October 2017

Global Patent Prosecution Newsletter

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A U.S. Perspective on Global Strategy

March-in Rights and Compulsory Licensing of Biopharmaceutical Inventions

Very few topics in international intellectual property have been as controversial as compulsory licensing. In the US, consumer groups have increasingly focused on march-in rights as a mechanism to lower drug costs. The October 2017 issue of Sterne Kessler's Global Patent Prosecution Newsletter includes information on march-in rights in the US and the use of compulsory licenses worldwide.

Sterne Kessler's Global Patent Prosecution Newsletter is designed to help meet the needs of biotech/pharmaceutical companies regarding global patent prosecution strategies. For more information, please contact Paul Calvo or John Covert. If you wish to unsubscribe from this and other newsletters, please click on the unsubscribe link below.

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By: Paul A. Calvo, Ph.D.

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Compulsory Licensing of Biopharmaceutical Inventions

By: Erin J. Hennan, Ph.D. and Paul A. Calvo, Ph.D.

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As a measure intended to protect against nonuse or unreasonable use of federally-funded inventions, 35 U.S.C. § 203 states that, "the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances . . . if the Federal agency determines that such—

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204."[ii]

As stated above, march-in rights were originally created to ensure that patent owners commercialized federally-funded inventions. Recently however, march-in rights have become a lightning rod for consumer groups to push for lower US drug prices.[iii] In the 37 years since their creation though, the US government has not exercised these rights although there have been several formal march-in petitions filed.

In the first such petition in 1997, the US government refused to exercise its rights to march in on

a patent owned by Johns Hopkins University.[iv] In *In re CellPro*, Johns Hopkins sued CellPro for infringement of a patent related to a stem cell-specific antibody. In response, CellPro first asked the court for a compulsory license and then petitioned the National Institutes of Health (NIH) to march in on the theory that Johns Hopkins had failed to effectively commercialize the patented invention.[v] NIH declined to exercise its rights reasoning that although Johns Hopkins commercialization efforts were slower than those of CellPro, the University was taking reasonable efforts to gain market entry of their antibody. Since *In re CellPro*, there have been a number of additional denials of march-in rights, including: *In re Norvir[vi]*, *In re Xalatan[vii]*, *In re Fabrazyme[viii]*, and most recently, *In re Xtandi[ix]*.

While march-in rights generally appear to be US-specific, the US and most other nations have rights under compulsory licenses. Authorized under 28 U.S.C. § 1498(a), compulsory licenses are available in the US, but the government has never exercised this right. This is in contrast with several other nations that have used these rights with respect to HIV and cancer drugs. In this issue's companion article, the use of compulsory licenses since enactment of the TRIPS agreement is discussed.

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[i] David S. Bloch, Alternatives to March-in Rights, Vanderbilt J. Ent. & Tech. L. 18:2:247
[ii] 35 U.S.C. § 203
[iii] https://www.ip-watch.org/2017/05/18/march-rights-lost-opportunity-lower-us-drug-prices/
[iv] *In re Petition of CellPro, Inc.* (Nat'l Inst. of Health, 1997) (determination), http://www.ott.nih.govsites/default/files/documents/policy/cellpro-marchin.pdf
[v] David S. Bloch, Alternatives to March-in Rights, Vanderbilt J. Ent. & Tech. L. 18:2:247
[vi] In the Case of Norvir® Manufactured by Abbott Laboratories, Inc. (Nat'l Inst. of Health, 2004) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf
[vii] In the Case of Xalatan® Manufactured by Pfizer, Inc. (Nat'l Inst. of Health, 2004) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf.
[viii] In the Case of Fabrazyme® Manufactured by Genzyme Corporation (Nat'l Inst. Of Health, 2010) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf.
[ix] https://www.keionline.org/sites/default/files/Final-Response-Goldman-6.20.2016.pdf

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The first decade or so, after the institution of TRIPS, saw a prevalence of compulsory licenses for HIV/AIDS drugs, with compulsory licenses issued in, for example, Zambia, Eritrea, Ghana, Malaysia, Indonesia, and Brazil.[1] Indeed, prior to 2011, two-thirds of compulsory license episodes were for HIV/AIDS drugs.[2] These compulsory license episodes included five separate episodes in Brazil with five different HIV/AIDS pharmaceuticals.[3] Out of these, all five lead to a discounted price, and one also led to a compulsory license.[4] As was seen in Brazil, the threat of a compulsory license is often used to obtain an outcome other than a compulsory license, for example, a heavily discounted product. When threatened with a compulsory license, large pharmaceutical companies are often willing to offer a discount on the price of the pharmaceutical in question to avoid a compulsory license. For example, under threat of a compulsory license, Roche slashed the price of the HIV/AIDS drug Nelfinar (Viracept) in Brazil to 30% of the price in the U.S.[5]

More recently, compulsory licenses have been issued more prevalently for cancer drugs, heart disease medications and second-line HIV drugs.[6] In particular, due to their high prices, an increasing number of oncology drugs are being threatened with compulsory licenses in countries such as India, Nepal, Thailand, South Korea and Columbia.[7]

The use of compulsory licenses has not been entirely without controversy however. For example, in 2012, India issued its first compulsory license, for the drug Sorafenib tosylate, which is used to treat kidney and liver cancer.[8] Following the grant of this compulsory license, the Indian government received a great deal of negative feedback from large pharmaceutical companies who accused them of favoring local drug manufacturers in the issuance of the license. The Indian government has not issued a compulsory license since, and at least three separate compulsory license attempts have been disallowed by the Indian Controller- two for anti-cancer drugs, and one

for a diabetes drug.[9]

Compulsory licenses are an important tool that countries can use to ensure their citizens have access to life-saving drugs at affordable prices. However, relatively few compulsory licenses have been issued due to competing factors including both the willingness of pharmaceutical companies to offer discounts when compulsory licenses are threatened, as well as push-back from companies alleging that countries that issue compulsory licenses are unfairly favoring local drug companies. The paucity of compulsory licenses may also be due to the lack of guidance provided by either TRIPS or the Doha Agreement about circumstances when compulsory licenses should be issued, and highlights the need for a further clarification of the parameters for compulsory licenses.

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[1] Neil George Cherian, *Using Compulsory Licenses to access pharmaceuticals: A Cross Case Analysis on Outcomes*, at 15 (November 2016) (unpublished Masters dissertation, University of Oslo); Reed Beall and Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS: Medicine, 9(1): at Table 1 and Text S1 (January 10, 2012).
[2] Reed Beall and Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS: Medicine, 9(1): at 4 (January 10, 2012).
[3] Reed Beall and Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS: Medicine, 9(1): at Text S1 (January 10, 2012).
[4] Reed Beall and Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS: Medicine, 9(1): at Text S1 (January 10, 2012).
[5] Reed Beall and Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS: Medicine, 9(1): at Text S1 (January 10, 2012).
[6] Neil George *Cherian, Using Compulsory Licenses to access pharmaceuticals: A Cross Case Analysis on Outcomes*, at 15 (November 2016) (unpublished Masters dissertation, University of Oslo).
[7] Neil George Cherian, *Using Compulsory Licenses to access pharmaceuticals: A Cross Case Analysis on Outcomes*, at 15 (November 2016) (unpublished Masters dissertation, University of Oslo).
[8] Maricel Estavillo, *India Grants First Compulsory Licence, For Bayer Cancer Drug*, Intellectual Property Watch, https://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/ (last visited October 4, 2017)
[9] *Patents and the Misunderstood Case of Compulsory Licensing in India*, https://www.bananaip.com/ip-news-center/patents-and-the-misunderstood-case-of-compulsory-licensing-in-india/ (last visited October 8, 2017)