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ALTERNATIVES TO THE PATENT SYSTEM THAT ARE USED TO SUPPORT R&D EFFORTS, INCLUDING BOTH PUSH AND PULL MECHANISMS, WITH A SPECIAL FOCUS ON INNOVATION-INDUCEMENT PRIZES AND OPEN SOURCE DEVELOPMENT MODELS

commissioned by the Secretariat

1. The Annexes to this document contain (i) a Study on Alternatives to the Patent System that are Used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models, undertaken in the context of the Project on Intellectual Property and Technology Transfer: 'Common Challenges – Building Solutions' (CDIP/6/4 Rev.), by Mr. James Packard Love, Director, Knowledge Ecology International, Washington, DC, USA, and (ii) a Peer Review of the above Study by Dr. Dominique Foray, École Polytechnique Fédérale de Lausanne (EPFL), Lausanne, Switzerland.

The CDIP is invited to take note of the information contained in the Annexes to this document.

[Annexes follow]

Note: The views expressed in this study are those of the author and do not necessarily reflect those of the WIPO Secretariat or any of the Organization's Member States.

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INCLUDING BOTH PUSH AND PULL MECHANISMS, WITH A SPECIAL FOCUS ON
INNOVATION-INDUCEMENT PRIZES AND OPEN SOURCE DEVELOPMENT MODELS

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EXECUTIVE SUMMARY

1. The grant of exclusive rights to use patented inventions is one of several important mechanisms for stimulating investment in innovative technologies. This paper discusses several alternatives to the grant of patent monopolies including direct government funding of research, tax policy, the creation of non-patent monopolies, mandates to fund research-based upon a percentage of product sales, and innovation inducement prizes.
2. All mechanisms for funding, subsidizing or inducing third party investments in innovation have benefits, as well as costs and limitations.
3. 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.
4. 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.
5. Like the patent system, other mechanisms for supporting innovation have trade related aspects, and emerging or possible global regimes of regulation.
6. Innovation inducement prizes are an ancient mechanism that has recently found a new constituency, as both a complement or a substitute to patent enforced products monopolies. These include *sui generis* one-off prize contests, with ad hoc rules, and more ambitious proposals for systems of innovation prizes that would compete more directly with patent monopolies to induce private investments in R&D, or systems of research grants or contracts. The paper compares innovation inducement prizes to patent monopolies, and to research grants or contracts, in a series of stylized examples that illustrate the motivations for using particular mechanisms.
7. The paper concludes with an analysis of competing proposals to induce innovation for new antibiotic drugs, an area of considerable market failure.

1. INTRODUCTION

1. This paper examines alternatives to the patent system for funding and supporting research and development and innovation.¹

¹ This study in support of the implementation of WIPO's Development Agenda Recommendations, specifically Recommendations 19, 25, 26 and 28 as described in the following Project Paper: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_6/cdip_6_4_rev.pdf The Study will look at alternatives for R&D efforts and support innovation aside from the currently existing patent system, as reflected in item (f) at Annex, page 4 of the above Project Paper.

2. WIPO defines a patent as “an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.” The modern system for granting patents is a complex system of global, plurilateral, bilateral and national rules and practices that determine what is and what is not a patented invention, the rights associated with the patent grant, the limitations and exceptions to patent rights, and the term of protection.

3. Over time the patent system has become an important focus of debates about innovation policies, including discussions about the costs and benefits and distributional impacts of patent grants, on both inventors and end users, and as a widely used metric to measure innovation and innovative capacity.

4. The patent system is an important mechanism to support innovation, but it exists within a larger ecosystem of innovation. One attempt to describe the larger ecosystem for innovation is the Global Innovation Index published annually by WIPO in collaboration with partners. The 2013 version of this index (GII 2013) ranks countries based upon 84 variables. Only three of the GII 2013 variables specifically mention patent activity, compared, for example, to thirteen variables related to education and seven variables on access to credit and investment. The 84 variables included in the GII are themselves only a small subset of the areas where government policies and practices influence innovative activity.

5. This paper will examine several but certainly not all non-patent methods for supporting innovation. The focus will be on the role of

1. research grants and contracts;
2. tax policies;
3. innovative finance mechanisms including research mandates; and
4. innovation inducement prizes.

There will also be a discussion of methods of promoting open innovation in the area of medical technologies, and software.

6. Some of these mechanisms are implemented both as alternatives and complements to the patent system. The discussion will explore the opportunities and challenges of supporting innovation without patents.

2. SURVEY AND TAXONOMY OF INNOVATION-INDUCEMENT REWARDS AND PROTECTIONS FOR CREATIVITY, INVENTION, AND INNOVATION

2.1. RESEARCH GRANTS AND CONTRACTS

7. Probably the oldest and most familiar instruments for supporting innovation are research grants and contracts. Governments, businesses, non-profit organizations, associations, regional and multilateral institutions and even individuals use grants and contracts for a wide range of research and innovation related tasks.

8. Research grants typically specify a set of research and development tasks, and are given to individuals or teams that are perceived to be sufficiently qualified. Research grants and contracts often address a combination of social and economic objectives, and may be conditioned upon a diverse set of terms, including obligations to conduct work or manufacturing domestically or in a specific geographic area, and may or may not set out terms of the use and licensing of intellectual property.

9. Compared to indirect mechanisms for stimulating R&D, such as various incentives to invest², grants and research contracts provide an instrument to ensure that R&D is funded and performed.

10. Grants or contracts have several advantages, and are particularly important where broad dissemination of research is considered valuable, the outcomes of the research cannot be easily or fully commercialized through patents³, researchers do not have access to alternative sources of finances, or the funder of the grant or contract seeks greater control of the research tasks or control or ownership of the research outcomes.

11. Research grants may be used to advance science, address a specific innovation problem, increase the competitiveness of domestic industry, or promote development. Government-run research programs often are mindful of the geographic allocation of grants, and in some cases have particular initiatives that are designed to promote social cohesion, the transfer of technology, or development.⁴

12. Governments that invest heavily in research grants and contracts in a particular sector such as energy, informatics, biotechnology, nanotechnology agriculture or informatics often do so both to advance science, address a social concern, and/or to develop domestic industrial capacity. These mixed goals are often described in publications justifying agency budgets. As discussed below, on average, public sector outlays on research increase in both absolute and percentage terms with the per capita income of countries.

2.1.1. Sources of funding for grants and research contracts

13. Often governments working within national borders are the source of funding for research grants or contracts, but there is a significant role for cross border cooperation by governments, and depending upon the subject matter, the private sector, including businesses, non-profit entities and individuals.

14. The amount of funding for grants and research contracts varies by country, and by purpose and sector of the economy. UNESCO publishes time series data on the amount of research and development funding for countries, including statistics on the percentage of research funded by businesses, governments, educational institutions, other non-profit entities, foreign and other sources. The UNESCO data show that the government role in funding of research is significant in most countries, and rises as a percentage of GDP, for countries with higher per capita incomes, as illustrated in Table 2.1.1 and Figure 2.1.1

² The incentives include patents on inventions. See also discussion of innovation inducement, prizes, priority review vouchers, rights in test data, and protection of trade secrets.

³ Suzanne Scotchmer, *Innovation and Incentives*, the MIT Press. 2004. Adam B. Jaffe, Manuel Trajtenberg, and Rebecca Henderson, Geographic Localization of Knowledge Spillovers as Evidenced by Patent Citations. Chapter 5 in Adam B. Jaffe and Manuel Trajtenberg, editors, *Patents, Citations, and Innovations: A Window in the Knowledge Economy*. MIT Press, 2002. R. R. Nelson, "The Simple Economics of Basic Scientific Research," *Journal of Political Economy*, 1959.

⁴ Under the European Union Seventh Framework Program (FP7), in some cases grants are favored when involving cross border collaborations. The European Union has special programs aimed at "unlocking and developing the research potential in the EU's 'convergence regions' and outermost regions." The EU Horizon 2020 program will be "exploring synergies with funds under the EU's Cohesion policy" and "identify potential centres of excellence in underperforming regions." Boosting growth: Commission announces EUR 80 billion for research and innovation, 2011-12-01.

Table 2.1.1

Government funded research as a percent of GDP	Government Funded Research	Gross Expenditure on R&D (GERD) / GDP	GDP / Per capita	Country
0.66%	\$463	2.87	70,573	Switzerland
0.83%	\$469	3.07	56,486	Denmark
0.92%	\$429	2.83	46,616	USA
0.67%	\$308	1.85	46,212	Canada
0.51%	\$233	1.71	46,019	Ireland
1.08%	\$484	2.79	44,916	Austria
1.00%	\$439	3.90	43,864	Finland
0.56%	\$241	3.26	43,118	Japan
0.51%	\$218	2.00	43,000	Belgium
0.84%	\$360	2.09	42,784	Singapore
0.85%	\$341	2.80	40,164	Germany
0.09%	\$36	0.09	40,091	Kuwait
0.83%	\$325	2.24	39,186	France
0.58%	\$210	1.80	36,233	UK
0.53%	\$177	1.26	33,761	Italy
0.35%	\$115	0.75	32,558	China, Hong Kong
0.64%	\$196	4.35	30,389	Israel
0.65%	\$194	1.39	29,956	Spain
0.34%	\$94	0.49	27,889	Cyprus
0.74%	\$170	2.11	22,942	Slovenia
0.72%	\$153	1.59	21,382	Portugal
1.00%	\$205	3.74	20,540	Republic of Korea
0.24%	\$46	0.68	19,625	Malta
0.62%	\$117	1.55	18,867	Czech Republic

Government funded research as a percent of GDP	Government Funded Research	Gross Expenditure on R&D (GERD) / GDP	GDP / Per capita	Country
0.31%	\$50	0.63	16,062	Slovakia
0.72%	\$101	1.63	14,062	Estonia
0.37%	\$49	0.75	13,327	Croatia
0.46%	\$58	1.16	12,796	Hungary
0.16%	\$20	0.42	12,671	Chile
0.45%	\$55	0.74	12,302	Poland
0.09%	\$11	0.40	11,520	Uruguay
0.37%	\$41	0.80	11,149	Lithuania
0.61%	\$67	1.16	10,978	Brazil
0.16%	\$17	0.60	10,743	Latvia
0.82%	\$87	1.16	10,710	Russian Federation
0.26%	\$26	0.84	10,135	Turkey
0.45%	\$41	0.62	9,133	Argentina
0.06%	\$5	0.15	9,070	Kazakhstan
0.17%	\$15	0.48	8,779	Mexico
0.39%	\$34	1.07	8,729	Malaysia
0.30%	\$24	0.48	7,783	Costa Rica
0.25%	\$19	0.46	7,687	Romania
0.39%	\$28	0.87	7,266	South Africa
0.09%	\$6	0.19	7,229	Panama
0.26%	\$16	0.60	6,335	Bulgaria
0.07%	\$4	0.19	6,180	Colombia
0.19%	\$11	0.22	5,843	Azerbaijan
0.41%	\$24	0.69	5,819	Belarus
0.45%	\$23	0.76	5,073	Serbia
0.42%	\$19	1.76	4,448	China

Government funded research as a percent of GDP	Government Funded Research	Gross Expenditure on R&D (GERD) / GDP	GDP / Per capita	Country
0.05%	\$2	0.07	3,444	El Salvador
0.39%	\$12	0.83	2,974	Ukraine
0.01%	\$0	0.04	2,882	Guatemala
0.17%	\$5	0.73	2,823	Morocco
0.09%	\$2	0.16	2,400	Sri Lanka
0.17%	\$4	0.28	2,286	Mongolia
0.08%	\$2	0.16	1,935	Bolivia
0.07%	\$1	0.09	740	Tajikistan
0.14%	\$0	0.24	341	Ethiopia

Figure 2.1.1

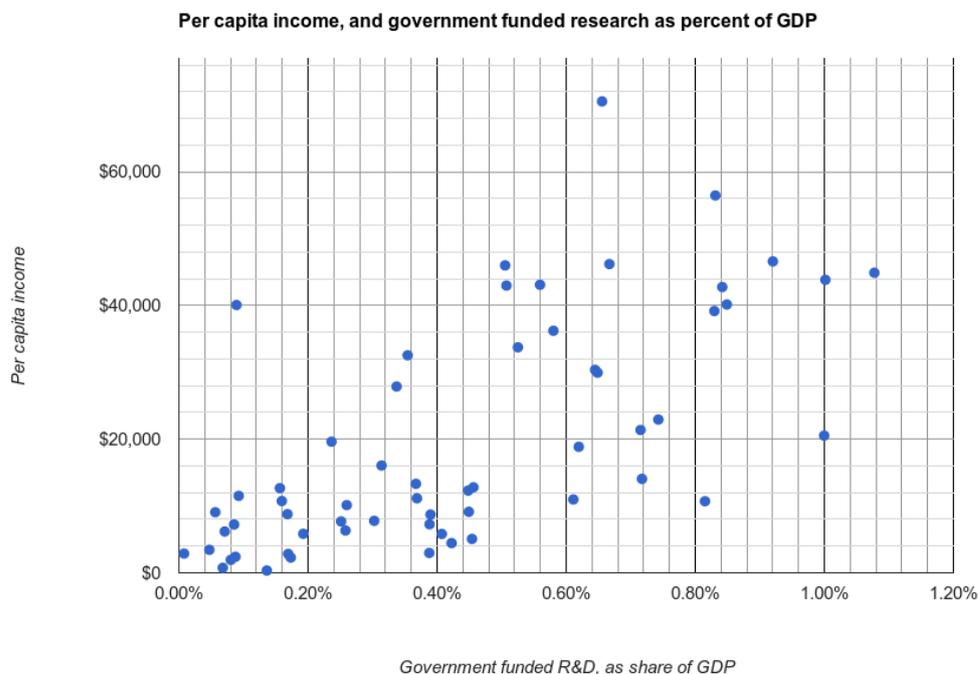
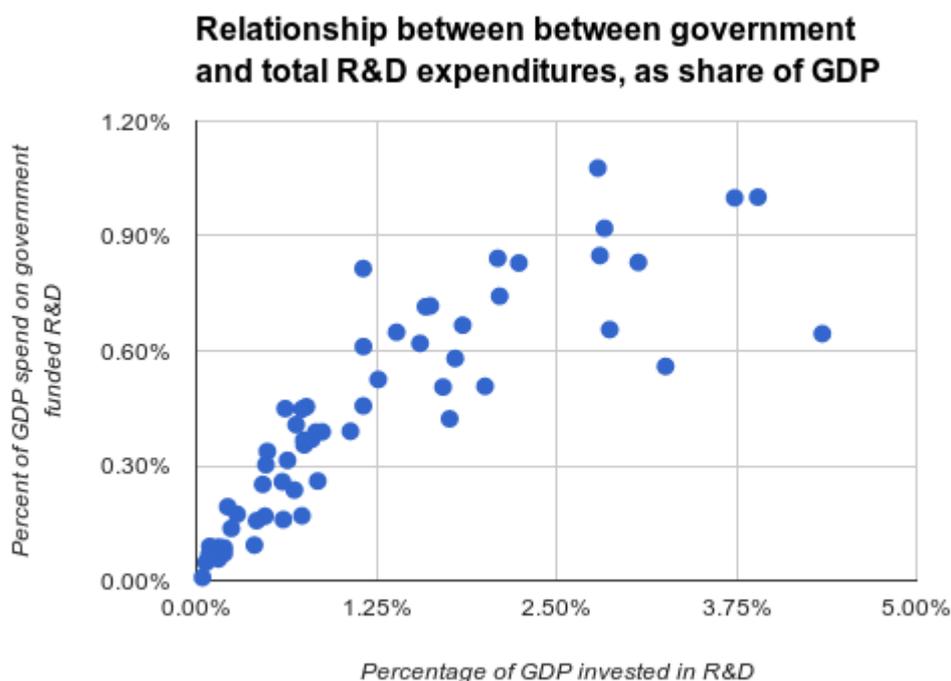


Figure 2.1.2.



15. Businesses, governments and other non-profit entities fund research in all stages of development. Often, the government role is larger for earlier stages of research, while businesses play a larger role in the later stages.

16. The United States National Science Board's 2012 edition of Science and Engineering Indicators breaks down R&D expenditures into three categories, basic, applied and development. For 2009, including all entities performing research, 19 percent was spent on basic research, 17.8 percent on applied research, and 63.2 percent on later stages of product development.

17. For basic research, governments and other non-profit entities performed more than 80 percent. Government and non-profit entities performed 42.4 percent of applied research, and 10.5 percent of research in final product development stages.

Table 2.1.2: R&D by stage of development and sector performing research

Total	Development	Applied	Basic	2009 data, in billions of USD
\$400.458	\$ 253.161	\$ 71.330	\$ 75.970	All performing sectors
	(.632)	(.178)	(.190)	
	\$ 226.554	\$ 41.055	\$ 14.784	Performed by business
	(.895)	(.576)	(.195)	
	\$ 26.607	\$ 30.275	\$ 61.186	Performed by government & non-profit researchers
	(.105)	(.424)	(.805)	

Source: Table 4-3, National Science Board, Science and Engineering Indicators, 2012. page 4-14.

18. As reported in the National Science Board study, there were considerable differences between federal agencies in the allocation of funding by stage of research. The U.S. Departments of Defense, Homeland Security and NASA -- three agencies for which the government is a major consumer of final products -- each invested more heavily in later stage development, while the Departments of Health, Agriculture, Energy and Transportation largely funded basic and applied research.

Table 2.1.3: Percent of total R&D by agency and stage of research, FY 2009

Development	Applied	Basic	Agency
90.0%	7.4%	2.5%	Defense
0.3%	47.0%	52.8%	Health & Human Services
27.3%	31.6%	41.1%	Energy
71.3%	11.5%	17.2%	NASA
8.4 %	50.8%	40.7%	Agriculture
29.0%	71.0%	0.0%	Transportation
48.4%	36.6%	15.1%	Homeland Security

Source: National Science Board, Science and Engineering Indicators, 2012. Table 4-17, page 4-35.

2.1.2. World Trade Organization regulation of research and development subsidies

19. The World Trade Organization (WTO) provides some regulation of government funded research grants, contracts and related subsidies under its Agreement on Subsidies and Countervailing Measures (SCM). There have been a number of SCM cases litigated in the WTO over the legality of government research grants and contracts, including several regarding large civil aircraft.

20. For example, in a series of disputes between the European Union and the United States, a WTO panel found that Boeing and Airbus had both benefited from extensive government research and development subsidies.⁵

21. Billions of dollars of government funded research and R&D related infrastructure provided by the U.S. Department of Defense, NASA and State governments to Boeing, and the European Commission and member states of the European Union to Airbus, were used to develop specific models of their larger carrier aircraft.

22. In considering the legality of government funding of R&D, the WTO panels consider the degree to which the government R&D spending is focused on early or late stages of research and development, or otherwise defined as “actionable” or “non actionable.” If actionable, the WTO considers whether the activity causes harm to firms in other countries. The research activities considered “non-actionable” are set out in Article 8.2 of the SCM. This Article includes a definition for “fundamental research,” and definitions and restrictions on the amount of support for “industrial research” and “pre-competitive” research.” The WTO considers funding of “75 per cent of the costs of industrial research or 50 per cent of the costs of pre competitive development activity” to be non-actionable. Research subsidies that are considered “assistance to disadvantaged regions within the territory of a Member given pursuant to a general framework of regional development” are also non-actionable.

2.1.3 Global public sector outlays on health R&D

23. In 1990, the UN Commission on Health Research and Development called for governments to spend 2 percent of health care budgets on research, a target reached by some but not all countries.

24. Outlays on health care research vary from country to country, as do the targets of that research, including differential emphasis on various stages of research and product development, from basic science to product development, on non-product development issues such as prevention and health care systems, and on diseases and conditions.

25. Among the more vexing issues are the consistent underfunding of research relating to diseases and conditions of low-income persons living in the developing countries⁶, and the challenge of providing greater access to the results of research funded through grants and research contracts. Like other areas of research, there is also a challenge of providing access to research that benefits persons in more than one country, and for which there are significant positive externalities that cannot be captured and monetized by private investors in research.

⁵ The cases initiated by the United States include DS316 and DS347. The cases initiated by the European Union include DS317 and DS353.

⁶ Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination, Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, April 2012.

26. Public health experts have created a taxonomy for diseases that describes the differential levels of resources for research, based upon where most patients live.⁷

- Type I diseases: are incident in both rich and poor countries, with large numbers of vulnerable populations in each.
- Type II diseases: are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries.
- Type III diseases: are those that are overwhelmingly or exclusively incident in developing countries.

27. In May 2008, the World Health Assembly (WHA), the decision-making body of the World Health Organization (WHO), adopted a resolution that requested the Director-General of the WHO:

to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.

28. In May 2010, the WHA enacted WHA63.28, which create a “consultative expert working group on research and development: financing and coordination.” This group, called the CEWG, issued a report in April 2012. Among the recommendations of the CEWG are proposals to set targets for government funding of health related R&D, and to create a binding treaty to enforce the lower bounds of those norms. As regards the overall levels of funding, the CEWG said:⁸

We concluded that all countries should commit to spend at least 0.01% of GDP on government-funded R&D devoted to meeting the health needs of developing countries in relation to product development for those types of diseases. In addition, we suggested that developing countries with a potential research capacity should aim to commit 0.05–0.1% of GDP to government-funded total health research and that developed countries should aim similarly to commit 0.15–0.2% of GDP to government-funded health research in general. The additional funding generated through fulfilling the 0.01% commitment should be used in particular with the following objectives:

1. address research and development gaps related to discovery, development and/or delivery of health technologies for diseases that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken;
2. utilize collaborative approaches, including open-knowledge approaches, for research and development coordination;
3. promote the de-linkage of the cost of research and development from product price; and
4. propose and foster innovative financing mechanisms.

⁷Background document provided by the WHO Secretariat, November 14, 2012. http://www.who.int/phi/3-background_cewg_agenda_item5_disease_types_final.pdf

⁸ Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. WHO. April 2012. Referred to as the CEWG Report. Pages 110-1.

29. The WHA is currently evaluating this recommendation, and considering a number of demonstration projects for government funding of research that will de-link R&D costs from product prices, and promote open innovation models.

30. In 2013, the WHA adopted resolution WHA66.22, which requests the Director General to convene a meeting in December 2013, to propose “implementation of a few health research and development demonstration projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken.” The WHO is asking that the demonstration projects focus on R&D gaps related to market failures, and which “demonstrate effectiveness of alternative, innovative and sustainable financing and coordination approaches to address identified R&D gaps.” The Director General has been asked to consider in the selection of the projects according to the same criteria referred to by the CEWG.

31. In the area of neglected tropical diseases (NTDs), the role of governments in funding research is particularly important, but at present, some private institutions also play an important role. In particular, a single private entity, the Bill and Melinda Gates Foundation (BMGF) rivals the United States National Institutes of Health (NIH) as the largest funder of research. The BMGF has also managed to enter into a number of strategic partnerships with governments that give this private organization influence on the policies and practices of several government research programs.⁹ The Wellcome Trust, a large private philanthropic institution located in the UK, is another example of a private institution that plays a particularly influential role in setting research priorities, including, example, the strong advocacy to ensure the results from the Human Genome Project entered the public domain, as “the heritage of humanity’ secure from control by private interests.”¹⁰

2.1.4. Access

32. There are several aspects of policy concerns regarding access to government-funded research. One concerns the access to knowledge, in connection with data, reports, papers and other published accounts associated with the scientific outcomes of the research. The second concerns the rights to use inventions, data and other research outcomes, in follow-on research, or to develop and sell products.

Access to knowledge government funded research

33. A number of governments and other non-profit donors have taken steps to ensure that the results of research projects are more widely disseminated to researchers. For example, the United States National Institutes of Health has adopted the following policy regarding manuscripts reporting research results.

“The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.”

34. Several governments have adopted similar policies, although not necessarily for all government funded research. In the United States, the NIH policy as regards open access to

⁹ For example: Memorandum of Understanding for the Strategic Cooperation between the European Commission (Research, Innovation and Science), and the Bill & Melinda Gates Foundation.

¹⁰ Isaac Rabino, Book Review, *The Common Thread: A Story of Science, Politics, Ethics, and the Human Genome*, *New England Journal of Medicine*, May 1, 2003
<http://www.nejm.org/doi/full/10.1056/NEJM200305013481824>

manuscripts did not apply to other federal agencies, such as those funding research on topics such as energy or agriculture. The Scholarly Publishing and Academic Resources Coalition (SPARC) and the Open Society Foundation, the Open Knowledge Foundation, are among the many entities promoting broader open access policy.¹¹

35. There are separate movements to provide more access to data, including not only the data sets created by governments, and also data produced by or used in various government funded research studies.

36. There are trade related aspects to the policies on access to knowledge from government-funded research, and there have been proposals to introduce requirements for open access in various trade agreements between countries. The fundamental trade issues are clear. While the public clearly benefits from the broad dissemination and of sharing knowledge, those benefits may accrue to foreign researchers, including researchers living in countries that do not fund research, and/or which may be perceived as competitors in the ultimate commercialization of research. In order to overcome concerns about the unequal sharing of costs and benefits from research, governments can and sometimes do take steps to negotiate agreements that ensure wider access to knowledge regarding research results. An example of this is the standard language in bilateral trade agreements negotiated with the United States for collaborative research and development activities, including this requirement:

"Each party shall be entitled to a non-exclusive, irrevocable, royalty-free license in all countries to produce, publicly distribute and translate scientific and technical journal articles, non-proprietary scientific reports and books directly arising from cooperation under this Agreement."¹²

37. There do not yet exist multilateral norms to provide expanded access to research results, although there have been several proposals for doing so.¹³

2.1.5. Intellectual property rights on government funded research

38. While there exist substantial disagreements regarding the benefits of open and proprietary research models, there is no disagreement that some types of research are best if widely shared on a non-discriminatory basis. Legislative efforts to harmonize policies on patents on government-funded inventions have provided some national norms, but practice is diverse and sometimes complex. The United States Bayh-Dole Act was enacted in 1980 to create a more uniform policy as regards the ownership of federally funded inventions, and it is often cited for the provisions that permit grant recipients to take title to patented inventions. But the Act also requires agencies to obtain a non-exclusive royalty free license to "practice or have practiced for or on behalf of the United States any subject invention throughout the world," and provides for "additional rights, including the right to assign or have assigned foreign patent rights in the

¹¹ See, for example, Press Release. Omnibus Appropriations Bill Codifies White House Directive, ARL. January 16, 2014., <http://www.sparc.arl.org/news/omnibus-appropriations-bill-codifies-white-house-directive>. "Washington, DC – Progress toward making taxpayer-funded scientific research freely accessible in a digital environment was reached today with Congressional passage of the FY 2014 Omnibus Appropriations Bill. The bill requires federal agencies under the Labor, Health and Human Services, and Education portion of the Omnibus bill with research budgets of \$100 million or more to provide the public with online access to articles reporting on federally funded research no later than 12 months after publication in a peer-reviewed journal."

¹² Quoted from "Agreement for scientific and technological cooperation between the European Community and the Government of the United States of America - Intellectual property. 05/12/1997." See: <http://goo.gl/hrtFeA>.

¹³ For example,, the draft 2005 A2K treaty, a 2004 proposal by the late Professor Barton, as an element of a proposal by KEI for a WTO agreement on the supply of public good, recommendations by Keith E. Maskus and Jerome H. Reichman in, "The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods," *Journal of International Economic Law*, 7(2), 279-320.

subject invention,” when necessary to meet an obligation “any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement.”

35 USC § 202 - Disposition of rights

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

The Bayh-Dole Act also provides for march-in rights¹⁴, to protect the public in a variety of cases of abuses of patent rights. The United States has used its rights in inventions to ensure that federal researchers, and in some cases, recipients of federal grants or contracts, can freely use inventions. Among the primary beneficiaries of the federal government’s royalty free rights are defense contractors, and in a more limited sense, researchers working on health related issues, including those working closely with the NIH and the CDC. However, the agencies administering the Bayh-Dole Act have been criticized for not exercising government rights in other cases, and in the more than 32 years since the Act was passed, no federal agency has formally overridden patent rights under the Bayh-Dole March-in right authority, raising doubts about the value of existing public interest safeguards.¹⁵

39. While the U.S. Bayh-Dole Act is an effort to create a uniform policy, there are exceptions and special cases. For example, for research relating to the development of “effective tests to measure, detect, and treat respiratory and pulmonary impairments in active and inactive coal miners,” the Secretary of Health and Human Resources is required to make conditions in all grants to ensure “all information, uses, products, processes, patents, and other developments . . . being available to the general public.”

¹⁴ 35 USC 203 - March-In rights, which exist separately and parallel to the royalty free patent rights.

¹⁵ Daniel Pruzin, NGOs, Academics Seek Congressional Review Of ‘March-in’ Petition for HIV/AIDS Therapy, BNA Life Sciences Law & Industry Report, October 10, 2013.

30 USC § 937 - Contracts and grants

(b) Research activities

The Secretary of Health and Human Services shall initiate research within the National Institute for Occupational Safety and Health, and is authorized to make research grants to public and private agencies and organizations and individuals for the purpose of devising simple and effective tests to measure, detect, and treat respiratory and pulmonary impairments in active and inactive coal miners. Any grant made pursuant to this subsection shall be conditioned upon all information, uses, products, processes, patents, and other developments resulting from such research being available to the general public, except to the extent of such exceptions and limitations as the Secretary of Health and Human Services may deem necessary in the public interest. [emphasis added]

40. There are also cases where the NIH and other parties have used licensing provisions to ensure that research is not encumbered by patents or other restricting licensing conditions. One such case is the International HapMap Project, a multi-country collaboration among researchers at academic centers, non-profit biomedical research groups and private companies in Canada, China, Japan, Nigeria, the United Kingdom, and the United States, to identify and catalog genetic similarities and differences genetic in human beings. The HapMap project began in 2002, seeking to encourage collaboration among researchers contributing to a common database of what was intended to be “pre-competitive” research resources. The managers were faced with the prospect that some might use the database to file patents, effectively creating new barriers for researchers. To address this risk, access to the database was initially restricted to registered users, who were asked to agree to limits on the uses of the data, as regards filing of patents. The “International HapMap Project Public Access License” prohibited users from filing any patent applications that contain claims to any composition or use of any single nucleotide polymorphism (“SNP”), genotype or haplotype data obtained from the Genotype Database. The HapMap license was restrictive, creating problems in the dissemination of the data, but designed to protect the database so it would later enter the public domain. After a period of time, the registration requirement was eliminated,¹⁶ and its initial purpose as considered to have achieved its objectives by many participants.

¹⁶

International HapMap Consortium Releases All Data to the Public, The Sanger Institute. December 13, 2004.

International HapMap Project Public Access License

License Version 1.1, August 2003

(<http://hapmap.ncbi.nlm.nih.gov/cgi-perl/registration>)

2. You may access and conduct queries of the Genotype Database and copy, extract, distribute or otherwise use copies of the whole or any part of the Genotype Database's data as you receive it, in any medium and for all (including for commercial) purposes, provided always that:

a. by your actions (whether now or in the future), you shall not restrict the access to, or the use which may be made by others of, the Genotype Database or the data that it contains;

b. in particular, but without limitation,

i. you shall not file any patent applications that contain claims to any composition of matter of any single nucleotide polymorphism ("SNP"), genotype or haplotype data obtained from the Genotype Database or any SNP, haplotype or haplotype block based on data obtained from the Genotype Database; and

ii. you shall not file any patent applications that contain claims to particular uses of any SNP, genotype or haplotype data obtained from the Genotype Database or any SNP, haplotype or haplotype block based on data obtained from, the Genotype Database, unless such claims do not restrict, or are licensed on such terms that that they do not restrict, the ability of others to use at no cost the Genotype Database or the data that it contains for other purposes.

41. In discussing the challenges of keeping the HapMap project free of patents, Arti Rai and James Boyle wrote:¹⁷

“In order to prevent leakage of the data outside the confines of this clickwrap license, to those who would then have no obligation to the HapMap commons, the license required those who sought the data to refrain from disseminating it to anyone who had not signed on to the license. Conventional publication of the data was not possible. This condition is no longer imposed because it is believed that the database has reached a sufficient density to be self-sustaining and to defeat subsequent patent claims. But the old requirements indicate one of the difficulties of the clickwrap approach; the comparative weakness of the contractual restraints paradoxically requires extremely broad restrictions on dissemination.”

42. Rai and Boyle discuss alternative approaches to protecting certain research assets as public good, free from proprietary claims, and discuss approvingly a 2005 proposal, in a draft treaty on Access to Knowledge to protect certain “qualifying open databases” from patent claims. The proposal Rai and Boyle referred to was set out in Article 5-6 of the 2005 draft treaty:¹⁸

¹⁷ Rai A, Boyle J (2007) Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons. PLoS Biol 5(3): e58. doi:10.1371/journal.pbio.0050058.

¹⁸ <http://keionline.org/content/view/235/1>

Proposal for Treaty of Access to Knowledge (May 10, 2005 Draft)

Article 5-6 - Knowledge Commons Databases

(a) The Knowledge Commons Committee (KCC) shall adopt procedures whereby persons, organizations or communities that seek to establish certain qualifying open databases apply for a time limited period during which no patent applications can be submitted that rely upon the data from the database. To qualify, the databases must address an important public interest, and be freely available to all.

(b) Members agree that during the time period determined in (a), no patents will be granted for patent applications that contain claims to particular uses of the data obtained from such a qualifying database, unless such claims do not restrict, or are licensed on such terms that they do not restrict, the ability of others to use the data at no cost.

43. Rai and Boyle also refer to “various commentators affiliated with the Access to Knowledge proposal” suggesting the possibility of “social patents’ legislation” for a type of patent right that would be secured at low or no cost, on the condition it not be used for exclusionary commercial purposes.

44. The author of this paper was a proponent of the social patent proposal, which was an elaboration on the licenses of right that exist in some national patent regimes, where patent fees are reduced when patent holders voluntarily abandon the right to exclude persons who use the patent, subject to reasonable royalties, set by an independent third party. In the countries that have license of right provisions in the patent law, the patent fees are typically reduced by half. For a social patent, one can imagine a deeper discount in fees, and a multilateral agreement to collectively honor the discounts in fees. The issues to be negotiated would include the terms that one could attach to a social patent, which could conceivably go behind simple FRAND licensing obligations or defensive patenting strategies, to achieve other purposes.

45. The United States Patent and Trademark Office has experimented with a special “Patents for Humanity” program to provide incentives for the humanitarian licensing of patents, not by waiving fees, but by creating a competition where the winners are awarded special vouchers for priority review of patent challenges, modeled after the FDA priority review voucher (discussed elsewhere), which rewards the development of new drugs for neglected tropical diseases.

2.1.6. National statutory provisions on intellectual property rights in government funded research

46. State practice for the management of intellectual property rights in government-funded research varies considerably. In many cases, the intellectual property right policies are negotiated between funders and grant or contract recipients with little or no legislative guidance. In some cases seeking to emulate aspects of the U.S. Bayh-Dole Act, countries have or are considering a statutory framework. Often these laws address the ownership of the patented inventions. In some cases, limited government rights to use patents are required. In few cases does the governments retain rights to address abuses.

Table 2.1.4. Selected national statutory provisions regarding intellectual property rights in government funded research

Government rights	Ownership	Country/ Region
	Article 59 of the Law on Higher Education provides that publicly funded universities and research institutes are financially autonomous and may seek to transfer their technology independent of the government. ¹⁹ Ownership, however, is jointly held between the university or research institution, the individual inventor and the National Council of Scientific and Technical Investigation. ²⁰	Argentina
“Under the National Principles, the ownership of inventions created during the course of research is initially vested in the research institution. The National Principles provide a unified approach to the management of IP arising from research funded by ARC and NHMRC and provide that research institutions should have policies in place governing the ownership, protection and exploitation of IP. In contrast to the policy adopted by the ARC and NHMRC under the National Principles, Government Research and Development Corporations adopt a policy of claiming part or full ownership of project results” ²¹	Generally, publicly funded research is owned by the university (academics may claim ownership only under certain circumstances) and government agencies do not claim ownership.	Australia
Exclusive licenses are restricted for those inventions related to national security and are considered of “relevant public interest” by a government act (the law does not define what is of “relevant public interest”) ²²	Publicly funded universities and institutes are given the right to exclusively license inventions, though they do not receive title to the invention.	Brazil

¹⁹ Law on Higher Education, No. 24521, Art. 59 (1995) (Arg.).

²⁰ Law on Patent and Utility Models No. 24,481, modified by 24,572 (1995) (Arg.).

²¹ Andrew F. Christie, et. al., *Analysis of the Legal Framework for Patent Ownership in Publicly Funded*

Research Institutions, available at <http://melbourneinstitute.com/downloads/Staff/DEST%20legalframework.pdf>

²² Carolina Rossini, *Innovation and Patent Ownership Policies and the Role of Universities as Public Spaces*.

<p>Article 51 governs compulsory licenses, but there are no specific government rights to publicly funded inventions.</p>	<p>Article 70.– The right to apply for the corresponding title and any industrial property rights deriving from the inventive or creative activity of persons hired to engage in dependent or independent work by universities or research institutions as referred to in DecreeLaw No. 1,263 of 1975 shall belong to the latter entities or to those whom it may specify, without prejudice to the regulation by its statutes of the manner in which the inventor or creator shall share in the benefits achieved through his work.</p>	<p>Chile</p>
<p>There are no provisions in the 1999 Act regarding government use or march-in rights.</p>	<p>The 1999 Act on Inventions at Public Research Institutions at Public Research Institutions clarifies that universities can have ownership of patents.²³</p>	<p>Denmark</p>
		<p>Finland</p>
<p>No march-in or government use rights specified.</p> <p>“Publicly funded research organisations in Germany are still not, however, required by law to disclose any patents on inventions arising from their research.”²⁴</p>	<p>Section 40-42 of Germany’s Law on Employee’s inventions lays out special provisions for inventions at universities.</p>	<p>Germany</p>
	<p>Professor privilege applies and professors can retain title to the invention (university has no title unless otherwise decided by the inventor).</p>	<p>Italy</p>

²³ Act on Inventions at Public Research Institutions at Public Research Institutions, available at <http://www.au.dk/en/about/organisation/index/6/67/6701actoninventionsatpublicresearchinstitutions/>

²⁴ Peter Tinnemann, et. al., *Patenting of University and Non-University Public Research Organisations in Germany*, (Nov. 18, 2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2987808/>

<p>Government retains a royalty free license to exploit the subject matter if the government makes clear a reason that the exploitation of the subject matter is necessary for the public interest. The institutions must grant a license to a third party if they have not exploited the subject matter in a reasonable period of time and the government makes clear that the exploitation of the subject matter is necessary.²⁶</p>	<p>Japan's Industry Revitalization Law permits universities and research institutions to retain ownership of intellectual property rights (previously, only the state or individuals could own title).²⁵</p>	<p>Japan</p>
<p>Licenses may only be concluded jointly by the joint patent owners.</p> <p>The Malaysian Patent Law contains explicit provisions regarding compulsory licenses (Sections 48-54) as well as rights of the government (Section 84).</p>	<p>The head of the Ministry of Science, Technology and Innovation stated that government funded research should be jointly owned by the government, In March 2006, however, the head of the ministry of Science, Technology, and Innovation announced that publicly-funded research would be jointly owned by the government, university, and the scientists involved.²⁷</p>	<p>Malaysia</p>
	<p>No specific language regarding publicly funded research, but title is governed by Norway's Law on Employees' Inventions. This law provides that title is granted to the employer, provided that notice is given to the employee (who is entitled to reasonable compensation).</p>	<p>Norway</p>

²⁵ International Research Collaboration Promotion Act, Law No. 57 (1996), Art. 30; Law of Enhancing Research and Development Structure for Industrial Technology, Law No. 33 (1998); See also Toshiko Takenaka, *Technology Licensing and University Research in Japan*, International Journal of Intellectual Property 27-36 (2005), available at http://www.ipaj.org/english_journal/pdf/Technology_Licensing_and_University_Research.pdf.

²⁶ *Id.*

²⁷ Gregory D. Graff, *Echoes of Bayh-Dole? A Survey of IP and Technology Transfer Policies in Emerging and Developing Economies*, in IP Handbook of Best Practices 179-80 (Anatole Krattiger ed., 2007) (citing Bernama (Malaysian National News Agency). 2006 National Nanotechnology Centre to Be Set Up under 9MP. 14 March. www.bernama.com.my/bernama/v3/news_business.php?id=185498).

<p>Sections 15 and 16 govern march-in rights, providing that the funding agency may assume ownership of IP covered under the Act "in case of national emergency or other circumstances of extreme urgency, or where the public interest requires . . . Such determination shall be made within thirty (30) days after the receipt of the recommendation of the Head of the GFA. Such recommendation shall be made within thirty (30) days upon the discovery of the potential IPR by the GFA or the disclosure of the same by the [research institution] pursuant to Section 8(c) of this Act, or upon written notice or petition by other government agencies or other interested persons."³⁰</p> <p>Rule 20 of the implementing regulation provides for "Assumption of Ownership" and explicitly states that an agency "may assume ownership of any potential IPRs in cases of national emergency or other circumstances of extreme urgency, or where the public interest requires, and in particular concerns for national security, nutrition, health, or the development of other vital sectors of the national economy, as determined by the head of the Parent Agency."³¹</p>	<p>Section 6(a) of the Act provides that the institution performing the government-funded research generally owns the IP rights to the innovation.²⁸ There are a few exceptions to this general rule of ownership, however, which include: 1) where the institution enters into a written agreement to share, limit, waive or assign its ownership in favor of the government-funding agency, but "may only be voluntarily executed by the [institution] to protect public interest . . ."; 2) where the institution fails to disclose potential IP rights to the government agency; 3) where the institution fails "to initiate the protection of potential IPRs within a reasonable time," but no more than three months from public disclosure.²⁹</p>	<p>Philippines</p>
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²⁸ An Act Providing the Framework and Support System for the Ownership, Management, Use, and Commercialization of Intellectual Property Generated From Research and Development Funded by Government and for Other Purposes (2009), *available at* http://www.senate.gov.ph/republic_acts/ra%2010055.pdf

²⁹ *Id.*

³⁰ *Id.*

³¹ Department of Science and Technology, Implementing Rules and Regulations (IRR) of Republic Act No. 10055 (2011), *available at* http://www.dost.gov.ph/index.php?option=com_joomdoc&task=cat_view&gid=318&Itemid=209

<p>Government may retain rights if stated in the research agreement.</p> <p>Article 1362 provides for compulsory licenses and Article 1368 provides for application procedures for open licenses.</p>	<p>Article 1373 gives the right to patent a publicly funded invention to the research institute that made the discovery, absent an explicit research agreement stating otherwise (such as a specific clause stating that the rights belong to the government).</p>	<p>Russia</p>
<p>March-in rights under Section 11(1)(e) of the 2010 Act provide the state with an “irrevocable and royalty-free licence” to be practiced anywhere in the world and applies to “health, security, or emergency needs.” March-in rights may be exercised by the government or “other third parties designated by the State.”</p>	<p>Recipient of funding owns the intellectual property; if the recipient is an institution, benefit-sharing arrangements are available to the intellectual property creators.</p>	<p>South Africa</p>
<p>Article 31 (Concessions for Intellectual Property without Consideration) (1) Notwithstanding the provisions of the State Property Act, the Government may, if particularly necessary for the industrial development, exempt a licensee for the intellectual property vested in the State as the results of research and development from royalties, fully or partially, or grant a gratuitous concession for such intellectual property to the researchers who have performed the research and development for the relevant task of research and development or the investors in the research and development project, as prescribed by Presidential Decree.</p>	<p>The Technology Transfer Promotion Law of 2000 gave national and public universities the status of a legal person, allowing them to claim patent rights.³² Article 16 of the Law enables publicly-funded universities to work with private firms and utilize their technologies and knowledge for commercial purposes.³³</p>	<p>S. Korea</p>

³² Risaburo Nezu, et. al., *Technology Transfer, Intellectual Property and Effective University-Industry Partnerships: The Experience of China, Japan, Philippines, Republic of Korea, Singapore and Thailand*, WIPO available at http://www.wipo.int/export/sites/www/freepublications/en/intproperty/928/wipo_pub_928.pdf

³³ *Id.*

<p>(2) Notwithstanding the provisions of the Commodity Management Act, the Government may, if particularly necessary for industrial development, grant a gratuitous concession for the instruments and facilities for research, product prototypes, and the like, which have been used in the research and development project and the rights to which have been vested in the State, to the researchers involved and enterprises participating in a task of research and development.³⁴</p>		
<p>The government retains first-use rights.³⁶</p>	<p>Article 6 of the Science and Technology Basic Law establishes that universities may own and manage the patents derived from their publicly-funded research³⁵</p>	<p>Taiwan (Province of China)</p>
<p>Guidelines contained in the UK's "Intellectual Property in Government Research Contracts" suggest that agencies secure a compulsory license or "march-in" right, particularly where there is non-commercialization.</p>	<p>Employer generally retains title to employee's/academics' research.</p>	<p>United Kingdom</p>

³⁴ Technology Transfer Promotion Law (2000), http://www.wipo.int/wipolex/en/text.jsp?file_id=282219

³⁵ Ross DeVol et al., *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization* at 285 (2006); see also Asia Pacific Legal Institute, *Science and Technology Basic Law Enacted – Birth of A New Technology Transfer Model (2000) available at http://apli.org/apli_special_taiwan.htm#Basic%20ST%20Law*.

³⁶ Ross DeVol et al., *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization* at 291 (2006).

ANNEX TO SECTION 2.1.

WTO Agreement on Subsidies and Countervailing Measures

Article 8 Identification of Non Actionable Subsidies

8.1 The following subsidies shall be considered as non actionable 23:

- (a) subsidies which are not specific within the meaning of Article 2;
- (b) subsidies which are specific within the meaning of Article 2 but which meet all of the conditions provided for in paragraphs 2(a), 2(b) or 2(c) below.

8.2 Notwithstanding the provisions of Parts III and V, the following subsidies shall be non actionable:

(a) assistance for research activities conducted by firms or by higher education or research establishments on a contract basis with firms if: 24, 25, 26 the assistance covers 27 not more than 75 per cent of the costs of industrial research 28 or 50 per cent of the costs of pre competitive development activity 29, 30; and provided that such assistance is limited exclusively to:

- (i) costs of personnel (researchers, technicians and other supporting staff employed exclusively in the research activity);
- (ii) costs of instruments, equipment, land and buildings used exclusively and permanently (except when disposed of on a commercial basis) for the research activity;
- (iii) costs of consultancy and equivalent services used exclusively for the research activity, including bought in research, technical knowledge, patents, etc.;
- (iv) additional overhead costs incurred directly as a result of the research activity;
- (v) other running costs (such as those of materials, supplies and the like), incurred directly as a result of the research activity.

(b) assistance to disadvantaged regions within the territory of a Member given pursuant to a general framework of regional development 31 and non specific (within the meaning of Article 2) within eligible regions provided that:

- (i) each disadvantaged region must be a clearly designated contiguous geographical area with a definable economic and administrative identity;
- (ii) the region is considered as disadvantaged on the basis of neutral and objective criteria 32, indicating that the region's difficulties arise out of more than temporary circumstances; such criteria must be clearly spelled out in law, regulation, or other official document, so as to be capable of verification;
- (iii) the criteria shall include a measurement of economic development which shall be based on at least one of the following factors:

one of either income per capita or household income per capita, or GDP per capita, which must not be above 85 per cent of the average for the territory concerned;

unemployment rate, which must be at least 110 per cent of the average for the territory concerned;

as measured over a three-year period; such measurement, however, may be a composite one and may include other factors.

(c) assistance to promote adaptation of existing facilities 33 to new environmental requirements imposed by law and/or regulations which result in greater constraints and financial burden on firms, provided that the assistance:

- (i) is a one time non recurring measure; and

- (ii) is limited to 20 per cent of the cost of adaptation; and
- (iii) does not cover the cost of replacing and operating the assisted investment, which must be fully borne by firms; and
- (iv) is directly linked to and proportionate to a firm's planned reduction of nuisances and pollution, and does not cover any manufacturing cost savings which may be achieved; and
- (v) is available to all firms which can adopt the new equipment and/or production processes.

Footnotes

Footnote 23. It is recognized that government assistance for various purposes is widely provided by Members and that the mere fact that such assistance may not qualify for non-actionable treatment under the provisions of this Article does not in itself restrict the ability of Members to provide such assistance.

Footnote: 24. Since it is anticipated that civil aircraft will be subject to specific multilateral rules, the provisions of this subparagraph do not apply to that product.

Footnote 25. Not later than 18 months after the date of entry into force of the WTO Agreement, the Committee on Subsidies and Countervailing Measures provided for in Article 24 (referred to in this Agreement as "the Committee") shall review the operation of the provisions of subparagraph 2(a) with a view to making all necessary modifications to improve the operation of these provisions. In its consideration of possible modifications, the Committee shall carefully review the definitions of the categories set forth in this subparagraph in the light of the experience of Members in the operation of research programmes and the work in other relevant international institutions.

Footnote 26. The provisions of this Agreement do not apply to fundamental research activities independently conducted by higher education or research establishments. The term "fundamental research" means an enlargement of general scientific and technical knowledge not linked to industrial or commercial objectives.

Footnote 27. The allowable levels of non-actionable assistance referred to in this subparagraph shall be established by reference to the total eligible costs incurred over the duration of an individual project.

Footnote: 28. The term "industrial research" means planned search or critical investigation aimed at discovery of new knowledge, with the objective that such knowledge may be useful in developing new products, processes or services, or in bringing about a significant improvement to existing products, processes or services.

Footnote 29. The term "pre-competitive development activity" means the translation of industrial research findings into a plan, blueprint or design for new, modified or improved products, processes or services whether intended for sale or use, including the creation of a first prototype which would not be capable of commercial use. It may further include the conceptual formulation and design of products, processes or services alternatives and initial demonstration or pilot projects, provided that these same projects cannot be converted or used for industrial application or commercial exploitation. It does not include routine or periodic alterations to existing products, production lines, manufacturing processes, services, and other on-going operations even though those alterations may represent improvements.

Footnote 30. In the case of programmes which span industrial research and pre-competitive development activity, the allowable level of non-actionable assistance shall not exceed the simple average of the allowable levels of non-actionable assistance applicable to the above two categories, calculated on the basis of all eligible costs as set forth in items (i) to (v) of this subparagraph.

Footnote 31. A "general framework of regional development" means that regional subsidy programmes are part of an internally consistent and generally applicable regional development

policy and that regional development subsidies are not granted in isolated geographical points having no, or virtually no, influence on the development of a region.

Footnote 32. "Neutral and objective criteria" means criteria which do not favour certain regions beyond what is appropriate for the elimination or reduction of regional disparities within the framework of the regional development policy. In this regard, regional subsidy programmes shall include ceilings on the amount of assistance which can be granted to each subsidized project. Such ceilings must be differentiated according to the different levels of development of assisted regions and must be expressed in terms of investment costs or cost of job creation. Within such ceilings, the distribution of assistance shall be sufficiently broad and even to avoid the predominant use of a subsidy by, or the granting of disproportionately large amounts of subsidy to, certain enterprises as provided for in Article 2.

2.2 TAX POLICIES

47. Tax policy can be used to stimulate private investments in R&D, although the extent, nature and design vary considerably. Typically governments consider tax concessions as an incentive, although the tax system is flexible enough to consider alternatives that would potentially increase tax liabilities for less favored actions.

48. A 2007 OECD report compared the use of tax incentive to "direct support" (grants and research contracts) to promote R&D efforts.

Tax incentives are more flexible as regards the research to be undertaken and leave it up to firms to direct the funding. Direct support enables more focus in government intervention, and can be linked to public policy priorities in the area of science and innovation." (Innovation And Growth: Rationale For An Innovation Strategy, OECD. 2007. page 20).

2.2.1 Tax Credits

49. A tax credit is a particular type of offset of a tax liability, often associated with income taxes, but also other taxes, such as the property tax credits associated with certain government economic development initiatives. While business expenses are normally deducted from the amount of taxable income, and reduce taxes by a fraction of the amount of the deduction, a tax credit will directly reduce the amount of the tax owed. Thus, for example, in a nation with a 35 percent income tax, a tax deduction of \$100 will lower the tax liability by \$35, while a tax credit of \$100 will lower the tax liability by \$100.

50. The value of a tax credit to a profitable firm with positive tax liability is obvious. For a firm without a profit or current tax liability, the tax credit may have value only if refundable, or if the tax law permits the transfer or sale of the tax credit to another taxpayer, or if the credit can be "carried forward" to a future period when the firm is potentially profitable. Normally tax credits have no value to non-profit organizations.³⁷

51. According to an OECD Report,³⁸ in 2006, 12 OECD countries offered R&D tax credits in their national income tax regimes. The tax credits were based either on the total volume or level of the firm's R&D investment (7 countries), the increase in R&D spending over a base period (2

³⁷ Subject to efforts by for-profit firms to create legal fictions in order to claim the credit.

³⁸ Jacek Warda, Tax Treatment of Business Investments in Intellectual Assets: An International Comparison, OECD STI Working Paper 2006/4. 2006. Page 13.

countries), or some combination of the two (5). For three countries, Austria, Portugal and Spain, the tax credits are refundable.

Table 2.2.1: R&D tax credits in OECD countries, 2004-2005

Special treatment of SMEs	Increment of R&D	Level of R&D	Country
		8%	Austria*
35% of level		20%	Canada - federal
	45%	5%	France**
	20%		<i>Ireland</i>
30% of level			Italy
15% of level		10-15%	Japan
	50%	15%	Korea
		30%	Mexico
42% of level		14%	Netherlands
20% of level		18%	Norway
	50%	20%	Portugal*
	50%	30%	Spain*
	20%		<i>United States - federal</i>
* Refundable, ** based upon combination			

Source: OECD 2006, Table 1.1

2.2.2. Enhanced Deductions

52. Another type of special treatment of R&D outlays is to permit an enhanced deduction, referred to the 2006 OECD study as R&D allowances. An allowance of more than 100 percent results in a larger deduction against income than other tax deductible expenditures, effectively lowering the firm's costs for undertaking R&D, relative to other expenses.

Table 2.2.2. R&D allowances from taxable income in OECD countries

Special treatment of SMEs	Increment of R&D	Level of R&D	Country
	175%	125%	Australia*
	135%	125%	Austria*
		113.5%	Belgium
		200%	Czech Republic
		150%	Denmark
		200-400%	Hungary
150% of level		125%	United Kingdom
* Tax incentive based on a combination of level and incremental increase in R&D.			

Source: OECD 2006, Table 1.2.

2.2.3. The US Orphan Drug Tax Credit

53. The United States has a special tax credit for R&D that only applies to clinical testing of drugs for certain diseases and conditions. The tax credit is part of a larger legislative framework created in the United States in 1983, and now mimicked in several other countries, typically without the tax credit feature.

54. The original motivation for the U.S. Orphan Drug legislation was to address a failure of U.S. companies to register, manufacture and sell drugs that were known to be effective in treating certain very rare illnesses.³⁹ These failures were dramatized in episodes of the television series Quincy, a popular show during the 1980s featuring a physician who was also a detective. As the legislation progressed in the U.S. Congress, it grew to include a number of incentives, privileges and subsidies for companies undertaking research or selling drugs.⁴⁰ What began as a focus on a handful of drugs for a tiny number of patients was expanded to any indication for a drug involving 200,000 persons or less in the United States.⁴¹

³⁹ United States Senate, Committee on the Judiciary, Subcommittee on Antitrust, Monopolies and Business Rights, Anticompetitive Abuse of the Orphan Drug Act: Invitation to High Prices, January 21, 1992, Serial Number J-102-48.

⁴⁰ An excellent history of the Orphan Drug Act is provided in David M. Richardson, "The Orphan Drug Tax Credit: An Inadequate Response to An Ill-Defined Problem," The American Journal of Tax Policy, Vol. 6:135. pp. 135-210, 1987. See also, Patricia J. Kenney, "The Orphan Drug Act--Is it a Barrier to Innovation? Does it Create Unintended Windfalls?" Food Drug Cosmetic Law Journal, Vol. 43, pp 667-679, 1988. James T. O'Reilly, "Orphan Drugs: The Strange Case of 'Baby M,'" Food Drug Cosmetic Law Journal, 42, 516-526, 1987. Donna Brown Grossman, "The Orphan Drug Act: Adoption or Foster Care?" Food Drug Cosmetic Law Journal, 39, 128-151, 1984.

⁴¹ Or even a population larger than 200,000 if there is no "reasonable expectation" of recovering the costs of developing and making the drug available.

U.S. Orphan Drug Tax Credit Definition of Rare disease or condition.

A rare disease or condition is one which afflicts:

200,000 or fewer persons in the United States or

More than 200,000 persons in the United States, but for which there is no reasonable expectation of recovering the cost of developing and making available a drug in the United States for the disease from sales of the drug in the United States.

55. The legislation included both new drugs and the use of old drugs for the orphan disease or condition. In addition to the tax credit, the U.S. Orphan Drug Act created a special seven-year regulatory monopoly to sell the product for the orphan indication, and preferential treatment for FDA approval.

56. The Orphan Drug Tax Credit (ODTC) was part of the initial Act in 1983, but was eliminated for the three-year period of 1995-1997. The law was amended at one point so that the credit could be carried forward to 15 future tax periods, and the credit is now a valuable asset even for a small firm that does not currently have taxable income.

57. The ODTC covers 50 percent of qualified clinical testing expenses, which are defined to including testing involving humans that takes place after the drug is designated as a possible treatment for an orphan indication, and before the FDA approves the marketing for that indication.⁴² There are a few limitations. Qualified clinical testing expenses do not include expenses to the extent they are funded by a grant, contract, or otherwise by a governmental entity or another person. There is also a requirement that the testing take place in the United States, but this is waived if "there is an insufficient U.S. testing population."

58. The ODTC would normally cover the Phase I, II and III human use trials for a drug that the FDA relies upon for a new drug approval -- providing a subsidy equal of 50 percent of the most expensive component of R&D for the products.

59. The FDA data are often touted as evidence of the success of the Orphan Drug Act, because they report a very large number of designations and drug approvals. What is less clear is the cost effectiveness of the ODTC, compared to possible alternatives, and more generally, the shortcomings of a tax credit financing as regards to leverage over pricing or access to products.

60. There is no transparency as regards the amount of the credit claimed by a particular taxpayer, for a particular drug, or for the indications for its use, even though such information would be useful to policy makers and voters.

61. The US IRS does publish aggregate data on the use of the credit, and the US FDA publishes data on Orphan Drug Designations and Approvals. The IRS data on the amount of the Orphan Drug Tax credit is available through year 2010.

62. In the 13-year period from 2000 to 2012, the USFDA approved 1744 Orphan Designations, while giving 213 products marketing approval for an orphan indication. During

⁴² The seven question IRS form 8820 and its instructions for the ODTC are available on the web at: <http://www.irs.gov/form8820>.

that period, the average time lag between the FDA orphan designation and approval for that indication was 4.7 years.

63. Using 5 years as the average lag for designation from market, in the past twelve years, approximately 18 percent of all Orphan Designations received marketing approval.

Table 2.2.3: Orphan Drug Designations and Approvals, and Credit, 1983-2012

Orphan Drug Credit (000 of USD)	Designations Approved for Marketing	Orphan Designations	Year
\$236	2	1	1983
\$105	3	40	1984
\$204	7	50	1985
\$6,530	6	33	1986
\$5,154	9	58	1987
\$8,053	9	73	1988
\$14,190	10	77	1989
\$15,637	11	89	1990
\$18,475	13	81	1991
\$17,826	14	55	1992
\$20,486	13	65	1993
\$21,166	11	59	1994
N/A	11	57	1995
N/A	25	57	1996
N/A	18	54	1997
\$80,392	20	68	1998
\$109,435	20	78	1999
\$112,954	13	70	2000
\$134,846	6	79	2001
\$146,900	14	64	2002
\$173,848	12	96	2003
\$209,488	13	133	2004

\$232,185	17	124	2005
\$303,951	24	142	2006
\$381,349	16	119	2007
\$450,163	14	165	2008
\$533,157	20	165	2009
\$647,799	14	195	2010
not published	25	203	2011
not published	25	189	2012

64. The ODTTC data is informative as regards the costs of research and development or orphan drugs. In the five-year period 2006 to 2010, the total amount of the credit was \$2.316 billion. This represents 50 percent of the costs of qualifying clinical testing on the drugs.

65. If all testing on the products qualified for the credit, this would also represent the average private outlays on testing, taking into account the costs associated with both the products that received approval, and those that did not.

66. While \$2.316 billion sounds like a lot of money, one needs to keep in mind that it was spent on a large number of products. During that same period of time, the FDA approved 786 designations for orphan indications, and approved 88 for marketing. The amount of the tax credit per approval was just \$26.3 million.⁴³

67. To recap, through the ODTTC, the U.S. paid for 50 percent of the costs of the clinical trials on new orphan drugs.

68. Given the subsidies from the tax credit, and the relatively modest private outlays on research for these products, how were they priced?

2.2.4. Orphan Oncology Drugs, 2011-2012

69. In 2011 and 2012, the US FDA approved 22 new oncology drugs.⁴⁴ Of the 22, 16 received at least one orphan designation, and 14 were approved by the FDA for an orphan designation, meaning the tests were eligible for the 50 percent of cost subsidy.

70. We have estimates for the prices for 20 of the 22 oncology drugs, including all of the products that have received orphan designations, and 4 of the products that did not.

- The median cost of treatment for the 14 oncology drugs that were approved for an orphan indication was \$104,219.
- The median cost for the 6 oncology drugs **not** approved for an orphan designation was \$55,705 -- roughly half.

⁴³ In practice, not all testing qualifies for the tax credit, but the numbers still suggest that private investment in the development of new orphan drugs is less than many assume.

⁴⁴ Classified by the FDA either as new chemical entity pharmaceutical drugs or new biologic products.

- The median cost for the 4 oncology drugs that were not even designated for an orphan indication was \$26,381, roughly a quarter of the price of the products approved for orphan indications.

Table 2.2.4: Median cost of treatment for 20 new oncology drugs, 2011-2012

Median cost for treatment ⁴⁵	
\$104,219	The 14 oncology drugs that received FDA approval for orphan indications
\$55,705	The 6 oncology drugs that received FDA approval for non-orphan indications, (including the two that received orphan designations for indications not yet approved by the FDA).
\$26,381	The 4 oncology drugs that did not receive any orphan Drug tax credit benefits

2.2.5. Taxing remittance of pharmaceutical profits

71. In response to a request for proposal for sustain systems of financing priority health research, in a proposal dated April 17, 2009, the Brazil Ministry of Health of Brazil proposed an “Innovative Mechanism For R&D For Developing Countries,” based on a system of taxation on the remittance of profits of the pharmaceutical industry. The revenues would be used for research and development for drugs and vaccines that addressed the public health needs of developing countries, and products resulting from those R&D activities would be made available to developing countries in accessible terms. Brazil proposed that the money from the tax on remittances of profits would create an R&D fund and that “the available resources could be drawn upon by the pharmaceutical industry, including the ones that paid the tax in the first place, in a partnership with national public or private laboratories from developing countries, on a public-private partnership fashion.”

72. In the Brazil proposal, the contribution of the pharmaceutical industry would be tied to profits realized and repatriated from developing countries, and it would be reinvested back in the countries in R&D projects of high public health priority, and to build domestic R&D capacity. In supporting their proposal, Brazil pointed to a different innovative financing method managed by UNITAID, that used a tax on airline tickets to fund public health activities, including money spent on R&D and capacity building for manufacturing drugs and diagnostic tests. While not mentioned in the Brazil proposal, one could have also pointed to a number of other policies to ensure that revenues and profits from drug sales are reinvested in R&D projects. These would include UK policies that permit higher prices for products when a company can demonstrate higher R&D outlays, or tax or regulatory policies that induce companies to invest in professional training, or to fund R&D in research activities, or various existing schemes or proposals to tax energy products to fund R&D for new energy sources.

⁴⁵ Course of treatment, or one year, whichever is less.

2.2.6. Reinvesting natural resource revenues in R&D projects

Brazil

73. Brazil is currently a significant and expanding source of crude oil. In a variety of initiatives, the Brazil government uses a combination of legal measures to require holders of oil exploration concessions to fund R&D. For example, under the Petroleum Law and Federal Decree 2,705, when production of oil or natural gas reaches certain targets: the concessionaire is required to make certain payments to the government, and to make investments in R&D.⁴⁶

“The Concession Contract also requires the concessionaires to invest an amount equal to 1 percent of the field's gross production income in R&D projects. This obligation is also established by the National Agency of Petroleum, Natural Gas and Biofuels (ANP) in Resolution No. 33/2005 (ANP Resolution), which provides detailed guidance on the performance of the R&D expenditures, including models of standard reports to be used by the concessionaires when evidencing their R&D investments to ANP.

Up to one-half of that 1 percent R&D expenditure may be directed to development activities in the concessionaire's own facilities or those of its affiliates, when located in Brazil, or may be contracted directly with national companies, regardless of whether those activities are involved with or are related to the operations under the Concession Contract. The remaining expenditure must be invested in institutions previously accredited by the ANP (Approved Institutions). The main purpose of this R&D investment requirement is to protect and channel the investments to institutions with high expertise, operational capability and technological standards.”

74. Some 17 oil and gas concessionaires currently have obligations to contribute to and invest in R&D projects. The R&D obligation contributed US\$500 to Brazil R&D expenditures in 2011, bringing the cumulative R&D investment from this program to more than \$3.3 billion since 1998. Looking forward, the program is expected to raise as much as \$2 billion per year for R&D projects, with the Government taking an active role identifying research priorities. In what is an evolving system of obligations, there is also the possibility that new policies will permit a share of the R&D money to be invested in a wider range of research initiatives, including even those relating to oil and gas related business management and economics.

Colombia

75. In 2011, Colombia wrote new laws to provide that ten percent of the royalties from both government and private exploitation of oil, coal, gold, platinum and other mineral resources will be invested in various research and development projects. Because of this change in the law, Columbia has become a co-sponsor of a proposal before the World Health Organization to fund a prize fund aimed to stimulate the development of new low cost diagnostic tests for cancer.

76. Norway is another country that uses natural resource assets to fund R&D programs.⁴⁷

2.2.7. Notes on Taxes compared to grants or research contracts

77. As noted above in the 2006 OECD study of R&D tax incentives, there are several differences between taxes and direct funding mechanisms such as grants or research contracts.

⁴⁶ Brazil: Research And Development In The Oil & Gas Industry In Brazil

⁴⁶ Last Updated: 22 May 2013 <http://www.mondaq.com/>

⁴⁷ Paul Smaglik, Norway: Turning oil into science, *Nature*, *Nature* 417, 4-5 (May 2002) | 10.1038/nj6884-04a

Under most tax regimes, the financial benefit is automatic to anyone qualifying for the benefit, while grants and contracts normally require a subjective and direct involvement by the government in allocating funds.

78. In theory, grants or contracts permit governments to more closely target R&D funding, and shape its outcomes. There are also many other differences, including those relating to the transparency of the subsidies, and the ownership of funded inventions.

79. For example, in the case of the Orphan Drug Act, the U.S. federal government is effectively funding half of the costs of clinical development of qualifying drugs, but unlike the grants administered by the NIH and other federal agencies, the government has no opportunity to share in the ownership of the inventions, or to place obligations on the drug developer for reasonable pricing of products.

80. Some governments have implemented tax credits with greater transparency. For example, the Massachusetts Tax Credit Transparency Report, issued each year, provides details of the amount of tax credits available to specific taxpayers in that state. The Massachusetts transparency report covers such programs as the Economic Development Incentive Program, the Life Sciences Tax Incentive Program (four separate tax credits), the Film Tax Credit, and the Medical Device Tax Credit. Many other governments, national and sub-national, are responding to demands for greater transparency of tax returns and tax expenditures.⁴⁸

Excerpts from IRS form 8820

Form 8820 (Rev. December 2012) Orphan Drug Credit

Definitions

Qualified clinical testing expenses.

...

Qualified clinical testing expenses do not include expenses to the extent they are funded by a grant, contract, or otherwise by a governmental entity or another person.

...

Clinical testing. Generally, clinical testing means any human clinical testing that meets all four of the following conditions.

1. The testing is carried out under an exemption for a drug being tested for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (Act).
2. The testing occurs after the date the drug is designated under Act section 526 and before the date on which an application for the drug is approved under Act section 505(b) (or, if the drug is a biological product, before the date the drug is licensed under section 351 of the Public Health Service Act).
3. The testing is conducted by or for the taxpayer to whom the designation under Act section 526 applies.
4. The testing relates to the use of the drug for the rare disease or condition for which it

⁴⁸ Tax morality and tax transparency: an overview, KPMG International. June 2013. Jonathan Dunn, Note on Tax Expenditures and Fiscal Transparency: 'Best Practices' and Current New Zealand Reporting, New Zealand National Integrity System Assessment, Additional Paper, January 3, 2014.

was designated under Act section 526. Rare disease or condition. A rare disease or condition is one which afflicts:

200,000 or fewer persons in the United States or

More than 200,000 persons in the United States, but for which there is no reasonable expectation of recovering the cost of developing and making available a drug in the United States for the disease from sales of the drug in the United States.

The above determinations are made as of the date the drug is designated under Act section 526.

Testing Not Eligible for the Credit

The credit is not allowed for clinical testing conducted outside the United States unless there is an insufficient U.S. testing population and the testing is conducted by a U. S. person or by another person not related to the taxpayer. Testing conducted either inside or outside the United States by a corporation to which section 936 applies is not eligible for the orphan drug credit.

2.3. SELECTED NON-PATENT PULL MECHANISMS THAT RELY ON MONOPOLIES AND HIGH PRICES

81. While the best known pull mechanism is the patent system, when implemented as an exclusive right to make, use and sell products, there exist a number of non-patent intellectual property or regulatory regimes that in various ways create time limited monopolies or entry barriers that are designed to raise prices for products.

2.3.1 Orphan drug exclusivity

82. As noted above, in 1983, the US Congress enacted the Orphan Drug Act, in order to facilitate the development and commercialization of drugs to treat diseases and conditions that afflict 200,000 or few patients in the United States. Among the features of the U.S. Orphan Drug Act is the grant of a seven-year monopoly on the use of the product for an FDA approved "Orphan" designation. Later the European Union, Japan and Australia were among countries adopting various types of incentives and subsidies to stimulate development of treatments for rare diseases, including in some cases, market exclusivity similar to the U.S. legislation. In the European Union, for example, the Orphan Drug exclusivity is 10 years. While the U.S. Orphan Drug exclusivity is an important example of a non-patent financing mechanism, it is controversial.⁴⁹

83. Companies use the Orphan drug exclusivity to create product monopolies and charge very high prices. For example, example, the "orphan" cancer drug Yervoy, which is used to treat melanoma, had a U.S. cost of \$124 thousand per treatment, and global sales of \$706 million in its first full year on the market (According to the FDA "Yervoy's safety and effectiveness were

⁴⁹ Press Release, NICE to assess high cost drugs for rare conditions, 20 July 2012; January 2013; "NPS Pharma: Controversy Over Super-Expensive Orphan Drug Prices" The Street, January 2013. Cohen J, Milne C-P. Is the increasing cost of treating rare diseases sustainable? Exp Opin Orphan Drugs. 2013; 1(8):581-583. doi:10.1517/21678707.2013.819289

established in a single international study of 676 patients⁵⁰). Juxtapid (lomitapide) for treating homozygous familial hypercholesterolemia costs \$250,000 a year.⁵¹ Gattex, a drug for short bowel syndrome, is priced at \$295,000 per patient per year.⁵² Gattex (teduglitide) for short bowel syndrome costs \$295,000 per year. Naglazyme (galsulfase) for mucopolysaccharidosis VI costs \$441,000 per year.⁵³ According to Reuters, the gene therapy for lipoprotein lipase deficiency (LPLD) "is likely to cost more than \$1 million per patient when it goes on sale in Europe this summer."⁵⁴

2.3.2. Pediatric Testing

84. The United States and the European Union provide for an extension of market exclusivity for pharmaceutical products that make fairly modest investments to test products on pediatric patients.

85. Under the US program, the Secretary of Health and Human Services publishes "a list of approved drugs for which additional pediatric information may produce health benefits," which generally "consists of those approved drugs for which there is a pediatric manifestation of any of the adult indications for which the product is approved."⁵⁵ A negotiation then may take place between the drug manufacturer and the government to see if there is a research study that the manufacturer is willing to conduct that will result in a six month extension of the various exclusivity benefits the manufacturer has under patent, orphan drug or test data exclusivities.

86. The European Union has a similar program,⁵⁶ which most commonly takes the form of a six-month extension of market exclusivity. The EU notes that companies try to use the same studies to qualify for both the EU and the US FDA pediatric extensions.⁵⁷

87. The cost to consumers of the six-month extension of market monopolies can be large, and in some cases involve billions of dollars.⁵⁸ With some studies involving less than 25 patients, the cost to consumers and reimbursement entities may far exceed the amount of investment in the tests, raising questions about the program's cost effectiveness as a way of funding clinical studies.

2.3.3. Rights to Rely upon Regulatory Test data

88. Various governments have a variety of special (*sui generis*) systems that provide an exclusive right to rely upon test data for product registration. These regimes have been implemented in several countries in the context of data used to register pharmaceutical and biologic drugs or agricultural products, including pesticides.

⁵⁰ <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm1193237.htm><http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm1193237.htm>

⁵¹ The High Cost of Orphan Drugs, Rare Disease Report. July 31, 2013.

⁵² Matthew Herper, Inside The Pricing Of A \$300,000-A-Year Drug, Forbes.Com, January 3, 2013.

⁵³ The High Cost of Orphan Drugs, Rare Disease Report. July 31, 2013.

⁵⁴ Ben Hirschler, Analysis: Entering the age of the \$1 million medicine, Reuters, January 3, 2013.

⁵⁵ Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act:

Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric "Rule," and their Interaction
<http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm077915.htm>

⁵⁶ The EU Paediatric Regulation is comprised of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use; and Regulation (EC) No 1902/2006, an amending regulation in which changes to the original text were introduced relating to decision procedures for the European Commission.

⁵⁷ Better Medicines for Children, From Concept to Reality, General Report on experience acquired as a result of the application of Regulation (EC) n° 1901/2006 on medicinal products for paediatric use.

⁵⁸ Such as the application for the extension by Pfizer for Lipitor.

89. Such regimes work a manner similar to the patent system, in the sense that they block competition from lower cost generic products by creating on a temporary monopoly on the right to rely upon scientific evidence that products are safe and effective. Until the expiration of exclusive rights in test data, a generic competitor must provide separate and sometimes redundant evidence of both the safety and efficacy of products, including clinical trials using both animal and human subjects.

90. The replication of experiments is intentionally designed to be a costly and time consuming barrier to entry for generic competitors, and it is also socially wasteful, and if seeking to replicate a known result, violates the ethical norms for experiments involving both animals and human subjects, including provisions in the Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects.⁵⁹

91. There are several reasons why test data exclusivity is promoted by drug developers as an incentive mechanism. The largest cost of drug development is typically associated with clinical trials, and this is not necessarily protected as a patented invention. Also, drug developers do not file and obtain patents in all national markets. PhRMA and other industry lobbies want the temporary monopoly on the right to rely on the evidence from trials to be an automatic intellectual property right not dependent upon invention, or formalities.⁶⁰ In practice, the rights associated with test data vary considerably from country to country, and range from no barrier to relying on third party evidence of safety and efficacy, to as much as twelve years of exclusive rights for such reliance. The United States has a system that provides zero, three, five or twelve years of rights, depending upon type of regulatory approval.

92. In the area of test data for agricultural products, several countries have implemented test data protection as a liability rule, whereby the data can be relied upon, subject to cost-sharing compensation to the originator during the period of protection. The European Union requires such cost sharing alternatives to exclusive rights in cases where testing would violate ethical norms on experiments with animals (other than humans), and has implemented a ban on exclusive rights for test data involving animal subjects when an experiment would be redundant and scientifically unnecessary.

93. The debates over the rules on test data include competing assertions regarding the obligations in the TRIPS Agreement,⁶¹ and in particular, the meaning of Article 39.3, which states:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

94. While the creation of a system of exclusive rights in test data is one way to implement Article 39.3 of the TRIPS, other approaches are also possible, including cost sharing regimes, or restrictions on disclosures, and despite wide differences in state practice, no country has sought a WTO panel report setting out the nature of the TRIPS obligations. Countries in the

⁵⁹ <http://www.wma.net/en/30publications/10policies/b3/>. For example, paragraph 20, which reads “Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.”

⁶⁰ James Love, Vietnam cables: Data exclusivity should be automatic, comprehensive, retroactive and without procedures and formalities, 15. September 2011. <http://keionline.org/node/1265>

⁶¹ Section 7: Protection Of Undisclosed Information.

European Union and the United States have sought to create new international norms for rights in test data in bilateral and regional trade agreements, sometimes with concessions or exceptions when those rights conflict with public health objectives.

2.4 INNOVATION INDUCEMENT PRIZES

95. The use of cash prizes has long predated the patent system as an inducement to innovation, but their role as a tool for stimulating and inducing innovation declined with the maturing of the patent system in the 18th and 19th centuries, and growth of the grants economy. Today there is renewed interest in the use of prizes, both as a novelty for addressing special innovation challenges, and a possible mechanism for more transformative changes in the ways innovation is financed. The literature on innovation inducement prizes is extensive, and growing. KEI has one annotated bibliography of articles and books on innovation prizes on the web here: <http://keionline.org/prizes/cites>.

96. Cash prizes can be implemented in diverse ways, including as rewards for both upstream innovations and end-products, with one or multiple winners, as one-off contests or part of a larger or even sustainable system of innovation, and with certain or variable rewards. Prizes can be tied to open licensing of intellectual property rights, and/or conditions requiring affordable access, or without such conditions. The criteria for qualifying for and winning prize money and the methods of selecting winners and valuing innovation require considerable thought, judgment and information.

97. At various times in history, prizes have been implemented or proposed as an alternative to patent monopolies. For example, during the 18th century Lyon France used a system of prizes to stimulate innovation in textile manufacturing⁶², and in the 19th century, the New York Times ran editorials proposing the United States substitute cash prizes for patent monopolies⁶³ and the UK quite seriously considered abolishing the patent system in favor of a national system of prizes.⁶⁴ More recently, the U.S. Senate has asked the U.S. National Academies to evaluate

⁶² Dominique Foray and Liliane Hilaire Pérez, "The economics of open technology and collective organisation and individual claims in the 'fabrique lyonnaise' during the old regime," included in *New Frontiers in the Economics of Innovation And New Technology: Essays in Honour of Paul A. David*, Edited by Cristiano Antonelli, Dominique Foray, Bronwyn Hall, and W. Edward Steinmueller. Liliane Pérez, "Inventing in a World Of Guilds: Silk Fabrics in Eighteenth-century Lyon," included in *Guilds, Innovation and the European Economy, 1400-1800*, Editors S. R. Epstein and Maarten Prak, Cambridge University Press; 1st edition, March 31, 2008, page 232. Liliane Hilaire-Pérez, and Catherine Verna, "Dissemination of Technical Knowledge in the Middle Ages and the Early Modern Era: New Approaches and Methodological Issues," *Technology and Culture*, Volume 47, Number 3, July 2006, pages 536-565. S.R. Epstein, "Transferring technical knowledge and innovating in Europe, c.1200-c.1800," in: *Endogenous Institutional Change*, 4-5 March 2005, Stanford Institute for Economic Policy Research, Stanford, USA.

⁶³ See, for example, the following editorial comment from the New York Times, on October 16, 1951: "The day, we apprehend, is coming when the whole system of patent granting will be done away with. The genius of the inventors will be directly rewarded by a bounty from Government, if his invention be of value; and if valueless, if will not have the prestige of a patent to disguise its vanity. We much doubt if the true policy of the public, and of the inventor, too, does not directly point to the abrogation of all protection laws." And, six months later: "Every mechanic, the poor and the rich equally, had the improved machine or process within reach. What he could not buy, he could at least make. The inventor, beyond the triumph of witnessing the general acceptance of his contrivance, and receiving the universal tribute of gratitude, had his pecuniary gratification." "The Rationale of Patents," *New York Times*, April 29, 1852.

⁶⁴ See, for example: Robert Andrew Macfie, *Recent discussions on the Abolition of patents for inventions in the United Kingdom, France, Germany, and the Netherlands: Evidence, Speeches, and Papers in Its Favour*. Longmans, Green, Reader and Dyer. January 1, 1869. One example of the commentary in the book: "No Patent brings its holder any immediate pecuniary right. He can only sue people who infringe his Patent, and the costliness of Patent suits is such that he is seldom able to protect himself. To make the property worth anything, a capitalist must take it up; but the capitalist, in doing so, stipulates for the lion's share of the profit. Probably in ninety-nine cases out of a hundred the reward was obtained by such speculators, and not by inventors. . . . Another reason against patents, stated by Lord Stanley--that the reward is usually out of all proportion to the service rendered--is also a strong one, if a better plan can be thought of; but the main reason, the injury to third parties, is the most serious." Page 258.

the benefits to using prizes rather than exclusive marketing rights to induce investments in the development of new drugs.⁶⁵

98. Beginning in 2002, innovation inducement prizes were seen as an important element of a larger strategy to eliminate monopolies on new drugs and vaccines, leading in 2005 to the introduction of the first of a series of legislative proposals in the U.S. Congress, in 2008 to a series of proposals by developing countries in Latin America and Asia for innovation prize fund in the WHO negotiations on innovation and intellectual property,⁶⁶ and a 2012 hearing in the U.S. Senate on replacing patent monopolies for prizes for HIV drugs.⁶⁷

99. In 2013, the World Health Organization issued a call for proposals to implement innovation, featuring in particular open innovation, the de-linkage of R&D costs and drug prices, and innovative financing mechanisms, including innovation inducement prizes, as recommended by the WHO CEWG. In the WHO consultations, a number of proposals for innovation inducement prizes were made, including proposals recommended by member states in regional consultations involving the development of new diagnostics for fever, Chagas Disease and cancer, as well as prizes relating to the development of new antibiotic drugs, and new drug regimens for tuberculosis. While ranking high by member states in regional consultations, none of the innovation inducement prizes were selected by a panel of experts convened by the Secretariat, to the disappointment of several health advocacy groups following

⁶⁵ 112th Congress, S.3187.ES, Section 906. Independent Study On Medical Innovation Inducement Model.

⁶⁶ Thomas C. Erren, Prizes to Solve Problems in and Beyond Medicine, Big and Small: It Can Work, 68 *Med. Hypotheses* 732, 733 (2007); D.F. Horrobin, Glittering Prizes for Research Support, 324 *Nature* 221 (1986); Michael Kremer. "Patent Buyouts: A Mechanism for Encouraging Innovation." *Quarterly Journal of Economics* 113: 1137-67, 1998; Burton A. Weisbrod, Solving the Drug Dilemma, *Wash. Post*, Aug. 22, 2003, at A21; James Love and Tim Hubbard. "A New Trade Framework for Global Healthcare R&D." *PLOS Biology*. 2(2): e52, 2004; Joseph A. DiMasi, and Henry G. Grabowski, Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D, June 25, 2004 Bernard Sanders, the Medical Innovation Prize Fund, 151 *Cong. Rec.* E149 (extensions of remarks Feb. 2, 2005); James Love. "Medical Innovation Prize Fund System of Remuneration." In *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*. James Love. WHO UNDP. 77-80 and 101-104, 2005; James Love and Tim Hubbard. "Paying for Public Goods." In *Code: Collaborative Ownership and the Digital Economy*. Edited by Rishab Aiyer Ghosh. MIT Press, Cambridge. 207-229, 2005; Thomas Pogge. "Human Rights and Global Health: A Research Program." *Metaphilosophy*. 1/2(36). 2005; Aidan Hollis. "An Optional Reward System for Neglected Disease Drugs." Department of Economics, University of Calgary; Institute of Health Economics, 2005; Joseph E. Stiglitz, Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations, 333 *Brit. Med. J.* 1279, 1279-80 (2006); Rachel Glennerster, Michael Kremer, and Heidi Williams. "Creating Markets for Vaccines Innovations Case Discussion: International AIDS Vaccine Initiative." *Innovations*, winter 2006, pp. 67-79; J. A. DiMasi & H. G. Grabowski, Should the Patent System for New Medicines Be Abolished?, 82 *Clinical Pharmacology & Therapeutics* 488, 488-90 (2007); Barder, Owen; Kremer, Michael; and Williams, Heidi. "Advance Market Commitments: A Policy to Stimulate Investment in Vaccines for Neglected Diseases." *The Economists' Voice*: Vol. 3 : Iss. 3, Article 1, 2006; Bruce G. Charlton, Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapeutic Innovation, 68 *Med. Hypotheses* 1, 2 (2007); Tim Hubbard and James Love, A New Trade Framework for Global Healthcare R&D, 2 *PLoS Biology* 147, 150 (2004); James Love and Tim Hubbard, The Big Idea: Prizes to Stimulate R&D for New Medicines, 82 *Chi.-Kent L. Rev.* 1519, 1528-34 (2007); Marlynn Wei, Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005, *B.U. J. Sci. & Tech. L.* 25, 44-45 (2007); Amy Dockser Marcus, Finding a Cure: Will Sharing Ideas Advance Cancer Research? Hedge-Fund Managers Offer \$ 1 Million Prize to Combat Scientists' Culture of Secrecy, *Wall St. J.*, Sept. 18, 2007, at D1; Aidan Hollis, Incentive Mechanisms for Innovation (Institute for Advanced Policy Research, Technical Paper TP-07005 (2007); James Love. "The Role of Prizes in Developing Low-Cost, Point-of-Care Rapid Diagnostic Tests and Better Drugs for Tuberculosis," MSF expert meeting on IGWG and R&D for tuberculosis, April 11, 2008; Ron Marchant, Managing Prize Systems: Some Thoughts on the Options, 2 *Knowledge Ecology Stud.* (2008); 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.

⁶⁷ See: Opening Statement of Chairman Sanders Subcommittee on Primary Health and Aging Hearing, The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative, May 15, 2012, and video, transcript and written submissions for the hearing, here: <http://www.help.senate.gov/hearings/hearing/?id=2d5dda75-5056-9502-5d1a-2a40d8a92d51>

the WHO discussions.⁶⁸ For a discussion of proposals to use prizes to simulate new innovation for antibiotic drugs, see Annex C.

100. Several governments have recently expanded their use of innovation inducement prizes, including an extensive set of initiatives by the Obama White House,⁶⁹ and newer expressions of interest by the European Commission, including funding a recent prize to induce innovation in vaccines.

101. The use of innovation inducement prizes can be compared to the use of other financing mechanisms, and in Annex A, innovation inducement prizes are compared to research grants or contracts, or patent grants, in a series of simplified stylized models.

102. A review of innovation prizes will illustrate the deep diversity in approaches to the design of the reward system.⁷⁰ Any taxonomy of prizes will naturally be incomplete. But it is useful to provide several working definitions.

2.4.1 Definitions

2.4.1.1. *One-off (Sui generis) prizes*

103. A prize that is designed for a special and limited purpose is sometimes described as a one-off or sui generis prize. Many well known prizes of this type are interesting and potentially useful examples of prizes to stimulate innovation, but are not necessarily seen as a sustainable system of innovation in the way that grants, patents and the various non-patent market exclusivity regimes are today.

104. One-off prizes can rely upon difficult-to-meet (high threshold) winning criteria that are quite specific, but also can be implemented where the criteria for qualifying or winning is less specific, and or more subjective, such as the recent EU prize for the “best” innovation in address the problem of heat stable vaccines.

2.4.1.2. *Prize Fund*

105. A prize fund can be created for a single one-off prize, or to fund a set of prizes, either to achieve a specific objective, or to provide a sustainable system of rewarding innovation.

2.4.1.3. *End Product Prize*

106. End product prizes are the reward for successful development of products that reach consumers, however defined. End product prizes are distinguished from interim results prizes, including so called “milestone” prizes, or open source dividend prizes, both in terms of practical issues of timing and the nature of the innovation, but also as regards the status of prizes as a mechanism to stimulate innovation. In the debate over the use of prizes for medical innovation, the World Health Organization (WHO) has identified “end product prizes” as controversial, largely because on an intellectual and political level, end product prizes most closely compete

⁶⁸ HAI and Medicus Mundi statements at WHO EB on CEWG demonstration projects, January 24, 2014, <http://keionline.org/node/1916>; Katy Athersuch, MSF intervention on CEWG R&D financing at WHO 134th Executive Board meeting, 134th WHO Executive Board meeting – Agenda item 9.3: Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, January 24, 2014.

⁶⁹ Jeffrey D. Zients, Deputy Director for Management, OMB, Guidance on the Use of Challenges and Prizes to Promote Open Government, Memorandum for the Heads of Executive Departments and Agencies, M-10-11, March 8, 2010.

⁷⁰ See: Selected Innovation Prizes And Reward Programs, KEI Research Note 2008:1.

with the notion that a temporary patent monopoly is needed to stimulate innovation. In practice, end product prizes can be designed as substitutes or complements to the patent monopoly.

107. One very important characteristic of the end product prize is that it only rewards outcomes that result in actual products that are used and useful, a feature that reduces the risk to the funder of the prize that the investment will not produce a useful result.

2.4.1.4. Interim Prizes

108. Interim prizes reward innovations that contribute to the development of end products. Implemented in many different ways, interim prizes can reward the solution to a narrow and specific technical issue, achievement of a pre-established goal in the development of a new technology, contributing the most to advancing a larger objective, or other outcomes that may be useful in developing new products. The World Health Organization (WHO) discussions about innovation prizes have given particular attention to “milestone” prizes, which are seen as less expensive, less ambitious, and less controversial than end product prizes, and use language that is familiar in the financing of biomedical innovations. The company InnoCentive grew out of an in-house program at Ely Lilly to use cash prizes to crowd-source narrow R&D problems, and at any given moment manages hundreds of challenges that can be described this way. But unlike end product prizes, money spent on interim prizes may or may not yield a useful and used product.

2.4.1.5. Open Source Dividend Prizes

109. As proposed in 2007 and later developed in various systems of prizes, the open source dividend is a mechanism to stimulate greater openness and sharing of research inputs. In initial formulations, the open source dividend was allocated a share of an end product prize, and distributed to persons, groups or organizations that openly and freely shared knowledge, data, materials or technology that was judged to have been helpful or instrumental in the success of the end product. The open source dividend can however be implemented entirely separately from end product prizes, or indeed any other prize mechanism. The open source dividend corrects for an obvious market failure -- the current lack of economic incentives to share research inputs. When research is more valuable to society open than when managed as a proprietary asset under restrictive licensing and access terms, the failure to induce open sharing is costly and wasteful. The open source dividend is designed to correct that market failure. If the open source dividend is financed out of revenues from product sales, it will reduce net returns to product developments, but it will also expand access to research inputs, and lower the costs of acquiring those research inputs.

2.4.1.6. High threshold, low threshold prizes

110. Innovation inducement prizes normally have standards for qualifying for the prize money, including required end points of varying degrees of specificity. A high threshold prize is one with a difficult end point, such as a requirement of a hard to attain accuracy of a diagnostic tool, or obtaining a high mile per gallon rating for a vehicle.

2.4.1.7. Competitive valuations

111. The size or valuation of prizes can be done in a variety of ways, including by using experts or funders of prizes to pre-specify rewards, or by using a competitive process to determine the amount. An example of a competitive process would be the proposals developed for medical or agricultural innovations that divide prize funds of a fixed size among multiple entities that qualify, based upon the performance of the entrants when compared to each other. For example, the U.S. legislation for a medical innovation prize fund would consider the evidence

submitted by several firms that a new product improved health outcome, benchmarked against existing treatments. The money in the prize fund would then be divided among the firms, so the amount of the prize for any product would be determined by its merits, relative to other products involved in the same competition.

2.4.2. Considerations in the management of innovation inducement prizes.

112. The patent system requires complex and expensive systems for awarding rights and resolving disputes. Grants and innovation prizes also requires considerable resources to manage and monitor.

113. Innovation inducement prizes can be implemented in the variety of ways, and the freedom to design incentives is itself a mixed blessing, because it requires prize sponsors to evaluate and choose rules. Once rules are established, prize sponsors need to manage and monitor the administration of the prizes. The development of more established templates or prize fund systems can lower the costs of designing prizes and improve efficiency, but like the patent and grant systems, also create targets for gaming the system.⁷¹

114. The great flexibility to design prizes creates opportunities to influence the direction of innovation, and to expand rather than reduce competition in the supply of goods and services.

ANNEX A: COMPARISONS OF GRANTS, PRIZES AND PATENTS

115. Decisions about how to finance innovative activities involve judgments of how best to manage uncertainty, and that uncertainty has several dimensions. An entity that wants a solution to a particular problem, or a better solution, begins not knowing the solution, or the possibilities that exist. The entity seeking the solution(s) also faces uncertainty as to which individual, team or organization has the skills and motivation to provide a solution, and the price necessary to induce third parties to undertake the work to find a solution.

116. The various methods of financing innovation are often shaped by traditions and habits - the NIH is accustomed to managing grants, and drug companies lobby for tax credits, patents and other intellectual property rights. But in order to avoid habits becoming bad habits, or ignoring opportunities to have better outcomes, it is useful to think more explicitly about the ways uncertainty can be managed.

117. The following examples illustrate simple models of uncertainty, pitting grants against prizes, and prizes against patents, using simple and stylized examples to show some (but by no means all) of the important factors.

1. GRANTS VERSUS PRIZES

118. The first set of examples focuses on the choice between grants and prizes to finance research to obtain a needed innovation -- referred to here as a solution. Each example begins with a set of stylized facts, and then calculates outcomes, taking into account some key variables, and the decision to use either grants or prizes.

119. The first set of stylized facts deals with the costs, the number of able and not able firms that could provide the solution, and the asymmetry of information about which firms are able.

⁷¹ Fiona Murray, Scott Stern, Georgina Campbell, Alan MacCormack, Grand Innovation Prizes: A theoretical, normative, and empirical evaluation, *Research Policy*, 41, 2012.

Stylized facts

- The costs of successfully undertaking the research and providing a solution is known to be roughly equal to \$1 million.
- There are 20 firms that appear to be qualified to undertake the work, but only some have the personnel, insights and knowledge to actually provide a solution.
- The potential suppliers could not credibly distinguish themselves to the seeker, but are realistic in terms of evaluating their own abilities and the abilities of their competitors.
- The able firms have equal chances of prevailing in a head to head prize competition.

Case 1: There are 2 of 20 able suppliers of the innovation

Using grants to finance innovation

120. The total cost of financing the innovation through grants, and the chances of success, depend upon the number of grants offered. The entity seeking the innovation could provide grants to all firms or several firms, knowing that the greater the number of grants, the greater the odds that one of the grant recipients is able to provide a solution.

121. The probability of a single grant producing a solution is .1, and with each new grant the odds improve until the 19th grant, when the probability of obtaining a solution is 1. The odds associated with different numbers of grants are given below⁷²:

Cumulative probability of obtaining solution	Probability of grant obtaining a solution (given past failures)	Number of
0.100	0.100	1
0.195	0.105	2
0.284	0.111	3
0.368	0.118	4
0.447	0.125	5
0.521	0.133	6
0.589	0.143	7
0.653	0.154	8
0.711	0.167	9
0.763	0.182	10
0.811	0.200	11

⁷² In this example, with a fixed number of able and not able firms, the calculations at any given stage depend upon what has already happened, more like blackjack than rolling dice. If unsuccessful after awarding a grant, the ratio of able to not able firms increases.

0.853	0.222	12
0.889	0.250	13
0.921	0.286	14
0.947	0.333	15
0.968	0.400	16
0.984	0.500	17
0.995	0.667	18
1.000	1.000	19
1.000	2.000	20

Table A1: Probability of selecting 2 of 20 able firms

122. In this example, 10 grants (\$10 million) would have a .76 probability of success. 14 grants (\$14 million) would be necessary to have more than a 90 percent chance of success, and 19 grants would guarantee a solution (\$19 million).

Using a Prize to finance innovation

123. Suppose instead, the seeker offered a prize for a solution, available to anyone who could perform. From the perspective of the able firms, the prize would be worth its face value, adjusted by the probability of winning. With equal chances, the two able firms perceive their chances of winning to be 1 of 2, or .5. Given the \$1 million cost of undertaking the work, the prize would have to be larger than $\$1 \text{ million} / .5 = \2 million . Any prize greater than \$2 million would induce entry by both able firms and produce a solution.

124. Therefore, in this set of stylized facts, the seeker would normally be better off using a prize than a grant.

125. If the grants were given out sequentially, and the delay in finding a solution had a zero opportunity cost (a less costly but time consuming option) the prize alternative would be less expensive about $17/19 = 89.5$ percent of the time.

126. If the grants were given out simultaneously (the faster but more costly option), the prize alternative would be less expensive for an amount of certainty in finding a solution greater than 19.5 percent.

Case 2: 10 of 20 able suppliers of the innovation

127. While Case 1 showed the prize approach leading to the better outcome, other examples can show the opposite. For Case 2, the stylized facts are similar to Case 1. There are exactly 20 potential suppliers, and suppliers cannot credibly distinguish themselves to the seeker, but are realistic in terms of their own abilities and the abilities of their competitors. But rather than 2, there are 10 able suppliers.

Using grants

128. Given the fact that 10 of 20 firms are able to provide a solution, far fewer grants are likely to be necessary. Indeed, just one grant might work, and three would offer roughly a .9 probability of success.

Using prizes

129. What about prizes? If each of the 10 able firms is equally likely to win, and believe the other able firms are equally willing to enter the contest, the odds of winning would be 1/10, and the prize would have to be more than \$10 million, far more expensive than the alternative of using grants.

130. The seeker could offer a smaller prize, and hope that at least one able firm would enter, on the expectation that not all able firms would follow. But this would run a risk that there would be no entrants.

Take home message

131. One lesson from this set of stylized examples is that grants are likely to be preferred in cases where the abilities of the suppliers of the research or solution are roughly equal, and are known or knowable, while prizes have advantages in cases where the abilities of the suppliers are significantly different and it is difficult to distinguish between more able and less able suppliers. Put another way, if it is fairly straightforward to identify researchers/firms that can provide an acceptable solution, it may be more cost effective to simply provide a grant or enter into a contract, than to run a competition, particularly when the competition requires suppliers of the innovations to make investments while taking into account a low probability of obtaining the prize. On the other hand, if it is difficult to both provide the solution and to identify which researchers/firms are able to do so, then a prize may be more cost effective.

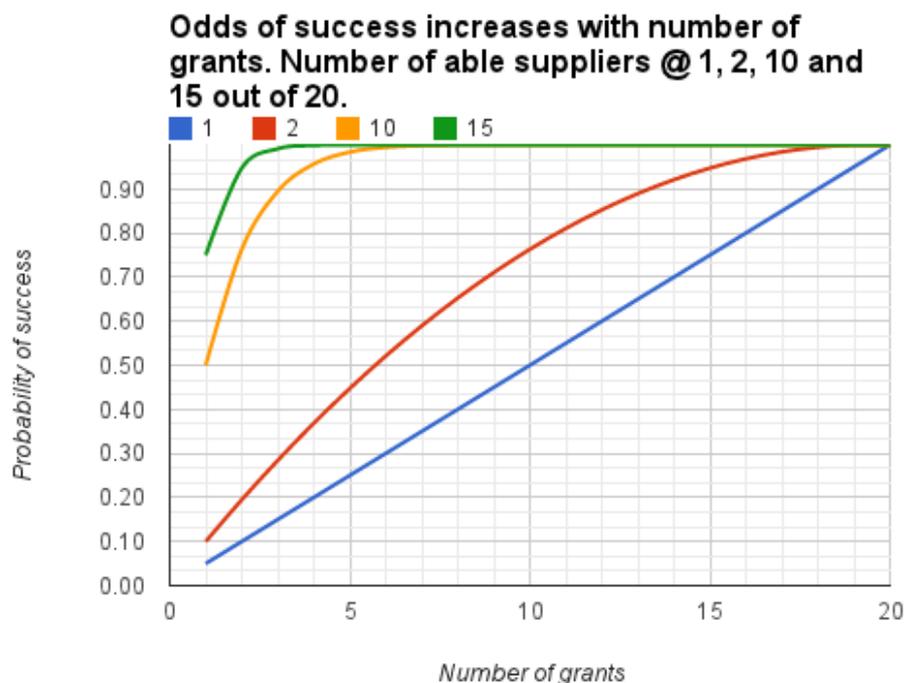


Illustration 1: Cumulative probability of success, different numbers of able firms

2. MONEY PRIZES COMPARED TO PATENT RIGHTS, PART 1

132. Patents are sometimes described as a type of prize, where the prize is a grant of a monopoly on an invention, rather than money. For a variety of reasons, patents have become a large focus of discussions of innovation policy, and a widely if not over emphasized tool to measure innovative activity. The following examples illustrate differences between patents (as a grant of a monopoly) to cash prizes.

Prizes versus Patents, as regards access to innovations

133. The first example looks at the choice of patents or prizes as they relate to access to innovations, using a stylized example with four countries, each with national health insurance, and an ability (willingness) to pay equal to one percent of per capita incomes.

134. In the example, the risk adjusted supplier cost of the innovation is \$200,000.

135. For the country populations and ability to pay, each country is a stylized representation of the four World Bank income groups. Populations and incomes are scaled from 2012 average World Bank data for high, upper middle, lower middle and lower income group countries. For example, the World Bank estimates that in 2012, 1.3 billion persons were living in high-income countries, with a per capita income of roughly \$37,000. The stylized country HI has 1,300 residents, and has a maximum willingness to pay of 1 percent of the average income, or \$376.⁷³ The countries UM, LM and L are likewise scaled after the World Bank country groups for upper middle income, lower middle income and lower income.

Maximum willingness to pay	Population	Country
\$ 376	1,300	HI
\$ 70	2,400	UM
\$ 19	2,500	LM
\$ 6	900	L

Table A2: Four-country population and willingness to pay

136. In this example, any reward that has an expected value of more than \$200,000 will induce entry and produce a solution, but at different costs for the various countries paying for the solution.

Patents versus prizes - with a single price

137. In the patent scenario, the supplier of the innovation obtains a patent, and charges the profit-maximizing price.

138. If only a single price is possible, the possible pricing points and revenues (price times population that can afford the product) for the patent holder are described below.

Price \$ 7	Price \$ 19	Price \$ 70	Price \$ 376	Demand	Stylized Country
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⁷³. In 2012, IMS estimates for the global market for pharmaceutical drugs are equal to 1.3 percent of global GDP.

				(units)	
\$ 7,800	\$ 24,700	\$ 91,000	\$ 488,800	1,300	HI
\$ 13,800	\$ 43,700	\$ 161,000		2,400	UM
\$ 14,400	\$ 45,600			2,500	LM
\$ 5,400				900	L
\$ 41,400	\$ 114,000	\$ 252,000	\$ 488,800		Feasible revenues

Table A3: Revenues under four prices

139. The preferred price for the patent holder is \$376, which limits the market to only those living in the highest income country, but generates revenues of \$488,800, a sum greater than the alternatives.

140. The price of \$376 limits access to only 1,300 persons, or about 18 percent of the total four-country population of 7,100.

141. If the reward for the successful innovation was instead an inducement prize, of any amount greater than \$200,000, and the innovation was freely available to end users, everyone would have access. This is the motivation behind the campaign for delinking R&D costs from product prices.

Patents versus prizes - with perfect price discrimination

142. If the patent holder were able to charge different prices in different countries, and each country had universal health insurance, the profit maximizing-strategy would be to charge the maximum ability to pay, in each of the four countries.

Total	\$ 6	\$ 19	\$ 70	\$ 376	Country
\$ 488,800				\$ 488,800	H
\$ 161,000			\$ 161,000		UM
\$ 45,600		\$ 45,600			LM
\$ 5,400	\$ 5,400				L
\$ 700,800					All Four markets:

Table A4: Monopoly revenues with price discrimination

143. Under what is essentially perfect price discrimination by a monopolist, revenues and access both expand. The increase in revenue is a benefit to the patent holder, but not necessarily to the reimbursement authorities footing the bill.

Patents versus prizes - with imperfect price discrimination

144. How realistic are the single price and perfect price discrimination models? That depends upon the good in question. For example, some companies are noted for seeking the nearly the

same price for cancer drugs, world wide,⁷⁴ and but some (but not all) vaccine markets may implement differential pricing more effectively, although pricing for some of the newer vaccines is so aggressive that access is far from universal.⁷⁵

145. If goods move in international trade, and/or are impacted by cross border pricing norms such as formal or informal reference pricing, and if there are gaps in insurance coverage, and differences in insurance coverage and incomes within countries, price discrimination is far from "perfect."

146. For example, in its 2014 "Special 301" submission to the United States Trade Representative, the Pharmaceutical Research And Manufacturers Of America (PhRMA) expressed concerns over the efforts by the government in Greece to obtain lower prices for medicines. PhRMA said "a hypothetical 10 percent price drop in Greece would have cost industry \$390 million in Greece but \$1 billion in Europe (i.e., 2.5 times more) and \$2.8 billion worldwide (i.e., 7.0 times more) if all countries re-referencing Greek prices through formal and informal links are included."⁷⁶ Perfect price discrimination is becomes more challenging (impossible) when one considers a world with more than 200 countries, vast differences within the World Bank income groups, and vast differences in incomes and insurance coverage within countries.

147. In practice, for most goods, some price discrimination exists, but it falls far short of "perfect" price discrimination. Moreover, the nature of the price discrimination is not always what one would expect, as monopolists may charge higher prices in lower income countries, in order to target an elite within a particular country, or to benefit from less competition among substitute goods.⁷⁷ In general, to the extent that prizes can induce the same innovation as patents, and if they are designed to make the innovation available freely to end users, access will be more equal than if patents are used.

148. When comparing innovation inducement prizes to patent monopolies, the policy implications will be different for goods that have more compelling reasons to be more equal in consumption or more widely used, such as medically important drugs, vaccines and diagnostic

⁷⁴. Andrew Martin, "Life-Saving Medicine, High Costs, and the Intractable Patent Puzzle," *Bloomberg Businessweek*, March 05, 2014

⁷⁵. Jaleesa Baukman, "Nearly 30,000 Unvaccinated Adults Die From Preventable Diseases Each Year," *University Herald Reporter*, February 6, 2014; Laura P., Hurley, et al, "U.S. Physicians' Perspective of Adult Vaccine Delivery," *Annals of Internal Medicine*, 2014;160:161-170; Andrew Pollack, "Pediatricians Voice Anger Over Costs of Vaccines," *the New York Times*, March 24, 2007; Pauline W. Chen, M.D., "Why Patients Aren't Getting the Shingles Vaccine," *the New York Times*, June 10, 2010; Laura P. Hurley et al, "Barriers to the use of herpes zoster vaccine," *Annals of Internal Medicine*, 2010 May;152(9):555-560; Laurie Barclay, MD, "Herpes Zoster Vaccine Is Safe, but Financial and Other Barriers Limit Its Use," *Medscape*, May 4, 2010; Jill Filipovic, "HPV Vaccine Out of Reach for College Students, College campuses are breeding grounds for HPV, the virus that can cause genital warts and cervical cancer. A new vaccine offers protection, but many students can't afford it," *AlterNet*, March 12, 2007; Emily Saarman, "Why Is the HPV Vaccine So Expensive? Good for the cervix, rough on the pocketbook," *Discover Magazine*, June 11, 2007; Amanda Hess, "HPV Costs Americans Nearly \$2 Billion To Treat. Why Is It So Expensive?," *Slate*, February 14, 2013; Donald G. McNeil Jr., "Cancer Vaccines Get a Price Cut in Poor Nations," *the New York Times*, May 9, 2013; Byung-Kwang Yoo, et al, "Cost of Universal Influenza Vaccination of Children in Pediatric Practices," *Pediatrics*, Vol. 124 No. Supplement 5 December 1, 2009 pp. S499 -S506; Carly Weeks, "The high cost of vaccination in Canada," *The Globe and Mail*, Nov. 26 2013; Lizell B. Badsen, et al, "Reduced price on rotavirus vaccines: enough to facilitate access where most needed?" *Bulletin of the World Health Organization* 2012; 90:554-556.

⁷⁶. Pharmaceutical Research And Manufacturers Of America (PhRMA) Special 301 Submission 2014.

⁷⁷ Note that Miami is a popular shopping destination for persons living in Latin America, and many goods are cheaper in Europe or the United States than they are in Africa or other developing countries.

tests, or innovations that reduce carbon emissions, than it will for goods that are perceived as non-essential, such as luxury automobiles.

Take home message

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 versus Patents, as regards value for money

150. In the single price case, the patent holder receives \$488,800, and in the perfect price discrimination case the patent holder receives \$700,800. Both amounts far exceed the \$200,000 cost of the innovation, and in both cases, the monopolist chooses a price that wipes out the entire budget in a country, leaving no surplus in perceived value.

151. One could construct a more nuanced demand curve, for example, by modeling 200 rather than 4 countries, and/or introducing intra-country disparities in the ability-to-pay, and even modeling the degree to which price discrimination is feasible, demonstrating that in realistic scenarios, a monopolist will offer a product at a relative bargain to some countries, compared to their maximum price. For example, the relatively flat pricing of some medicines in Europe often presents better potential values for Northern Europe, which has higher incomes, than for some countries in Southern or Eastern Europe, which have lower incomes. But in any case involving patents, the fact is that the monopolist has no incentive to limit prices to its costs.

152. In theory, if an innovation inducement prize was used instead of a patent, the innovation could be obtained for less money. This of course assumes that the managers of the prize can adequately estimate the amount necessary to induce investments in the innovation, an issue explored in the next example.

153. In the current example, a prize of say \$250,000 would be large enough to induce the supply of the innovation, providing the supplier with an extra profit of \$50,000, while making the innovation available to everyone, leaving only the matter of sorting out who should pay for the \$250,000 prize money. If the prize money were paid in direct proportion to relative income shares of each country, the cost would be allocated as follows among countries.

<i>Consumer Surplus</i>	<i>Prize Money</i>	<i>Relative share of four country national income</i>	<i>Maximum value of consumers</i>	<i>Country</i>
314,428	\$174,372.15	70 %	\$ 488,800	HI
103,566	\$57,434.36	23 %	161,000	UM
29,333	\$16,267.12	6.5 %	45,600	LM
3,474	\$1,926.37	.8 %	5,400	L
\$450,800	250,000		\$ 700,800	All Four markets

Table A5: Four-country share of prize money, and net consumer surplus

154. In this example, the use of the prize is a much better value for money proposition than the grant of a monopoly, from the perspective of the end user. The innovation is valued at \$700,800, but the cost from the supplier is \$250,000. What makes this possible is the change in who sets the price. If the monopolist sets the price, much if not the entire consumer surplus disappears. When the end users set the price, and the cost of supplying the innovation is known, it is possible to set the price closer to the suppliers cost.

Take home message

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.

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.

3. PRIZE DESIGNS

157. The patent system is designed in such a way that an entrepreneur can perceive a business opportunity in bringing an innovation to the market, and make that happen, so long as it is possible to attract financing, including from private parties hoping to exploit the patent monopoly on the innovation. The ability to exploit these business opportunities gives the patent system a number of advantages over systems that require third parties to identify innovation needs and set rewards.

158. Beginning in the late 1990s, following the publicity around the launching of the Rockefeller Prize and the first X-Prize, a number of academic researchers, philanthropic organizations, businesses, governments and non-profit organizations began to rethink how prizes might be managed, leading to experimentations with a variety of new prize designs, as well as considerable scholarship on past prize contests.

159. Among the earliest types of prizes were those that required achieving a very difficult end-point, or those that rewarded a “best” result, possibly with a lower set of mandatory requirements. The prizes with very difficult endpoints, or “high threshold” prizes, require insight into what is both feasible and valued as regards an innovation. The “best” type prizes could be specified with objective metrics to determine winners, or more subjective evaluations, and could be fairly general or more specific as regards the criteria qualifying for the prize.

160. An important set of prizes are those designed to advance broad objectives, are not highly specific regarding the nature of the qualifying technology or outcome, and which have variable rewards based upon evidence of benefits. Examples would be the prize fund in the 18th century to improve technologies in the Lyon silk industry, or the more recent proposals for prize funds to enhance innovations in the areas of agriculture or medicine that use both evidence of outcomes and competitive mechanisms to determine the amount of prize rewards that are available to multiple winners.

161. What is now better understood is the rich diversity of possible prize designs, and the greater flexibility to design new innovation incentives. The great flexibility to design prize rewards has advantages in terms of the freedom to re-calibrate and refashion the incentive landscape for innovation -- constant innovation the ways to stimulate innovation. But these flexibilities come with costs, including a lack of practical experience in using new systems, and the need to educate potential suppliers and funders of innovation about the new approaches. Ironically, the systems of grants and patent monopolies benefit from not being innovative, because they are more familiar and more widely tested.

4. MONEY PRIZES COMPARED TO PATENT RIGHTS, PART 2

Divergence between private and social values of innovations

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

163. An innovation is a demonstration of 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.

164. 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 more socially beneficial.

Uncertainty

165. In the examples above, the benefits of the innovation and the costs of supplying the innovation were both assumed to be known. In practice, both are often uncertain. This uncertainty is important in comparing the use of prizes and patents.

5. THE SIZE OF THE REWARDS

166. In 2010, the US International Revenue Service reported that manufacturers in the Pharmaceutical and Medicine sector claimed royalties of \$27 billion, equal to 8.4 percent of business revenues⁷⁸, an amount roughly equal to the budget of the National Institutes of Health

⁷⁸. The IRS figures include royalties on patents, know how, trademarks and other licensed intellectual property.

that year. In the same year, the global pharmaceutical market was \$891 billion. The amount devoted to innovation inducement prizes for this sector was very small. For innovation prizes to become a more significant rival to the patent system, they have to develop sustainable financing mechanisms that scale rewards in reasonable proportion to the tasks at hand.

167. One area where there is interest in creating sustainable funding mechanisms for innovation inducement prizes are medical inventions. Examples in the United States include S.626 (113th Congress), which would allocate .02 percent of the country GDP for innovation prizes for new drugs to treat HIV/AIDS, S.627 (113th Congress), which would allocate .55 percent of GDP for innovation prizes to reward the development of new medicines, various proposals to fund cancer drugs out of a share of national treatment outlays for cancer, and proposals for a global HIV/AIDS prize fund partly funded by a share of outlays on treatments for HIV/AIDS. There are several reasons why the pharmaceuticals sector has been the focus of several proposals, including concerns of access to high priced patented medicines, the high costs of funding R&D through patent monopolies, and the relative ease of funding innovation prizes in a market that already depends upon third party financing of purchases and reasonably well understood metrics to describe the value of innovation outcomes that are already used to justify pricing and reimbursement policies for patented medicines.

168. Outside of the area of medicines, there is a paucity of proposals to create sustainable funding mechanisms for innovation inducement prizes. Prize funds have been proposed to sustain innovation in agriculture, but little work has been done on the funding mechanisms. In the energy field, where there has been a large amount of activity as regards innovation prizes, virtually all prizes are one-off projects, funded around a specific R&D objective. In contrast, the patent system is a permanent reward mechanism, creating the legal mechanism for the patent holder to effectively tax users of the invention for the term of the patent protection.

ANNEX B: SELECTED EXAMPLES OF INNOVATION INDUCEMENT PRIZES

169. Innovation inducement prizes have been used long before patents or other intellectual property systems were developed. Reports of various pecuniary incentives for inventions include even the fable of Archimedes' famous "Eureka" moment, when he conceived a solution to testing the purity of a gold crown, in response to a reward offered by the King of Sparta. In the past two decades, there has been an explosive growth in the number of innovation inducement prizes offered. KEI's 2008 Research Note on "Selected Innovation Prizes And Reward Programs"⁷⁹ is a 51-page survey organized by 16 diverse subject areas. There are a growing number of other surveys of innovation prizes, including, for example, two from Harvard Business School,⁸⁰ a 2009 McKinsey Survey,⁸¹ several surveys cited in a 2013 NESTA working paper,⁸² and InnoCentive's public documentation of many of the more than 1,600 prize contests the firm has managed or is managing.

170. The following are a few examples of such past innovation inducement prizes, to illustrate the diversity of objectives and approaches.

⁷⁹ KEI Research Note 2008:1

⁸⁰ Karim R. Lakhani, Lars Bo Jeppesen, Peter A. Lohse, Jill A. Panetta, The Value of Openness in Scientific Problem Solving, Harvard Business School Working Paper, No 07-050, 2007; Liam Brunt, Josh Lerner and Tom Nicholas, Inducement Prizes and Innovation, Working Paper, 11-118, December 5, 2011.

⁸¹ "And the winner is ..." Capturing the promise of philanthropic prizes, McKinsey & Company, March 3, 2009.

⁸² Abdullah Gök, The Impact of Innovation Inducement Prizes, Manchester Institute of Innovation Research, University of Manchester, Nesta Working Paper 13/18, November 2013, www.nesta.org.uk/wp13-18.

MEDICAL TECHNOLOGIES

Prize4Life

171. Prize4Life is a U.S. nonprofit organization that describes its mission as “accelerating the discovery of treatments and cures for ALS (amyotrophic lateral sclerosis, also known as Lou Gehrig's disease).” Avichai Kremer, the co-founder and driving force behind Prize4Life, was diagnosed with ALS in 2004, and under his leadership, Prize4Life has managed a number of innovation inducement prizes focusing on different aspects of ALS research.

Context

172. ALS is a terrible disease, leading to neurological deterioration that is “inexorably progressive.” The odds of being diagnosed with ALS are somewhat higher for males, and persons of European descent. The European incidence is estimated at 2 to 3 cases per 100,000 in the general population. In the United States, the Centers for Disease Control and Prevention (CDC) estimate that approximately 5,000 persons are newly diagnosed each year. Over sixty percent of patients die within three years, and only 10 percent of the remaining patients survive for more than 8 years.⁸³

173. The United States, the European Union, and other countries consider ALS an orphan disease with special incentives for R&D on rare diseases, and governments have provided direct funding for research. A keyword search for “amyotrophic lateral sclerosis” using the U.S. National Institutes of Health (NIH) database on grant awards⁸⁴ locates 4,669 records, including grants associated with 94 clinical studies, 297 patents and 244 published studies citing support from 300 NIH funded projects. Despite these efforts, the root cause of the disease is still unknown. The only effective drug on the market to treat ALS is riluzole, which provides symptomatic relief, and extends the average survival of patients by 3–6 months.

The Prize4Life Prizes

174. Prize4Life launched a highly publicized \$1 million prize for an ALS biomarker in 2006.⁸⁵

175. In 2007, Prize4Life awarded five researchers a total of \$75,000 in “Thought Prizes to encourage promising concepts.” In 2009, Prize4Life awarded \$100,000 in “Progress Prizes” to two research groups.

176. In 2011, the \$1 million biomarker prize was awarded to Dr. Seward Rutkove, for development of electrical impedance myography (EIM) which allows for a much more sensitive measure of disease progression.⁸⁶ According to InnoCentive, a for-profit organization that helped manage the prize competition for Prize4Life, some 2,969 “solvers” were engaged in the contest, submitting 108 proposed solutions.⁸⁷

⁸³ Orla Hardiman, Leonard H. van den Berg & Matthew C. Kiernan, “Clinical diagnosis and management of amyotrophic lateral sclerosis,” *Nature Reviews Neurology* 7, 639-649 (November 2011).

⁸⁴ <http://projectreporter.nih.gov/reporter.cfm>

⁸⁵ \$1M prize for the discovery of biomarker for ALS, *Harvard Gazette*, November 30, 2006; Stephen Smith, The business of survival: A B-school graduate turns his disease into a business plan -- one that he hopes could literally save his life, *Boston Globe*, May 28, 2007; Steven Edwards, Harvard Graduate Holds X-Prize-like Competition for ALS Research, *Wired.Com*, May 28, 2007.

⁸⁶ Prize4Life Awards \$1 Million Prize for Major Milestone in ALS Research, InnoCentive Press Release, February 7, 2011.

⁸⁷ Case Study: Prize4Life, InnoCentive. 2012.

177. In 2008, a \$1 million “ALS Treatment Prize4Life” was offered for researchers who could “extend the lives of ALS mouse models by 25 percent.” On October 2010, the competition was closed, with no winner. On June 6, 2012, the contest was reopened, with somewhat revised endpoints. In its own commentary of the contest, Prize4Life notes that in the first competition, the offer of the prize drew 33 teams from both academia and industry, including 17 that were new to ALS research and drug development, illustrating an impact characteristic of such competitions. Even an “unsuccessful” prize contest can stimulate investments in R&D and critical thinking about the problem.

178. The third major prize initiative was the “DREAM Phil Bowen ALS Prediction Prize4Life,” launched on July 11, 2012. The ALS Prediction Prize was done, in partnership with the Dialogue for Reverse Engineering Assessments and Methods (DREAM), a project sponsored by IBM, Columbia University, NIH Roadmap Initiative, and The New York Academy of Sciences. The ALS prediction prize, which featured smaller financial rewards (\$50,000 divided between three winning entrants), was an effort to mine ALS patient data collected in previous clinical trials.⁸⁸ For the prediction prize, InnoCentive reported, “Solvers will NOT be required to transfer intellectual property to receive an award. Rather, receiving the full award will be contingent upon permission to submit the results and the algorithm to a peer reviewed scientific journal (for which the Seeker will pay the associated publication costs).”⁸⁹

179. One goal of the Prize4Life was to expand interest in ALS research. One measure of success is the level of NIH funding for ALS related research. The number of NIH grants in the RePORTER database of awards, using the search term “amyotrophic lateral sclerosis,” was 870, for the six-year period, fiscal year 2001 through fiscal year 2006. In the six years following the announcement of the ALS Biomarker prize (fy 2007 to fy 2012), there were 1,957, an increase of 125 percent. For the total project funding, the sums are \$278 million in the six years before, and \$700 million for the six years after, an increase of 152 percent. While not all of the grants were focused exclusively on ALS research, the sharp increase in projects mentioning ALS suggests innovation prizes can attract the attention of researchers, and grant money.

NIH grants using search term ““amyotrophic lateral sclerosis”, in RePORTER database, searched March 7, 2014.

Sub Project Funding	Sub Projects	Total Funding	Projects	Fiscal Year
\$5,059,686	31	\$24,931,857	94	2000
\$3,051,367	19	\$29,838,954	115	2001
\$5,215,044	28	\$38,904,848	125	2002
\$1,464,967	7	\$46,890,982	154	2003
\$1,181,993	30	\$54,770,702	172	2004
\$2,410,069	22	\$50,635,174	150	2005
\$4,369,863	43	\$56,642,882	154	2006
\$11,727,797	98	\$101,668,484	279	2007
\$8,916,317	72	\$124,061,430	314	2008
\$9,508,932	48	\$118,764,540	324	2009
\$8,835,106	43	\$119,900,976	335	2010

⁸⁸ Prize4Life Announces \$50,000 ALS Prediction Prize Winners, InnoCentive Press Release, November 13, 2012.

⁸⁹ The DREAM-Phil Bowen ALS Prediction Prize4Life Challenge. Challenge ID: 9933047.

\$7,644,914	40	\$111,296,076	342	2011
\$10,466,360	32	\$124,446,452	363	2012
\$9,131,999	33	\$107,077,295	349	2013
\$1,470,770	5	\$25,235,405	85	2014

The 2013 NHS Innovation Challenge Prizes

180. The UK's National Health Service (NHS) is currently managing a larger number of "Innovation Challenges." The NHS prizes are an example of a "needs driven" innovation program, and typically focus on measures that improve health outcomes and lower NHS costs. Like the EU vaccine prize, the UK limits the competition to UK residents.

181. The following examples are challenges closed in 2013.

Better management of pregnancy

Achieve a 10% reduction in numbers of pre-term births through the better management of risks.

Medicines – reducing waste, increasing benefits

To reduce avoidable medicines waste by 50% and increase adherence to high cost and critical medicines regimens by 30%.

Control of Infection

A Reduction of MSSA (Methicillin-sensitive staphylococcus aureus) and/or E.COLI Bacteraemias across a health economy by 30%.

Earlier cancer diagnosis

Achieve a step change in the proportion of patients diagnosed with cancer at stages 1 and 2 rather than at the later stages (3 and 4).

Receiving emergency care in the right place, first time

To increase the number of people who receive emergency care in the right place and complete their care in the first location.

Reducing avoidable attendances in primary care

Reducing avoidable attendances occurring in a primary care setting (GP, Dentists, Pharmacists, AHP or Optician) by 20% with no reduction in the care and quality of the service.

Improved diagnostic investigation

Introduce innovative redesign of services coupled with newer uses of technology to enable the right diagnostics to be performed first time and be acted upon faster to: improve patient pathways, experience and outcomes; reduce diagnostic turnaround times to action by at least 50% or reduce inappropriate demand by at least 20% and/or enable at least 25% of appropriate tests to be provided in the community or by direct access.

Identification and diagnosis of Chronic and Obstructive Pulmonary Disease (OPD)

Use newer technology and other innovations to redesign services: to improve identification and diagnosis of the disease by 25% and reduce the current misdiagnosis level to below the current 30% and/or reduce admissions and readmissions by 33%.

Reducing Falls and falls injuries

Use collaborative approaches to achieve, for residents in Long-Term Care Settings, at least a 20% reduction in each of the following five measures: falls; falls Injuries; falls-related hospital admissions; falls-related ambulance call outs; and the number of fallers who have a subsequent fall within 12 months.

EARLY ARCHITECTURAL PRIZES

182. Prizes were frequently used in connection with innovative architecture designs and construction technologies. Thiru Balasubramaniam describes two competitions from the 15th century.

The Baptistery of San Giovanni Competition

In 1401, the Arte di Calimala (Guild of Cloth Merchants) of Florence commissioned the first architecture prize in Renaissance Italy for the design of bronze doors for the Baptistery of San Giovanni. Seven Tuscan goldsmiths and sculptors including Filippo Brunelleschi, Lorenzo Ghiberti, Jacopo della Quercia, Simone da Colle, Niccolò d'Arezzo, Niccolò di Pietro Lamberti, and Francesco di Valdambino vied for contention.⁹⁰ The jury narrowed the finalists to Brunelleschi and Ghiberti. Ghiberti pursued an open approach and solicited technical advice from the jury of goldsmiths, sculptors and painters whereas Brunelleschi worked in isolation “always fearful that some unworthy soul would bungle his plans or steal credit for them”.⁹¹ The judges issued a joint commission to both Brunelleschi and Ghiberti. Ultimately, the commission fell to Ghiberti because Brunelleschi withdrew his name from consideration. The Arte di Calimala awarded Ghiberti a salary of 200 gold florins per year for his work on the bronze doors, a commission that lasted 21 years.⁹² This 1401 competition spurred a bitter rivalry between Brunelleschi and Ghiberti, which spilled over into the Florence Cathedral Prize.

The Basilica di Santa Maria del Fiore (Florence Cathedral) Prize

In 1418, the Arte della Lana (Guild of Wool Merchants) of Florence who administered the Opera del Duomo (the office in charge of cathedral works) announced a competition for the design of a dome to vault the cathedral of Santa Maria del Fiore according to the following specifications:

“Whoever desires to make any model or design for the vaulting of the main Dome of the Cathedral under construction by the Opera del Duomo - for armature, scaffold or other thing, or any lifting device pertaining to the construction and perfection of said cupola or

⁹⁰. Leader Scott, Ghiberti and Donatello with Other Early Italian Sculptors, Sampson Low, Marston, Searle & Rivington, 1882.

⁹¹. Ross King, Brunelleschi's Dome, Bloomsbury, 2000.

⁹². Leader Scott, Ghiberti and Donatello with Other Early Italian Sculptors, Sampson Low, Marston, Searle & Rivington, 1882.

vault- shall do so before the end of the month of September. If the model be used shall be entitled to a payment of 200 gold Florins.”⁹³

As in the case of the bronze doors of the Baptistery of San Giovanni, the finalists for this competition were the two goldsmiths, Filippo Brunelleschi and Lorenzo Ghiberti. The Arte della Lana rejected the ultramontane, Gothic influence of flying buttresses favored by the French and the Milanese, thus creating a design challenge for vaulting the Dome. Although the Florentine jury granted a joint commission to Brunelleschi and Ghiberti, Brunelleschi's plans, inspired by Roman architectural techniques used in the construction of the Pantheon, were ultimately selected as the basis for the building of the dome.⁹⁴ Brunelleschi's dome, upon completion, had a diameter of 46 meters and a height of 114.5 meters.⁹⁵ Since flying buttresses were forbidden, the technical challenge for Brunelleschi was to build a dome that would not collapse under its own weight.

The Florentine cathedral prize spurred Brunelleschi to solve this problem without the use of external scaffolding, centering or buttresses thus saving on cost and labor, as scaffolding required a not insignificant amount of imported timber.⁹⁶ One engineering marvel invented by Brunelleschi during the construction of the dome of Santa Maria del Fiore was the three-speed ox-hoist with a reversible gear. This ox-hoist enabled the transport of 70 million pounds of material.⁹⁷ The reversible gear permitted the loading of materials without having to unyoke the oxen and have them walk counter-clockwise. Although Brunelleschi's design for the cupola of Santa Maria del Fiore was the basis for the dome, the Opera del Duomo did not award the prize money of 200 gold florins to Brunelleschi as promised. However, his invention of the reversible ox-hoist was considered such a feat of engineering that the Opera del Duomo did award Brunelleschi 100 gold florins “for his ingenuousness and labors in connection with the device newly invented by him for hoisting which is more useful than the one previously employed.”⁹⁸ For all the power and ingenuity of Brunelleschi's reversible gear ox-hoist, it could not shift beams “infinitesimal distances in any direction-up, down, or sideways” so a new machine therefore was “required so they could be laid in place with pinpoint accuracy.”⁹⁹ Consequently, In 1423, the Duomo announced a new competition for a machine that solves this problem. As in the case of the ox-hoist, Brunelleschi's design for a castello (a crane capable of moving materials laterally and vertically) proved to be the winning entry.

Even though Brunelleschi did not receive the promised reward of 200 gold florins for his winning design for vaulting the dome of Santa Maria del Fiore, the prize did serve as an incentive for the successful completion of an architectural challenge that spurred follow-on

⁹³ Ross King, *Brunelleschi's Dome*, Bloomsbury, 2000.

⁹⁴ Howard Saalman, *Filippo Brunelleschi: The Cupola of Santa Maria del Fiore*, London: A. Zwemmer Ltd., 1980.

⁹⁵ <http://en.firenze-online.com/visit/informations-florence.php?id=2>

⁹⁶ Rachel Slavinsky, *Filippo Brunelleschi and the Creation of Il Duomo*, The University of Tampa Journal of Art History, Vol 1, Yr 2006. Slavinsky notes,

⁹⁷ Ross King, *Brunelleschi's Dome*, Bloomsbury, 2000. One notable exception to Brunelleschi's good fortune was his design for the transport ship, *Il Badalone* (The Monster). In 1421, the Florentine Republic granted him the world's first patent, a three-year monopoly for a “kind of ship, by means of which he thinks he can easily, at any time, bring in any merchandise and load on the river Arno and on any other river or water, for less money than usual.” Seven years after the grant of this exclusive monopoly, Brunelleschi's monster ship embarked on her maiden voyage from Pisa with 100 tons of white marble and capsized on the Arno. This did not mark an auspicious beginning for the modern patent system.

⁹⁸ *Ibid.*

⁹⁹ *Ibid.*

innovation including the invention of machines such as the reversible gear ox-hoist, the castello and the winning design for wooden and stone chains to undergird the cupola (a prize also worth 100 gold florins). Brunelleschi's success in these related competitions resulted in a tripling of his salary for his work on the dome.

TEXTILES

The Lyon Prize Fund to Foster Local Silk Industry

183. In 1711, the city of Lyon created a prize fund based on taxes levied on foreign silk in order to foster innovation in the local silk industry.¹⁰⁰ Referred to as the *Caisse du droit des étoffes étrangères*, the prize fund lasted for several decades during which Lyon was the center of extraordinary innovation. The administration of the prize fund was a collaborative between academic and municipal institutions including the Académie de Lyon, the provost of merchants and the guild inspectors. As observed by Foray and Perez, the Lyon silk prize fund:

“was a model and a kind of laboratory for the enlightened government as it was based on a dynamic relationship between patrimonial ideals and emulation, and it actually enhanced social networks and cohesion.”¹⁰¹

184. In the Lyon model, innovators were rewarded for disclosing new technologies and training Lyon artisans, an approach noted for its focus on knowledge diffusion and technology transfer. The prize valuations were based on an analysis of the impact of the innovations on the profits from the silk trade. For example, in 1760, Ringuet submitted a new design for a loom for brocades which imitated paintings and embroider. For this innovation, the administrators of the Lyon prize fund granted him a bonus of 300 pounds for the first 10 looms he created, 200 pounds for the next 10 looms and 100 pounds for a third set of silk looms Ringuet set up in Lyon. With robust and sustainable funding from the tax on raw silk:

“inventors were rewarded not only for the invention, but also for providing technical know-how in using the inventions, often through payments for each artisan that was trained in a new method. Follow-on inventions were encouraged and rewarded. The system of rewards, which was in place for many decades, was highly sophisticated, and involved independent assessments of the practical value of the inventions, involving both expert advice and empirical evidence of the value of the innovation in commerce, and as well as methods of resolving disputes over the amount of awards.”¹⁰²

A Privilege Fund to Support Knowledge of Windmill Technology Diffusion: The Venetian Privilege Fund (1332)

185. By the early 14th century, Venice had established a privilege fund to reward those who diffused knowledge of windmill technology in Venice.¹⁰³ In 1332, Bartolomeo Verde, received

¹⁰⁰ Dominique Foray and Liliane Hilaire Perez 'The economics of open technology and collective organisation and individual claims in the fabrique lyonnaise' during the old regime," included in *New Frontiers in*

¹⁰⁰ *The Economics of Innovation And New Technology: Essays in Honour of Paul A. David*, Edited by Cristiano Antonelli, Dominique Foray, Bronwyn Hall, and W. Edward Steinmueller, May 2000.

¹⁰¹ Ibid.

¹⁰² Knowledge Ecology International, Selected Innovation Prizes and Reward Programs, *KEI Research Note 2008:1*, March 7, 2008. http://keionline.org/misc-docs/research_notes/kei_rn_2008_1.pdf

¹⁰³ Paul David, The Evolution of Intellectual Property Institutions and the Panda's Thumb, Prepared for a presentation of the International Economic Association of Moscow, 24-28 August 1992.

payment in agreement for erecting a windmill within 6 months of the payment. As observed by Prager:

“Verde was not necessarily the first inventor of this kind of mills. He was probably the only one who knew how to build them, and the government hoped to spread and promote this knowledge. Payments of the same kind were repeatedly made in the fifteenth century, to persons claiming knowledge of either established or new systems of millwork; the same as to designers of new or improved types of ships, and probably to many others...Such financial aid was one of the early forms of recognition for new arts. Under the guild system, all such recognition was different, and in some respects had to be different from what it is in a free economy. Whoever proposed new technology needed, in the first place, especially created power or license to infringe existing guild monopolies by making, selling or using the new invention. Such specially created rights were called privileges. They were not, originally, exclusive rights.”¹⁰⁴

PLASTICS

The 1863 Billiard Ball Prize, and the development of the modern plastics industry

186. In the 19th Century, billiards was becoming more popular, but the rising cost of ivory billiard balls, made out of increasingly scarce elephant tusks more than 2-7/16 inches in diameter, was threatening to slow the growth of the entire billiards industry.¹⁰⁵ In 1863, the Albany-based firm Phelan & Collander, the leading U.S. billiard supply company, offered a \$10,000 prize for the inventor of a suitable substitute for the ivory used in billiard balls. The prize motivated John W. Hyatt to search for such an invention. His first of several patents was obtained in 1865,¹⁰⁶ and he worked several more years to improve the design. In 1872, the *New York Times* reported that the new “composition” billiard balls manufactured by the Hyatt Billiard Ball Company had many advantages, and were selling well, at about half the price of ivory balls.¹⁰⁷ Hyatt would call his invention celluloid, a product that would later have a plethora of other applications, and represented a key event in the development of the modern plastics industry.¹⁰⁸ It is unclear whether or not Hyatt ever received the \$10,000 cash prize, and while the prize undoubtedly stimulated the inventive activity, the purse may have later been perceived as a lesser benefit than the patents on the invention.

¹⁰⁴ Prager, Frank (1944), "A History of Intellectual Property from 1545 to 1787," *Journal of the Patent Office Society*, vol. 26 (November), pp. 711-760.

¹⁰⁵ John Frederick Walker, *Ivory's Ghosts: The White Gold of History and the Fate of Elephants*, *Atlantic Monthly Press*, January 6, 2009.

¹⁰⁶ US Letters Patent No. 50,359, dated October 10, 1865.

¹⁰⁷ “Our State Institutions. The Manufacturers of Albany.” *The New York Times*. January 19, 1872.

¹⁰⁸ “Will Honor J.W. Hyatt. Chemist will confer a medal for fifty years of work,” *the New York Times*. January 19, 1914; Edwin E. Slosson, *Creative Chemistry: Descriptive of Recent Achievements in the Chemical Industries*. The Century Co., 1919, page 129;

AGRICULTURAL AND FOOD

Food Related Prizes to Feed a Growing Population in France

187. In the 18th and 19th centuries, France sought a wide range of new technologies in agriculture to combat food shortages, supply an ever-growing population, and address the food needs of a traveling military. For example, following the famine of 1769, the French Provincial Académie de Besançon sponsored a prize in 1771 to discover the optimal vegetable for times of famine. As a result, the potato, which at the time was largely unknown and unused in France, was discovered to be a significant source of nourishment. Antoine Parmentier won the prize in 1773 for his investigation of the nutritional value of starches.¹⁰⁹ Napoleon was a great supporter of the role of entrepreneurial approaches to innovation in technology and sciences. Around the turn of the 19th century, Napoleon created a series of prizes concerning food and agricultural technology, largely as it related to supplying troops whilst engaging in extended military campaigns. To that end, the Society for the Encouragement of Industry offered a 12,000 franc prize to enhance the preservation of food. This method would be instrumental for Napoleon's army, who sought to better feed his troops when an invaded country was not able or inclined to provide food. The prize was won in 1809 by Nicolas Francois Appert whose method of heating, boiling, and sealing food in airtight glass jars would become the standard for long-term food preservation, and is in fact largely the same processed used by canneries today.¹¹⁰

Prize for source of fertilizer less expensive than guano

188. In the mid 1850s, bat guano imported from Peru was found to be a highly effective and popular means of fertilizing crops in the United Kingdom. In light of this fact, demand for the imported substance was high, and the price had risen to an untenable level for UK domestic farmers. As a result, the Royal Agricultural Society of England offered a prize for the discovery of a manure equal in fertilizing properties to Peruvian guano. The criteria of the 1,000 pound prize stipulated that the guano substitute be available in an unlimited supply to English farmers at a rate not exceeding 5 pounds per ton.¹¹¹ This prize is an example of a national government offering a prize to overcome a perceived market failure and to promote a national economic interest.

Agricultural Prizes to Promote Nation-Specific Solutions: Burkina Faso Innovation Prizes (1994)

189. In order to promote the innovation of solutions to agricultural challenges faced in Burkina Faso, the "Forum National de la Recherche Scientifique et des Innovations Technologiques" (which includes the Ministries of Trade and Commerce, and Education) was established in 1994. The Forum managed innovation prizes, most of which were related to agricultural. Among the 2006 prizes offered was the Prix du Directeur Général du CIRDES for innovations in water management relating to raising cattle. The prize was won by M. Zongo Boubacar for his invention of a bike pedal-driven turbine to power a water pump. Another prize awarded by the

¹⁰⁹ "Took Potato to France: Antoine Parmentier's Service to be Recognized by French Farmers," New York Times, December 14, 1913; J.H. Gilbert, "The Potato, The Science of Potato Growing," Reprinted from the Agricultural Student's Gazette, Cirencester, included in the Dublin Review, 1890, page 84; William Stuart, The Potato: Its Culture, Uses, History and Classification, J. B. Lippincott Company, 1927; Kenneth J. Carpenter, Protein and Energy: A Study of Changing Ideas in Nutrition, Cambridge University Press, 1994.

¹¹⁰ Nicholas Appert, In The Art of Preserving All Kinds of Animals and Vegetable Substances for Several Years: A Work Published By Order of The French Minister of the Interior, on the Report of the Board of Arts and Manufacture, Published in 1811, s. n. p.

¹¹¹ The Cultivator, a Monthly Journal Devoted to Agriculture, Horticulture, Floriculture and to Domestic Rural Economy, 1852. page 355.

Forum in 1996 went to Dr. Sie Moussa for nine new rice varieties, as the best product to fight poverty.¹¹²

Australian Department of Agriculture, Fisheries, and Forestry (DAFF) Science and Innovation Awards for Young People in Agriculture, Fisheries, and Forestry

190. Since 2000, the Australian Department of Agriculture, Fisheries, and Forestry (DAFF) has offered Science and Innovation Awards for Young People in Agriculture, Fisheries, and Forestry. The awards were established in order to foster and support young Australians that are working on science and technology innovations that will have long-term benefits for Australia's rural industries.¹¹³ The categories of research projects vary annually, but in the past have included Australian Animal Welfare Strategy, Cotton Research and Development Corporation, Meat and Livestock Australia Award, and Sugar Research and Development Corporation. The competition is open to Australians age 18-35 and winners receive funding for continuing research projects, industry visits, further study, or attending conferences. Winning research projects earn approximately \$20,000 in funding, and the overall winner of the Minister's Award is given an extra \$31,000 in funding.¹¹⁴ The 2013 Minister's Award was awarded to Dr. Zhong-Hua Chen for his project, "Functional analysis of stomatal movement genes for barley salt tolerance: connecting gene to yield performance in saline soil."¹¹⁵

Annual Agri-Food Innovation Prizes to Encourage Canadian Rural Communities and Agricultural Industries

191. Beginning in 2007, the Ontario Ministry of Agriculture and Food has held the Premier's Award for Agri-Food Innovation Excellence program which seeks to encourage the development of Canadian rural communities and agricultural industries through innovations that expand products, services, and technologies. The program is open to farmers, primary producers, processors, and agri-food related organizations. In the past examples of innovation areas have included improved business practices, environmental stewardship, food safety and traceability, and energy and bio-economy. Forty-five recipients are awarded Regional Awards which include a plaque, woodmark, gate sign, and \$5,000. Three higher levels of prizes are awarded, the Leaders in Innovation Awards (\$25,000), the Minister's Award (\$50,000), and the Premier's Award (\$75,000). The 2011 Premier Award winner, P.R. Short and Son fruit grower, designed a better basket for the tender fruit industry that would keep fruit fresher longer and would greatly reduce damage from transport.¹¹⁶ The 2010 Minister's Award was given to Duizer Farms, for a new dairy barn design that makes it possible for a single milk producer to manage a milking herd of up to 120 cows. Since its inception, the Premier's Award for Agri-Food Innovation Excellence program has garnered more than 1,000 applications.

¹¹² Centre National de Recherche Scientifique et Technologique. "Forum national de la Recherche Scientifique et des Innovations Technologiques (FRSIT): Historique." Last updated 2011. <http://www.cnrst.bf/spip.php?article45>. Accessed 20 Sept 2013.

¹¹³ Brand Tasmania Newsletter. "Awards for Young Scientists." Issue 66, Nov 2006. <http://www.brandtasmania.com/newsletter.php?ACT=story&issue=66&story=4> Accessed 18 Sept 2013.

¹¹⁴ Agrifood Skills Australia. "Awards and Prizes." Last updated 2011. <http://www.agrifoodskills.net.au/page/awards>. Accessed 18 Sept 2013.

¹¹⁵ Australian Government, Department of Agriculture. "2013 Science and Innovation Awards." Last updated 07 March 2013. <http://www.daff.gov.au/abares/conferences-events/scienceawards>. Accessed 18 Sept 2013.

¹¹⁶ Ontario Ministry of Agriculture and Food. "Premier's Award for AgriFood Innovation Excellence 2011." Last updated 09 Oct 2012. http://www.omafr.gov.on.ca/english/premier_award/2011/winners/premier.htm. Accessed 18 Sept 2013.

20TH AND 21TH CENTURY AERONAUTICS PRIZES

192. In the early 20th century, a handful of prizes were offered for the development and piloting of airplanes that could meet increasingly ambitious flight goals. In 1900, the Deutsch Prize of 100,000 francs was offered by Henry Deutsch de la Meurthe for the development of an airship that could fly an 11km course around the Eiffel tower in under 30 minutes. Alberto Santos-Dumont was awarded the prize, which the Brazilian government matched, despite exceeding the time limit by 40 seconds.¹¹⁷ Other early aviation prizes offered include the Scientific American Prize (1908), which awarded \$2,500 to Glenn Curtis for being the first person to publicly fly an airplane in America for 1 kilometer, and the Daily Mail Trans-Atlantic Prize (1913), which offered 10,000 British pounds for

the first pilot to traverse the Atlantic within 72 hours. The Daily Mail Prize was awarded to John Alcock and Arthur Whitten Brown after World War I in 1919.¹¹⁸ More recent prizes regarding innovation in space technology follow below.

193. NASA Space Act Awards (1958): In 1958, NASA established the Inventions and Contributions Board. This board was given the authority to make awards for technological developments in aeronautics that contribute towards NASA's goals. At the outset, it was authorized to offer Space Act Awards of up to \$100,000. The program is still ongoing and has awarded dozens of prizes.¹¹⁹

194. Ansari X-Prize (1995): The first X-Prize was sponsored by the Ansari family in 1995 and was modeled after the Orteig Prize of 1927 won by Charles Lindbergh. The X-Prize offered \$10 million to the first private team to successfully build and launch a spacecraft capable of carrying three people to an altitude of 100 kilometers two times in two weeks. In 2004, the Scaled Composites team, led by aerospace engineer Burt Rutan and financier Paul Allen, successfully completed the mission and was awarded the Ansari X-Prize for their spacecraft SpaceShipOne.¹²⁰

195. Google Lunar XPRIZE (2007): In 2007, Google announced the Google Lunar XPRIZE, the largest international incentive based prize of at the time. The prize seeks to build upon the private space industry developments spurred on by the Ansari X-Prize. In order to win the \$40 million offered in prize money, a private company must successfully land on the surface of the moon, travel 500 meters across the surface and send back two live "mooncasts" to Earth. Additionally, there are bonus prizes offered for extra achievements such as exploring lunar artifacts and surviving the lunar night.

The Google Lunar XPRIZE is currently ongoing and must be completed by December 31, 2015.¹²¹

¹¹⁷ Knowledge Ecology International, 2008, pg. 11.

¹¹⁸ Knowledge Ecology International, 2008, pg. 12.

¹¹⁹ NASA. "NASA Technology Awards and Incentives." Last updated 20 Nov 2012.

http://techtransfer.gsfc.nasa.gov/awards_info_nasa.shtml#spaceact. Accessed 19 Sept 2013.

¹²⁰ X-Prize Foundation. "Ansari X-Prize." Last updated 2011. <http://space.xprize.org/ansari-x-prize>. Accessed 19 Sept 2013.

¹²¹ Google Lunar XPRIZE. "Prize Details." Last updated 2013. <http://www.googlelunarxprize.org/prize-details>. Accessed 19 Sept 2013.

PRIZES WITH ENVIRONMENTAL EFFECTS

Premium for the Prevention of Smoke (1855)

196. In a conscientious early example of an environmental prize, the Steam-Coal Collieries' Association at Newcastle offered a reward in 1855 for the invention of a method to prevent the emission of smoke from the chimneys of boilers. The Association outlined several technological stipulations for the winning invention including that it should not diminish the durability or evaporating power of the boiler. The reward offered was 500 pounds and was won by Mr. Charles Wye Williams for his, "Essay on the Prevention of the Smoke Nuisance."¹²²

Grainger Challenges (2005)

197. In 2005, the US National Academy of Engineering announced its first competition in a planned series of Grainger Challenges for the development of a filtration device that was both economical and could remove arsenic from well water in developing countries. The Academy offered prizes of \$1 million for first place, \$200k for second place, and \$100k for third place. The winner was announced in 2007 as Abul Hussan for his SONO filter. Hussan's water filtration system has already been implemented widely to provide clean drinking water for people in developing countries.¹²³

Unlock the Value Mining Prize (2007)

198. A Canadian mining company, Barrick Gold Corporation, announced a prize in 2007 intended to increase the silver yield for their Velado mine in Argentina. The Barrick Corporation sought an economically viable way to recover silver from silica-encapsulated ore. After reviewing proposals, if an idea was judged to have merit, Barrick would fund the research, pay consulting fees, provide resources, expertise, and help test the proposal. In addition to those terms, if the proposal proved to be successful, the winning proposal would be awarded an extra \$10 million. Although numerous teams had advanced in the process (winning \$25,000 and further research funding), as of 2010 no team had won the overall \$10 million prize.¹²⁴¹²⁵

Prize for Innovation in Clean Energy Technologies for the Future, the General Electric Ecomagination Challenge (2010, 2011)

199. In 2010 and 2011, General Electric conducted two open call challenges as a part of GE's push to innovate clean energy technologies for the future. The 2010 competition was titled ecomagination Challenge: Powering the Grid and sought breakthroughs on developing a cleaner, more efficient grid, while the 2011 competition titled ecomagination Challenge: Powering your Home was geared towards generating innovative ideas for home energy creation, management, and use.¹²⁶ Selected challenge entrants were offered the opportunity to develop a commercial relationship with GE which consisted of evaluation of their business strategy with GE technical and commercial teams, development and distribution of their innovation through GE's infrastructure and partnerships, growth through existing GE customer

¹²² The Mechanics' Magazine, January 1st - June 30th, 1855, Edited by R.A. Brooman, Vol. LXII. London: Robertson, Brooman and Company, 1855, page 464.

¹²³ Weiss, R. "GMU Teacher's Ingenuity Nets \$1 Million Prize." *Washington Post*, Feb. 2, 2007.

¹²⁴ Barrick Corporation. "Barrick Advances Nine Teams in Unlock the Value Research Program." Last updated 2008. [http://www.barrick.com/investors/news/news-](http://www.barrick.com/investors/news/news-details/2008/BarrickAdvancesNineTeamsinUnlocktheValueResearchProgram/default.aspx)

[details/2008/BarrickAdvancesNineTeamsinUnlocktheValueResearchProgram/default.aspx](http://www.barrick.com/investors/news/news-details/2008/BarrickAdvancesNineTeamsinUnlocktheValueResearchProgram/default.aspx). Accessed 19 Sept 2013.

¹²⁵ Nobel, Carmen. "Barrick Gold offers \$10 million Silver Prize." *The Street*. 12 May 2010.

¹²⁶ GE: ecomagination Challenge. "How It Works." Last updated 2013.

<http://challenge.ecomagination.com/ct/b.bix?c=home>. Accessed 19 Sept 2013.

relationship, and a pledge of \$200 million in capital from GE and its partners. Submissions were assessed by both an evaluation committee consisting of representatives from GE and its investment partners as well as an ecomagination Challenge panel of judges consisting of business and energy technology experts. One example of a winning innovation from the 2010 competition was Winflex, which produces rotors for wind turbines from light, flexible, and inexpensive cloth sheets which reduces installation costs by 50% and shortens the return on investment to 3-4 years without subsidies.¹²⁷ From the 2011 Challenge, one of the winning innovations was from Pythagoras Solar, which developed solar window technology that is energy efficient, generates solar energy, and does not sacrifice the appearance of a traditional window.

MISCELLANEOUS PRIZES

Prize for Best Software to Predict Film Ratings by Users, the Netflix Prize (2009)

200. In 2009, Netflix, an online DVD-rental and streaming service, held an open competition to innovate the best collaborative filtering algorithm. The algorithm was needed to predict user ratings for films, based on previous ratings of other films without any identifying information about the users, in order to better tailor movie and show recommendations to its users. The winning team, BellKor's Pragmatic Chaos, bested Netflix's own previous work on the algorithm with a 10.06% improvement in results. BellKor's Pragmatic Chaos earned a prize of \$1 million, and in accordance with the rules, prepared three papers concerning the system descriptions that are available to the public.¹²⁸ In 2010, a second Netflix Prize competition was announced, but after the Federal Trade Commission raised questions about user privacy and a lawsuit was filed regarding the use of Netflix data in research programs, Netflix decided not to pursue a second prize competition.¹²⁹

Public Competition for Ideas and Software Apps to Improve the Lives of Citizens, Businesses and Tourists in Rio de Janeiro: Rio Ideias and RioApps (2013)

201. The city government of Rio de Janeiro has launched a public competition to create software applications that improve the city and the lives of its residents, businesses, and tourists. The city's Department of Science and Technology initiated the two-part competition which consists of Rio Ideias and RioApps. Rio Ideias invited citizens to submit proposals of ideas that could be turned into apps to benefit the city. The best 30 ideas, chosen through a combination of a public vote and a jury, received cash prizes of approximately \$400. The ideas chosen spanned fifteen categories including health, education, social development, tourism, and culture, and were then moved on to the next stage of the competition RioApps (which is currently ongoing). The RioApps stage invites independent developers and IT firms to create and submit applications that address the previously selected Rio Ideias proposals. Winning applications will receive cash prizes between about \$2,000 and \$12,250. Applications can be designed for the Internet, PC, mobile devices, or other software platforms available to the public. A jury of Rio de Janeiro city government officials and Brazilian business and technology experts choose winning applications.¹³⁰

¹²⁷ GE: ecomagination Challenge. "The Winning Partners." Last updated 2013. <http://challenge.ecomagination.com/ct/e.bix?c=ideas>. Accessed 19 Sept 2013.

¹²⁸ Netflix Prize Forum. Last updated 21 Sept 2009. <http://www.netflixprize.com/community/viewtopic.php?id=1537>. Accessed 19 Sept 2013.

¹²⁹ Netflix Blog. "Netflix Prize Update." Last updated 12 March 2010. <http://blog.netflix.com/2010/03/this-is-neil-hunt-chief-product-officer.html>. Accessed 19 Sept 2013.

¹³⁰ Rio Prefeitura. "The Challenge." Rio Apps. <http://rioapps.com.br/> Accessed 19 Sept 2013; Mari, Angelica. "Rio de Janeiro launches competition to foster software innovation." ZDNet. 21 Aug 2013.

INNOCENTIVE MANAGED PRIZES

202. InnoCentive, a firm that was originally part of Eli Lilly, the pharmaceutical company, has managed more than 1,600 prize contests. Originally the prize competitions were primarily designed to address specific innovation problems that various pharmaceutical and other life science and manufacturing firms were trying to solve. Later InnoCentive developed a number of clients in the non-profit, foundation and government sectors.

203. Most of the InnoCentive contests involve fairly modest sums, ranging from a few hundred dollars to several thousand. A few prizes have have \$1 million rewards. Governments or non-profit entities generally sponsor the larger prizes.

204. In recent years InnoCentive has created a number of “Pavilions’ to market prizes, with a variety of partnerships or themes, including publishers such as *Nature* and *the Economist*, and themes such as Developing Country Innovation, the Environment, or Global Public Health. Here are the titles of recent prize contests in a few of the Pavilions.

Nature Innovation Pavilion

- Enhancing Bio-Efficacy of Low Water-Soluble Active Ingredient (AI) for Seed Treatments;
- Solid-waste Management in Humanitarian Response;
- Genmab Challenge: Pioneering Applications for DuoBody Technology;
- EPA ToxCast TM Challenge – Biological and/or Chemical Insights Needed to Revolutionize Screening for Chemical Safety;
- Future Clothes Washing Technology;
- Novel Approaches for Selectively Expressing a Phenotype
- Cleveland Clinic: Improving Endothelial Cell Recovery;
- Home Test for Phenylalanine;
- Identifying Revolutionary Platform Technologies for Advancing Life Sciences Research;
- Cleveland Clinic: Early Detection of Inflammatory Bowel Disease;
- Biomarkers of Treatment Response in Retinal Neovascular Disease;
- Stabilizing Foamed Emulsions;
- Pfizer, Neusentis Challenge: Demonstrating Molecular Engagement with an Ion Channel;
- Endoscopic Biliary Access;
- Estimating Age from DNA;
- Rapid, High Accuracy Weighing of milligram-Scale Powder;

- Mechanisms and Innovative Ideas for Early Detection of Complications Due to Diabetes;
- Cleveland Clinic: Early Warning Indicator for Contamination or Fouling of a Central Venous Catheter;
- SciBX and InnoCentive Challenge: Identifying Questions Surrounding the Endocytic Uptake of Therapeutics;
- Expose Data Relationships Through Visualization of Thomson Reuters Web of Science Content.

The Economist Innovation Pavilion

- The Economist-Lumina Foundation Quantified Work Challenge;
- The Economist-Nielsen Data Visualization Challenge;
- The Economist-InnoCentive Entrepreneurship Challenge;
- The DREAM-Phil Bowen ALS Prediction Prize4Life Challenge;
- Early Diagnostic Tools for Pancreatic Cancer;
- The Economist-InnoCentive Smart Systems Challenge;
- Foundation for Prader-Willi Research;
- London School of Hygiene and Tropical Medicine Challenge: Better Pit Latrines using Black Soldier Fly Larvae;
- Describe Large-Scale Uses for Human-Machine Teamwork;
- The Economist-InnoCentive Transparency;
- InnoCentive 2012 Video Challenge: Unlikely Innovation;
- Systems to Monitor Institutional Corruption;
- Quantitative Model to Aid Strategy Decisions When Applying Open Innovation;
- Medical Device Market Access Models for India;
- A GRI (Glucose Responsive Insulin) for Better Treatment of Type 1 Diabetes;
- The Economist/Qualcomm Challenge: Pictures of Tomorrow;
- Games for Health: Inspiring Adolescents to take Control of their Health;
- The Economist-InnoCentive Human Potential Index Challenge;
- Eliminate Potholes - StreetBump for Boston!;
- Communication Platform to Connect Vulnerable Communities with Climate Change Solutions;

- Educational GUI for Collaborative Problem Solving;
- European Business Model for Customer-Driven Regulated Markets;
- A Communication Platform to engage the “Hidden Community” of Family Caregivers;
- Permanent Bond Between Polyethylene Films;
- Educating About the Importance and Acceptance of Purifying Drinking Water.

Developing Country Innovation Pavilion

- Solid-waste Management in Humanitarian Response;
- Latrine Lighting in Emergencies;
- Highly Efficient Inactivation of Fungal Biomass;
- Afraid to Talk About Death? Solutions to Engage People in Care Planning!;
- Additives that Enable Sustained Release from Polyolefin Substrates;
- Scientists Without Borders and Johnson & Johnson Challenge: Increasing Global Diagnosis and Treatment of Unipolar Depression and Anxiety;
- Medical Device Delivery System to be Used in Rural Areas of Africa;
- Seeking a Mechanism for Secure Communications During a Crisis;
- Vegetarian Gelatin Substitute for Jellies & Marshmallows;
- USAID & Humanity United: How to Identify and Spotlight Intentional and Unintentional Enablers of Mass Atrocities?;
- USAID & Humanity United: A Safe Way to Document and Capture Evidence of an Atrocity;
- Storage Container that Protects Seed and Grain from Rodents;
- Robust Packaging Decoration Process for HDPE Containers;
- Diverse Experts Required: Formulating, Filling & Monitoring;
- More Sustainable Wood-Like Materials;
- London School of Hygiene and Tropical Medicine Challenge: Better Pit Latrines using Black Soldier Fly Larvae;
- Increasing the Affordability of Inactivated Poliovirus Vaccine in Low- and Middle-income Countries;
- Medical Device Market Access Models for India;
- A GRI (Glucose Responsive Insulin) for Better Treatment of Type 1 Diabetes;

- Educating About the Importance and Acceptance of Purifying Drinking Water.

Public Good Pavilion

- USAID & Humanity United: A Safe Way to Document and Capture Evidence of an Atrocity;
- The Future of ICT-Enabled Growth and Jobs in the EU: Current Barriers and How to Overcome Them;
- The Future of ICT-Enabled Growth and Jobs in the EU: Business Model Innovation and Innovative Policies;
- Quantifying the Number of Post-Secondary Certificates and Certifications with Significant Economic Impact;
- Metal Removal from Mine Drainage Water;
- EPA ToxCast TM Challenge – Biological and/or Chemical Insights Needed to Revolutionize Screening for Chemical Safety;
- I'm Sad: Help Me Talk About My Depression;
- Afraid to Talk About Death? Solutions to Engage People in Care Planning!;
- CHALLENGING NUTRIENTS: Transformative Strategies for Reducing Excess Nutrients in Waterways;
- Mechanisms to Enhance Solver Collaboration & Teamwork;
- United Way Challenge: Engaging the Public;
- System for Locating People Using Electricity Dependent Medical Equipment During Public Health Emergencies;
- Show Me The Data!;
- Improving Clarity of College Information Using the "College Scorecard";
- 2013 Innovation in Arms Control Challenge: What Information Technology Tools and Concepts Can Support Future Arms Control Inspections?;
- Mobile and Novel Chemical Warfare Agent Destruction and/or Neutralization;
- Correlations to Determine the Complete Economic Impact of Post-Secondary Education;
- Visualizing the Impact of Significant Increases in Post-Secondary Education;
- Seeking a Mechanism for Secure Communications During a Crisis;
- Support Plate Replacement in Humanitarian Air Drops;
- Treating Orphan Diseases: Repurposing Discontinued Pharmaceuticals;
- Design of Student-centric Websites for Open-Enrollment Colleges and Institutions;

- PXE – Evaluating Hypotheses and Suggesting Experiments for a Rare Disease;
- USAID & Humanity United: How to Identify and Spotlight Intentional and Unintentional Enablers of Mass Atrocities?;
- What Disruptive Innovations Does Pharma Need To Discover Tomorrow's Drugs?

InnoCentive's Intellectual property policies

205. The intellectual property rights are designed by the entity funding the prize (the seeker), often with a focus on preserving the rights of the donor to use the “solutions” proposed, but the diversity of policies on intellectual property is also notable.

206. Here are some examples from recent prize contests:

Real Time Detection of Microbial Contamination in Fluid Streams.

AWARD: \$20,000 USD | STATUS: Under Eval | ACTIVE SOLVERS: 260 | POSTED: 9/12/13

- This is a Theoretical Challenge that requires only a written proposal to be submitted. The Challenge award will be contingent upon theoretical evaluation of the proposal by the Seeker.
- To receive an award, the Solvers will have to transfer to the Seeker their exclusive Intellectual Property (IP) rights to the solution. However, the Seeker will be willing to consider a licensing agreement for a partial award if exclusive IP cannot be transferred by the Solver.

Increasing Patient Centricity of the Pharma Industry.

STATUS: Awarded | ACTIVE SOLVERS: 336 | POSTED: 7/15/13

- This is an Ideation Challenge, which has the following unique features:
- There is a guaranteed award. The awards will be paid to the best submission(s) as solely determined by the Seeker. The total payout will be \$5,000, with at least one award being no smaller than \$3,000 and no award being smaller than \$1,000.
- The Solvers are not required to transfer exclusive intellectual property rights to the Seeker. Rather, by submitting a proposal, the Solvers grants to the Seeker a royalty-free, perpetual, and non-exclusive license to use any information included in this proposal.

My Air, My Health: An HHS/EPA Challenge

STATUS: Awarded | ACTIVE SOLVERS: 503 | POSTED: 6/05/12

- This Challenge is structured in 2 Phases – 4 awards of \$15,000 are available to Phase 1 finalists, and a single award of \$100,000 is available for the winner of Phase 2:
- This is a Theoretical Challenge that requires only a written proposal to be submitted. The Challenge award will be contingent upon theoretical evaluation of the proposal by the Seeker. To receive an award, the Solvers will not have to transfer their exclusive IP rights to the Seeker. Instead, they will grant to the Seeker non-exclusive license to practice their solutions.

Seeking Viridicatin Analogues

AWARD: varies | STATUS: Under Eval | ACTIVE SOLVERS: 57 | POSTED: 11/29/13

- **Intellectual Property:** In return for the Initial Transfer Fee of \$300 per compound, you are expected to grant the Seeker only a non-exclusive license to use your compound for internal, research purposes (for example, researching the molecule's properties or preparing derivatives of the molecule).
- The Challenge Specific Agreement does, however, require that you do not disclose the structures of any molecules requested by the Seeker for a period of 180 days after delivery of the compound(s) to the Seeker. In this time, the Seeker will test your molecule(s) to determine if they desire exclusive rights to the molecule(s), for which they will pay you a second award.

Seeking Inhibitors of the Factor Xa Enzyme (EC 3.4.21.6)

AWARD: varies | STATUS: Under Eval | ACTIVE SOLVERS: 61 | POSTED: 12/02/13

- **Intellectual Property:** In return for the Initial Transfer Fee of \$500 per compound, you are expected to grant the Seeker only a non-exclusive license to test your compound(s) in their in-house assays and/or use the compound(s) to prepare other compounds for in-house testing.
- The Challenge Specific Agreement does, however, require that you do not disclose the structures of any molecules requested by the Seeker for a period of 180 days after delivery of the compound(s) to the Seeker. In this time, the Seeker will test your molecule(s) to determine if they desire exclusive rights to the molecule(s), for which they will pay you a second award.

Konica Minolta Challenge: Disruptive Technologies to Enhance the Way We Do Business

AWARD: \$5,000 USD | DEADLINE: 3/14/14 | ACTIVE SOLVERS: 340 | POSTED: 2/10/14

- This is an Ideation Challenge, which has the following unique features:
- There is a guaranteed award. The award will be paid to the best submission as solely determined by the Seeker. The total payout will be a single award of \$5,000.
- There is a discretionary award. The Seeker may award up to an additional \$5,000 for any solution deemed truly exceptional.
- The Solvers are not required to transfer exclusive intellectual property rights to the Seeker. Rather, by submitting a proposal, the Solvers grants to the Seeker a royalty-free, perpetual, and non-exclusive license to use any information included in this proposal, including for promotional purposes.

ARPA-E Challenge on Optimizing Biofuels: Non-Destructive Energy Measurement of Plants

AWARD: \$30,000 USD | STATUS: Under Eval | ACTIVE SOLVERS: 213 | POSTED: 12/21/13

- This is a Theoretical Challenge that requires only a written proposal to be submitted. The Challenge award will be contingent upon theoretical evaluation of the proposal by the Seeker. To receive an award, Solvers will not be required to transfer their exclusive IP rights to the Seeker. Instead, a Solver will grant to the Seeker a non-exclusive, transferrable (including the right to sub-license) license to practice their solution. The award amount for this Challenge varies from \$5,000 to \$30,000 based on the breadth of compounds the proposed solution can measure.

Pfizer, Neusentis Challenge: Demonstrating Molecular Engagement with an Ion Channel

STATUS: Awarded | ACTIVE SOLVERS: 208 | POSTED: 9/16/13

- This is an Ideation Challenge, which has the following unique features:
- There is a guaranteed award. The awards will be paid to the best submission(s) as solely determined by the Seeker. The total payout will be \$10,000, with at least one award being no smaller than \$5,000 and no award being smaller than \$2,000.
- The Solvers are not required to transfer exclusive intellectual property rights to the Seeker. Rather, by submitting a proposal, the Solvers grants to the Seeker a royalty-free, perpetual, and non-exclusive license to use any information included in this proposal, including for promotional purposes.

GlaxoSmithKline Electroceutical Ideation Challenge

STATUS: Awarded | ACTIVE SOLVERS: 396 | POSTED: 4/11/13

- This is an Ideation Challenge, which has the following unique features:
- There is a guaranteed award. The awards will be paid to the best submission(s) as solely determined by the Seeker. The total payout will be \$5,000, with no award being smaller than \$1,000.
- The Solvers are not required to transfer exclusive intellectual property rights to the Seeker. Rather, by submitting a proposal, the Solvers grants GSK a royalty-free, perpetual, and non-exclusive license to use any information included in this proposal.

Identifying Revolutionary Platform Technologies for Advancing Life Sciences Research

AWARD: \$52,000 USD | STATUS: Under Eval | ACTIVE SOLVERS: 912 | POSTED: 10/11/13

- The Seekers for this Challenge are Burroughs Wellcome Fund, The Gordon and Betty Moore Foundation, The John Templeton Foundation, The Kavli Foundation, Research Corporation for Science Advancement, and W. M. Keck Foundation.
- Intellectual Property – Solvers are not required to transfer exclusive intellectual property rights to the Seekers. Rather, by submitting a proposal, the Solvers grant to the Seekers a royalty-free, perpetual, and non-exclusive license to use the title and a general description of the proposed platform technology, but not the general approach that the Solver proposes for developing the technology. For this Challenge, the Seekers may use submissions in the following ways:
- The Seekers will share Solvers' entire submissions with members of the judging panel, solely for the purpose of determining finalist and awarded submissions.
- The Seekers may choose to follow up directly with a Solver about an idea to encourage its advancement, by requesting the direct submission of a grant application by that Solver.
- Only if explicitly authorized by a Solver, the Seekers may choose to share a Solver's entire submission with other potential funding sources and/or the general public.
- The Seekers may decide to initiate a broader funding call to encourage the advancement of a proposed platform technology submitted by a Solver. The Seekers will

not, however, publicize the details of the Solver's general approach to developing the technology.

INSTINCT: The IARPA Trustworthiness Challenge

AWARD: See details | DEADLINE: 5/05/14 | ACTIVE SOLVERS: 285 | POSTED: 2/19/14

- INSTINCT: Investigating Novel Statistical Techniques to Identify Neurophysiological Correlates of Trustworthiness
- To receive an award, Solvers will be required to grant the United States Government certain rights, detailed in the Challenge Specific Agreement (CSA), for United States Government purposes. Commercial rights will remain the property of the authors/inventors. The United States Government's rights in the Solution IP will not limit the rights of Solvers to use, release, perform display, disclose or publish their submission. However, the Solution IP will remain subject to any other applicable restrictions (e.g., Export Control).

ANNEX C: APPROACHES TO SIMULATING INNOVATION FOR THE DEVELOPMENT OF NEW ANTIBIOTIC DRUGS

Introduction

- (1) R&D Subsidies.
- (2) Policies regarding regulatory barriers for registering products.
- (3) Extending terms for patents and other intellectual property rights
- (4) Innovation inducement prize type incentives to reward innovation and/or conservation

Innovation Inducement Prizes

Antibiotic Conservation and Effectiveness (ACE) program

Strategic Antibiotic Reserve (SAR)

Pricing of antibiotics

Antibiotics Health Impact Fund (aHIF)

Antibiotics Innovation Funding Mechanism (AIFM).

- (5) Other

Pigouvian Taxes

Antibiotic Innovation and Conservation (AIC) fee

Transferable Patent Extensions

Transferable Priority Review Vouchers

Advanced Marketing Commitment (AMC), and Advanced Purchase Commitment (APC)

Call options for antibiotics

INTRODUCTION

"What makes antibiotics unusual is that their very use undermines their future usefulness, as bacteria evolve resistance."¹³¹

1. There are large challenges associated with the development of new antibiotic drugs and diagnostic tests that will reduce their misuse, and in recent years there have been a number of proposals to stimulate innovation for new antibiotic drugs. These can be divided into proposals to (1) increase public sector funding, tax credits and other subsidies of R&D (2) reduce regulatory costs and barriers for registering products (3) extending terms for patents and other intellectual property rights, (4) using innovation inducement prize type incentives to reward innovation, and (5) other.

(1) R&D SUBSIDIES.

2. Recommendations to stimulate the production of new drugs typically include proposals to expand government funding of R&D, as well as the provision of other subsidies, such as special tax deductions or credits, or concessionary financing.

3. Government funding of research and development of new antibiotic drugs and relevant diagnostics, while falling short of what many health experts feel is needed, is important. The US NIH/NIAID has a number of initiatives underway that they describe as "Combating Drug Resistance With Basic Research," which are designed to:

- Develop new insights into the mechanisms of resistance;
- Develop new insights into how pathogens cause disease;
- Investigate the role of host factors;
- Deciphering microbial genomes;
- Develop next generation sequencing technologies; and
- Develop new computer-assisted modeling efforts.

4. NIH/NIAID funding supplements funding by other U.S. government agencies¹³², the European Union,¹³³ and other governments.

In some cases, the public sector funding in the area of antibiotic drugs has a component that is partly designed to enhance the capacity and competitiveness of domestic industries. Examples

¹³¹ Eric Kades, Eric, "Preserving a Precious Resource: Rationalizing the Use of Antibiotics," (2005) 99 Northwestern University Law Review, . 615 2004-2005. Page 626. Available at Faculty Publications. Paper 52. <http://scholarship.law.wm.edu/facpubs/52>. Citing the earlier works by Clem Tisdell, *Exploitation of Techniques That Decline in Effectiveness With Use*, 37 Public Finance /Finances Publique 428 (1982), and Gardner Brown and David Layton, *Resistance Economics: Social Cost and the Evolution of Anti-biotic Resistance*, *Environment and Development Economics*. 349, 354 (1996).

¹³² Including specialized programs relating to public health emergencies and bio-warfare, and the Orphan Drug Tax Credit.

¹³³ Including, for example, the action plan against the rising threats from antimicrobial resistance adopted by the European Commission in answer to the Council Conclusions and European Parliament resolution to "establish an EU-wide plan to combat AMR, the New Drugs for Bad Bugs program."

of this would include the U.S. Biomedical Advanced Research and Development Authority (BARDA)¹³⁴ and the European Union Innovative Medicines Initiative (IMI).

5. Despite the obvious cross-border importance of the development of new antibiotics and relevant diagnostics, the public sector funding of R&D is not currently part of global trade negotiations, other than the restrictions on public sector R&D funding found in the WTO Subsidies and Countervailing Measures (SCM) agreement.¹³⁵

(2) POLICIES REGARDING REGULATORY BARRIERS FOR REGISTERING PRODUCTS.

6. In recent years, the U.S. Congress and the U.S. FDA have taken steps to lower the costs of registering new antibiotic drugs. Title VIII of Food and Drug Administration Safety and Innovation Act (FDASIA), entitled Generating Antibiotic Incentives Now (GAIN), provides that an antibiotic drug may be designated as a qualified infectious disease product (QIDP), and is eligible for fast track designation and priority review, measures which effectively lower the costs of R&D.

7. While beneficial in terms of lowering R&D costs for the QIDP, fast track and priority review status involve a lowering of the standards for establishing the safety and efficacy of new products, increasing the risk of adverse events associated with the use of the drug, and also are associated with a slower approval for the non-antibiotic drugs that do not qualify for fast track or priority review.

(3) EXTENDING TERMS FOR PATENTS AND OTHER INTELLECTUAL PROPERTY RIGHTS

8. There are a number of proposals to extend the duration of exclusive rights in patents, test data, and other types of regulatory or intellectual property rights associated with antibiotic drugs. In 2012, the U.S. Congress enacted "Generating Antibiotic Incentives Now (GAIN)" amendments to the U.S. Food and Drug Administration laws that expanded certain regulatory market monopolies for certain antibiotic drugs.¹³⁶

9. Some would go further. For example, in his 2005 paper,¹³⁷ "Preserving a Precious Resource: Rationalizing the Use of Antibiotics," Eric Kades makes a case for "infinite-term patents on antibiotics." Kades was not only interested in increasing incentives to develop new drugs, he saw the high monopoly price as a useful in order to "prolong the useful life of the drug, and create incentives for drug makers to hold some antibiotics in reserve to meet the extraordinary demand that will arise if and when there is a bacterial plague."

¹³⁴ See, the BARDA Strategic Plan 2011-2016. "Where vaccine and biological therapeutics manufacturing capacity is concerned, BARDA will continue to enter into public-private partnerships with manufacturers to build and/or retrofit medical countermeasure production facilities within the U.S., increasing domestic access to medical countermeasures."

¹³⁵ And similar restrictions within Europe, under Article 107 of the Treaty on the Functioning of the European Union.

¹³⁶ For example, in the US, July 9, 2012. P.L. 112-144, Title VIII—Generating Antibiotic Incentives Now, Sec. 801. Extension Of Exclusivity Period For Drugs.

¹³⁷ Eric Kades, Eric, "Preserving a Precious Resource: Rationalizing the Use of Antibiotics," (2005) 99 Northwestern University Law Review, . 615 2004-2005. Page 626. Available at Faculty Publications. Paper 52. <http://scholarship.law.wm.edu/facpubs/52>. An earlier version of the paper is available as Eric A. Kades, Plagues, Policy, & Patents: Addressing Overuse of Antibiotics, William & Mary Law School Working Paper No. 2003-Kades-1, March 11, 2003.

10. Taken by themselves, the proposals to extend the commercial monopoly for the antibiotic drugs undoubtedly increase investor returns, but not without costs to users, and increases perverse incentives as regards the promotion of use of antibiotic drugs.¹³⁸ In a number of realistic scenarios, an expanded term of the monopoly will extend the period when the drug developer has an economic incentive to promote high utilization of the antibiotic drugs, undermining the longer-term value of the resource.

11. Long product monopolies create incentives to take into consideration the longer-run life cycle value of the antibiotic resource. But offsetting these potentially positive conservation effects are the high private rate of discount used to evaluate future sales, as well as the firm's interest in exploiting the resource before it is removed from the market for safety reasons, or replaced by a better drug.

(4) INNOVATION INDUCEMENT PRIZE TYPE INCENTIVES TO REWARD INNOVATION AND/OR CONSERVATION

12. A variety of proposals have been made to use innovation inducement prizes to stimulate innovation for new antibiotic drugs. Innovation inducement prizes can be implemented in different ways, and this is reflected in the diversity of proposals for such prizes. The most interesting proposals are those that completely de-link the returns to investors from the prices of products, and which effectively eliminate the current incentives to unhelpfully promote the low value uses of the drugs undermining conservation goals.

Innovation Inducement Prizes

13. Among those endorsing a radical delinkage of R&D incentives from product prices is Richard Bergström, currently the Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA).¹³⁹

“Incentives that separate the financial return from the use of a product are the only way to change this behaviour,” said Bergström at a conference held at Uppsala University in September 2010. “Intelligent pull incentives, such as advance commitments and prizes, provide financial rewards to the developer that are not based on the volume of use of the novel antibiotic. With the right set-up, pharma companies will have no incentive to drive use. Maybe they will not do any promotion at all. Use would be agreed with public policy-makers, purchasers and national health systems.”

14. The use of prizes to reward antibiotic drug development has been proposed by a number of authors.¹⁴⁰ In 2012, in a bill regarding the reauthorization of certain FDA programs, the U.S. Senate voted to ask the National Academies to undertake a study of the feasibility, costs and benefits of using innovation inducement prizes to reward the development of new drugs.¹⁴¹ The Infectious Disease Society of America endorsed this study:¹⁴²

¹³⁸ Kevin Outterson, Balch Samora and Keller-Cuda, "Will Longer Antimicrobial Patents Improve Global Public Health? 7 *Lancet Infectious Diseases* 559-66 (2007),, and Kevin Outterson, "All Pain, No GAIN: Need for Prudent Antimicrobial Use Provisions to Complement the GAIN Act," 30 *APUA Clinical Newsletter* 13 (2012). Robert Weissman and Anthony So, "Generating Antibiotic Incentives Now: GAIN -- Or Just Greed," *the Huffington Post*, June 6, 2012. Glyn Moody, How Extending Patent Protection For Antibiotics Creates Perverse Incentives To Render Them Useless. from the monopolizing-ourselves-to-death dept. *TechDirt*. June 29, 2012.

¹³⁹ Quoted in "Race against time to develop new antibiotics," *Bulletin of the World Health Organization* 2011;89:88–89. doi:10.2471/BLT.11.030211/

¹⁴⁰ 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); James Love. "Prizes, not prices, to stimulate antibiotic R&D.," *SciDev.net*. March 26, 2008; Tyler Cowen, To Fight Pandemics, Reward Research, *New York Times*, May 4, 2013; Editorial.

[Footnote continued on next page]

“IDSA also is pleased to support Sec. 906 of the legislation, which calls the National Academies of Science to evaluate the feasibility and possible consequences of the use of innovation inducement prizes to reward successful medical innovations in targeted areas, including antibiotics. IDSA has long held that according to economic modeling a combination of incentives are necessary to spur new antibiotic R&D. Prizes are one potential incentive that could be a useful component of a larger effort to drive innovation. We also suggest requesting NAS experts to consider and make recommendations about formation of public private partnerships to support antibiotic development.”

15. The Senate wanted the National Academies to consider the approaches set out in legislation to create the Medical Innovation Prize Fund [S.627, 113th Congress]. The legislation, introduced by Senator Sanders, would create a system of end product, interim and open source dividend prizes¹⁴³ to reward developers of new prescription drugs and vaccines, as a substitute for the grant of a monopoly.

16. The Sanders legislation was designed to eliminate monopolies on new drugs, and use prizes to induce innovation that was responsive to health needs. Section 9(c) of S.627 sets out the criteria for prize valuation. Two provisions directly and indirectly address the valuation of antibiotic drugs.

(6) In the case of antibiotics or other products for which drug resistance is a significant public health problem, the expected life cycle benefits of the antibiotic or other product, with appropriate adjustments that reward the conservation of the resources, taking into account drug resistance that is related to use of the product.

(7) In the case of products used in stockpiles for potential threats to the public health, the risk adjusted benefits of stockpiling the products.

17. Some academic observers have proposed prize type mechanisms that are not designed to eliminate drug monopolies, or lower drug prices, including several that propose large cash rewards to induce conservation.

Antibiotic Conservation and Effectiveness (ACE) program

18. In 2011, Aaron Kesselheim and Kevin Outterson proposed the creation an Antibiotic Conservation and Effectiveness (ACE) program that would create \$10 billion or more annually in incentives to companies, to stimulate R&D and also reduce consumption of antibiotics in order to achieve conservation objectives. This proposal would effectively bribe drug manufacturers to manage antibiotics more efficiently, using massive “enhanced” reimbursements conditioned on meeting conservation targets. Kesselheim and Outterson see the drug manufacturers as

[Footnote continued from previous page]

Drugs win prizes; New incentives are needed in search for antibiotics. *Financial Times*. June 4, 2012; Anthony D So, Neha Gupta, Otto Cars, Tackling antibiotic resistance. Concerted action is needed to provide new technologies and conserve existing drugs. *BMJ* 2010;340:c2071. doi: 10.1136/bmj.c2071; Time for the EU to lead on innovation: EU policy opportunities in biomedical innovation and the promotion of public knowledge goods. HAI Europe/ TACD Policy Paper, April 2012. Elias Mossialos, Chantal M Morel, Suzanne Edwards, Julia Berenson, Marin Gemmill-Toyama, David Brogan. Policies and incentives for promoting innovation in antibiotic research. World Health Organization 2010, on behalf of the European Observatory on Health Systems and Policies.

¹⁴¹ Kevin Outterson, Antibiotic prize study in PDUFA V reauthorization bill, the *Incidental Economist*, April 24, 2012.

¹⁴² April 24, 2012 letter, Mark A. Leasure, CEO of IDSA to Senators Harkin and Enzi, regarding Prescription Drug User Fee Act (PDUFA) reauthorization legislation..

¹⁴³ James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," *Annals of Health Law*, Vol. 18, No 2, Summer (2009) pages 155-186.

politically active and influential actors that currently are undermining conservation goals, and see the new, more expensive reimbursement policies as the price for harnessing their efforts in a socially responsible manner.¹⁴⁴

formulary restrictions and preauthorization requirements can be effective stewardship tools, but pharmaceutical manufacturers generally disfavor such measures since they dampen demand for their products. These managed-care techniques restrict access to their products through tiered formularies or as part of step therapy.¹⁴¹ The industry has fought these restrictions in many ways, including litigation in the highest courts.¹⁴² Since pharmaceutical companies are such powerful institutional actors, any public health program that faces strident drug company opposition will have difficulty succeeding. Our ACE proposals are designed to align private financial incentives with public health goals in a way that makes the drug companies full partners in antibiotic conservation efforts. . . . Make no mistake: we are proposing a very substantial increase in payments for antibiotics, driven by the social value of these important drugs.”

19. An enhanced reimbursement of \$10 billion annually would indeed be likely to induce socially useful changes in marketing efforts by some companies, in some countries, but it also goes without saying it is both expensive and of limited benefit when and where the products are off patent and use is not controlled by the developer. To appreciate the size of the proposed subsidy, consider some comparisons.

- The fiscal year 2013 budget for the entire U.S. FDA was \$4.031 billion.
- The total cumulative value of the U.S. Orphan Drug Tax Credit subsidy was \$3.03 billion, over its first 25 years.¹⁴⁵

The annual cost is greater than:

- the U.S. PEPFAR program budget, or
- the combined federal outlays on the National Institutes of Cancer and the National Institute of Allergy and Infectious Diseases (NIAID).

Strategic Antibiotic Reserve (SAR)

20. In the same 2011 paper, Kesselheim and Outterson also proposed a separate initiative, a Strategic Antibiotic Reserve (SAR). Comparing it to programs that pay farmers to not grow crops, Kesselheim and Outterson propose that “companies . . . be rewarded today for not selling the antibiotic, preserving a precious resource for dire future needs.” Funded through “supplemental cash prizes for placing important new antibiotics in the Strategic Antibiotic Reserve,” the authors say “These amounts must be quite substantial in order to properly align incentives, ranging towards a billion dollars per year for an important drug class.” Like ACE program, Kesselheim and Outterson would make “the financial arrangement with the company . . . entirely voluntary, based on a contract with the government.” They add, “If a company tried to hold out with a critically important antibiotic . . . the government would retain the ability to use a compulsory license, with payment of just compensation for the taking.”

¹⁴⁴ Aaron S. Kesselheim and Kevin Outterson, *Improving Antibiotic Markets For Long Term Sustainability*, 11 *Yale Journal of Health Policy, Law & Ethics* (Winter 2011)

¹⁴⁵ The total is from 1983 to 2010, and includes the most recent data available from the IRS. The credit was not in effect in 1995-1997.

21. Unclear is for how long such a large subsidy would be paid, given the objective of holding the products off the market for some unforeseen future need, or how the subsidy would work in places and times when patents and other intellectual property rights did not exist.

Pricing of antibiotics

22. In discussing both proposals, Kesselheim and Outterson dismiss concerns over the pricing and affordability of drugs:

“Generic access to cheap antibiotics is not entirely positive for public health, even on a merely static basis. Cheap (or free) antibiotics drive resistance and reinforce the overall low reimbursement levels in this drug class.¹⁴⁶”

23. While Kesselheim and Outterson belittle concerns over the affordability of drugs, citing a study of Wal-Mart’s low cost pricing of generic antibiotics, their proposal for the SAR gives as an example the patented antibiotic daptomycin, which is hardly cheap. In 2009, the Canadian Expert Drug Advisory Committee (CEDAC) recommended that daptomycin (Cubicin) not be listed as reimbursable for the treatment of complicated skin and skin structure infections and *Staphylococcus aureus* bloodstream infections, citing, among other things, its high cost.¹⁴⁷

“The drug cost for daptomycin (Cubicin) is \$165 per day. This is more expensive than other alternative treatments such as vancomycin (\$92.54), cloxacillin (\$0.70-\$14.40) and linezolid (\$141.28). . . . The Canadian Expert Drug Advisory Committee (CEDAC) recommended that daptomycin (Cubicin) not be listed. . . . Executive Officer Decision: Based on the CED’s recommendation, the Executive Office decided not to fund daptomycin (Cubicin). Status: Funding not available through the Ontario Public Drug Programs”

Antibiotics Health Impact Fund (aHIF)

24. In a similar vein, Outterson, Pogge and Hollis have also separately proposed a specialized antibiotics health impact fund that would offer a “completely voluntary . . . alternative revenue stream of up to several billion dollars per drug over the ten-year registration period.”¹⁴⁸ The ability of the aHIF to regulate use is stronger when products are patented and the developer can arguably control use, but patent coverage is normally limited by place and time. Outterson, Pogge and Hollis propose that the control over the drug be enhanced through “an

¹⁴⁶ The article includes a footnote, which refers to the text quoted here:

¹⁴⁶ “Recently, antibiotics have been featured prominently in low-cost generic drug dispensation programs by many national retail pharmacies. For example, Wal-Mart’s low-cost program allows patients to buy 12 different varieties of the antibiotic amoxicillin for \$4 per month. See Wal-Mart \$4 Medication List, <http://www.usatoday.com/money/industries/health/drugs/walmart-druglist.pdf> (last visited September 2, 2009). While such generic drug programs have been rightly extolled for helping promote access and adherence to essential medicines, low-cost antibiotic access has been linked to overuse of these drug, particularly in lower-income settings. Beatriz Espinosa Franco et al., *The Determinants of the Antibiotic Resistance Process*, 2 *INFECT. DRUG RESIST.* 1 (2009). See also Karen Caffarini, *Antibiotic Giveaways Stoke Fear of Patient Pressure*, *AM. MED. NEWS*, Jan. 29, 2009, <http://www.ama-assn.org/amednews/2009/01/26/bisc0128.htm>. For a recent empirical analysis finding increased antibiotic consumption with free programs, see Shanjun Li & Ramanan Laxminarayan, *Are Physicians’ Prescribing Decisions Sensitive to Drug Prices? Evidence from a Free-Antibiotics Program* (2010) www.ssrn.com/abstract=1598804.

¹⁴⁷ Recommendations and Reasons: Daptomycin, Committee to Evaluate Drugs (CED), Ministry of Health and Long-Term Care, November 2009

¹⁴⁸ Kevin Outterson, Thomas Pogge, and Aidan Hollis, “Combating Antibiotic Resistance Through The Health Impact Fund,” chapter in *The Globalization of Health Care*, Oxford University Press (2012).

international agreement not to permit other firms to sell aHIF-rewarded antibiotics, regardless of the patent status,” effectively turning the proposal into a permanent global monopoly with regulated prices and large annual subsidies.

25. In both the ACE and aHIF proposals, Kesselheim, Outterson, Pogge and Hollis recommend antitrust waivers, to permit some level of collaboration among firms in order to achieve conservation objectives.

26. Collectively the ACE, SAR and aHIF proposals provide little support for and indeed, create new barriers to efforts by developing countries to maintain the capacity to manufacture affordable and accessible antibiotics.

Antibiotics Innovation Funding Mechanism (AIFM).

27. In the context of a WHO call from proposals to demonstration new models for R&D that featured open innovation, delinkage of R&D costs from product prices, and innovative and sustainable financing mechanisms, KEI has proposed the creation of the Antibiotics Innovation Funding Mechanism (AIFM).¹⁴⁹ The AIFM is a proposal to impose taxes or user fees on the use of antibiotic drugs, including human and agricultural uses, and use the revenue from the taxes or user fees to finance a system of grants and innovation inducement prizes. Like the current Sanders prize fund legislation, the innovation inducement prizes would include prizes for end products, interim results and an open source dividend.

28. The KEI WHO proposal would use innovation inducement prizes to reward innovation for new antibiotics, but would rely upon regulatory measures to control utilization. These regulatory measures could include regulatory quotas, by geographic area of field of use, decentralized mechanisms to manage quotas, and possible monetization and trading of quota amounts, subject to limits on the transfer of a quota amount from a low income country to a high income country.

29. The various Outterson et al. proposals would use prize type rewards to both stimulate innovation and regulate use, focusing on the role of the drug developer as the global regulator, ultimately with enhanced powers to enter into collusive contracts and extend market exclusivity beyond the scope of current patent law.

30. In the KEI proposed system, the regulatory regime would reinforce the policy of a switch to a delinkage regime, where rewards for innovation are not tied to product prices and sales.

31. Regulatory limits on use would make it less expensive to induce participation in voluntary prize fund schemes (particularly important in cross border implementation of regimes) or patent buyouts or takings.

32. In the Outterson proposals, the prize system would compete with the option of promoting and selling antibiotics, with fewer regulatory restrictions. The various measures to strengthen monopolies would be consistent with higher prices for products outside of the subsidy regimes. And, the amount of the subsidy to induce socially appropriate restrictions on use would grow with escalations of the threats of inappropriate utilization.

33. Both KEI and the Outterson proposals endorse or provide for greater public investment in R&D for new antibiotics.

¹⁴⁹ James Love, KEI proposal for Antibiotics Innovation Funding Mechanism (AIFM), shortlisted for demonstration project by WHO's EURO region, November 21, 2013. <http://keionline.org/node/1832>

34. KEI, Outterson and Kesselheim have endorsed¹⁵⁰ the use of compulsory licenses or other measures to limit the exercise of patent rights. Pogge has opposed the use of compulsory licensing of patents.¹⁵¹ Hollis has both proposed¹⁵² and opposed¹⁵³ the use of compulsory licensing of patents, in various articles.

(5) OTHER

Pigouvian Taxes

35. One obvious and often proposed intervention to discourage low value uses of antibiotic drugs is to impose taxes on their use. In theory, a tax could be designed to correct market prices so the private costs match the social costs of the consumption. This approach is sometimes referred to a Pigouvian tax, after the economist, Arthur C. Pigou, who proposed using taxes (or subsidies) to discourage (or encourage) actions that caused negative (or positive) externalities.

Antibiotic Innovation and Conservation (AIC) fee

36. In a 2011 policy paper, the Infectious Disease Society of America (IDSA) proposed an Antibiotic Innovation and Conservation (AIC) fee.¹⁵⁴ 75 percent of the AIC fee be used to fund R&D for new antibiotic drugs, and 25 percent be used to fund “antimicrobial stewardship.”

¹⁵⁰ Aaron S. Kesselheim and Kevin Outterson, Improving Antibiotic Markets For Long Term Sustainability , 11 *Yale Journal of Health Policy, Law & Ethics* (Winter 2011).

¹⁵¹ Aidan Hollis and Thomas Pogge, The Health Impact Fund, Making New Medicines Accessible for All, A Report of Incentives for Global Health, 2008, Page 53-54. "It may seem as though compulsory licenses — as envisioned in the TRIPS Agreement and reaffirmed in the 2001 Doha Declaration — are a practical solution to this dilemma. By issuing a compulsory license, a government can force down the price of a patented invention by compelling the patent holder to license it to other producers for a set percentage (typically below 10 percent) of the latter's sales revenues. Yet, compulsory licenses cannot fully solve the dilemma because, insofar as governments actually use them to improve access by the poor to patented medicines, compulsory licenses weaken the innovation incentives that were supposed to result from the extension of strong intellectual property rights into the less developed countries. See also: Excerpts from HIF: compulsory licensing. <http://keionline.org/blogs/2008/11/18/excerpts-from-hif-compulsory-licensing>.

¹⁵² Aidan Hollis, The link between publicly funded health care and compulsory licensing, *Canadian Medical Association Journal*, 2002 October 1; 167(7): 765–766. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC126509/>.

¹⁵³ Hollis and Poge, 2008.

¹⁵⁴ IDSA Policy Paper, CID 2011:52 (Supl 5). From page S407 of the report: “With respect to public monies, IDSA proposes creation of an Antimicrobial Innovation and Conservation (AIC) Fee. The AIC Fee would be a flat fee (e.g., \$3 per daily dose, inflated by the consumer price index annually) charged against the wholesale purchase of every daily dose unit of antibiotics (both branded and generic) in the US, including for human, animal and plant agriculture, and aquaculture use. The fee would be paid by the dispensing entity (e.g., pharmacy, animal feed mill, aquaculture company, etc.) at the time of wholesale purchase from the supplier. The rationale for such a fee is that effective antibiotics represent a “shared societal benefit,” and every antibiotic manufacturer, prescriber, and user must share the responsibility to maintain this benefit. Antibiotic resistance resulting from antibiotic use (both appropriate and inappropriate) is an example of the “tragedy of the commons”. A prescription may help the individual patient, plant, or animal, but such use also causes collective erosion of the benefit (effectiveness of antibiotics) for society as a whole. Analogously, use of highways by a vehicle has a cost to all users. Tolls (and differential rates) are means to have users pay their fair share of societal costs for establishing and maintaining a shared benefit. Because of the emergence of resistance, use of antibiotics differs from use of all other drugs that affect only the individual patients taking them. Hence, an AIC Fee would be charged to maintain the “shared societal benefit” of effective antibiotic therapy. Obviously, safeguards need to be incorporated into the AIC Fee structure to ensure that any costs passed on to consumers will not negatively impact vulnerable populations’ access to these important drugs.”

¹⁵⁴

Transferable Patent Extensions

37. There have been a number of proposals to create transferable patent extensions, sometimes referred to as “wild card” patent extensions, as a reward for developing new antibiotic drugs.¹⁵⁵ The mechanism is the grant of a legal right to extend the life of a patent, on a non-antibiotic drug. If the patent extension is fully transferable, it can be used for any product, including a highly profitable drug sold by a different firm, including products with monthly sales exceeding hundreds of millions of dollars. The value of the transferable patent extension depends upon the term of the patent extension.

38. The transferable patent extension works like a prize, the value of which is expected profit from the extension of the monopoly of the non-antibiotic drug. Under most proposals, the transferable patent extension would be an uncertain and non-transparent economic benefit to the developer of the antibiotic drug¹⁵⁶, and would impose large costs on society.

39. For several reasons, the transferable patent extension is expected to impose larger costs on society than the benefit to the developer of the antibiotic drug. Consider the following.

40. First, among blockbuster products, there is typically a significant difference in the value of the monopoly. The company that stands to benefit the most from the monopoly normally would need to pay no more for the patent extension than the value of the extension to a company that would benefit less. Thus, there is likely to be a systematic undervaluing of the patent extension, in an auction of the extension. For example, based upon 2012 sales, the three top grossing drugs facing patent expiration in 2013 were:

2012 Sales	Date of patent expiration	Drug
\$4.9 billion	December 11, 2013	Cymbalta
\$2.9 billion	December 31, 2013	Avonex
\$2.52 billion	May 7, 2013	Humalog

41. A patent extension used for Cymbalta would likely be sold at no more than the value of the extension for the drug Avonex, a drug with sales 40 percent less than the Cymbalta.

42. Second, the profit margin is less than 100 percent of sales, due in part to the costs of promoting and marketing the product. This may be particularly true for mature blockbuster drugs facing competition within a therapeutic class. For this reason, only a fraction of the higher cost of the consumers will be available as a benefit to the developer of the antibiotic drug.

¹⁵⁵ Crossing The Valley Of Death: Bringing Promising Medical. Countermeasures To Bioshield. *Hearing Before The Subcommittee On Bioterrorism And Public Health Preparedness of The Committee On Health, Education, Labor, And Pensions United States Senate.* 109th Congress. June 9, 2005. S. Hrg. 109-148; Walter E. Stamm, Letter to Senator Richard Burr, regarding wild-card patent extension. June 24, 2005; Li-Hsien Rin-Laures and Kevin M. Flowers, Using Wild-Card Patent Extensions to Bolster Drug Research, *The National Law Journal.* September 8, 2005; Spellberg B, Miller LG, Kuo MN, Bradley J, Scheld WM, Edwards JE. Societal Costs Versus Savings from Wild-Card Patent Extension Legislation to Spur Critically Needed Antibiotic Development. *Infection*, June 2007, Volume 35, Issue 3, pp 167-174; J. Sonderholm, “Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics,” *Journal of Law, Medicine & Ethics* 37, no. 2 (2009): 240-245.

¹⁵⁶ Amy Kapczynski, Commentary: innovation policy for a new era., *J Law Med Ethics.* 2009 Summer;37(2):264-8. doi: 10.1111/j.1748-720X.2009.00

43. In light of the above, suppose, for example, that owners of the blockbuster drugs anticipated that a one-year extension of the monopoly protects 80 percent of their revenues (at the expense of consumers), and that half of that would be realized as profits. The following highly simplified calculations illustrate inefficiency of the transferable patent extension as a funding mechanism.

<i>Minimum net loss [cost to consumers - maximum bid] (billions)</i>	<i>Maximum bid for patent extension, assuming only one extension available. (billions)</i>	<i>Value of patent extension to firm (billions)</i>	<i>Cost of patent extension to consumers (billions)</i>	<i>Expected sales, with monopoly (billions)</i>	<i>Drug</i>
\$ 2.76	\$ 1.16	\$1.96	\$3.92	\$4.9	Cymbalta
\$ 1.392	\$.928	\$1.16	2.32	\$2.9	Avonex
		\$.928	\$1.856	\$2.52	Humalog

44. In this simple example, consumers pay \$3.92 billion in higher prices for Cymbalta to obtain *at best* \$1.16 billion as a reward for development of new antibiotic drugs.

Transferable Priority Review Vouchers

45. Some have proposed the U.S. priority review voucher program¹⁵⁷ be extended to antibiotic drugs. The priority review voucher program creates a transferable right to have the US FDA evaluate the approval of a new drug as if it was a priority medicine.

46. The priority review voucher was originally created to stimulate investment in the development of drugs for neglected diseases, and it has been controversial.¹⁵⁸ Since the voucher is only valuable when used for non-priority medicines, it has the predictable effect of diluting the benefits of priority approval for actual priority medicines, and creating a risky rush to judgment on a drug that has few medical benefits, if any, associated with its approval.¹⁵⁹ Since its creation in 2007, the voucher program has been extended to include “rare pediatric diseases.”¹⁶⁰ Obviously there are limits to how many drugs can be considered as eligible for “priority” review at the FDA.

¹⁵⁷ David Ridley, Henry Grabowski, J. Moe, Developing drugs for developing countries. *Health Affairs* 25 (2) 313–324. (2006) doi: 10.1377/hlthaff.25.2.313.; David B Ridley, Alfonso Calles Sánchez, Introduction of European priority review vouchers to encourage development of new medicines for neglected diseases, *The Lancet*, Volume 376, Issue 9744, 11–17 September 2010, Pages 922–927; Andrew S. Robertson, Rianna Stefanakis, Don Joseph, Melinda Moree, The Impact of the US Priority Review Voucher on Private-Sector Investment in Global Health Research and Development, *Plos Neglected Tropical Diseases*. Aug 28, 2012. DOI: 10.1371/journal.pntd.0001750.

¹⁵⁸ Anderson T Novartis under fire for accepting new reward for old drug. *Lancet* 373 (9673) 1414. (2009) doi: 10.1016/S0140-6736(09)60804-7.

¹⁵⁹ Aaron Kesselheim, Drug development for neglected diseases—the trouble with FDA review vouchers. *New England Journal of Medicine (NEJM)* 359: 1981–1983. (2008) doi: 10.1056/NEJMp0806684; Aaron S Kesselheim, Priority Review Vouchers: An Inefficient and Dangerous Way to Promote Neglected-Disease Drug Development. *Clinical Pharmacology & Therapeutics* 85, 573-575 (June 2009). doi:10.1038/clpt.2009.50.

¹⁶⁰ Roxanne Palmer. Congress vouchers for priority review of childhood disease, *Nature Medicine* 18, 181 (2012) doi:10.1038/nm0212-181.

47. The primary advantage and appeal of the transferable patent extensions and the transferable priority review voucher for the Congress is that they are largely off-budget subsidies, and the non-transparency of the costs of the mechanisms are seen as a benefit by their proponents.

Advanced Marketing Commitment (AMC), and Advanced Purchase Commitment (APC)

48. An advanced marketing commitment is a commitment to provide subsidies for the purchases of drugs. The subsidy is designed to expand the market, in order to induce investments in R&D.¹⁶¹ An advanced purchase commitment is a commitment to buy a quantity of drugs at prices high enough to induce investments in R&D. Both the AMC and the APC are typically presented as voluntary offers by governments or other donors, without an obligation on drug developers to sell at AMC or APC prices. The AMC and APC mechanisms can be described as efforts to set a floor on the market. In cases where the government is the only purchaser, such as for certain biodefense agents¹⁶², or vaccines for poor populations, the AMC and APC are seen as part of a procurement effort that includes both an R&D and a supply component, and like other financing mechanisms, may be combined with grants and other subsidies.¹⁶³

49. Both the AMC and the APC present challenges regarding the information needed to send end-points and the appropriate valuation of prices or purchasing subsidies.¹⁶⁴ The US government use of APCs in regard to its Bioshield program have been controversial, and suppliers of products have lobbied the US Congress to shift risks of development to the government¹⁶⁵, and reduce the discretion of the funding agencies to not purchase when products receive FDA approval, including approval using lower standards based only on animal studies.¹⁶⁶

¹⁶¹ Adrian Towse and Hannah Kettler. Advance price or purchase commitments to create markets for treatments for diseases of poverty: lessons from three policies. Bulletin of the World Health Organization, April 2005. Owen Barder, Michael Kremer, Heidi Williams. Advance Market Commitments: A Policy to Stimulate

¹⁶¹ Investment in Vaccines for Neglected Diseases. *Economists' Voice*. February 2006; Rachel Glennerster, Michael R. Kremer, Jean Lee, Ruth Levine, Georg Weizsäcker, Heidi Williams. Advance Market Commitments for Vaccines Against Neglected Diseases: Estimating Costs and Effectiveness, *Health Economics*. 2007 May;16(5):491-511.

¹⁶² Chris Schneidmiller, FDA Offers First License to Drug Produced by Bioshield Program, Global Security Newswire. December 17, 2012.; GlaxoSmithKline (GSK) Inks \$196 Million Biomedical Advanced Research and Development Authority (BARDA) U.S. Anthrax Treatment Deal, BioSpace. September 20, 2013.

¹⁶³ Bolken TC, Hruby DE. Discovery and development of antiviral drugs for biodefense: experience of a small biotechnology company. *Antiviral Res*. 2008 Jan;77(1):1-5. Epub 2007 Aug 15.

¹⁶⁴ Michael Kremer, Creating Markets for New Vaccines Part II: Design Issues, NBER Working Paper No. 7717. May 2000; Donald W. Light. Advanced Market Commitments: Current Realities and Alternate Approaches. A HAI Europe/Medico International Publication. Paper Series Reference 03-2009/01 2009.

¹⁶⁵ John Carroll, Traversing the Landscape Of Project BioShield, *Biotechnology Healthcare*. 2007 October; 4(5): 7-8.

¹⁶⁵ PMID: PMC2651710.

¹⁶⁶ Steve Usdin, Antibiotics reset. GAIN Act, FDA stance only first steps to refilling antibiotic pipeline in U.S. BioCentury. November 19, 2012. Alexander Gaffney, In First for Animal Rule Pathway, FDA Approves GSK's Raxibacumab, *Regulatory Focus*, December 17, 2012.

Call options for antibiotics

51. Elias Mossialos and colleagues have proposed a system of Call Options for Antibiotics (COA)¹⁶⁷ based upon a Call Option for Vaccines (COV) proposal by Brogan & Mossialos.¹⁶⁸ In this approach, governments offer to buy rights to purchase drugs at fixed affordable prices, during earlier stages of development. The money from the option is used by developers to defray R&D costs.

52. The COA and COV approaches can first be compared to the Advanced Market Commitment (AMC) or Advanced Purchase Commitment (APC) approaches. Whereas the AMC and APC approaches require governments to commit to buy, the COV and COA approaches require developers to sell. Whereas the AMC and APC approaches only provide funding to developers when products reach the market and are used, and the COA and COV approaches provide cash funding at earlier stages of development.

53. The COA and COV approaches can also be compared to interim results innovation inducement prizes, with the call option interpreted as an alternative to a license to use an invention, leaving the monopoly intact, but creating a mechanism to negotiate prices at the time of providing funding.

[Annex II follows]

¹⁶⁷ Elias Mossialos, Chantal M. Morel, Suzanne Edwards, Julia Berenson, Marin Gemmill-Toyama and David Brogan, Policies and incentives for promoting innovation in antibiotic research, European Observatory on Health Systems and Policies. 2010.

¹⁶⁸ David Brogan and Elias Mossialos. Applying the concepts of financial options to stimulate vaccine Development. Nature Reviews Drug Discovery 5, 641-647 (August 2006) | doi:10.1038/nrd2035.

REVIEW OF STUDY (F): JAMES PACKARD LOVE, “ALTERNATIVES TO THE PATENT SYSTEM THAT ARE USED TO SUPPORT R&D EFFORTS, INCLUDING BOTH PUSH AND PULL MECHANISMS, WITH A SPECIAL FOCUS ON INNOVATION-INDUCEMENT PRIZES AND OPEN SOURCE DEVELOPMENT MODELS

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STRUCTURE

The study develops a survey and a taxonomy of innovation-inducement rewards and protections for creativity, invention and innovation. Four alternatives are presented and assessed:

- Research grants and contracts;
- Tax policies;
- Non patent mechanisms that rely on monopolies and high prices;
- Prizes.

There are 3 annex which provide useful complements: Annex A proposes comparisons of grants, prizes and patents; annex B provides a number of examples of innovation-induced prizes; annex C proposes an approach to stimulating innovation in the domain of new antibiotic drugs.

My view is that the structure is clear and consistent. A stronger introduction could be helpful particularly to explain the criteria that are used to compare the alternatives. These criteria are never exposed in a systematic way (see below *missing elements*).

Annex A includes very important topics: prizes versus patents; prize design, etc. – so important for the core argument of the study that it is not very clear why these topics are put in an annex and not being presented in the core of the text

Annex B is perhaps too long – providing an unnecessary large number of examples of prizes while the heterogeneity of the cases (historical period, sectors) makes it difficult to get a final idea about the value of prizes as an alternative for patent.

Annex C is fine as a concrete case where almost all alternatives are deployed.

Finally, a discussion of open innovation is announced in the introduction but the reader cannot find it (at least in a dedicated section or annex).

MAIN IPR CONTRIBUTIONS

This study offers good insights about under what conditions a mechanism like prize offers a superior solution to foster innovation as compared with patent from a social point of view. For example, the development about *perfect versus imperfect price discrimination* as an important determinant of the value of patent relative to prize is an excellent contribution.

To be fair with the study, one needs to note that the main contributions of the paper are not on IPR *per se* but rather on the alternatives' choices that are available to policy makers.

ELEMENTS MISSING

One missing element has already been mentioned. This is about the development and explanation of the set of criteria that are (more or less implicitly) used to compare and assess alternatives. Of course knowledge access is one of these criteria as well as the ability to provide sufficient incentives. These two criteria are explicitly mentioned. But a few others should be made more transparent because they should be fully part of any full comparison and assessments of alternatives. For instance:

Direction: the ability to influence not only the rate but also the direction of invention and innovation (patents don't display this ability while prize does). This is a very important criteria for policy which needs to address Grand Challenges.

Competition: to what extent the mechanism enhance competition or minimize it?

Full support over the whole process from idea to product: some of the mechanisms are useful and effective only for one portion of the process going from idea to product. It is very rare to have a mechanism providing a full support along the whole process and this is why in most cases different mechanisms must be deployed to go from idea to product.

Monitoring cost: in the domain of research, information asymmetry and moral hazard raise big problems of monitoring. Some mechanisms can minimize them while a few others make them very costly.

Implementation: each mechanism has advantage and shortcomings that are interesting to know.

I realize that another element is missing just during my reading of the study: it is fine to compare tools but perhaps the most interesting thing should be to compare tools as associated with a particular institution which has some kind of strategic goals. Example :

- a patent granted to a University which then will impose humanitarian licensing to the licensee will have a different social value than a patent granted to a big pharma
- a patent can be bought out (M.Kremer)
- a patent produced in the framework of a product development partnership will be used in a very different way (so as to maximize access) than a patent granted to a pharma

This means that what really matters is **how institutions can use patent (and other mechanisms) according to their strategic objectives** (in terms of profit (or non profit), access, etc..) and to what extent one mechanism (such as patent) is flexible enough to accommodate fundamentally different strategic objectives. This is probably a key issue in a world where patents are a central policy instrument so that the problem is not to abolish the system but to make it more effective – meaning able to respond to different kind of objectives set by different kind of institutions.

What I want to stress here is that the economic analysis of patenting has been too often carried out *in isolation* while it should be very useful to analyse patent *as connected* with different kind of institutional-types. A patent granted to a big pharma which wants to maximize profits and a patent granted to a university which tries to impose humanitarian licensing terms are two different animals, and this needs to be included in the analysis.

My last comment on missing elements refers directly to a paper recently published (by Murray et al., *Research Policy*, 41, 2012). This paper is interesting in showing that a prize is not a simple mechanism or an easy tool to encourage innovation but involves complex issues of management, coordination and evaluation. The paper shows also that there are a variety of non-prize incentive effects that are just as salient to participants (publicity, attention, credibility, community-building). These findings should be taken into account in the assessment's exercise between various incentive mechanisms.

IPR GUIDANCE FOR POLICYMAKERS

I think the whole Annex A provides a lot of useful guidance (again I do not understand why the arguments and examples provided in the annex are not located in the core of the paper). However, but this is not a problem or a weakness for me, the guidance for policy makers are more at the higher level of choices between alternatives than at the level of IPR design and management.

OVERALL ASSESSMENT/RECOMMENDATIONS

This is an interesting study providing useful information and insights on some problems and issues that are not so well known by economists and policy makers.

Recommendations are linked with the list of missing elements. The three points mentioned above are indications about some additions that could be useful. Another recommendation concerns the structure: appendix A too important to be left as an appendix, appendix B too long and perhaps not that useful.

[End of Annex II and of document]