Order of The Court of Bucharest

Granting Compulsory Licence for the Public, Non-Commercial Use of Any and All Patents Relevant For the Manufacture, Import, or Sale of Generic Hepatitis C Medicines

Having received the request of the Government of Romania for a compulsory licence for the public, non-commercial use of any and all patents relevant for the manufacture, import, or sale of generic medicines to treat the hepatitis C Virus, and,

CONSIDERING:

(1) Studies estimating between 3.2 and 6 percent of Romania's population is infected with hepatitis C virus (HCV);[1]

(2) That this rate of infection is one of the highest rates in all of the European Union;

(3) That new HCV medicines exist that are both safer and significantly more effective than previous medications;

(4) That these same new HCV medicines are, by virtue of their high costs, inaccessible to most of the Romanian population;

(5) That under Article 46 of Romanian Law No. 64/1991 of October 11, 1991 on Patents (as last amended by Law No. 28/2007), the Court of Bucharest (the "Court") has the authority to grant a compulsory licence;

(6) That Article 46 paragraph 4(c) of Law No. 64/1991 specifically authorizes the grant of a compulsory licence for public, non-commercial use;

(7) That Article 46 paragraph 5 of Law No. 64/1991 exempts a compulsory licence granted for public, non-commercial use from the conditions of Article 46 paragraph 2;

(8) That Article 47 of Law No. 64/1991 provides that the Government or third parties authorized by the Government may be the beneficiaries of the compulsory licence;

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[1] One study estimated the prevalence in 2007 at 6.0 percent (Esteban, Juan I., Silvia Sauleda, and Josep Quer. "The changing epidemiology of hepatitis C virus infection in Europe." Journal of hepatology 48.1 (2008): 148-162.); The incidence rate in 2011 was estimated by one study to be 3.5 percent (Cornberg, Markus, et al. "A systematic review of hepatitis C virus epidemiology in Europe, Canada and Israel." Liver International 31.s2 (2011): 30-60.); another study estimated the prevalence in 2011 to be 4.5 percent (Lavanchy, D. "Evolving epidemiology of hepatitis C virus." Clinical Microbiology and Infection 17.2 (2011): 107-115.).

(9) That the Court's authority to grant a compulsory licence is further supported by (i) the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) Article 31, (ii) the Doha Declaration on TRIPS and Public Health, paragraph 5(b), and (iii) European Regulation 1257/2012,

THE COURT ORDERS:

(1) That pursuant to Article 46 paragraph 4(c), a compulsory licence (the "Licence") is hereby granted to the Romanian Government, including all ministries, bureaus, departments, and designated third parties (collectively, the "Romanian Government"), for the public, non-commercial use, without prior authorization from the patent owners, of the patent rights of any and all patents, current, pending, or future, either as standalone drugs or as part of a combination therapy, relevant for the manufacture, import, or sale of generic versions of HCV medicines including but not limited to:

sofosbuvir (Brand name Sovaldi®)
sofosbuvir/ledipasvir fixed-dose combination (Brand name Harvoni®)
GS-5816 (investigational compound)
GS-5816/sofosbuvir fixed-dose combination (investigational compound)
daclatasvir (Brand name Daklinza®)
dasabuvir/ombitasvir/paritaprevir + ritonavir fixed-dose combination (Brand name Viekira Pak™)
simeprevir (Brand name Olysio®)

(2) That the Licence shall additionally be subject to the following conditions:

(a) The Licence shall be non-exclusive, non-assignable, and non-transferable;

(b) The Licence shall be authorized solely for supply of the domestic market in Romania in the field of use for the treatment of HCV in the Territory of Romania. Nothing in the authorization will be construed as granting any rights under any patents to use or sell the products for ultimate use outside of the field of use and/or outside of the Territory of Romania.

(c) When importing products under this Licence, Parties shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories, consistent with the need to protect patient privacy and the confidentiality of patient data.

(d) The Licence shall be limited to the term of the patent(s), for any quantity that is used solely in Romania, and shall remain in effect unless HCV ceases to be a

public health issue in Romania and a reduction in the term does not unduly prejudice the interests of the generic medicine supplier;

(e) Any generic producer that uses the patents described in (1) shall be required to pay royalties to the patent holder(s) at a rate to be negotiated between the producer and the patent holder. If there is no agreement within ninety (90) days, the royalty rate shall be set at either:

(i) an amount equal to 7 percent of the generic price; or
(ii) an amount consistent with the World Health Organization (WHO) Tiered Royalty Method

(f) Royalties shall be paid to the patent holder(s) on a quarterly basis, with royalty payments due no later than thirty (30) days after the end of each quarter;

(g) Where multiple patent holders hold patents on the same product, royalties shall be allocated among the patent owners according to one of the following methods:

(i) upon agreement among the patent owners, or, failing agreement among the patent owners, either,
(ii) Mutually agreed upon arbitration of the dispute, with the costs of arbitration to be paid by the patent owners, or
(iii) According to the recommendation of an expert appointed by the Court, with the costs of the expert paid by patent owners.
(iv) When a product consists of a combination of patented and unpatented inventions, the total royalty will be adjusted down to account for the partial patent coverage.
(v) For option (iii), the allocations should be based upon the “utilization ratio,” which considers the relative importance of each patented invention relative to the product.

The Ministry of Health will notify the patent owner(s) of the compulsory licence within a reasonable time, and shall, upon the final and irrevocable decision of this Court, notify OSIM for appropriate registration and publication.

Announced on __ _____, 2015

Signed

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