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WORLD HEALTH ORGANIZATION TO DISCUSS RESEARCH AND DEVELOPMENT TREATY

The World Health Organization (WHO) will consider later this month whether to negotiate a research and development treaty for diseases that primarily affect developing countries. Some of the treaty proposals could affect intellectual property (IP) rights for pharmaceutical and medical device companies worldwide, as well as adversely affect business models for product development and marketing.

After a multi-year effort, on April 5, 2012, the WHO's Consultative Expert Working Group (CEWG) on Research and Development: Financing and Coordination released a report calling for the negotiation of a binding treaty to regulate the financing and coordination of research and development (R&D) for diseases that primarily affect developing countries.[1] The report will be discussed at the WHO ministerial level World Health Assembly (WHA) in Geneva, commencing May 21. If Member States reach consensus about the desirability of a treaty, the WHO could then begin a formal treaty negotiation process. It appears that the United States has yet to take a public position on negotiation of an R&D treaty, although there are indications that it would not support such an initiative. The upcoming debate at the WHA in Geneva will be a critical indicator of global sentiment for a multinational treaty on R&D in the health care sector.

Covington & Burling LLP's attorneys and non-attorney policy advisors include former senior officials from the U.S. Department of State and the U.S. Trade Representative's Office. Their experience and expertise in multilateral diplomacy, trade negotiations, and IP law and policy make Covington well positioned to advise clients on the legal and policy implications of future WHO treaty negotiations.

BACKGROUND ON THE CEWG REPORT

The CEWG report is the latest in a series of WHO initiatives to address concerns about R&D resources for diseases that primarily affect developing countries. According to the CEWG report, the concerns focus "in particular on the failure of [IP] rights to stimulate innovation in healthcare products needed by developing countries, and . . . the constraints created by such rights for access to needed products, especially by the poor."[2] In 2008, the World Health Assembly adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), which called for the establishment of a working group on financing and coordination of R&D for diseases that affect developing countries. Pursuant to the GSPA-PHI, the WHO established the Expert Working Group on Research and Development: Coordination and Financing (EWG). The EWG delivered its final report in 2010, but some developing countries criticized the report, charging that the EWG rejected proposals without consideration or explanation.[3]

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[1] WORLD HEALTH ORGANIZATION, CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION, RESEARCH AND DEVELOPMENT TO MEET HEALTH NEEDS IN DEVELOPING COUNTRIES: STRENGTHENING GLOBAL FINANCING AND COORDINATION (Apr. 2012), *available* here (hereinafter "CEWG Report").

[2] *Id.* at 17.

[3] *See id.* at 18-19.

To remedy the perceived problems with the EWG report, WHO Member States established the CEWG in 2010 in World Health Assembly Resolution 63.28.[4] In line with the resolution, the CEWG defined its mandate to include "the financing and coordination of research and development for health products and technologies (including, for example, medicines, vaccines, diagnostics, devices, and delivery technologies) related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases."[5]

Notable Elements of the Report

The CEWG report recommends that WHO Member States negotiate a binding treaty to be adopted by a two-thirds vote of the World Health Assembly pursuant to Article 19 of the WHO Constitution. To date, only one health treaty, the Framework Convention on Tobacco Control, has been adopted via the WHO mechanism.

Although the report is careful to note that the treaty provisions must be negotiated by Member States,[6] it makes several recommendations. The report sets out objectives a treaty should achieve, including: securing access to and affordability of health technologies by delinking R&D costs and product prices; enhancing capacity in and technology transfer to developing countries; and "[g]enerating R&D outcomes as public goods."[7] The report recommends that funding come from government contributions to a financing mechanism established by the treaty and that governments consider existing or new taxes to raise funds, including taxes with health benefits (e.g., tax on tobacco sales).[8] To coordinate R&D and innovation, the report suggests establishment of a Global Health R&D Observatory and an advisory mechanism under the auspices of the WHO.[9]

The CEWG report examines a number of specific proposals made by Member States, non-governmental organizations, and others. If treaty negotiations commence, these and other proposals may receive renewed interest and support from Member States, such as China, Brazil, South Africa, and India, that have substantial diplomatic clout and have advocated weakening IP rights in the past. Proposals with the potential to affect IP rights include:

- **Open Approaches to R&D and Innovation:** The report discusses open innovation, open source drug discovery, precompetitive R&D platforms, and equitable licensing.[10] These proposals involve, to differing degrees, disclosure of information and licensing of IP rights that many IP owners currently hold in confidence or decline to license.
- **Patent Pools:** The report considers both "downstream" and "upstream" patent pools. "Downstream" patent pools envision patent holders licensing patents to finished products to pools with conditions, including, for example, limited geographic scope and requirements for royalty payments.[11] "Upstream" patent pools involve making available IP that could be used to develop new drugs and other health products.[12]

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[4] *See* WHO Res. 63.28, WHA63/2010/REC/1, Resolutions and Decisions Annexes at 61 (May 17-21, 2010), *available* here.
[5] CEWG Report at 20.
[6] *Id.* at 122.
[7] *Id.* at 123.
[8] *Id.* at 74-75, 123.
[9] *Id.* at 102.
[10] *Id.* at 182-90.
[11] *Id.* at 169-71.
[12] *Id.* at 57, 171-72.

- **Elimination of Data Exclusivity:** The report considers, but does not endorse, a proposal to eliminate the data exclusivity regime that currently prevents competition for a set period beginning when a product is approved for marketing by preventing other companies from seeking "regulatory approval of an equivalent product on the basis of data submitted by the originator company without the [originator company's] approval."[13] Most developed countries interpret the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to require Member States to adopt some form of data exclusivity,[14] which could prevent this proposal from gaining traction in a treaty negotiation.

If treaty negotiations commence, IP holders in the pharmaceutical, medical devices, and broader health care markets may be impacted by these or other proposals and eventual treaty provisions aimed at fostering knowledge and technology transfer.

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Covington is deeply familiar with the decision-making process and procedures of the WHO as a result of the experience our attorneys, such as Daniel Spiegel (former U.S. Ambassador to the U.N. in Geneva), and non-attorney policy advisors, including Anne Pence, who spent years working on multilateral and health policy matters at the Department of State. They have been closely following WHO matters relating to IP and trade issues, with the collaboration of John Veroneau (former Deputy United States Trade Representative and former General Counsel to the Office of the United States Trade Representative), Marney Cheek (formerly Associate General Counsel of USTR), and Lisa Peets, a partner in Covington's London office who specializes in IP policy matters. They would be pleased to discuss these matters as they may relate to your business.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our international practice group:

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[13] *Id.* at 152.
[14] Id. at 153.