

# Human Rights and the De-linkage of R&D Costs and Drug Prices

James Love

Knowledge Ecology International

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# Radical IPR Scenario # 1

- In 2002, Aventis, the giant pharmaceutical firm, held a three-day scenario planning session in Ottrott-le-Haut, France, to consider what might happen if there were radical changes in the business models for new drug development. The meeting was authorized by the Aventis CEO and the company's board of directors, and included more than two dozen high-level Aventis executives and two critics of the existing regime . . .
- One product of this meeting was initially dubbed "Radical IPR Scenario # 1." It involved a proposal to eliminate marketing monopolies for new pharmaceutical drugs, in return for a system of large cash prizes. In order to ensure the entire world shared the costs of drug development, there would be a global treaty that set minimum levels of support for R&D, either through similar prizes funds or other research projects, including open source research similar to the Human Genome Project.

November 28, 2007. James Love and Tim Hubbard. "The Big Idea: Prizes to Stimulate R&D for New Medicines." *Chicago-Kent Law Review*, Volume 82, Number 3 (2007).

## INTRODUCTION: THE CORE IDEA

The current system of financing research and development (“R&D”) for new medicines is deeply flawed by the impact of high prices on access to medicine, the wasteful spending on marketing and R&D for medically unimportant products, and the lack of investment in areas of greatest public interest and need. It can and should be replaced with something better.

The system for financing new drug development can be radically improved—spending less overall, aligning investment incentives more efficiently—while making drugs available to everyone at cheap generic prices. Reforming the way we pay for R&D on new medicines involves a simple but powerful idea. Rather than give drug developers the exclusive rights to sell products, the government would award innovators money: large monetary “prizes” tied to the actual impact of the invention on improvements in health care outcomes that successful products actually deliver.

# Burton A. Weisbrod, "Solving the Drug Dilemma," The Washington Post on August 22, 2003.

- Economists have long recognized similar dilemmas when start-up costs are very high but marginal production costs are low. Pharmaceuticals are a clear example, as are telephone and electricity distribution. In all these cases, the economically efficient solution is two-part pricing—a flat charge for access plus a variable charge that depends on level of usage.
- Drug companies have two distinct outcomes but only one instrument for pricing them. They develop new drugs and they manufacture the actual pills or products consumed by individual patients, but they can price only the pills. The patent system is the root problem. It encourages innovation by granting a monopoly and then allowing the owner to set prices for the resulting product. Thus the only way that R&D, including clinical testing, costs can be covered is through high prices for the resulting pills.
- When R&D costs are small, there is no serious problem. But when R&D costs are very large relative to production costs—as is the case for pharmaceuticals—using price for pills as the only mechanism for rewarding the product developer drives price upward. Prices become far higher than they should be, far higher than the cost of producing the pills, and far higher than is economically efficient.
- The solution: Two prices—one for the R&D, another for the resulting pills. This solution is not painless, but neither is the course that public policy is now on.

## **SIXTY-FIRST WORLD HEALTH ASSEMBLY - WHA61.21**

24 May 2008

Global strategy and plan of action on public health, innovation and intellectual property

Element 5. Application and management of intellectual property to contribute to innovation and promote public health

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases

(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries

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## 2.3 Improving cooperation, participation and coordination of health and biomedical research and development.

(c) Encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical r&d, including *inter alia*, an essential health and biomedical R&D treaty

# Implementation of de-linkage

- 2005/2007 Medical Innovation Prize Fund bills
- April 2008/2009 Barbados/Bolivia prize proposals to the WHO IGWG
  - Cancer Prize Fund
  - Chagas Disease Prize Fund
  - Diagnostic Test for Tuberculosis
  - Prize Fund for Donor Supported Markets
  - Priority Medicines and Vaccines
- MSF/DNDi
  - MSF TB Diagnostic Prize
  - DNDi interim results prizes
- Prizes with strong IPR and monopolies
  - The Hollis/Pogge voluntary prize fund
  - Gates Foundation/X-Prize TB diagnostic prize
- Other academic proposals
  - Reasonable Rx: solving the drug price crisis By Stan Finkelstein, Stan N. Finkelstein, Peter Temin, 2008
  - Burton A. Weisbrod, "Solving the Drug Dilemma," The Washington Post on August 22, 2003.
  - Joseph Stiglitz. "Give Prizes, Not Patents." New Scientist, p. 21. JSeptember 16, 2006.

# Open Source Dividend

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.

- First developed in connection with a prize for TB diagnostics
- Generalized to all 3 generation prize proposals