

To Link, Or Not To Link, That Is the Question:

Analysis of the Medicines Patent Pool as an Alternative Incentive Model for Delinking Research and Development Costs from the Prices of Pharmaceutical Products

The patent system currently provides the most important legal instruments to incentivize R&D in the pharmaceutical sector. Patent protection grants the pharmaceutical industry a temporary monopoly and allows it to extract profits through prices that are significantly higher than marginal production costs. Patent protection provides incentives to investors allocate their resources in the development of treatments with a large market potential. That is to say, in a market in which the treatment can be sold at high volumes and/or high prices for populations with a high ability to pay. Private investment in pharmaceutical R&D is thus profit-oriented and does not necessarily reflect the most urgent public health needs. In the present patent-driven innovation system, the returns for investment in pharmaceutical innovation are generally incorporated into the prices of new generation products. In this context, this paper aims to investigate how and to what extent it is possible to delink R&D costs from medicines' price. More specifically, it analyzes the Medicines Patent Pool (MPP) as an alternative incentive model for delinking R&D costs from pharmaceutical products and for improving access to medicines in low-income countries. The main question that this study aims to answer is: how and in which situations the prices of medicines should be delinked from their R&D's costs? In light thereof, this study is divided into three main parts. The first section depicts not only the functioning and the importance of the patent system in fostering innovation in the pharmaceutical sector, but also describes its deficiencies in providing solutions for other problems, such as, increasing health costs, antimicrobial resistance and the development of treatment for rare and neglected diseases. The second section explains the concept of de-linkage and presents its different types of push mechanisms, such as open source drug discovery and development, grants, tax breaks; and pull mechanisms, such as innovation prizes, advance market/purchase commitments and priority review voucher (PRV). It addresses the main advantages and disadvantages of these new types of "delinking" finance mechanisms. The third section analyses the MPP as an alternative incentive model for delinking research and development costs from the prices of pharmaceutical products. It describes the MPP's model to improve access to HIV, hepatitis C and tuberculosis medicines, its strategy, governance and funding. This case study constitutes a good example on how the pharmaceutical industry is gradually advancing and trying to develop mechanisms to cope with the trend towards more openness in terms of collaboration and access to knowledge. The methodology adopted in the development of this research is bibliographic, descriptive and exploratory. The relevance of this work resides in contributing to the discussions on how openness could be operationalized with the context of pharmaceutical patent protection in a way to enhance access to medicines in low-income countries. The author's personal contribution to this subject lies on providing a perspective of who has worked as Policy Advisor at the Swiss Federal Institute of Intellectual Property and comes from a developing country.

References

AGITHA, T. Alternative Incentive Models Delinking R&D Costs from Pharmaceutical Product Price. *Journal of Intellectual Property Rights*, v. 18, p. 491-498, sep. 2013.

ESTÈVES, Natacha. Open Models for Patents: Giving Patents a New Lease on life? *The Journal of World Intellectual Property*, v. 21, n. 1-2, p. 2-14, March. 2018.

GERVAIS, Daniel; CHRISTIE, Andrew; BORS, Cindy; CLAYTON, Ellen. Improving Access to Medicines in Low-Income Countries: a Review of Mechanisms. *The Journal of World Intellectual Property*, v. 18, n. 1-2, p. 1-28, 2015.

GURGULA, Olga. Monopoly v. Openness: Two sides of IP coin in the Pharmaceutical Industry. *Journal of World Intellectual Property*, v. 20, n. 5-6, p 206-220, nov. 2017.

HELLER, Michael; EISENBERG, Rebecca. Can Patents Deter Innovation? The Anticommons in Biomedical Research (1998) 280 *Science* 698.

LOVE, James; HAIDER, Narmeen; HOLLIS, Aidan. Delinking Proposals and the Measurement of Health Benefits. *Whittier Law Review*, v. 38, n. 3, p. 349-362, 2014.

OGUAMANAM, Chidi. Patents and Pharmaceutical R&D: Consolidating Private-Public Partnership Approach to Global Health Crises. *The Journal of World Intellectual Property*, v. 13, n. 4, p. 556-580, 2010.

COASE, Ronald. The Problem of Social Cost. *The Journal of Law & Economics*, v. 3, p. 1-44, oct. 1960.

THIRUTHY, Narendran. R&D Crisis in Drug Discovery for Neglected Diseases: Scope for an Open Source Approach to Pharmaceutical Research. *Journal of Intellectual Property law & Practice*, v. 11, n. 8, p. 599-611, 2016.

WORLD HEALTH ORGANIZATION. An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines. UNITAID Discussion Paper. Geneva: UNITAID, 2015.