



United States of America
Etats-Unis d'Amérique
Vereinigte Staaten von Amerika

Report Q202

in the name of the United States Group
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The impact of public health issues on exclusive patent rights

Questions

1) Analysis of current law and case law

- 1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

Yes, in general. Except for the Bolar exception discussed below, this exception is limited to narrowly non-commercial uses such as "gratifying a philosophical taste, or curiosity, or for mere amusement." *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 221 U.S.P.Q. 937, 940 (Fed. Cir. 1984). This exception does not even extend to pure scientific research if research is the infringer's business. *Madey v. Duke University*, 307 F.3d 1351, 64 U.S.P.Q.2d 1737, 1746 (Fed. Cir. 2002).

- 2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

Yes. 35 USC § 271(e). The exception is broadly applied to pre-clinical testing of drugs or potential drugs "at least as long as there is a reasonable basis to believe that the compound tested could be the subject of ... and the experiments will produce the types of information relevant to" an application for approval for clinical trials or marketing. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005). The exception is effectively limited to drugs for human use; other biological products would be covered only to the extent that they are regulated as drugs. The exception does not apply if the drug "is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other process involving site specific genetic manipulation techniques," or is "a new animal drug or veterinary biological product." (If a license for commercial exploitation is applied for, the license sought must not take effect before the patent expires. 35 USC § 271(e)(2).)

- 3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

No.

- 4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

No.

- 5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Yes. Where a medical practitioner performs a medical activity that infringes or actively induces infringement of a patent, the medical practitioner and a related health care entity (hospital, clinic, medical school, etc.), are exempt from suit for infringement, and from injunction, damages, and attorneys' fees. 35 U.S.C. § 287(c). The exemption extends to the performance of a medical or surgical procedure on a human body, organ, or cadaver, or on a nonhuman animal used in medical research or instruction directly related to the treatment of humans. However, the exemption does not extend to use of a patented product, a patented use of a composition of matter, or to a process that infringes a biotechnology patent §287(c) (2)(A).

- 6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

Yes, compulsory licensing of patents has been allowed under the laws of the United States under limited circumstances. One longstanding use of compulsory licenses is as a remedy for violations of antitrust laws. See *Besser Mfg. Co. v. United States*, 343 U.S. 444, 447 (1952) (referring to compulsory licenses as "a well-recognized remedy" in this area). While in modern practice it is rare for courts to order such compulsory licenses in cases litigated to verdict, they are frequently agreed to in consent decrees. 2-8 Roger M. Milgrim and Eric E. Bensen, *Milgrim on Licensing* § 8.55 (2007). Congress has occasionally provided for the compulsory licensing of specific classes of patents considered especially important to public welfare. Examples of this include patents related to "nuclear material or atomic energy," 42 U.S.C. § 2183, and patents that are "necessary to enable any person" to comply with the restrictions of the Clean Air Act when "the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly." 42 U.S.C. § 7608. The broadest legal authority for the compulsory licensing of patents exists when patents are used by the federal government, as recognized in 28 U.S.C. § 1498(a), which creates a mechanism for compensating the owners of such patents. Courts interpreting this statute have held that the government's right to do this is "premised on a theory of an eminent domain taking under the Fifth Amendment." See, e.g., *Tektronix, Inc. v. United States*, 213 Ct. Cl. 257 (Ct. Cl. 1977). This also protects private contractors who use or manufacture patented inventions for the federal government. *Crater Corp. v. Lucent Techs.*, 255 F.3d 1361, 1363 (Fed. Cir. 2001). Some commentators have suggested that the Supreme Court's recent rejection of a general policy of granting permanent injunctions against patent infringers in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), creates a de facto compulsory license in favor of patent infringers who are willing to let the courts decide the appropriate licensing fee. See, e.g., Andrew Beckerman-Rodau, *The Supreme Court Engages in Judicial Activism in Interpreting the Patent Law in eBay, Inc. v. MercExchange, L.L.C.*, 10 Tul. J. Tech & Intell. Prop. 165, 204 (2007).

No, we are not aware of any compulsory licenses granted in the United States for the domestic manufacture and supply of pharmaceutical products.

- 7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

Yes. The United States was the first country to accept new Article 31bis TRIPS, doing so on December 17, 2005. http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

No, we are not aware of any other legislative amendment in the United States with a view to implementing the WTO decision of August 30, 2003.

No, we are not aware of any compulsory licenses granted in the United States for the importation or exportation of pharmaceutical products.

- 8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

Yes. The United States government's power of eminent domain allows it to make use of patented inventions without previous license, with a method for compensating the owners of such patents established by 28 U.S.C. § 1498, as discussed above in the answer to Question 6. No limitations to this power, beyond the requirement of just compensation found in the Fifth Amendment to the United States Constitution, have been recognized.

- 9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

Yes. We are not aware of any circumstances in which the United States government has actually expropriated a patent completely, as opposed to simply using it without the owner's permission. However, the way the law of eminent domain has been applied in the United States suggests that the government could expropriate any patent it chose to, limited only by the Fifth Amendment's requirement of just compensation.

- 10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

The Orange Book, which, as mentioned in the question, provides up to date information on generic drug approvals, is made available by the Food and Drug Administration in electronic form at <http://www.fda.gov/cder/ob/default.htm>.