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MEDICAL PROCEDURE PATENTS IN THE TPP:

A COMPARATIVE PERSPECTIVE ON THE HIGHLY UNPOPULAR U.S. PROPOSAL [1]

The Trans-Pacific Partnership (TPP) Intellectual Property Chapter published by WikiLeaks[2] reveals that after years of negotiations, the United States still seeks to impose medical procedure patents on Asian and Latin American countries.[3] All eleven other negotiating countries oppose the proposal. Medical procedure patents raise healthcare costs. Health providers, including surgeons, could be liable for the methods they use to treat patients. Essentially, except for when a surgeon uses her bare hands, surgical methods would be patent eligible subject matter under the U.S. proposal. While U.S. law immunizes certain care providers from infringement liability, the U.S. TPP proposal fails to include these safeguards, risking yet more serious consequences for TPP negotiating countries.

Only Two Countries Recognize Medical Procedure Patents

Article 27.3 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) preserves member nations' rights to determine whether to include diagnostic, therapeutic, and surgical methods – otherwise known as "medical procedure patents" – for treating humans and animals as patentable subject matter.[4] Article 27.2 of TRIPS expressly grants members the right to choose not to recognize patents on inventions that have the potential

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[1] Public Citizen's Global Access to Medicines Program, November 2013, contact bkilic@citizen.org or pmaybarduk@citizen.org.
Special thanks to Tiffany Jang for her extensive research.

[2] Available at: http://wikileaks.org/tpp. Further analysis available at: www.citizen.org/tppa.

[3] The U.S. proposal regarding patentable subject matter includes Article QQ.E.1(3): " … [E]ach party shall make patents available for inventions for the following … (b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, if they cover a method of using a machine, manufacture, or composition of matter."

[4] The text of TRIPS Art. 27.3 reads:

> Members may also exclude from patentability:
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

to intervene with the state's efforts to protect public order, morality, and human, animal, and plant welfare.[5]

Numerous free trade agreement (FTA) provisions, including NAFTA Article 1709(3)(a), reinforce TRIPS Articles 27.2 and 27.3, which expressly permits members to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." Other US FTAs that include provisions similar to TRIPS Articles 27.2 and 27.3 are the US-Australia FTA,[6] the US-Bahrain FTA,[7] the US-Colombia TPA,[8] the US-Jordan FTA,[9] the Korea-US FTA,[10] the US-Oman FTA,[11] the US-Panama FTA,[12] the US-Peru TPA[13] and the US-Singapore FTA.[14]

The only TPP countries - and the only countries in the world - to recognize medical method patents are the United States and Australia. Unsurprisingly, in 2009, more than 80 countries had banned medical procedure patents.[15] For example, the European Patent Office (EPO) does not permit the patenting of surgical, treatment, or diagnostic methods, pursuant to Article 53(c) of the European Patent Convention (EPC), which states that patents shall not be granted on "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body..." The EPC prohibition against surgical, diagnostic, and treatment method patents is strictly enforced: the presence of just a single surgical step in a multi-step method would exclude the method from patentability.

Similarly, while the Japan Patent Office (JPO) will allow some medical procedures to be patented, it strictly enforces restrictions against the patenting of surgical, treatment, or diagnostic

[5] The text of TRIPS Art. 27.2 reads:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

[6] Art. 17.9(2)(b) (mirroring the language in TRIPS Art. 27.3)
[7] Art. 14.8(1) (mirroring the language in TRIPS Art. 27.2 and TRIPS Art. 27.3)
[8] Art. 16.9(2) (specifically invoking TRIPS Art. 27.2 and TRIPS Art. 27.3)
[9] Art. 18(a) (mirroring TRIPS Art. 27.2); Art. 18(b) (mirroring TRIPS Art. 27.3)
[10] Art. 18.8(2)(a) (mirroring TRIPS Art. 27.2); Art. 18.8(2)(b) (mirroring TRIPS Art. 27.3).
[11] Art. 15.8(2)(a) (mirroring TRIPS Art. 27.2); Art. 15.8(2)(c) (mirroring TRIPS Art. 27.3)
[12] Art. 15.9(2) (specifically invoking TRIPS Art. 27.2 and TRIPS Art. 27.3)
[13] Art. 16.9(2) (specifically invoking TRIPS Art. 27.2 and TRIPS Art. 27.3)
[14] Art. 16.7(1)(specifically invoking TRIPS Art. 27.2 and TRIPS Art. 27.3)
[15] *WMA Statement on Patenting Medical Procedures*, World Medical Association, accessed from http://www.wma.net/en/30publications/10policies/m30/.

methods practiced on human subjects. For example, while surgical methods practiced on non-human animals are patentable, those practiced on humans are not.[16] Methods of administering medicine, organ implantation, and disease prevention are likewise unpatentable.[17] Additionally, surgical methods requiring the use of as few as one surgical device are also unpatentable under JPO policies.[18] Examples of medical procedures that are patentable in Japan include methods practiced on non-human animal subjects, as stated above, methods for collecting data,[19] and methods for treating samples extracted from the human body *unless* the procedure is performed under the assumption that the samples will be returned to the same human body.[20] Thus, JPO policies on patentable subject matter, like EPO policies, clearly reflect a desire to protect medical procedures against monopolization by patentees.

In the United States, patents on surgical, diagnostic, and treatment methods are a consequence of a 1952 amendment to the Patent Act, which added "new and useful processes" to the list of patentable subject matter.[21] By 1995, despite public outcry against what was deemed an unethical practice, it was estimated that as many as fifteen medical procedures were patented weekly[22].

Medical Procedure Patents Raise Healthcare Costs

Medical procedure patents create significant transaction costs for patients. Physicians or healthcare providers could be charged additional royalties on top of the one-time cost of a medical device each time they practice a patented method. Ordinarily, a patentee's rights would be exhausted with the sale of a patented good. The patenting of medical *processes* essentially nullifies the effect of patent exhaustion in specific instances, giving patentees rights over downstream uses of a patented medical device. Physicians, healthcare providers, or other companies, who infringe medical procedure patents may then be liable to pay high damages that are "adequate to compensate for the infringement," but no less than a reasonable royalty rate.[23]

[16] Examination Guidelines for Patent and Utility Model in Japan ("Examination Guidelines"), Part II Requirements for Patentability, Chapter 1 Industrial Applicable Inventions, p.5, accessed from http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/2_1.pdf.
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.* at 7.
[21] *Opinions on Ethics and Professionalism*, American Academy of Orthopaedic Surgeons, accessed from http://www.aaos.org/about/papers/ethics/1209eth.asp.
[22] *E.g.*, Brett G. Alten, Left To One's Devices: Congress Limits Patents on Medical Procedures, Fordham Intell. Prop. Media & Ent. L.J., Vol. 8:837 (1998) at note 8.
[23] 35 U.S.C. § 284

Courts often set a reasonable royalty rate based on the "percentage of infringing sales resulting from the unauthorized use of the patented invention."[24] In *Medtronic Sofamor Danek USA, Inc. v. Globus Medical, Inc.*, for example, the court found defendants liable for $2,085,269.20 in damages for infringing patents on "devices and methods used by spinal surgeons to stabilize bony structures." Insurance companies typically cap the amount they will reimburse on any given procedure.[25] Price hikes resulting from medical procedure patenting are likely to be shifted onto consumers, either in the form of higher co-payments or higher insurance premiums.[26]

The additional costs that medical procedure patents impose may be no small deal for the patient. While patients are billed anywhere from $1500 to $2000 per stent used in coronary angioplasties, the actual cost of manufacturing the stent is only $15.[27] A high-tech scan may cost a hospital "a few cents of electricity" and "a couple of hundred dollars [sic] worth of a technician's or a doctor's time," but the patient is typically billed "several thousand dollars" per diagnostic procedure.[28]

Medical Associations Oppose Medical Procedure Patents

Numerous medical associations - American and foreign alike - have taken strong positions against medical procedure patents. In its "Statement on Patenting Medical Procedures," the World Medical Association condemned medical procedure patents as "unethical" and "contrary to the values of the medical profession."[29] Similarly, the American Academy of Orthopaedic Surgeons raised concerns that "[t]he granting of Medical Procedure Patents may pose a serious threat to medical advancement, medical education, and patient care, as well as contribute to the spiraling costs of health care."[30] In addition to the cost concerns that it raises, patenting of medical procedures creates additional legal barriers to the use of patented medical devices, a scenario almost certain to impede technology transfer and impose significant challenges to a medical practitioner's ability to treat patients without fear of infringing medical procedure patents under current EPO and JPO policies.

[24] Medtronic Sofamor Danek USA, Inc. v. Globus Med., Inc., 637 F. Supp. 2d 290 (E.D. Pa. 2009).
[25] Steve Dirksen, Note, *A Reconsideration of the Physicians' Immunity Statute*, 2001 Duke L. & Tech. Rev. 0027 (2001).
[26] *Id.*
[27] *Patent system adds hundreds of billions every year to health care costs*, John Hanrahan, Nieman Watchdog, accessed from http://www.niemanwatchdog.org/index.cfm?fuseaction=background.view&backgroundid=402#sthash.UjN9T.
[28] *Id.*
[29] *See supra note 13.*
[30] American Academy of Orthopaedic Suregeons, *supra* note 11.

U.S. Proposal for TPP Fails to Include Safeguards in U.S. Law

U.S. law contains some safe harbors that protect medical practitioners using patented diagnostic, therapeutic, and surgical methods from infringement liability. Under 35 U.S.C. § 287(c)(1), medical practitioners and health care entities cannot be sued for the performance of a "medical activity"[31] that would ordinarily constitute infringement under §§ 287(a) and (b). However, § 287(c)(2)(a)(i) imposes significant limitations on the § 287(c)(1) safe harbor because it expressly states that "the use of a patented machine, manufacture, or composition of matter in violation of such patent" is not protected under the § 287(c)(1) safe harbor. In other words, a medical practitioner may be sued if the medical activity he or she engaged in involves both a patented procedure and a patented device. As a corollary, under U.S. law, medical practitioners may still use unpatented machines, manufactures, and compositions of matter and be free infringement liability. That is, unless the patented medical procedure is tied to a patented machine, manufacture, or composition of matter, the medical practitioner cannot be sued for infringement.

According to the legislative history of § 287(c), the first proposal introduced in Congress[32] that would address the problem of medical procedure patents sought to keep the USPTO from issuing patents on medical methods except those involving the use of a *patentable* machine, manufacture, or composition of matter.[33] Other medical activities that do not fall under the § 287(c) safe harbor for medical practitioners include "the practice of a patented use of a composition of matter in violation of such patent"[34] and "the practice of a process in violation of a biotechnology patent."[35]

[31] "[T]he term "medical activity" means the performance of a medical or surgical procedure on a body…" 35 U.S.C. §287(c)(2)(A).
[32] H.R. 1127 (104th Congress, 1st Session).
[33] "LIMITATION ON ISSUANCE OF PATENTS. On or after the date of the enactment of this Act, a patent may not be issued for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis, except that if the technique, method, or proess is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacture, or composition of matter may claim such technique, method, or process."
[34] 35 U.S.C. § 287(c)(2)(A)(ii). However, the term "patented use of a composition of matter" as used in § 287(c)(2)(A)(ii) is limited by subsection § 287 (c)(2)(F), which provides that "the term 'patented use of a composition of matter' does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method."
[35] 35 U.S.C. § 287(c)(2)(A)(iii)

U.S. Should Abandon TPP Proposal

Public Citizen agrees with the American Medical Association's concern that "[t]he patenting of medical procedures poses substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis..."[36] Medical procedure patents create new costs for patients and raise ethical concerns. The U.S. should abandon its proposal to impose medical procedure patents on TPP countries.

If, in spite of the unanimous opposition, the proposal were to survive, then, at a bare minimum, medical practitioners must be afforded broad immunities. For example, U.S. law at §287(c) leaves medical practitioners and health care entities vulnerable to infringement liability in too many instances (i.e. whenever a physician uses patented technology as part of a medical procedure).

The U.S.-proposed TPP measure provides for surgical method patents which "cover a method of using a machine, manufacture, or composition of matter." In other words, except for when a surgeon uses her bare hands, surgical methods would be patent eligible subject matter. The provision fails to recognize the distinction between patented and unpatented devices, and is therefore distressingly even broader than U.S. law.

Any inclusion of medical procedure patents in the TPP is deeply concerning and should be opposed. If nevertheless such a provision survives, safe harbors should at least immunize medical practitioners whenever the patented medical procedure that is practiced involves an unpatented machine, manufacture, or composition of matter.

[36] *Ethical Issues in the Patenting of Medical Procedures*, Council on Ethical and Judicial Affairs, CEJA Report 1 – A-95, American Medical Association, accessed from http://www.ama-assn.org/resources/doc/code-medical-ethics/9095a.pdf.