

# **Alternatives to the patent system used to support R&D Efforts**

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# Some conclusions

- {p1} The grant of exclusive rights to use patented inventions is just one of several important mechanisms for stimulating investment in innovative technologies.
- {p2} All mechanisms for funding, subsidizing or inducing third party investments in innovation have benefits, as well as costs and limitations.

# Alternatives examined in the paper

- Grants/contracts
- Tax policy/tax credits
- Non-patent mechanisms to grant exclusive rights or marketing monopolies
- Research mandates
- Innovation inducement prizes

{p3} The patent system has the advantage of decentralized decision making, a reward system that can dynamically mobilize resources directly from the users that benefit from the invention, and disclosures of inventions.

The costs of the patent system include high prices for products, legal barriers to the use of inventions for follow-on innovations, and the considerable costs of evaluating and enforcing patents. The patent system is also of limited value for certain research and development activities, including for the development of products with small commercial market potential, including pre-commercial research and development, research outcomes that cannot be successfully monopolized and monetized, and particularly risky development projects, to mention a few of several well-known limitations of the patent system.

{p4} Each of the alternatives to the patent system likewise has advantages, as well as costs and limitations. Policy makers have the freedom to use a variety of innovation inducing mechanisms to achieve goals, either as a substitute for or a complement to the patent system.

Economic analysis of the costs and benefits, and suitability of various mechanisms to achieve context specific innovation objectives is encouraged. Also, the use of several mechanisms, in combination, can be useful to overcome the glaring shortcomings of a particular mechanism.

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Like the patent system, other mechanisms for supporting innovation have trade related aspects, and emerging or possible global regimes of regulation.

# Public funding of Research

Weak or non-existent global norms to expand public sector funding of R&D in public goods

Governments have poor track records in preventing abuses of patent rights for government funded inventions

# **Problems with tax credits**

Often lack of transparency, regarding the use and value of tax credits

Governments often do not obtain rights in inventions subsidized by tax credits

# Palbociclib (Ibrance)

Drug for HER2 negative breast cancer patients that is priced by Pfizer at \$118,200 per year.

*From the US patent*

"The core laboratory research for this project was funded primarily through the Revlon/UCLA Women's Cancer Research Program and the longtime philanthropic support of Ronald O. Perelman. Additional resources were provided by a U.S. Department of Defense Innovator Award (W81XWH-05-1-0395) and the Noreen Fraser Foundation. The clinical trial itself was supported entirely by Pfizer Inc."

The key scientific work was directed by Dr. Dennis Slamon, the same scientist who relied upon Revlon funding to lead the development of Herceptin, a Roche drug for HER2 positive breast cancer patients, a saga described in moving detail in the movie, "Living Proof," and the book: Her-2: The Making of Herceptin, a Revolutionary Treatment for Breast Cancer.

# US Orphan Drug tax credit

- 2010 to 2014, 27 of 41 (66 percent) new cancer drugs approved by the US FDA were eligible for a 50 percent Orphan Drug tax credit for expenditures on clinical trials.
- In 2014, 9 of 10 of the new cancer drugs were eligible for this tax credit

# Research mandates

US Cisplatin example

Brazil

Colombia

# Suggestions regarding WIPO, (1)

- Deepen understanding of trade related aspects of non-patent innovation mechanisms, including grants, taxes and innovation inducement prizes
- Explore use of non-patent financing mechanisms to address R&D, when strong patent rights lead to socially unacceptable outcomes as regards access, affordability.

# Suggestion for WIPO, (2)

- Encourage greater transparency of the costs and benefits (and distribution of costs and benefits) for both patent and non-patent mechanisms.
- Introduce more rigorous analysis of value of money/cost effectiveness of different mechanisms

## Prizes when social value of innovation is higher than private value

{p 162-164}.

There are many well-known cases where the social value of innovations is higher than the private value. A few examples of this include

- An innovation demonstrating a technology that is not commercially viable, but which builds a bridge to future technologies that will be viable, such as a more efficient photovoltaic or better energy storage technologies.
- An innovation that in practice cannot be easily monopolized, even with a patent, such as the discovery of a new use of an existing drug, or an innovation that can be implemented with readily available technologies and tools.
- A low cost diagnostic tool to identify medical diseases or conditions that is most valuable when its price approaches zero.
- Identification of negative characteristics or products, such as security risks or adverse medical consequences.
- The open sharing of knowledge, materials and data that third parties may find useful.
- The development of free software tools that rely upon open and non-proprietary standards.

In such cases, patents may be irrelevant, ineffective or counter productive, and the use of an innovation inducement prizes can create private incentives that induce private actors to take actions that are more socially beneficial.

# Patents v prizes, access

*Para 149.*

For goods where it is difficult, costly or impossible to implement differential pricing of goods among users of different incomes, and where there exist feasible ways of collecting money for a cash prize, the benefits of prizes over patents may be significant in expanding access.

## Prizes v Patents, as regards regulating prices and arbitrage

{p 155}. In theory, the patent system can be regulated in such a way that the patent owner loses its ability to charge unfettered monopoly prices, for example, through price controls or threats to eliminate the patent monopoly by granting a compulsory license or by the elimination of the patent altogether. The question to policy makers is then, which is easier to administer: a system of price controls to moderate monopoly pricing strategies, or the prize system? One consideration in this simple stylized model will be the feasibility of implementing price controls with different prices in different countries. If there is free movement of goods, or cross country pricing norms, it may be difficult to implement efficient price controls globally, while maintaining sufficient incentives to innovation.

{p 156}. An innovation prize system that delinks product prices from R&D costs then has the advantage of eliminating the need to police cross border arbitrage or other activities that undermine global pricing norms that are designed to limit price gouging while preserving incentives to innovate and allocating the costs of innovation fairly among countries (and end users). Delinkage is a more simple and elegant solution, assuming there are feasible ways to financing the prize money, and agreement on how to share the costs.

# **Digression on open source dividend**

For pharmaceutical drugs, software development, or other sectors, open source development would enhance the rate of innovation, and lower upstream R&D costs to product developers.