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Re: Prospective Grant of Exclusive License: Small Molecule Therapeutics Against Hepatitis C Virus Infection: A Notice by the National Institutes of Health on 03/27/2015. Document Citation: 80 FR 16389, Page: 16389 -16390 (2 pages), Document Number: 2015-06974, URL: https://federalregister.gov/a/2015-06974

Dear Dr. Chang,

We are writing in regard to the Federal Register notice (the "Notice") concerning possible exclusive licenses for patents on the Prevention and treatment of Hepatitis C Virus infection. [80 FR 16389-16390].

The United States and other countries are currently faced with extreme hardships in paying for treatments for the hepatitis C virus (HCV), and in the past, have also been confronted by barriers to innovation as a consequence of restrictive licensing of HCV patents. Any license on NIH-owned patents should include provisions that do the following:

1. Ensure that the patented "invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms" [See: 35 USC 201(f)], including specifically for prices that are reasonable. In evaluating the reasonableness of the price, we suggest that the following conditions apply, as separate tests:

    a. The price should be no higher than the unweighted average price in other countries that are economically similar and competitive with the United States in world markets, such as Canada, Australia, France, the UK, Germany and Japan. This would be a test to ensure the US does not pay more for its own NIH funded inventions, making the US less competitive in global markets.

b. The prices should be low enough that reimbursement bodies, both public and private, provide reimbursement for all HCV patients, regardless of the severity of the liver damage, with low co-payments.

2. Enable research. The NIH should ensure that third parties may conduct research on or with the invention, royalty free and without permission.

3. The license should provide that under 35 USC 202(c)(4), the World Health Organization (WHO) may request from the NIH a license to practice or have practiced on its behalf, the patented invention, subject to the following procedures:

    a. The WHO can identify an important public health concern that is not being met by the holder of the license to the NIH owned invention, including but not limited to the goal of access to medicine for all;

    b. The WHO can explain the steps it has taken to address the issues, including attempts to negotiate voluntary licenses from the holder of the license to the NIH owned invention; and

    c. The WHO can explain how its proposed use and licensing of the invention will address the unmet health need, without unreasonably prejudicing the legitimate interests of the license holder, taking into account the legitimate interests of third parties and the goal of access to medicine for all.

4. Transparency. The NIH should require the license holder to provide the NIH with reports that detail its R&D outlays on the drug, including the costs of each clinical trial, with overhead as a separate line item. The NIH should require the license holder to provide the NIH with reports on annual sales, as measured by both units and revenues, by country, and within the United States, by major type of reimbursement body and government agency.

In our opinion, each of the requested provisions in the contract are not only reasonable, but very modest in terms of ambition, and respond to obvious concerns about the license involving patents on HCV treatments.

We could request that an NIH funded invention be less expensive in the United States than elsewhere, or limited to some multiple of actual investments, adjusted for risks, or suggest any number of other public interest safeguards that would be justified by the public's funding of the invention. The points listed above are not only reasonable licensing terms, they should be looked at as minimal terms for the grant of exclusive rights on an NIH owned invention, assuming the NIH is operating with the interests of the public in mind.

(KEI and Public Citizen agree that the contents of this letter are fully available to the public under FOIA.)

Sincerely,

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ANNEX

The statutory legal basis for our comments to this Notice is found in 35 U.S.C. § 202(c)(4), which provides that every funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions that effectuate the following:

> With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: ***Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights*** *in the subject invention, as are determined by the agency* ***as necessary for meeting the obligations of the United States*** *under any treaty,* ***international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement,*** *including military agreement relating to weapons development and production.* [Emphasis added.]

This statutory obligation is in turn implicated by several relevant international agreements, including the World Health Assembly's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA61.21), and the 2001 Doha Declaration on TRIPS and Public Health.

WHA61.21

In WHA61.21, the Sixty-First World Health Assembly put forth the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, with the aim of "promot[ing] new thinking on innovation and access to medicines, as well as … provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area."[1] Among the stated goals of the Global Strategy include, in paragraph 14(e), "encourag[ing] and support[ing] the application and management of intellectual property in a manner that . . . promotes access to medicines for all…"

Various "elements" put forth in the annex of WHA61.21 are critical to the Global Strategy's implementation, including Element 2, on promoting research and development; Element 4, on the transfer of technology; and Element 5, on the application and management of intellectual property to contribute to innovation and promote public health. These elements are to be implemented through specific actions immediately relevant to this Notice, including:

[1] http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

Section 2.4, calling for "the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms";

Section 4.3, calling for the development of "new mechanisms to promote transfer of and access to key health-related technologies … (b) to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries…";

Section 5.1, calling for the "sharing of information and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries," including, in subsection (a), "the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products..."

Relevant Provisions from WHA61.21

(2.4) Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries … (d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms.

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies (a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices (b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

(5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries (a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries (b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries (c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for

analysis of the information contained in those databases, and improve the quality of patents. (d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs (e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement (f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries (g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs (h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries.

Doha Declaration on TRIPS and Public Health

Further obligations are imposed upon the United States Government via the Doha Declaration on TRIPS and Public Health, which was designed to respond to concerns about the implications of the TRIPS Agreement on global public health issues and access to medicines.[2]

The Doha Declaration states, in paragraph 4:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
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> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

[2] Available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf