

John Dalli
Commissioner for Health and Consumers
Directorate General Health and Consumers
European Commission
Rue de la Loi 200
B-1049 Brussels

12 January 2012

Dear Commissioner Dalli,

In anticipation of the upcoming World Health Organization (WHO) Executive Board meeting on 16-23 January 2012, we wish to draw your attention to item 6.14 of the provisional agenda: the WHO's Consultative Expert Working Group (CEWG) on Research and Development Financing and Coordination.

The Consultative Expert Working Group is currently preparing a report recommending, among other measures, that Member States enter into a globally binding treaty to regulate the financing and coordination of health-related research and development (R&D) with an emphasis on supporting developing countries' needs. European companies are deeply committed to innovation in public health for the benefit of the developed and developing world. We are concerned, however, that a binding R&D treaty may ultimately undermine one of the key drivers for innovation in health products and technologies: intellectual property rights (IPR). This could result in losing important innovations in health technologies of particular relevance to developing countries and emerging markets, diminishing Europe's critical competitive advantage and setting a dangerous precedent in terms of IPR erosion for other industry sectors.

Today, healthcare innovators invest heavily and consistently in R&D. As documented by WHO's Global Initiative on Health Technologies, for example, the medical device industry spends up to 12% of its income on R&D. When the needs are known, it innovates specifically to address global health issues.

In addition, today's innovation ecosystem for healthcare products and technologies is truly global. Innovation is no longer limited to the needs of developed country markets. Many major providers of health technologies engineer solutions for use in the developing world with price points suited for those markets. Our members also undertake product development on the ground in many emerging markets, in close collaboration with health ministries in order to ensure that their products fully reflect developing countries' priorities and needs.

As stated in our 2 November 2011 letter to the Transatlantic Economic Council (TEC) cochairs, intellectual property rights play a critical role in incentivizing investments in global innovation. IPRs are a key part of the solution to health care challenges around the world. The research-intensive and highly competitive nature of the medical device and

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technology sectors renders these sectors uniquely dependent on robust IPR protection. The large capital costs and significant risks associated with the development of ever more complex medical technologies, along with their adaptation to developing-country applications, have rendered patents and trade secrets a critically important way to reward research, protect value and innovation, as well as sustain the dissemination and broad deployment of technologies.

The WHO dialogue on public health and innovation is unquestionably an important one. The outcome of this process should reflect the reality that innovation will be most robust and can be best sustained when it is led by the private sector, driven by market needs, and supported by strong IPR protection. This is why, we fail to understand the need for the proposed global treaty on R&D and remain concerned that it could open the door to a weakening of IPR protection. An R&D treaty could ultimately become an unnecessary distraction from successful and repeatedly proven market-based approaches to innovation in the field of health products and technologies. Even more worryingly, some proposals, including but not limited to an R&D treaty, might weaken the global IPR regime, undermining market-based incentives for innovation and potentially slowing industry progress towards solutions for major global health needs.

Given the imminence of discussions on the WHO proposals and their potential danger to intellectual property rights, health care innovation and the overall economic interests of the EU, we urge you to reject any efforts to erode intellectual property rights and reject any proposal to negotiate a global R&D treaty. We remain committed to work together with you towards fostering innovation to improve global health, and to secure Europe's global competitive advantage and economic well-being.

A similar letter is being sent to Commissioner De Gucht.

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Yours sincerely,

Philippe de Buck