24 June 2022

Additional written comments by Knowledge Ecology International to the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response

Via: governanceunit@who.int.

Re: ***The open source dividend as a model for incentives to share biological resources, inventions, data, and other inputs***

Introduction

One model for benefit sharing is a mechanism sometimes described as the Open Source Dividend. The basic idea is to set aside a portion of the commercial rewards from a medical product to be shared with persons or communities that openly shared knowledge, data, materials, and technology on a royalty-free and nondiscriminatory basis.

The allocations to recipients of the dividend would be based upon the extent to which biologic resources or other materials, knowledge, data, and technology were openly shared, and contributed to the successful development of a new product (or improved processes for manufacturing products).

Among the proposals for determining the allocations is a process that involves appointment of a temporary expert jury, when a new product enters the market. This group of experts, focusing on just one product, would collect and evaluate the evidence supporting nominations from the public, regarding persons or organizations that openly shared the knowledge, data, materials or technology that was useful in the development (or manufacturing) of that specific product.

Early proposals for an open source dividend to encourage the open sharing of knowledge, data, materials or technology included:

- Work in 2007 and 2008 by Médecins Sans Frontières expert group on a possible $100 million innovation inducement price to reward developments of an effective and inexpensive, rapid, point of care diagnostic test for tuberculosis,
- A 2008 workshop at on workshop on medical innovation prizes at the United Nations University at Maastricht, the Netherlands,
- Several proposals, from 2008 to 2009, by the governments of Bolivia, Barbados, Bangladesh, Bolivia and Suriname, in connection with a WHO evaluation of measures to de-link incentives to invest in biomedical R&D from the grant to temporary monopolies.

See the discussion on the open source dividend in: James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," Annals of Health Law, Vol. 18, No 2, pages 155-186, Summer 2009.

The Open Source Dividend proposal was subsequently included in versions of U.S. legislation for a Medical Innovation Prize Fund (see, for example, Section 11 of S.1137, 112th Congress), and as part of an innovative incentive fund for new and more effective treatments of bacterial infections (S.1801, 116th Congress, Section 409K).

In 2014, this report from the World Intellectual Property Organization (WIPO) described the Open Source Dividend as follows:

> 2.4.1.5. Open Source Dividend Prizes
> 109. As proposed in 2007 and later developed in various systems of prizes, the open source dividend is a mechanism to stimulate greater openness and sharing of research inputs. In initial formulations, the open source dividend was allocated a share of an end product prize, and distributed to persons, groups or organizations that openly and freely shared knowledge, data, materials or technology that was judged to have been helpful or instrumental in the success of the end product. The open source dividend can however be implemented entirely separately from end product prizes, or indeed any other prize mechanism. The open source dividend corrects for an obvious market failure -- the current lack of economic incentives to share research inputs. When research is more valuable to society open than when managed as a proprietary asset under restrictive licensing and access terms, the failure to induce open sharing is costly and wasteful. The open source dividend is designed to correct that market failure. If the open source dividend is financed out of revenues from product sales, it will reduce net returns to product developments, but it will also expand access to research inputs, and lower the costs of acquiring those research inputs.
> Source: *Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models, WIPO, CDIP/14/INF/12, September 19, 2014.*
> https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_14/cdip_14_inf_12.pdf

How large of incentives to share openly?

In proposals for delinkage of R&D incentives from the temporary grant of a monopoly, the open source dividend was set as a fixed percent of a market entry reward (sometimes referred to as an end product prize) -- from 5 to 10 percent of the total outlay from a prize fund. But as noted in the WIPO report, the open source dividend can be implemented as a standalone incentive, financed out of a percent of a product's revenues.

To illustrate, suppose the open source dividend was set at 2 percent of product sales. The 2021 sales of the BioNtech/Pfizer COVID 19 vaccine was $37 billion. The Moderna COVID 19 vaccine sales were $17.7 billion in 2021. Two percent of sales would have been $740 million and $354 million, respectively for the two vaccines. Had the open source dividend been in place, and sales were the same, more than $1 billion would have been redistributed to persons and entities that openly shared the samples, knowledge, data, and technology that made these two vaccines possible.

The actual amount of an open source dividend will be a matter of policy. The greater the share for the open source dividend, the greater are incentives for sharing biological resources, inventions, data, manufacturing know-how and scientific knowledge. One can debate whether an open source dividend share should be a lower number, like 1 percent, or higher, like 4, 5 or even 10 percent. But the current rate of zero is hard to justify on economic grounds, given the non-zero value society places on openness for biomedical science and technology.

Who pays, who benefits?

Any open source dividend will be forward looking, shaping the incentives to share knowledge, biologic resources, data, etc, for new products. It would bind only the countries that were willing to implement the dividend, even though everyone can, at least potentially, benefit from the open sharing of knowledge, technology and data.

One possible incentive for countries to implement the open source dividend could be geographic restrictions on which persons or entities could receive money from an open source dividend fund. If inventions or other rights are shared, there could be restrictions on the geographic scope of a license, limiting the license to countries signing up for a pandemic treaty or agreement (or an optional protocol on the open source dividend, if implemented in this manner).

Impact on product developers

If the open source dividend is funded by what amounts to a royalty on product sales, the product developers will have a reduction in net revenues when the open source royalty is paid. But if the incentive works, it will also have several positive outcomes for the product developer.

- First, the developer will have greater freedom to operate, when inventions and other rights are openly and non-discriminatory available.

- Second, because the open sharing will have to be royalty free, it will reduce the costs of commercially acquiring knowledge, know-how, biologic resources, rights to inventions and data.

Impact on innovation

The open source dividend will correct a market failure -- the current lack of incentives to share knowledge and other inputs useful for the development of new products. It will lower barriers to entry, and reduce transaction costs that plague companies seeking to acquire access to inventions, data, cell lines, and manufacturing know-how, and provide new and powerful economic incentives for persons and communities to create and share the knowledge, tools and infrastructure that accelerates and improves product development. t