Examples of Terms that KEI has Recommended for Inclusion in NIH Licenses

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Re: National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning (89 FR 45003)

Since 2015, Knowledge Ecology International (KEI) has commented on 114 prospective exclusive licenses as noticed by the National Institutes of Health (NIH) in the Federal Register. In our comments, KEI has requested the NIH include license terms promoting affordable and equitable access in the US and globally. The following are non-exhaustive examples of terms requested by KEI in our comments submitted to the NIH for various licenses.

PRICING AND ACCESS IN USA

1. **Price discrimination/International High Income Country Reference pricing.** (used for most of the comments). The license should place restrictions on charging US residents higher prices than the median prices charged in countries with the seven largest GDP and per capita incomes of 50 percent or more than the United States per capita income.

2. **Pricing cap**. (used for some but not all licenses). In any case, and in addition to any other considerations of what constitutes a reasonable price, the license holder is expected to limit the cost of the products or services to U.S. residents to no more than the lesser of either (a) the average annual per capita income in the United States, or (b) the amount of the average annual per capita income in the United States, per quality adjusted life year (QALY) benefit of the product.

3. **Years of exclusivity.** (used in several licenses). We propose the license include terms that reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the terms stipulate that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the sublicense could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater

than reasonably necessary to provide the incentive for bringing the invention to practical application."

4. **Alternative years of exclusivity**. (Used in at least one case). The exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least $1 billion in cumulative global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first five years of exclusivity, the NIH can extend the exclusivity by another 3 years, upon a showing that such extension is reasonable in light of the risk adjusted R&D costs to bring the product market, and the net revenues from sales.

5. **Exclusivity outside the US (in high income countries).** We ask that if exclusive rights are granted, that this only be in high income countries, but not in the United States. Or at a minimum, have the U.S. exclusivity shorter than the exclusivity in other high income countries, perhaps after global revenue targets are reached.

GLOBAL ACCESS

6. **Global registration and affordability.** The license should require the licensee to disclose the steps that each will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

7. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

8. **Non-exclusivity in low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide some mechanism giving effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

9. **Option for license to WHO.** 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.

10. **Technology Transfer.** The NIH should include a provision to provide for technology transfer, including licenses to inventions and data, manufacturing know-how, and access to biologic resources, to companies or other entities that could provide access to the technology in developing countries, in the event that licensees do not serve these markets, or if the prices it charges are not reasonably affordable in developing countries.

TRANSPARENCY

11. **Transparency of R&D outlays.** The licensees should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We note that this is not a request to see a company business plan or license application. We are asking that going forward companies be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

12. **Sales and Access Transparency. (**Units sold by country are the best evidence of access, and tracking sales is important for judging adequacy of incentive). With regard to sales we request an annual report that provides data on the following variables:
    a. Units of sales, by country
    b. Revenue for sales, by country.

13. **Transparency of government subsidies.** With regard to government subsidies for research, we request a report that provides data for the following, by year:
    a. Grants and research contracts from government agencies, with data on the funding agency, the identifier of the grant or contract, and the amount of the grant or contract;
    b. Tax credits associated with R&D for the product, including the U.S. orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial); and
    c. Other government R&D subsidies.

14. **Acknowledgement of federal funding - publication and publicity. (Stevens Amendment obligation).** The licensee should be required to include, when issuing statements, press releases, and other documents describing the development of any product that includes the licensed inventions, a statement that describes the role of the licensed inventions and the total and proportionate contribution of federal funding to the research and development performed to bring the inventions to market.

15. **WHO Transparency Resolution.** In 2019, the United States endorsed the adoption of the World Health Assembly (WHA) Resolution 72.8, titled “Improving the transparency of markets for medicines, vaccines and other health products.” In this license, the NIH should incorporate, to the extent possible, transparency norms that meet or exceed the standards outlined in WHA72.8.

Attachment:

KEI NIH Comments on Exclusive Licenses (as of July 22, 2024) - Selected Metadata.