] factor weighs heavily in favor of Terumo's proposed injunctive relief, as opposed to Braun's much more expansive proposal. If the Court were to immediately and entirely exclude Terumo's Surshield from the market, medical professionals who are currently using Terumo's device would be required to stop doing so. In at least some instances, this would result in medical professionals being abruptly deprived of a device for which they have expressed a preference, and have been specifically trained to use. (See, e.g., D.I. 385, Omiecinski Decl., ¶¶ 10–11) Terumo's reputation would also be harmed to a degree disproportionate to the infringement found by the jury. What would appear to many to be an urgent, "recall-like" decree from this Court is simply not warranted under the circumstances presented here. (See id. ¶ 14)
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> . . .
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> The Court concludes that the public interest likewise favors entry of the more limited injunctive relief proposed by Terumo, as opposed to the injunction sought by Braun. The Court reaches this conclusion largely for the reasons already described, primarily the impact of Braun's requested relief on medical professionals currently using Terumo's Surshield, Again, the Court does not minimize the importance of the competing considerations relied on by Braun—including, especially, the public interest in strong and consistent enforcement of patent rights. See Callaway, 585 F.Supp.2d at 622 (finding insufficient evidence "to counter the strong public policy favoring the enforcement of patent rights recognized by the courts.") (internal quotation marks omitted). However, in the overall circumstances presented here, particularly the public interest in access to competing alternatives to safe medical devices, see, e.g., Cordis Corp. v. Boston Scientific Corp., 2003 WL 22843072, at *6 (D.Del. Nov. 21, 2003) (denying preliminary injunction in part due to "the obvious concern of depriving the public of the best and safest medical devices by limiting competition"), the public interest favors the more limited injunction proposed by Terumo.

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