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Article: Prizes for Innovation of New Medicines and Vaccines

NAME: James Love, M.P.A.* and Tim Hubbard, Ph.D.**

BIO: * James Love, M.P.A., is Director of Knowledge Ecology International (KEI). This paper was presented in a keynote address at Loyola University Chicago School of Law's Second Annual Beazley Symposium on Access to Health Care, "Perspectives on Patents and Patients: Can They Co-Exist?" in November 2008.

** Tim Hubbard, Ph.D., is Head of Informatics at The Wellcome Trust Sanger Institute, Cambridge, UK, and Joint Head of the Ensembl genome annotation project.

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SUMMARY:

... With prizes rather than monopolies, where rewards would be tied to actual health benefits, drug developers could not benefit from investments in marketing activities that expand access to medicines of marginal benefits at high prices. ... These exclusive rights are associated most importantly with patents on pharmaceutical inventions, but also include a growing set of non-patent mechanisms to bar competition; for example, market exclusivity associated with pediatric drug testing as a reward for the development of "orphan" drugs and biologics, and to prevent unauthorized competitors from relying upon clinical trial data to register new products. ... Specifically, legislation similar to S.2210, the Medical Innovation Prize Fund (MIPF), would eliminate exclusive marketing rights for all prescription medicines. ... (d) Requirements-In awarding prize payments under this section, the Board shall comply with the following: (1) In cases where a new drug, biological product, or manufacturing process offers an improvement over an existing drug, biological product, or manufacturing process and the new drug, biological product, or manufacturing process competes with or replaces the existing drug, biological product, or manufacturing process, the Board shall continue to make prize payments for the existing drug, biological product, or manufacturing process to the degree that the new drug, biological product, or manufacturing process was based on or benefited from the development of the existing drug, biological product, or manufacturing process. (2) The Board may not make prize payments based on the identity of the person who manufactures, distributes, sells, or uses the drug, biological product, or manufacturing process involved. (3) The Board may award prize payments for a drug, a biological product, or a manufacturing process for not more than 10 fiscal years, regardless of the term of any related patents. (4) For any fiscal year, the Board may not award a prize payment for any single drug, biological product, or manufacturing process in an amount that exceeds 5 percent of the total amount appropriated to the Fund for that year. ... If prizes are used to reward innovations, it is possible to expand access and redesign R&D incentives to more efficiently stimulate investments that improve health outcomes.

TEXT:

[*155] I. Introduction

Although difficult to measure precisely, the U.S. market for pharmaceuticals is approaching \$300 billion, including more than \$ 100 billion paid for by the federal government. n1 Outlays, including federal obligations, are expected to increase dramatically as the population ages. n2 The new administration faces a daunting task in terms of managing the system; it must find ways to stimulate innovation, control costs, and ensure that people have access to new products at affordable prices.

Changes are needed in the way that drug developers are rewarded, in order to address many of the best-known flaws of the current system. These flaws expose the need to control costs, promote useful innovation and expand access. Four options are discussed, each building upon the others, and departing further from the status quo.

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1. The first option is to retain almost everything about the current system, but to replace the exclusive rights to make or sell a product, following approval by the Food and Drug Administration (FDA), with mega cash prizes that are linked to the impact of the product on health care outcomes. n3
2. The second option builds on the first, but allocates a portion of the prize money to non-affiliated and non-remunerated parties whose open and freely-licensed research, data, materials, know-how or technologies were instrumental in the success of the final product.
3. The third option builds on option two by setting aside some of the money for investments and prizes that would be made in the translational or early phases of development, to be managed by competitive intermediaries, who will be resourced on the basis of their measurable and objective contributions to products that actually succeed.
4. The fourth option would eliminate patent thickets by removing the exclusive right to use inventions in upstream research in favor of a system that gives the freedom to use inventions so long as the patent owners receive remuneration.

[*157] These proposals are not a substitute for the important and significant role of governments and donors in funding of research through grants, which are necessary to promote and sustain research programs, and which will continue to play an important role in the development of new products. The use of prizes is intended as an alternative to the "pull" incentives now implemented as legal monopolies to make, use or sell products. n4

II. The Rationale

To many consumers and policy experts, high prices for medicines are the most visible flaw in the current system. n5 This is most dramatically true for products that treat severe illnesses. In addition to causing hardships related to affordability, including millions of uninsured and under-insured persons, consumers and third party payers avoid the use of high priced medicines, leading to less access and worse health outcomes. n6 Employers who bear the costs of medicines through health benefits find ways to avoid hiring or retaining workers who need expensive medications. Further, the relatively high prices for medicines in the United States puts U.S. employers at a competitive disadvantage. n7

Despite sharp increases in prices and high rates of growth in sales revenue, the current system suffers from low productivity. The rate of introduction of new chemical entities is relatively stagnant, particularly as it relates to products that offer significant therapeutic improvements over existing treatments. n8

There are a plethora of explanations for the productivity slowdown; including an increasingly complex patent landscape that blocks innovation, poor incentives to share research and provide access to knowledge, and few capital market incentives to invest in translational products that have low commercial prospects, but which may yield useful scientific information for follow-up research efforts. n9

Investment in research and development (R&D) for new medicines is driven both by the U.S. domestic and foreign markets. n10 According to [*158] recent figures from IMS Health, a health care information and consulting firm, in 2007, the United States represented approximately 40% of the global market for pharmaceutical drugs, n11 considerably higher than the U.S. share of the global Gross Domestic Product (GDP) (27% in 2006), n12 or population (4.6% in 2006). n13

Globally, for every dollar spent on drug purchases, less than nine cents are reinvested in R&D. n14 Most private sector R&D outlays are directed at products that offer few benefits over existing medicines. A significant share of R&D outlays on clinical trials offer little or no scientific value, and are rather used to generate data to advance marketing claims in areas where similar products engage in non-price marketing claims competition involving highly dubious trial design and reporting. n15

This lack of R&D has other effects. There is a dearth of R&D for new antibiotics, and perverse incentives for patent owners to over promote them before patents expire, despite overuse leading to increased drug resistance. n16 Likewise, there is inadequate investment in vaccines. n17

The international dimension of drug development is enormous, and often troubling. Through its trade policy, the United States exerts pressure on countries to adopt strict intellectual property rules and practices to weaken [*159] or abandon price control mechanisms. n18 These pressures are most effective in influencing developing countries, particularly those which rely upon exports to the U.S. market. At the same time, the U.S. government is a leading funder of global health care for acquired immunodeficiency syndrome (AIDS), tuberculosis, and malaria, with growing demands that the United States fund treatment in other areas. These programs are largely unsustainable and limited in reach without access to competitively priced generic products. As the primary incentive for private new drug development is a prospective marketing monopoly, there is little private sector investment in diseases that primarily affect low income persons living in developing countries, n19 or in emerging public health threats, such as Severe Acute Respiratory Syndrome or avian flu.

The costs of the current system are related to poorly designed incentives for product development, a deeply flawed and highly manipulated marketing effort, and weak efforts to regulate prices. The economic and political power exercised by a handful of companies with a comparative advantage in marketing products make the situation even more difficult to manage.

Many proposals for health care reform call for difficult trade-offs. To control insurance costs, access to treatment and care is rationed. In the area of new medicines and vaccines, policy makers and consumers are conditioned to think of innovation and access as mutually exclusive objectives in conflict with each other. High prices and poor access to new products are accepted as necessary to induce investment in the next generation of products. We argue that the reforms proposed here can break this mold, offering greater innovation and greater access, at a lower cost.

The core idea is to separate the market for innovation from the market for innovative products. Generic competition would be allowed for all products as soon as they enter the market, driving prices down. The developers of new medicines and vaccines would be rewarded directly by prizes. The prizes would be linked to the impact of innovations on health [*160] care outcomes, regardless of who actually delivered the product to patients.

The elimination of all legal barriers to the competitive supply of the products would be linked to the Food and Drug Administration (FDA) approval process. Patents would be used, not as monopolies for market products, but as mechanisms to stake claims on the prize money. Prizes would also reward unpatented innovations and investments.

For the new approach to work in the U.S. market, the rewards for product development will have to be very large, involving billions of dollars. However, the expense of the prizes would be far less than the amount that is now spent to support the current regime of temporary legal monopolies for new medicines.

The use of cash prizes to eliminate legal monopolies for products provides a powerful opportunity to address several flaws that plague the current system. In particular, policy makers would have far more freedom to design incentives efficiently. For example, rewards can be directly linked to the improvements in health outcomes, when benchmarked against existing treatments, rather than rewarding the replication of benefits already available from existing products. This has the benefit of driving investment toward treatments that address unmet needs. The elimination of the product monopolies and the enabling of generic competition will also lower prices, reducing treatment costs and personal hardships, while expanding access.

It is also possible to design prizes to reward and encourage collaboration and the sharing of knowledge, materials and technologies. Prizes can encourage investments in translational research with low prospects for commercial success, but which is of significant value in terms of advancing scientific knowledge.

Like other mechanisms for financing R&D, such as grants, or the management of incentives that rely upon exclusive marketing rights, the implementation of prize systems is fraught with challenges. However, these challenges are manageable. But before considering prizes further, it is useful to discuss the challenges of managing the current system, using price controls.

III. The limits of price negotiation/ regulation strategies

The use of prizes to replace monopolies is a radical change in the business model for pharmaceutical innovation. A less dis-

ruptive approach is to continue to reward drug development with product monopolies, while reforming the way in which the U.S. government negotiates or regulates prices. As the largest market in the world, the United States has enormous economic clout and could obtain far lower prices, if so inclined. One approach to obtain competitive prices for products with plausible substitutes within a therapeutic class is to use restricted formularies, rewarding the [*161] cheaper products with favorable reimbursement and co-payment policies. n20 In the absence of collusion, such policies can drive down prices. An alternative approach that even works when products do not face competition within a therapeutic group is to simply insist on prices of a particular amount and threaten the use of compulsory licenses and procurement of medicines from generic suppliers if drug manufacturers refuse to sell at those prices. n21 These or many combinations of similar approaches are clearly feasible. Why are prizes a superior alternative?

For the U.S. government, the easy part is lowering prices; this is just a matter of political will. More challenging is how to design a pricing policy that provides the right incentives for innovation, is not wasteful, and does not impose unnecessary barriers for access for new medicines. Any price negotiation strategy that is based entirely upon voluntary actions will leave intact monopoly power for medicines that do not have sufficient therapeutic alternatives. As seen in medicines for cancer, AIDS, and other severe illnesses, patent owners are quite willing to offer very aggressive prices that break private and government budgets, and which lead to rationing. n22 But even if the government is capable of exercising great power in negotiations or regulation, it will have difficulty setting incentives right, so long as the incentives are linked to the price. For example, suppose a treatment for heart disease works with efficacy measured by an index value of 100, and a new drug comes on the market that has the same exact same efficacy of 100, or an efficacy of 101. With most price regulation policies, the new products would have at least as high a price as the older product. But the medical value of the follow-invention is not significant, it is only replicating something that already exists. This is an important flaw in a policy that links R&D incentives to prices. Incentives to copy existing medicines are too high, and incentives to address treatment gaps are too low. n23 Monopoly supply with price regulation also leaves intact powerful and difficult to monitor incentives to invest in wasteful marketing activities.

Current efforts to create pricing strategies that overcome some of the best-known flaws in the current system include performance pricing contracts and linking prices closer to independent evidence of [*162] effectiveness. n24 However, these efforts are second-best efforts to imitate the pricing models that are proposed with prizes, operating in an environment where legal monopolies have enormous resources to lobby for changes to game the system.

Many of the more ingenious efforts to reform pricing policies involve extensive price discrimination—different prices for different indications and uses of medicine, and different prices for different patients, based upon incomes, insurers or geographic regions. n25 Unfortunately, tiered pricing and other price discrimination efforts are difficult to administer and enforce, and are often frustrated by off-label uses, diversion, parallel trade or third party/foreign reference pricing schemes. n26

With prizes rather than monopolies, where rewards would be tied to actual health benefits, drug developers could not benefit from investments in marketing activities that expand access to medicines of marginal benefits at high prices. The de-linking of R&D incentives from prices provides much more freedom to design incentives that reward the types of innovation that improve health outcomes. This separation would stimulate an environment where every patient can benefit from marginal cost pricing of products, consumers and third party payers have no incentives to restrict access to the newest medicines, and it is no longer necessary to introduce trade distorting restrictions on the free movement of goods.

IV. Implementing Innovation Inducement Prizes in the U.S. Market

A. Option 1: Replace the exclusive rights to make or sell a product, following FDA approval, with large cash prizes that are linked to the impact of the product on health care outcomes.

The most important reform in the system of incentives for drug development is to eliminate the set of exclusive rights that are now offered to induce development of new drugs. These exclusive rights are associated most importantly with patents on pharmaceutical inventions, but also include a growing set of non-patent mechanisms to bar competition; for example, market exclusivity associated with pediatric drug testing as a [*163] reward for the development of "orphan" drugs and biologics, and to prevent unauthorized competitors from relying upon clinical trial data to register new products. n27 Taken together, these measures are explicitly designed to grant legal monopolies on new medicines, with the intention that the monopoly profits will stimulate useful R&D. As discussed above, the shortcomings of such a system are many; including, hardships associated with high prices (a barrier to access and a burden for consumers, employers and society at large), investments in the development of medically unimportant products, as well as wasteful and often harmful marketing activities.

This option of cash prizes, one of four increasingly ambitious reforms discussed in this article, considers a key change in the business model for rewarding developers of new medicines. Specifically, legislation similar to S.2210, n28 the Medical Innovation Prize Fund (MIPF), would eliminate exclusive marketing rights for all prescription medicines. n29 Addition-

ally, the incentives now associated with expected monopoly profits would be replaced with large cash rewards for successful products. n30 The fundamental idea is to separate the market for products from the market for innovation by removing the link between R&D incentives and product prices. By allowing for competition and low generic prices for the products themselves, utilization of newer products would no longer be discouraged simply because of the high prices now associated with patented inventions.

1. Recent Interest in Medical Innovation Prizes

The use of prizes to reward innovation has long been of interest to [*164] economists and others, as evidenced by a plethora of recent proposals to use prizes to stimulate research into areas as diverse as the environment, energy, climate control, mining, space travel, software, and airport security. n31 More recently, however, there has been a growing interest in using prizes to simulate R&D in the areas of medicinal technologies. n32

2. 1999 to 2004

The early roots of this interest include a number of different proposals and initiatives. In 1999, Michael Kremer and others proposed creating large rewards for investments in vaccines for malaria and certain tropical diseases. n33 In 2001, the pharmaceutical company Eli Lilly created the firm InnoCentive to administer a series of commercially-sponsored prizes to solve specific problems in the area of life sciences. n34 Later, a number of philanthropic organizations sponsored medical innovation prizes, including but not limited to the X-Prize Foundation, the Prize4Life Foundation, and the Gotham Prize. n35

In 2002, the pharmaceutical company Aventis held discussions on possible future pharmaceutical scenarios, including one proposed by Tim Hubbard and James Love that featured prizes and the elimination of monopolies on all new medicines. n36 This scenario was presented at a number of academic and policy workshops in 2003 and 2004. Separately, in August 2003, the economist Burton Weisbrod published an editorial in the Washington Post, which called for "two prices-one for the R&D, another for the resulting pills." n37 Weisbrod noted, "this solution is not painless, but neither is the course that public policy is now on." n38

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3. 2005 to 2006

In 2005, Representative Bernard Sanders introduced the first MIPF proposal, n39 setting out a particular implementation of the new approach and stimulating additional interest among academics. In 2006, Joseph Stiglitz began publishing a number of widely read articles calling for the use of prizes to reward drug development. n40 In May of 2006, the World Health Assembly passed resolution WHA60.30. In the context of the addressing the unmet health needs of developing countries, the resolution called upon the Director General of the World Health Organization (WHO) to "encourage the development of ... incentive mechanisms ... addressing the linkage of the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products." n41

4. 2007 to 2008

In 2007, Senator Sanders re-introduced the MIPF as S.2210. n42 Also in 2007, John Edwards called for prizes rather than monopolies to stimulate drug development. n43 In 2008, Stan Finkelstein and Peter Temin from the Massachusetts Institute of Technology published *Reasonable Rx: Solving the Drug Price Crisis*, a book calling for the separation of the R&D incentive from the price of the drug. n44 In April 2008, in a WHO negotiation over new approaches to stimulating medical R&D, the governments of Barbados and Bolivia made five separate proposals to use prizes for medical innovation. n45 In May of 2008, the World Health Assembly adopted a Global Strategy and Plan of Action, which among other items, agreed to:

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Explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries. n46

5. The Medical Innovation Prize Fund Approach

The two U.S. MIPF bills proposed by Congressman Sanders presented the first fully specified possible implementation of prizes in the context of a major market for medicines. n47 The drafters of the MIPF sought to address several important

technical questions relating to the allocation of prizes. n48 The basic approach followed one of the scenarios outlined in the 2002 Aventis scenarios-planning exercise. n49

a. The prize fund will receive an annual contribution based upon a fraction of the GDP. n50

b. All of the annual funding is spent every year on qualifying products and processes. n51

c. The prize fund of a fixed size is divided among qualifying products, in a zero sum competition. The more given to one product, the less available to competitors. n52

d. Every new product "wins" something, but products that have a greater impact on health outcomes receive more. n53

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e. New products (and processes) participate in the fund for 10 years. n54 The reward in any given year is independent of future rewards, and is based upon the best available evidence (at that time) of the impact of the product on health outcomes. n55

f. The impact on health outcomes is benchmarked against available technologies, rather than placebos. n56

g. Products that are registered with the FDA at "roughly" the same time are compared to products "that were not recently developed." n57

The distinction between individual "Prizes" and a "Prize Fund" is important and worth emphasizing. When designing for a single outcome, it is hard to choose the appropriate size of the "Prize." If the prize is too small, the incentive is insufficient to stimulate R&D. If the prize is too large, the mechanism is inefficient. A "Prize Fund" avoids this issue by allowing different R&D innovations to compete against each other (item 3. above). Over time the number of competitors and the scale of their investments in R&D innovations will equilibrate to match the overall size of the Prize Fund, ensuring efficient allocation.

Three other features deserve discussion. First, the MIPF provides that the amount of the prize money that any one product can receive in a given year is limited to 5% of the annual prize fund payments. n58 Second, in cases where there is a follow-on product, the MIPF would continue to make payments to the original product, even when its market share falls to zero, to "the degree that the new ... product, or manufacturing process was based on or benefited from the development of the existing ... product, or manufacturing process." n59 Third, the MIPF provides specific set-asides for areas of public health priority; including (A) current and emerging global infectious diseases; (B) severe illnesses with small client populations, and; (C) neglected diseases that primarily afflict the poor in developing [*168] countries. n60 (See Document 1.)

Document 1: S.2210 Criteria for Prize Payments

SEC. 9. PRIZE PAYMENTS FOR MEDICAL INNOVATION.

- (a) Award-For fiscal year 2008, and each subsequent fiscal year, the Board shall award to persons described in subsection
- (b) prize payments for medical innovation relating to a drug, a biological product, or a new manufacturing process for a

drug or biological product.

(b) Eligibility-To be eligible to receive a prize payment under subsection (a) for medical innovation relating to a drug, a biological product, or a manufacturing process, a person shall be-

(1) in the case of a drug or biological product, the first person to receive market clearance with respect to the drug or biological product; or

(2) in the case of a manufacturing process, the holder of the patent with respect to such process.

(c) Criteria-The Board shall, by regulation, establish criteria for the selection of recipients, and for determining the amount, of prize payments under this section. Such criteria shall include consideration of the following:

(1) The number of patients who would benefit from the drug, biological product, or manufacturing process involved, including (in cases of global neglected diseases, global infectious diseases, and other global public health priorities) the number of non-United States patients.

(2) The incremental therapeutic benefit of the drug, biological product, or manufacturing process involved as compared to existing drugs, biological products, and manufacturing processes available to treat the same disease or condition, except that the Board shall provide for cases where drugs, biological products, or manufacturing processes are developed at roughly the same time, so that the comparison is to products that were not recently developed.

(3) The degree to which the drug, biological product, or [*169] manufacturing process involved addresses priority health care needs, including-

(A) current and emerging global infectious diseases;

(B) severe illnesses with small client populations (such as indications for which orphan designation has been granted under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)); and

(C) neglected diseases that primarily afflict the poor in developing countries.

(4) Improved efficiency of manufacturing processes for drugs or biological processes.

(d) Requirements-In awarding prize payments under this section, the Board shall comply with the following:

(1) In cases where a new drug, biological product, or manufacturing process offers an improvement over an existing drug, biological product, or manufacturing process and the new drug, biological product, or manufacturing process competes with or replaces the existing drug, biological product, or manufacturing process, the Board shall continue to make prize payments for the existing drug, biological product, or manufacturing process to the degree that the new drug, biological product, or manufacturing process was based on or benefited from the development of the existing drug, biological product, or manufacturing process.

(2) The Board may not make prize payments based on the identity of the person who manufactures, distributes, sells, or uses the drug, biological product, or manufacturing process involved.

(3) The Board may award prize payments for a drug, a biological product, or a manufacturing process for not more than 10 fiscal years, regardless of the term of any related patents.

(4) For any fiscal year, the Board may not award a prize payment for any single drug, biological product, or manufacturing process in an amount that exceeds 5 percent of the total amount appropriated to the Fund for that year.

6. Relationship to Patents

While the MIPF eliminates market exclusivity for products, it does not [*170] eliminate patents. n61 Patents will continue to be available for new medicines, and are valuable assets, not as legal monopolies, but to make claims on the prize fund money. Strictly speaking, the Sanders bills did not change the system of exclusive rights for drug, biologic, or vaccine development until after a product received FDA approval. n62 Drug developers would have to litigate or negotiate with patent owners to obtain the necessary rights to register products, as they do today. In practice, however, the elimination of the post-marketing approval exclusive rights would create a very new dynamic for patent owners. The total reward for drug development would be fixed by the size of the prize fund. n63 A patent system that created too many barriers to product development would be easier to reform, because changes would not change the overall system of sustainable rewards.

7. The Size of the Prize Fund

The 2007 version of the prize fund used 60 basis points of U.S. GDP for the level of funding. n64 This was approximately \$ 80 billion in 2008. n65 The amount of the fund was the subject of considerable discussion and analysis, n66 although the level of proposed funding is not easily explained by any single number. Among the data examined were the total global outlays on R&D, n67 industry-wide pharmaceutical profits from U.S. sales of medicines, the market capitalization of the pharmaceutical industry, the size of pharmaceutical royalties reported to income tax authorities, the estimated risk adjusted costs of drug development, and other factors.

The amount of the prize fund in S.2210 is considerably larger than the total global private sector R&D outlays on new medicines, as estimated by the International Federation of Pharmaceutical Manufacturers, and considerably larger than estimated profits from the U.S. market, which includes profits from drug development, but also profits from manufacturing, distribution and marketing of products. n68

In terms of the magnitude of the S.2210 prize fund, it is important to keep in mind that new medicines are used everywhere on the planet, and the U.S. economy is only about one quarter of global GDP and roughly one- [*171] third of high income GDP. n69 If foreign consumers (governments, employers, and individuals) collectively added rewards that only equaled U.S. outlays, the relevant reward would be \$ 160 billion. n70 If foreign consumers doubled U.S. contributions, global rewards would be \$ 240 billion, more than a third of 2007 global pharmaceutical sales, and more than four times the 2007 global private sector outlays on pharmaceutical R&D. n71 Given the disproportionate size of the existing U.S. contribution to global medical R&D costs, the implementation of a prize fund in the United States would provide substantial benefits even if other countries did nothing. However, it would be better for all if there were incentives for all countries to sup-

port R&D costs equitably. Treaty structures to incentivise this have been proposed n72, but are beyond the scope of this article.

8. Net Benefits of the Prize Fund Approach

a. Price Savings

The cost of the proposed MIPF in S.2210 is roughly \$ 80 billion per year at current levels of GDP. n73 Eliminating monopolies on medicines will lead to substantial savings in prescription drug outlays, although the total amount of the savings is hard to determine. In recent years, the Generic Pharmaceutical Association has estimated that the average price of a generic drug prescription is about 30% of the price for a brand name drug. n74 IMS reports that generic prescriptions compose 65% of the market by volume and 20.5% by revenue, suggesting that the brand name products are 7.2 times more expensive than generics. n75 Even this may understate the potential savings from eliminating drug monopolies. The long period of the monopoly, including the ability to build up the trademark, creates price contours that influence the pricing of generics. In contrast, where markets are competitive and distribution systems are efficient, competition can radically change prices. For example, Plavix, a popular medicine for heart disease, was priced at roughly \$ 2 per pill in Thailand before it issued a [*172] compulsory license and imported generic versions. n76 The generic versions were priced at less than 3 cents per pill. n77 Another example is the AIDS drug nevirapine, which costs \$ 13.50 in the U.S. for a daily dose of two 200-milligram tablets. n78 In countries where competition is allowed, two generic tablets are available for 13 cents, a price decrease of 99%. n79 For many products, including those for severe illnesses, savings of 95% to 99% are feasible, once competition is allowed.

Even with large price savings, it does not appear that the \$ 80 billion cost of the MIPF will be offset by federal outlays on pharmaceutical in the near term. In 2007, the combined federal outlays on prescription drugs has been estimated at approximately \$ 100 billion. n80 It would take a projected price decrease of 80% across the board to break even. n81 The Congressional Budget Office is unlikely to make such a prediction. The bill, however, will create enormous savings for state and local governments and private sector employers and individual consumers. The findings of S.2210 suggest national saving in excess of \$ 200 billion per year, n82 and this is certainly realistic.

If S.2210 is reintroduced it may be appropriate to consider sharing the cost of the prize fund with other beneficiaries of the bill, including in particular states and employers, and or private health insurance companies.

b. Better Targeting of R&D

To some prize fund proponents, the most important benefit is the improved targeting of R&D incentives. Today, most R&D spending is wasted on products that offer almost no realistic chance of offering significant health benefits over existing products. n83 The prize fund would dramatically reduce incentives for investments in medically unimportant products, while making it highly profitable to invest in products that truly improve health care outcomes.

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c. Incentives for Rational Marketing Practices

Marketing practices today are rational responses to our system of R&D incentives. With a legal monopoly to sell and product, and returns based upon the number of units sold at monopoly prices, companies have enormous incentives to invest in marketing of products to doctors and consumers, even for uses where the drug is of marginal use or even dangerous. n84 If prizes are implemented as rewards for improvements in health outcomes, irrational uses of medicines become a negative rather than a positive.

d. Reactions to S.2210

The 2005 and 2007 versions of the MIPF have been debated in a number of workshops, meetings, and consultations, where the proposal has received high marks from many pharmaceutical experts, n85 but also some skepticism and criticism. Much of the criticism concerns the anticipated political difficulties associated with major and potentially disruptive changes for a large and politically powerful sector of the economy. n86 Even many of these critics have suggested that the proposal has merit, but should be implemented on a smaller scale, either for special health problems like neglected diseases that predominantly concern low income persons living developing countries, or for products such as antibiotics where current market incentives are particularly perverse. n87

There are also debates over technical details of the valuation methods, the size of the fund, the allocation of funding among beneficiaries, the global trade framework for R&D, and certain legal issues. n88

In addition to the concerns that the MIPF approach is too ambitious, are those that say it is not ambitious enough. n89

In particular, some would prefer a system that relies entirely upon open source research, or one that includes deeper reforms in the patent system. n90 Modifications to the basic prize fund [*174] proposal are considered next.

B. Option 2: Open Source Dividends to Reward the Sharing of Knowledge, Data and Technology

One explanation of the low productivity in drug development is that scientists and firms involved in medical R&D are not sufficiently open in terms of access to knowledge, and that restrictive licensing practices discourage research in areas where patents exist. New development models in the field of software and innovative information services have enhanced interest in approaches that promote more access to knowledge, and greater sharing and freedom to use and improve upon innovations pioneered by others. n91

If prizes are used to reward innovations, it is possible to expand access and redesign R&D incentives to more efficiently stimulate investments that improve health outcomes. n92

One criticism of prizes as an incentive is a concern that the prospect of a prize does not encourage sufficient openness or sharing of knowledge, materials, and technology. n93 Some have argued that a prize program that rewards unpatented inventions, as does S.2210, may result in less openness, because of reduced incentives to disclose inventions. n94 Even if the prize fund approach is neutral in terms of incentives to be open or share knowledge, it is important to encourage and expand more openness. Fortunately, prizes can also be designed to reward more access to knowledge, materials and technology.

Historically, there are many innovation inducement prizes that mainly or partly were designed to reward openness and technology sharing. Recent examples include the Gotham prize for cancer research, the National Academies prize for the development of economical filtration devices for the removal of arsenic from well water in developing countries, or numerous software prizes, such as Sun Microsystem's Open Source Community Innovation Awards Program. n95 One can also look to earlier prizes to stimulate access to knowledge, such as the system of prizes [*175] administered by the city of Lyon France in the eighteenth century to promote sharing of innovations in the silk manufacturing industry, n96 the British Elkington reward for disclosing an important technology to drain farmland, prizes to encourage the disclosure and sharing of effective irrigation practices in Italy and France or the French prize for "the best manual, or practical and elementary instructions upon the art of piercing or boring Artesian wells." n97

The issue of secrecy, openness and prizes was discussed at length in a 2008 workshop on medical innovation prizes at the United Nations University at Maastricht, the Netherlands, and in an MSF workshop examining the possible use of prizes to stimulate the development in a rapid low-cost point of delivery test for tuberculosis. n98 In the spring of 2008, the governments of Barbados and Bolivia submitted five proposals to use prizes to stimulate medical R&D to the WHO. n99 Several of these prizes formally introduced the notion of "open source" dividends to encourage greater openness. n100 Among the specific proposals was the notion of sharing the final product prizes with individuals, firms, and communities that share knowledge, materials and technologies in a non-discriminatory and royalty free manner. n101 There was also a proposal to share of the open source dividends with journals that published research in full text without subscription fees, creating a new incentive for journals to more openly share research findings. n102 The prize proposals submitted by Barbados and Bolivia contained systems for rewards of interim research results that were only available to entities that offered royalty free open licenses inventions, [*176] data, materials, and know-how. n103 (See Document 2 and Document 3.)

Document 2: Working Document- Barbados and Bolivia, Proposal 1

Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis

Incentives for Collaboration and Access to Knowledge

In order to ensure there are incentives for openness and sharing among researchers, the Grand Prix prize money would be divided as follows: The winning entrant would get 90 percent of the prize money; the remaining 10 percent of the prize money would be given to unaffiliated and uncompensated (by the winning entrant) scientists and engineers that openly published and shared research, data materials and technology, on the basis of who provided the most useful external contributions to achieving the end result. This would include research, data, materials and technology that were either placed in the public domain, or subject to open, non-remunerated licenses.

The biannual "best contributions" prizes would only be available to technologies that were placed in the public domain, or licensed to the TBLA.

To qualify for the "best contributions" prize, published research findings would have to be freely available on the Internet in full text. As an incentive to journals to make articles available to the public for free, 10 percent of the "best contributions" prize given for a published article would be available to a peer reviewed journal that published the article, on the condition that the journal made the article available for free immediately upon publication.

Document 3: Working Document - Barbados and Bolivia, Proposal 3.

Priority Medicines and Vaccines Prize Fund (PMV/pf)

Incentives for Collaboration and Access to Knowledge

[*177]

In order to ensure there are incentives for openness and sharing among researchers, the Final Product Prize money would be divided as follows. The winning entrant would get 90 percent of the prize money. The remaining 10 percent of the prize money would be given to unaffiliated and uncompensated (by the winning entrant) scientists and engineers that openly published and shared research, data materials and technology, in the basis of who provided the most useful external contributions to achieving the end result. This would include research, data, materials and technology that were either placed in the public domain, or subject to open, non-remunerated licenses.

It is anticipated that the next version of the MIPF will include the notion of open source dividends. n104 Every 1% of the U.S. MIPF is worth \$ 800 million annually, so even a small percentage sharing of prize money could dramatically enhance incentives to operate open libraries and databases and publish in open journals. n105

C. Option 3: Adding prizes for interim benchmarks and discrete technical problems, and translational research through competitive intermediaries.

Some firms have suggested that a system of rewards for the development of successful products should be modified, so that a system of prizes would reward earlier steps in the development process. n106 Such firms, typically small pharmaceutical and biotechnology firms, often rely upon financing that focuses on the achievement of interim benchmarks, such as the completion of Phase I or II clinical trials. n107 These trials are expensive and, more often than not, do not result in successful commercial products; however, even these unsuccessful efforts yield useful information. In an efficient capital market, investors would finance a portfolio of projects; however, capital markets are not efficient for a variety of reasons. n108 The asymmetric distribution of information between companies and investors makes it difficult for investors to accurately evaluate proposed investments. This leads to under-investment in projects that, while having a low probability of resulting in a marketable final product, contribute to better understanding of scientific and engineering challenges and opportunities. n109

It is, of course, possible to fund such projects through grants and other up-front subsidies that are not tied to performance, and to some extent, [*178] these subsidies exist. n110 For example, the U.S. Orphan Drug Act indirectly subsidizes 50% of the costs of human use clinical trials, n111 and the U.S. National Institutes of Health directly finances thousands of clinical trials for a wide range of diseases. n112 However, approaches that rely entirely on up-front subsidies have well-known shortcomings. Decisions about which projects to fund through grants can suffer from uncritical evaluations of the probability of success. n113 Also, most current efforts to subsidize clinical trials fail to address the relationship between the public subsidy and the prices of products. n114

Prizes that reward successful outcomes can be implemented as an alternative to a set of exclusive rights. Unfortunately, it is much more difficult to evaluate the value of interim benchmarks than it is final products that have concrete and observable utility in terms of influencing health [*179] outcomes. n115 In any centrally managed prize program for medical research, the criteria for rewarding interim outcomes will be controversial, and difficult to evaluate, and will suffer from many of the limitations that now exist with systems of grants. n116

Rather than search for consensus on one or more ingenious systems for valuing interim results, policy makers can create an environment where decentralized institutions make such valuations. n117 In this approach, there is no need to legitimize the valuation criteria, but rather to legitimize the actors that make such valuations. Multiple intermediaries would be resourced to award prizes for interim results, using their own methods. The legitimacy of the intermediaries would be based upon the competition to obtain funds.

In a 2002 Aventis scenarios-planning exercise, one model for funding such prizes was to require employers to contribute to such intermediaries, with the freedom to choose intermediaries. n118 An intermediary that was successful in attracting funding from employers would have legitimacy by virtue of the election by the employer, in a competitive environment. Governments would play roles in terms of ensuring transparency and accountability. n119 The 2008 proposals submitted by Bolivia and Barbados contained the notion of competitive intermediaries in connection with a proposed prize fund for priority medicines and vaccines. n120 (See Document 4.) If the MIPF followed this approach, it would allocate \$ 16 billion per year in interim prizes, an amount roughly half the current NIH budget.

Document 4: Working Document - Barbados and Bolivia, Proposal 3

Priority Medicines and Vaccines Prize Fund (PMV/pf)

Upstream Prizes

Twenty percent of the Priority Medicines and Vaccines Prize Fund (PMV/pf) money will be allocated to three or more institutions that [*180] run prize competitions to reward earlier stages of product development. These will include smaller technical challenges, and also rewards for the successful development of early benchmarks in drug development, such as the completion of phase I/II clinical trials.

Innovation inducement prizes that focus on solving small technical challenges are similar to the type of prize competitions now being offered by the Lilly-launched start-up company, InnoCentive, or non-profit organizations such as the X-Prize Foundation. These prize competitions could be outsourced to firms or non-profit organizations with expertise in managing such innovation prizes.

The early benchmark prizes are similar to those used by venture capital funds or big pharma companies to reward success in upstream product development.

The competing institutions that run the upstream prizes will be evaluated periodically to determine how successful they were in investing in products that were successful. The upstream prize managers who invest in products that are successful and improve outcomes will also be rewarded by earning "points" that will entitle them to shares in the final product prizes. Upstream prize managers that do poorly will face reduced allocations or termination.

D. Option 4: A system of compensatory liability to reduce the problem of patent thickets in upstream research.

1. Liability rules rather than exclusive rights

Governments often implement patents rights n121 as a set of exclusive rights, subject to some limited permitted uses, and the understanding that abuses of exclusive rights are sanctionable by governments or courts. But patents can also be implemented so that everyone has the freedom to use the invention, subject only to an obligation to pay remuneration. n122

Compulsory licenses or a system of prizes such as the one envisioned by S.2210 are types of liability rules. Through such rules, one may, in return [*181] for payment of damages, use protected material without the consent of the patent holder. n123 There are many possibilities for liability rules, including instances where exclusive rights have some role, but where the threshold for obtaining compulsory licenses is low, and one can realistically anticipate obtaining non-voluntary

authorizations in the event that voluntary negotiations fail. The range of possibilities is large along a continuum that begins with automatic rights to use inventions, and ends with no rights to use inventions outside of voluntary authorizations from patent owners.

Among the examples of automatic rights are those in *28 U.S.C. 1498*, concerning "the use or manufacture of an invention ... by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government." n124 Under this law, persons authorized by the government have complete freedom to use any patent, but the federal government accepts liability to compensate patent owners for the use. n125 Disputes about the amount of compensation are settled by the courts. n126 Corporations providing goods and services to the U.S. Department of Defense often use *28 U.S.C. § 1498*, but the statute extends to any use "for" the government, including, for example, the use of the patented blackberry email service to federal employees, n127 the building of bridges, or the acquisition of pharmaceutical drugs.

There are several examples of mandatory compulsory licenses that have been implemented by governments. For instance, in 1980, when the United Kingdom (UK) joined the European Union, it extended patent terms from 16 to 20 years. n128 To deal with the transition to the longer term, the UK created a mandatory "license of right" for the extended term. n129 The United States did the same thing when it implemented the WTO's Trade-Related Aspects of Intellectual Property Law (TRIPS) Agreement, and switched from a 17 to a 20 year patent term. n130 More recently, the European Union has created a mandatory cross-licensing provision in the Directive on the [*182] Legal Protection of Biotechnological Inventions, to ensure that European plant breeders and inventors have the freedom to make improvements on inventions. n131 The European Union and India have both created mandatory compulsory licensing regimes to respond to cases where medicines are exported to a developing country under the new August 30, 2003 decision of the WHO to implement Paragraph 6 of the Doha Declaration on TRIPS and Public Health. n132

Beginning in 2006, the United States has taken a step toward a system of liability rules for patents. In a decision involving patent infringement by the popular Internet auction service eBay, the U.S. Supreme Court held that courts must consider the possibility of a forward looking remuneration as an alternative to the enforcement of an injunction to protect the exclusive rights of the patent owner. n133 Since the eBay decision, injunction cases involving patent infringement have become a compulsory licensing proceeding. n134 Microsoft has obtained two compulsory licenses under the new eBay doctrine. n135 Abbott Laboratories, Roche Pharmaceuticals, Johnson and Johnson, Toyota, and many other well-known technology firms have sought compulsory licenses, making the argument that the public interest is best served by allowing infringements to continue, subject to remuneration to patent owners. n136

The flexibility to implement liability rules within patent systems is constrained somewhat, but not completely, by the WTO's TRIPS Agreement. TRIPS is a complicated legal framework that includes seven parts, including of particular relevance Part I, "General Provisions And Basic Principles," Part II, "Standards Concerning The Availability, Scope [*183] And Use Of Intellectual Property Rights," and Part III, "Enforcement Of Intellectual Property Rights." n137

Most early discussions of non-voluntary authorizations to use patents have focused on Parts I and II, and the provisions of Articles 30 (Exceptions to Rights Conferred) and 31 (Other Use Without Authorization of the Right Holder), as well as the proposed 31bis. n138 When attention is focused on Article 31 of TRIPS, two provisions appear to present an obstacle to the use of liability rules. The first provision is in Article 31(b) of TRIPS, and provides that non-voluntary authorizations to use patents "may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." n139 This requirement, which is waived in four important cases, n140 is not by itself an onerous burden for some forms of liability rules. Prior voluntary negotiation is often useful to reduce the burden on the state or the courts of evaluating reasonable terms for non-voluntary authorizations. Potentially more problematic is the provision in Article 31(f) of the TRIPS that limits non-voluntary authorizations to uses "predominantly for the supply of the domestic market." n141 Once considered a severe restriction on the use of compulsory licenses, Article 31(f) is not absolute. n142 The restriction is waived entirely within Article 31 when the authorization is a remedy to an anticompetitive practice, something that is broadly defined under TRIPS Articles 8 and 40. n143 Article 31(f) also does not apply to imports or exports authorized under Article 30, which is a different provision under which governments can provide for non-voluntary uses of patents, including cases of importing and exporting patented products to use in researching or testing for drug registration requirements. n144 Some scholars argue that the exhaustion of rights under Article 6 of TRIPS is another area where exports of patented [*184] inventions may take place without the permission of patent owners. n145 In Article 31bis, the WTO created a special and controversial exception to Article 31(f) of TRIPS that only applies in practice for exports to developing countries. n146

More recently, attention has been drawn to an entirely different flexibility in TRIPS, not in Parts I or II but in the enforcement of rights under Part III. n147 The recent court cases in the United States following the eBay decision were about injunctions, n148 a topic addressed in Article 44 of TRIPS. n149 According to this Article, WTO members need not grant

injunctions in cases where intellectual property owners receive compensation. n150 There are indeed many cases where non-voluntary uses of intellectual property rights are actually addressed in the context of remedies to infringement, rather than through the creation of exceptions to those rights. n151 For example, Canada and India, among other countries, do not grant injunctions in cases involving infringements of architectural plans for buildings that are partly or fully constructed, but rather requires compensation to copyright owners, n152 a practice that is allowed under TRIPS Article 44.2. n153 The U.S. International Trade Commission explicitly withholds injunctive relief for certain infringing patented goods into the U.S. Market, when such imports enhance competition and consumer welfare. n154 In U.S. patent infringement cases, injunctive relief is withheld [*185] in a growing number of cases, including cases where the good is exported. For example, in the *In-nogenetics v. Abbott Laboratories*, royalties for a "running royalty" were set in Euros. n155

The success or failure of a system of liability rules for patents will partly depend upon the method of setting remuneration or compensation. The durable appeal of exclusive rights regimes, despite the enormous costs they impose in terms of high prices and blocked innovation, is that the valuation of patents is determined by private parties, each protecting its own interests. Interest groups, legislators, and courts are often skeptical that courts, governments, or third parties can manage acceptable alternatives that remove the ability to block usage, but still assign values to patents that are both fair to users and adequately stimulate investment in research and development.

Patent owners often express concern that compulsory licensing will lead to a bias in favor of low rates of compensation and insufficient rewards for innovation. n156 They also question the assumption that patents inhibit innovation, since in a voluntary context, patent owners always have the option of licensing rather than blocking welfare-enhancing innovations. n157 In practice, however, both patent owners and users have incomplete and asymmetric information about the value of patents in a particular use, and each have incentives to act strategically, factors that contribute in practice to an underutilization of patented inventions.

The disputes about compulsory licensing or other types of liability rules are particularly heated in the context of pharmaceutical inventions, which are often very inexpensive to copy. n158 In a world where R&D incentives are linked to drug prices, any relaxation of exclusive rights can lead to competition that reduces monopoly rents and undermines incentives to invest in R&D. n159 For this reason, patent offices and courts have often allowed patent doctrines to stray far from their putative purpose of [*186] rewarding invention. The expanding subject matter for patents and the low standards for an inventive step can be thought of as indirect efforts to use patents to protect investments.

The importance of patents in protecting investments is more important for pharmaceutical inventions than it is for many other technology fields. One observes very different perspectives on the patent system in other industry sectors. For example, in the software, telecommunications, and computing sector, a growing number of firms favor the abolishment or weakening of software patents, and patent reform has been framed as a call for higher standards of patentability, and a relaxation of exclusive rights in favor of incremental steps toward liability rules. n160

By introducing a system of prizes to reward drug development, breaking the link between R&D incentives and product prices, the pharmaceutical industry's interest in patent reform would change dramatically. The relevant factor in determining the overall R&D industry revenues is no longer the potential revenues from drug sales, which is influenced in part by the ability to exercise exclusive rights in products, but rather the size of the prize fund. A patent system that requires costly litigation, creates long bargaining delays, and blocks innovation can be seen as a negative, as will a system that excessively rewards inventions at the expense of investments.

V. Conclusion

The current system for supporting innovation in the area of medical technologies is costly, inefficient, and leads to underutilization of new inventions, as well as unequal access. It is possible to do a better job of managing the current system, but it is also possible to radically refashion the approach, to provide for more innovation and more access, at a smaller cost. Unlike other reforms in the health care sector that rely upon rationing of access to control costs, the use of prizes to reward innovation would expand access and increase investments in areas where innovation is most important. It is not easy to change existing systems of innovation, but neither is it easy not to change. It is difficult to imagine a more expensive system of innovation that produces so little in terms of new medicines and vaccines. A reform of the reward system for new medicines has enormous potential to enhance innovation and access, not only in the United States, but everywhere. Those who object to change should have the burden of justifying the costly system of monopolies that we struggle with today.

Legal Topics:

For related research and practice materials, see the following legal topics:

Patent Law
Inequitable Conduct
General Overview
Patent Law
Infringement Actions
Exclusive Rights
Manufacture, Sale & Use
Patent Law
Ownership
General Overview

FOOTNOTES:

n1. Pharm Exec Staff, Pharm Exec 50: The Winners' Circle, Pharmaceutical Executive, May 1, 2008, at 74, 82.

n2. Pharmaceutical Research & Mfrs. of Am., Pharmaceutical Industry Profile 2008, 19-26 (2008).

n3. For different views on the use of prizes to stimulate medical R&D, see generally 151 Cong. Rec. E149 (extensions of remarks Feb. 2, 2005) (statement of Rep. Bernard Sanders); Bruce G. Charlton, Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapeutic Innovation, 68 Med. Hypotheses 1, 2 (2007); J. A. DiMasi & H. G. Grabowski, Should the Patent System for New Medicines Be Abolished?, 82 Clinical Pharmacology & Therapeutics 488, 488-90 (2007); 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); Tim Hubbard & James Love, A New Trade Framework for Global Healthcare R&D, 2 PLoS Biology 147, 150 (2004) [hereinafter Hubbard & Love, A New Trade Framework]; James Love & Tim Hubbard, The Big Idea: Prizes to Stimulate R&D for New Medicines, 82 *Chi.-Kent L. Rev.* 1519, 1528-34 (2007) [hereinafter Love & Hubbard, The Big Idea]; Ron Marchant, Managing Prize Systems: Some Thoughts on the Options, 2 Knowledge Ecology Stud. (2008); 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); 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; Burton A. Weisbrod, Solving the Drug Dilemma, Wash. Post, Aug. 22, 2003, at A21; Aidan Hollis, Incentive Mechanisms for Innovation (Institute for Advanced Policy Research, Technical Paper TP-07005 (2007); James Love, The Role of Prizes in Stimulating R&D (2007), available at http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_JamesLove-KEI_prizes.pdf; James Love, Consumer Project on Tech., Submission of CPTECH to IGWG First Public Hearing (2006), http://www.who.int/phi/public_hearings/first/en/ (last visited Feb. 16, 2009).

n4. Love & Hubbard, The Big Idea, *supra* note 3, at 1528.

n5. *Id.* at 1520.

n6. *Id.* at 1525-26.

n7. *Id.*

n8. *Id.* at 1528. The FDA Center for Drug Evaluation and Research found that of the 1,284 new drug approvals from 1990 to 2004, only 289 (22.5%) were for "priority" reviews, defined as a product that presents a "significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease." *Id.* Of the priority products, only 183, or 14.3% of the total new drug approvals, were classified by the FDA as new molecular entities. *Id.*

n9. Pharmaceutical Research & Mfrs. of Am., *supra* note 2, at 3-8.

n10. Love & Hubbard, The Big Idea, *supra* note 3, at 1522-23.

n11. IMS Health, Inc., IMS Health Reports Annual Global Generics Prescription Sales Growth of 3.6 Percent, to \$ 78 Billion, Med. News Today, Dec. 11, 2008, <http://www.medicalnewstoday.com/articles/132702.php> [hereinafter IMS Health Reports].

n12. Daniel Workman, Richest GDP Countries 2006: Nations with World's Wealthiest & Fastest-Growing GDPs, Suite 101, July 3, 2007, http://international-trade-leaders.suite101.com/article.cfm/richest_gdp_countries_2006

(the U.S. share of high-income countries GDP was about 28% in 2006).

n13. Hoover Institution, Facts on Policy: U.S. Population Milestones (2006), <http://www.hoover.org/research/factsonpolicy/facts/4444946.html> (last visited Apr. 16, 2009).

n14. Love & Hubbard, *The Big Idea*, supra note 3, at 1523. In 2007, the share of global sales invested in R&D was 8.2%. Global pharmaceutical sales were estimated at \$ 712 billion for 2007. *Pharm Exec Staff*, supra note 1, at 84. Total private industry outlays on pharmaceutical R&D were estimated at \$ 58.8 billion for 2007. See *Pharmaceutical Research & Mfrs. of Am.*, supra note 2, at 2.

n15. James Love, *Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines*, Consumer Project on Technology (2003); Robert Langreth, *Drug Marketing Drives Many Clinical Trials*, Wall St. J., Nov. 16, 1998, at A10; Richard Smith, *Medical Journals and Pharmaceutical Companies: Uneasy Bedfellows*, 326 *Brit. Med. J.* 1202, 1202-05 (2003).

n16. N. Kent Peters et al., *The Research Agenda of the National Institute of Allergy and Infectious Diseases in Antimicrobial Resistance*, *J. Infectious Diseases* 1087, 1087-93 (2008); James Love, *Prizes, Not Prices, to Stimulate Antibiotic R&D*, Sci. & Dev. Network, Mar. 26, 2008, <http://www.scidev.net/en/opinions/prizes-not-prices-to-stimulate-antibiotic-r-d.html> [hereinafter, Love, Prizes, Not Prices].

n17. Inst. of Med., *Calling the Shots: Immunization Finance Policies and Practices 1* (2000).

n18. See, e.g., Office of the U.S. Trade Representative, 2008 Special Report (2008) (with respect to the entirely legal and transparent use of compulsory licenses to expand access to medicines for AIDS, heart disease, and cancer, the U.S. Trade Representative (USTR) wrote "while the United States recognizes the importance of Thailand's public health challenges, Thailand's recent policies and actions regarding the compulsory licensing of patented medicines have contributed to continuing concerns regarding the adequate and effective protection of IPR [intellectual property rights] in Thailand. The United States is awaiting further information on the new Thai government's approach in this area and hopes to work constructively on this and other IPR issues in order to strengthen Thailand's IPR regime.").

n19. Comm'n on Intellectual Prop. Rights, Innovation & Pub. Health, World Health Organization, *Public Health Innovation and Intellectual Property Rights* (2006), available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

n20. Etienne E. Pracht & William J. Moore, *Interest Groups and State Medicaid Drug Programs*, 28 *J. Health Pol. Pol'y & L.* 9, 25 (2003).

n21. Brian T. Liberis, *Compulsory Licensing and the TRIPS Agreement: A Solution to High Drug Prices in the United States?*, 28 *Suffolk Transnat'l L. Rev.* 57, 65-66 (2005).

n22. James Love, *AstraZeneca Tells New Zealand Cancer Patients They Will Withdraw Cancer Drug from the Market to Protest Government Pressures to Lower Prices*, Huffington Post, Dec. 18, 2005, <http://huffingtonpost.com/james-love/astrazeneca-tells-news-zea-b-12475.html>.

n23. See Hubbard & Love, *A New Trade Framework*, supra note 3, at 148.

n24. James Love, *The Role of Prizes in Developing Low-Cost, Point-of-Care Rapid Diagnostic Tests and Better Drugs for Tuberculosis* (2008), http://www.keionline.org/misc-docs/Prizes/prize_tb_msf_expert_meeting.pdf [hereinafter Love, *The Role of Prizes*]; Meredith B. Rosenthal et al., *Pay for Performance in Commercial HMOs*, 355 *New Eng. J. Med.* 1895 (2006).

n25. Love & Hubbard, *The Big Idea*, supra note 3, at 1548.

n26. *Id.*

n27. In the United States, the period of exclusivity for pharmaceutical drugs is five years for new chemical entities. 21 U.S.C. § 355(c)(3)(E)(ii) (2006); 21 U.S.C. § 355(j)(5)(F)(ii) (2006); 21 C.F.R. § 314.108(b)(2) (2008). The period of exclusivity is three years for a new indication for a drug. 21 C.F.R. § 314.108(b)(4)(iv) (2008). In Europe, the period of exclusivity for pharmaceutical test data can be extended to a maximum of eleven years. See Council Directive 2004/27, art. 10, 2004 O.J. (L 36) 34, 40 (EC). Manufacturers of biologic products are asking for twelve years of exclusivity in the U.S. market as a condition to the introduction of a system of bio-similars to promote entry by generic products. See Pathways for Biosimilars Act, H.R. 1548, 111th Congress (2009). By requiring generic suppliers to replicate experiments on humans, these intellectual property regimes routinely violate the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. For example, paragraph 17 of the Declaration, states "physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results." World Med. Ass'n, Declaration of Helsinki (2008).

n28. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. (2007).

n29. *Id.* § 5 (2007).

n30. *Id.*

n31. James Love, Would Cash Prizes Promote Cheap Drugs?, *New Scientist*, Nov. 12, 2007, at 24; Jim Tharpe, \$ 500,000 Prize for Quick Lines at Airport, *Atlanta J. Const.*, Jan. 8, 2008, at A1.

n32. Matt Richtel, Silicon Valley Meets "American Idol" with Prizes to Inspire Inventors, *N.Y. Times*, Feb. 16, 2007, at C8.

n33. Unlike the approach recommended here, Kremer and colleagues focused on subsidies to the prices paid by consumers, rather than prize rewards operating independent of prices. Rachel Glennerster & Michael Kremer, A Better Way to Spur Medical Research and Development, 23 *Reg.* 34, 36 (2000).

n34. Cornelia Dean, If you Have a Problem, Ask Everyone, *N.Y. Times*, July 22, 2008, at F1; Innocentive.com, About Us, <http://www.innocentive.com/about-us-open-innovation.php> (last visited Jan. 29, 2009).

n35. See Elizabeth Bernstein, Gotham Prize Honors New Cancer Research, *Wall St. J.*, Apr. 1, 2008, at D3; Steve LeVine, The X Factor: Can Big Money Contests Save Innovation?, *Bus. Wk.*, Dec. 1, 2008, at 54; Prize4life.org, Our Story, http://www.prize4life.org/page/about/our_story (last visited Feb. 8, 2009).

n36. Love & Hubbard, *The Big Idea*, supra note 3, at 1521-22.

n37. Burton A. Weisbrod, Editorial, Solving the Drug Dilemma, *Wash. Post*, Aug. 22, 2003, at A21.

n38. *Id.*

n39. Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. (2005).

n40. See, e.g., Joseph Stiglitz, supra note 3, at 1279-84; Joseph Stiglitz, Give Prizes Not Patents, *New Scientist*,

Sept. 16, 2006, at 21.

n41. W.H.A. Res. 60/30, § 3, P 4, U.N. DOC. A60/VR/11 (May 23, 2007).

n42. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. (2007).

n43. Posting of Sarah Rubenstein to Health Blog, Edwards Pushes Prizes Over Patents for Drugs, <http://blog-s.wsj.com/health/2007/11/14/Edwards-pushes-prizes-over-patents-for-drugs/> (Nov. 14, 2007, 11:07 EST).

n44. Stan Finkelstein & Peter Temin, *Reasonable Rx: Solving the Drug Price Crisis* (2008). The book jacket included positive reviews from Kenneth Arrow, the Nobel Laureate in Economics, Roger Williams, the Chief Executive Officer of the United States Pharmacopeia, Representative Barney Frank, and Dr. Jurgen Drews, a retired President of Roche Pharmaceutical Group Global Research. Id.

n45. The proposals were: (1) Prize Fund for Development of a Low-Cost Rapid Diagnostic Test for Tuberculosis, (2) Prize for the Development of New Treatments for Chagas Disease, (3) Priority Medicines and Vaccines Prize Fund (PMV/pf), (4) Cancer Medicines and Vaccines in Developing Countries, and (5) A Licensed Products Prize Fund (LP/pf) for Donors. Working Document Proposed by Barbados and Bolivia, <http://www.keinonline.org/misc-docs/b b igwg/ working document barbados bolivia.pdf> (Apr. 2008).

n46. W.H.A. Res. 61/21, § 36, P 5.3(a), U.N. Doc. A61/Vr/8 (May 24, 2008)

n47. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. (2005).

n48. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. §§9, 11(c) (2007); Medical Innovation prize Act of 2005, H.R. 417, 109th Cong. §§9, 11(c) (2005).

n49. Love & Hubbard, *The Big Idea*, supra note 3, at 1522.

n50. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 15(a)(2) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 16(a)(2) (2005) (allocating 50 basis points in the 2005 bill, and 60 basis points in the 2007 bill).

n51. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 15(b) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 16(b) (2005).

n52. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 11(c) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 11(c) (2005).

n53. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9 (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9 (2005).

n54. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9(d)(3) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9(d)(3) (2005).

n55. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9(c) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9(c) (2005).

n56. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9(c)(2) (2007); Medical Innovation Prize

Act of 2005, H.R. 417, 109th Cong. § 9(c)(2) (2005).

n57. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9(c)(2) (2007).

n58. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. §§9(d)(4), 15(a)(2) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. §§9(d)(4), 16(a)(2) (2005) (At present levels of proposed funding, this would be roughly \$ 4 billion per year, or \$ 40 billion (plus the rate of growth in GDP) over a ten-year period.).

n59. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9(d)(1) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9(d)(1) (2005).

n60. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9(c)(3) (2007); Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9(c)(3) (2005).

n61. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 2(11) (2007).

n62. See *id.* § 3.

n63. *Id.* § 9(d)(4).

n64. *Id.* § 2(18).

n65. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 2(18) (2007).

n66. Wei, *supra* note 3, at 32.

n67. Love & Hubbard, *The Big Idea*, *supra* note 3, at 1541. According to PhRMA, global private sector R&D outlays for new medicines were \$ 58.8 billion in 2007, \$ 56.1 billion in 2006, and \$ 51.8 billion in 2005. *Id.* at 1524.

n68. *Id.* at 1523.

n69. The World Bank, *Gross Domestic Product 2007 1, 4* (2008), <http://siteresources.worldbank.org/DATA-STATISTICS/Resources/GDP.pdf>.

n70. See Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 2(18) (2007).

n71. See *id.* (offering \$ 80 billion as the U.S. outlay amount); see also Love & Hubbard, *The Big Idea*, *supra* note 3, at 1522 (stating IMS estimates of global sales for pharmaceutical products).

n72. Hubbard & Love, *A New Trade Framework*, *supra* note 3, at 150.

n73. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 2(18) (2007).

n74. Generic Pharmaceutical Ass'n, *Facts at a Glance* (2009), <http://www.gphaonline.org/about-gpha/about-generics/facts>.

n75. IMS Health Reports, *supra* note 11; see also Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 2(12) (2007).

n76. Third World Network Info Service on Intellectual Property Issues, Thailand to Import Plavix Generics from India, Third World Network, Aug. 29, 2007, [http://www.twinside.org.sg/title2/intellectual property/info.service/twn.ipr.info.080701.htm](http://www.twinside.org.sg/title2/intellectual%20property/info.service/twn.ipr.info.080701.htm).

n77. *Id.*

n78. Kaisernetwork.org, Boehringer to Reduce Price of Antiretroviral Nevapine in Low-, Middle-Income Countries, Official Says, May 16, 2007, [http://www.kaisernetwork.org/Daily reports/rep index.cfm?DR ID=44932](http://www.kaisernetwork.org/Daily%20reports/repindex.cfm?DRID=44932).

n79. *Id.*

n80. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 2(13) (2007).

n81. *Id.* § 2(14).

n82. *Id.* § 2(15).

n83. Love & Hubbard, *The Big Idea*, *supra* note 3, at 1551.

n84. An example of this is the extensive marketing of Vioxx to patients who could have used equally effective and safer medicines. See e.g., *id.* at 1534; Alex Berenson, *Studies Find Higher Risk with Vioxx*, N.Y. Times, Sept. 13, 2006, at A18; Stephanie Saul, *Media: Drug Makers to Police Consumer Campaigns*, N.Y. Times, Aug. 3, 2005, at C7.

n85. See generally, Knowledge Ecology Int'l, *Experts Comment on S.2210, The Medical Innovation Prize Fund (2007)*, [www.keionline.org/misc-docs/Prizes/experts on s2210.pdf](http://www.keionline.org/misc-docs/Prizes/experts%20on%20s2210.pdf).

n86. Wei, *supra* note 3, at 44.

n87. Love & Hubbard, *The Big Idea*, *supra* note 3, at 1531.

n88. *Id.* at 1535-46. Including particularly those relating to the transition from the current system and the degree to which the prize fund is consistent with the WTO TRIPS Agreement. *Id.* at 1543-44.

n89. *Id.* at 1521-22.

n90. *Id.*

n91. Tim O'Reilly, *What is Web 2.0: Design Patterns and Business Models for the Next Generation of Software*, 65 *Communications & Strategies*, 17, 17 (2007).

n92. Love & Hubbard, *The Big Idea*, *supra* note 3 at 1553.

n93. Julien Penin, *Patents Versus Ex Post Rewards: A New Look*, 34 *Res. Pol'y* 641, 651 (2005).

n94. *Id.* at 652.

n95. See generally, Ushma S. Neill, The Gotham Prize: A Beacon for Cancer Researchers, 117 J. Clinical Investigation 2016, 2016 (2007); Benjamin Krohmal, Knowledge Ecology Int'l, Prominent Innovation Prizes and Reward Programs (2007); Press Release, Open Source, Open Source Communities Announce Participation Details for Sun Sponsored \$ 1 Million Innovation Awards Program, <http://www.thesun.com/aboutsun/pr/2008-01/sunflash.20080129.2.xml>.

n96. Dominique Foray & Liliane Hilaire Perez, The Economics of Open Technology: Collective Organization and Individual Claims in the 'Fabrique Lyonnaise' During the Old Regime, in New Frontiers in the Economics of Innovation and New Technology: Essays in Honour of Paul A. David 239, 243 (Cristiano Antonelli et al. eds., 2006).

n97. See Selected Innovation Prizes and Reward Programs, KEI Research Note 2008:1, 7-9 (2008) (providing details of reward systems), [http://www.keionline.org/misc-docs/research notes/kei rn 2008 1.pdf](http://www.keionline.org/misc-docs/research%20notes/kei%20rn%202008%201.pdf).

n98. Love, The Role of Prizes, *supra* note 24.

n99. Proposed by Barbados and Bolivia (Apr. 2008), [http://www.keionline.org/misc-docs/ b b igwg/working document barbados bolivia.pdf](http://www.keionline.org/misc-docs/b%20b%20igwg/working%20document%20barbados%20bolivia.pdf).

n100. Proposal 1: Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis (Apr. 2008), [http://keionline.org/misc-docs/b b igwg/prop1 tb prize.pdf](http://keionline.org/misc-docs/b%20b%20igwg/prop1%20tb%20prize.pdf) [hereinafter Proposal 1]; Proposal 2: Prize for the Development of New Treatments for Chagas Disease (Apr. 2008), [http://keionline.org/misc-docs/b b igwg/prop2 ca-hagas-prize.pdf](http://keionline.org/misc-docs/b%20b%20igwg/prop2%20chagas-prize.pdf) [hereinafter Proposal 2]; Proposal 3: Priority Medicines and Vaccines Prize Fund (PMV/pf) (Apr. 2008), [http://keionline.org/misc-docs/b b igwg/prop3 pmv pf.pdf](http://keionline.org/misc-docs/b%20b%20igwg/prop3%20pmv%20pf.pdf) [hereinafter Proposal 3].

n101. Proposal 1, *supra* note 100, at 2-3; Proposal 2, *supra* note 100, at 3; Proposal 3, *supra* note 100, at 2.

n102. Proposal 1, *supra* note 100, at 3; Proposal 2, *supra* note 100, at 3; Proposal 3, *supra* note 100, at 2-3.

n103. Proposal 1, *supra* note 100, at 2-3; Proposal 2, *supra* note 100, at 3; Proposal 3, *supra* note 100, at 2.

n104. Love, The Role of Prizes, *supra* note 24, at 7.

n105. *Id.*

n106. Love, Prizes Not Prices, *supra* note 16.

n107. See *id.*

n108. *Id.*

n109. See *id.*

n110. For discussions of the rationale for and the possibility of funding clinical trials as public goods, see generally Marcia Angell, The Truth About The Drug Companies: How They Deceive Us And What To Do About It, (Random House 2005); Dean Baker, Cent. for Econ. and Pol'y Research, The Benefits and Savings from Publicly-Funded Clinical Trials of Prescription Drugs (2008); I. Chalmers, Underreporting Research is Scientific Misconduct, 263 J. Am. Med. Ass'n 1405 (1990); T. Bodenheimer, Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry, 342 *New Eng. J. Med.* 1539 (2000); Rich McManus, Abolitionist Angell Calls for Clinical Trial Reform, 53 NIH Record No. 15 (2001); John Yaphe et al., The Association Between Funding by Commercial Interests and Study Outcome in Randomized Controlled Drug Trials, 18 *Fam. Prac.* 565 (2001); Sameer S. Chopra, Industry Funding of

Clinical Trials: Benefit or Bias?, 290 J. Am. Med. Ass'n 113 (2003); Joel Lexchin et al., Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review, 326 BMJ 1167 (2003); Samuel O. Thier, et al., Financial Anatomy of Biomedical Research, 294 J. Am. Med. Ass'n 1333 (2005); Benjamin Djulbegovic et al., Treatment Success in Cancer: New Cancer Treatment Successes Identified in Phase 3 Randomized Controlled Trials Conducted by the National Cancer Institute-Sponsored Cooperative Oncology Groups, 1955 to 2006, 168 Archives Internal Med. 632 (2008); Tracy R. Lewis et al., The Case for Public Funding and Public Oversight of Clinical Trials, The Economists' Voice (2007); Crystal Phend, NCI-Sponsored Cancer Trials Offer Decent Clinical Return on Investment, MedPage Today, Mar. 24, 2008; Thomas Alured Faunce, Senior Lecturer, Intellectual Monopoly Privileges, Cost-Effectiveness Evaluation and the Knowledge Commons New Political Paradigms for Wisdom in the Age of Corporate Globalisation, Presentation at TACD meeting on the politics and ideology of intellectual property rights (Mar. 2006); Thomas Alured Faunce, Toward a Multilateral Treaty on Safety and Cost-Effectiveness of Medicines and Medical Devices, WHO Public Hearing on Public Health, Innovation and Intellectual Property, (Nov. 14, 2006).

n111. James Love & Michael Palmedo, Costs of Human Use Clinical Trials: Surprising Evidence From the US Orphan Drug Act (2001), <http://www.cptech.org/ip/health/orphan/irsdata9798.html>.

n112. About ClinicalTrial.gov, <http://clinicaltrials.gov/ct2/info/about> (last visited Mar. 18, 2009).

n113. See James Love, Dir. Of the Taxpayer Assets Project, Ctr. For the Study of Responsive Law, Comments Presented to the Second National Institute of Health CRADA Forum (Sept. 8, 1994), <http://www.cptech.org/pharm/crada2.html>.

n114. See id.

n115. Love, The Role of Prizes, *supra* note 24, at 6.

n116. Id. at 7.

n117. Id.

n118. Love & Hubbard, The Big Idea, *supra* note 3, at 1530.

n119. See James Love & Tim Hubbard, Paying for Public Goods, in Code: Collaborative Ownership and the Digital Economy (Rishab Aiyer Rhosh ed., MIT Press 2005).

n120. Working Document Proposed by Barbados and Bolivia, http://www.keinonline.org/misc-docs/bb_igwg/working_document_barbados_bolivia.pdf (Apr. 2008).

n121. United States Patent & Trademark Office, General Information Concerning Patents (2005), <http://www.uspto.gov/go/pac/doc/general/>. This also applies to some degree with other intellectual property right regimes, including copyright, and several sui generis regimes, including those involving drug registration data or plant breeder rights. Id.

n122. Jerome H. Reichman, Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation, 53 *Vand. L. Rev.* 1743, 1797-98 (2000); Mark A. Lemley, Should A Licensing Market Require Licensing?, 70 *Law & Contemp. Probs.* 185, 202 (2007).

n123. Ian Ayers & J.M. Balkin, Legal Entitlements as Auctions: Property Rules, Liability Rules, and Beyond, 106 *Yale L.J.* 703, 704 (1996).

n124. 28 U.S.C. § 1498 (2006).

n125. *Id.* This provision also applies to copyrights and plant breeder rights. *Id.*

n126. *Id.*

n127. Paul M. Shoenhard, Who Took My IP? - Defending the Availability of Injunctive Relief for Patent Owners, 16 *Tex. Intell. Prop. L.J.* 187, 233 (2008).

n128. Yi Deng, The Effects of Patent Regime Changes: A Case Study of the European Patent Office, 25 *Int'l J. Indus Org.* 121, 125 (2007).

n129. James Love, Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D, 40 *U.C. Davis L. Rev.* 679, 687 (2007).

n130. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round, 33 *I.L.M.* 1197 (1994) (1994) [hereinafter TRIPS Agreement].

n131. Council Directive on Legal Protection of Biotechnological Inventions 98/44, art. 52, 1998 O.J. (L 213) 17 (EC). "Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory license where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent." *Id.*

n132. Regulation 816/2006 of the European Parliament and of the Council, 2006 O.J. (L 157) (EC); Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation, 68 *U. Pitt. L. Rev.* 491, 584-85 (2006).

n133. *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006).

n134. Lawrence M. Sung, In the Wake of Reinvigorated U.S. Supreme Court Activity in Patent Appeals, 4 *J. Bus. & Tech. L.* 97, 124 (2009).

n135. James Love, Racist and Ignorant Reactions on Thailand Compulsory License, *The Huffington Post*, Jan. 25, 2007, <http://www.huffingtonpost.com/james-love/racist-and-ignorant-react b 39618.html>.

n136. *Id.*; Marc Longpre, Federal Circuit Likely to Uphold Preliminary Injunction in Amgen, Roche Case, *Fin. Times (Pharmawire)*, July 15, 2008, available at <http://www.ft.com/cms/s/2/d1013b44-5277-11dd-9ba7-000077b07658.html>; James Love, Abbott Recently Sought Compulsory License in US Patent Dispute, (2007), <http://www.keionline.org/content/view/43/>.

n137. TRIPS Agreement, *supra* note 130.

n138. *Id.* pt. I, arts. 30, 31.

n139. *Id.* art. 31(b).

n140. *Id.* ("This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use... ."); *Id.* art. 31(k) ("where such use is permit-

ted to remedy a practice determined after judicial or administrative process to be anti-competitive... "). There is no obligation for prior negotiation for non-voluntary licenses issued under Article 31bis of TRIPS.

n141. Id. art. 31(f).

n142. See Charlene A. Stern-Dombal, Tripping Over TRIPS: Is Compulsory Licensing Under eBay at Odds with U.S. Statutory Requirements and TRIPS?, *41 Suffolk U. L. Rev.* 249, 265-66 (2007).

n143. See TRIPS Agreement, *supra* note 130, arts. 8, 40.

n144. See Panel Report, Canada - Patent Protection of Pharmaceutical Products, Complaint by the European Communities and Their Member States, WT/DS114/R (Mar. 17, 2000).

n145. See, e.g., Carlos Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries 71-72 (2000).

n146. World Trade Organization, Amendment of the TRIPS Agreement, WT/L/641 (Dec. 8, 2005).

n147. TRIPS Agreement, *supra* note 130, at part III.

n148. See e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006); see also *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331 (Fed. Cir. 2006).

n149. TRIPS Agreement, *supra* note 130, art. 44.

n150. TRIPS Agreement, *supra* note 130, art. 44.2.

n151. See *eBay*, 547 U.S. at 394 (opening the door for district courts to deny injunctive relief in favor of reasonable royalties); Brian J. Love, The Misuse of Reasonable Royalty Damages as Patent Infringement Deterrent 4-7 (Mar. 11, 2009) (unpublished paper), <http://works.bepress.com/brianlove/2> (discussing reasonable royalty damages in patent infringement cases).

n152. Canadian Copyright Act, R.S.C. ch. C 42 § 40; The Copyright (Consolidation) Act, 1957, No. 14, Acts of Parliament, 1957, § 59.

n153. TRIPS Agreement, *supra* note 130, art. 44.2.

n154. Trade Agreement Act of 1979, 19 U.S.C. § 1337(d) (2006) ("Exclusion of articles from Entry (1) If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry in the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry."); see also Posting of James Love, When Customs Authorities May Allow Infringing Goods to be Imported into the United States, Knowledge Ecology International Policy Blog, June 9, 2007, http://www.keionline.org/component/option,com_jd-wp/Itemid,39/p,32/.

n155. *Innogenetics, N.V. v. Abbot Labs.*, 512 F.3d 1363, 1380-81 (Fed. Cir. 2008) ("While the market entry fee was based upon the projection that Abbott could sell its product through 2019, even Abbott acknowledges that such future sales would be subject to the running royalty, a compulsory license. We remand to the district court to delin-

eate the terms of the compulsory license, such as conditioning the future sales of the infringing products on payment of the running royalty, the 5-10 Euros per genotyping assay kit.").

n156. See William Fisher, *Intellectual Property and Innovation: Theoretical, Empirical, and Historical Perspectives* 13 (2001), available at <http://cyber.law.harvard.edu/people/tfisher/Innovation.pdf>; Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 *Berkeley Tech. L.J.* 853, 862 (2003).

n157. See Fisher, *supra* note 156, at 7.

n158. See Fisher, *supra* note 156, at 13; Chien, *supra* note 156, at 866, 872, 879.

n159. See Chien, *supra* note 156, at 862, 872.

n160. See, e.g., Robert Hunt & James Bessen, *The Software Patent Experiment*, Q3 *Bus. Rev.* 22, 23, 30 (2004).