A Prize System as a Partial Solution to the Health Crisis in the Developing World

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Each year, roughly nine million people in the developing world die from infectious diseases.[1] Millions more endure suffering caused by the same diseases. Many of those deaths and much of that pain could be avoided by modifying the combination of laws and government programs that provide incentives for the development and distribution of drugs. In a recent paper, we argued that such modifications are morally imperative, despite the fact that they would increase the already substantial extent to which the cost of developing new drugs is borne by the residents of the developed world, either by raising their taxes or by increasing the prices they pay for patented pharmaceutical products.[2]

The difficult question, in our judgment, is not whether we should modify our laws and institutions to address this crisis, but which combination of reforms would alleviate the problem most fairly and efficiently. We are currently working on a book that examines and compares a wide variety of potential solutions.[3] In this paper (which will eventually appear as a chapter in that book), we focus on one option: replacing or supplementing the patent system, as the main method by which we encourage the creation of new drugs, with a system of government prizes.

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[1] See WORLD HEALTH ORGANIZATION, WORLD HEALTH REPORT 2004.
[2] WILLIAM W. FISHER, III & TALHA SYED, *Global Justice in Health Care: Developing Drugs for the Developing World*, 40 U.C. Davis Law Review 581 (2007).
[3] WILLIAM W. FISHER, III & TALHA SYED, Drugs, Law, and the Health Crisis in the Developing World (Stanford University Press. forthcoming).

Producing new pharmaceutical products – and then verifying their effectiveness and safety – is both expensive and risky. Substantial financial incentives are essential to induce firms to engage in this activity. The current patent system provides those incentives by empowering the firms that develop novel and nonobvious pharmaceutical products to prevent others from making, using, selling, or importing those products. Armed with that authority, the firms are able to sell the products for prices much higher than the costs of manufacturing them. The resultant profits provide the carrots necessary to prompt the firms to engage in the inventive activity in the first instance.

A prize system would work quite differently. Instead of authorizing drug developers to exclude competitors, the government would pay successful developers. Other firms, including generic drug manufacturers, would be free to make and sell the drugs in question. The resultant competition would keep drug prices close to the modest costs of manufacturing them. The money necessary to run such a system would come, not from consumers (or their insurers), but from taxpayers.

Would a prize system of this general sort be better than the patent system? More to the point, would it be more effective in alleviating the health crisis in the developing world? A substantial body of literature addresses those questions. In this paper, we marshal and critically evaluate that literature – and add to it some arguments of our own.

The discussion is organized as follows. In Section A, we explore the major potential strengths and weaknesses of prize systems. In Section B, we consider how a prize system focused on the production of drugs aimed at communicable diseases might be designed so as to capitalize on its strengths and mitigate its weaknesses.

A. Pros and Cons

A prize system of the sort sketched briefly above has five potential benefits. First, it would enable us to avoid the most serious of the drawbacks of the current patent system – namely, the social-welfare losses caused by the monopoly pricing of patented products. The patent system, as we have seen, enables the firms holding the patents to charge consumers much more for the drugs to which they pertain than the cost of producing those drugs. Indeed, that's the point of the system. Unfortunately, pursuit of this strategy has the effect of placing the drugs out of the financial reach of some people. Economists commonly refer to the deaths or suffering of the people who are thus "priced out of the market" as forms of "deadweight loss." In the developing world, this effect is especially grave, because so many people are both poor and uninsured and thus unable to afford the prices of patented products.

This drawback of a patent system can be mitigated in various ways – for example, through systems of price discrimination in the marketing of the drugs or through similarly discriminatory insurance systems. Such mitigation strategies are considered in other sections of our forthcoming book.[4] Suffice it to say for present purposes that their capacity to solve the aspect of the problem that concerns us here – namely, welfare losses caused by the unavailability of affordable drugs in developing countries – is limited.

A prize system, by contrast, is capable of eliminating this problem altogether. As indicated above, competition among manufacturers of the drugs whose development is

[4] Id. at chpt. 6. An analysis of the advantages (and disadvantages) of price discrimination in sales of intellectual products in general and drugs in particular may be found in WILLIAM W. FISHER, III, *When Should We Permit Differential Pricing of Information?*, 55 UCLA Law Review 1 (2007).

stimulated by the prizes would keep prices low for everyone. Access to the drugs would thus be radically increased.[5]

Second, a prize system can take advantage of the way in which knowledge concerning actual or potential pharmaceutical products is typically distributed.[6] Ordinarily, governments have (or can obtain) better information concerning the aggregate health benefits of drugs than private parties. Why? Because government agencies regularly collect and assess data concerning the incidence and impact of diseases and thus are well positioned to ascertain the welfare gains that could be reaped by developing and distributing vaccines or cures for each ailment. By contrast, governments ordinarily have knowledge inferior to that of private firms concerning the relative merits of potential lines of innovation – which drugs aimed at particular diseases would work best, which of the possible ways of developing such drugs are most promising, and the cost of each of those routes.

The inferiority of the government's information concerning the merits of potential lines of research gives both a prize system and a patent system a clear advantage over a system of government grants as a way of inducing innovation. In a grant system (sometimes called a "push" system), government officials must decide which projects are most likely to generate solutions to particular health problems. Too often, they make those decisions poorly.[7] By contrast, in both a patent and a prize system, private firms

[5] See ROBERT C. GUELL & MARVIN FISCHBAUM, *Toward Allocative Efficiency in the Prescription Drug Industry*, 73 Milbank Quarterly, (1995);STEVEN SHAVELL & TANGUY VAN YPERSELE, *Rewards versus Intellectual Property Rights*, 44 Journal of Law and Economics 525, (2001); THOMAS POGGE, *Human Rights and Global Health: A Research Program*, 36 Metaphilosophy 182, (2005).

[6] See MICHAEL R. KREMER, *Creating Markets for New Vaccines, Part I: Rationale*, NBER Working Paper #7716, 53 (2000);BRIAN D. WRIGHT, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 American Economic Review 691, (1983).; Winters and Nelson.

[7] The most notorious example of poor decision-making in this regard is the failed effort of USAID to stimulate the development of a malaria vaccine. During the 1980s, the agency spent over $60 million on a

compete to develop solutions to health problems. In doing so, they are able to rely upon their own information concerning the costs and probability of success of alternative routes – and to respond quickly to new information on those fronts.

The superiority of the government's information concerning the social benefits of particular innovations would seem to give both a prize system and a grant system an equally clear advantage over a patent system, under which R&D investments are directed toward lines of innovation that private firms consider most potentially lucrative, not those that are most socially beneficial. However, Brian Wright has pointed out that the demerits of a patent system in this respect are not so certain. In theory, a government administrator could adjust the duration of – or the set of rights associated with – each individual patent to reflect the social value of the specific invention at issue. A patent system that incorporated such a mechanism could be just as good as a prize or grant system in capitalizing on the government's superior knowledge concerning the social benefits of drugs.[8] Perhaps so, but this contemplates a patent system fundamentally different from the one we have inherited. So long as all patents (or at least all patents within a given technological field) last the same amount of time and carry with them the same set of rights, the fine tuning that Wright identifies will be infeasible, and a prize system, which invites such fine tuning, will be superior to it.

The third major potential advantage of a prize system is that it is capable of correcting all three of the biases that distort (from a social welfare standpoint) the output

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project that, in its judgment, would likely lead to an effective vaccine. In the end, the initiative produced nothing of value. See ROBERT S. DESOWITZ, The Malaria Capers: Tales of Parasites and People (W.W. Norton. 1991). In truth, the probative value of this example is limited. The principal investigator, it turned out, was lining his own pockets, and the agency's project director was receiving kickbacks. Thus, this particular episode may reveal more about the potential for a few corrupt actors to waste a great deal of money than it does about the merits of "push" programs in general.

[8] WRIGHT, 703.

of new pharmaceutical products under the current, patent-based system: the bias toward drugs aimed at ailments that disproportionately afflict the rich; the bias toward "me-too drugs" (the term conventionally used to describe drugs that, when introduced into the market, offer little or no health benefits over extant drugs[9]); and the bias away from vaccines. Each of these distortions is well documented – and is discussed in detail in our forthcoming book – so we review them here only briefly. The first is the natural outgrowth of the fact that roughly 95% of the revenue of American, European, and Japanese pharmaceutical firms come from developed countries, in which reside only 20% of the world's population. It should not be surprising that the firms concentrate their resources on research projects likely to produce drugs that address diseases common in those countries. The second of the biases is harder to explain, but that it exists is now beyond dispute. One indication: in the United States, 57% of the new molecular entities licensed by the Food and Drug Administration between 1990 and 2004 constitute "me-too" drugs – as evidenced by the fact that they were processed by the agency using its "standard review" system, rather than its "priority review" system.[10] The causes of the third bias are myriad: the inability of the sellers of vaccines to capture all of the positive externalities generated by their consumption; the heuristic that causes people to underestimate the likelihood that they will contract a serious disease; the greater stringency of the manufacturing regulations applicable to vaccines; the fact that the

[9] An example: Prozac was the first commercially available antidepressant to rely upon the principle of suppressing the uptake of serotonin. Drugs that rely upon the same principle but were introduced into the market later – such as Paxil, Zoloft, and Celexa – are commonly considered "me-too" drugs. They may work better for some populations, but their advantages over Prozac are modest. See BENEDICT CAREY, *Is Prozac Better? Is It Even Different?*, New York Times September 21, 2004.

[10] See U.S. FOOD AND DRUG ADMINISTRATION, *CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type*, (2008). Other estimates of the percentage of drugs that consist of me-too drugs are even higher. See, e.g., BRYAN P. SCHWARTZ & MARHI KIM, Economic Prizes: Filling the Gaps in Pharmaceutical Innovation 34 (2005).

largest purchasers of vaccines are governments, which frequently use their bargaining power to drive prices down; and the continued threat to vaccine producers of products-liability judgments, despite efforts by legislatures to shield them from this hazard. The aggregate effect of these pressures is striking: the number of vaccines currently on the market is tiny – roughly 47 in the United States. All of these distortions could be reduced or eliminated by a prize system – most simply, by ensuring that the sizes of the prizes are adjusted to match the incremental health benefits of each innovation.

The fourth potential benefit of a prize system is that it could reduce socially wasteful expenditures by pharmaceutical firms. The largest potential source of savings consists of marketing costs. Estimates of the magnitude of those costs under the current regime vary. Some scholars contend that pharmaceutical firms devote roughly one third of their revenues to marketing their products.[11] Meredith Rosenthal and her colleagues suggest that the number is closer to 15%.[12] Dean Baker and Norkio Chatani point out that "[a]ccording to the industry's own data, in 2000 it employed almost twice as many people in sales promotion as in research, 87,810 in sales compared to 48,527 in research."[13] These differences aside, there is little question that the amount that the firms are currently spending on marketing is substantial. For reasons explored in chapter 4 of our forthcoming book, only a portion of those expenditures redound to the benefit of society at large. In brief: To the extent that advertising better informs either patients or doctors concerning the merits of drugs and thus enables them to improve their own or

[11] See Angell 2004; Love and Hubbard
[12] See MEREDITH B. ROSENTHAL, et al., *Demand Effects of Recent Changes in Prescription Drug Promotion*, 6 Frontiers in Health Policy Research (2003).
[13] DEAN BAKER & NORIKO CHATANI, *Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research*, Center for Economic and Policy Research Briefing Paper, 9 (2002).

their patients' health, it is plainly beneficial. However, to the extent that advertising functions to expand or stabilize the market share of one of several substitute products – or leads to increases in drug consumption unjustified by health benefits – it is wasteful or pernicious. A prize system, if it were structured properly, might reduce these outlays. Most intriguing is the possibility that the mechanism for determining the magnitude of the awards might be designed so as to reduce firms' incentives to engage in pernicious forms of promotion, while preserving their incentives to engage in beneficial forms of promotion. Another potential source of savings involves litigation costs. The resources currently consumed by lawyers and the court system resolving disputes involving pharmaceutical patents are enormous.[14] A prize system would not be free of disputes, of course. But it might be designed to reduce the incidence of those controversies and the costs of resolving them.

The last of the potential advantages of a prize system – at least when viewed from some normative angles – is that it would create opportunities for progressive redistribution of wealth. Most of the money necessary to fund a prize system would come from developed countries, where per-capita wealth and income are above average. Moreover, the majority of such countries have progressive systems of income taxation, which concentrate tax burdens on the wealthy. By contrast, most of the people who would benefit from a prize system would likely be poor residents of developing countries. The net effect: wealth would be transferred from rich to poor.[15]

[14] See Id. at 11. For an extensive discussion of the rapidly rising costs of resolving patent disputes of all sorts, see JAMES BESSEN & MICHAEL J. MEURER, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators At Risk 120-46 (Princeton University Press. 2008).

[15] For arguments concerning why such an effect would be desirable – as well as objections to those arguments, see FISHER & SYED, *Global Justice in Health Care*.

Unfortunately, the picture painted thus far is misleadingly rosy. Prize systems have major potential disadvantages as well. The first and perhaps most serious is that the increase in tax burdens necessary to finance a prize system can lead to an inefficient diminution in labor. Knowing that they will earn less per hour, at least some of residents of developed countries (upon whom the bulk of the taxes would be imposed) would likely work fewer hours. Predicting the magnitude of this effect is extremely difficult. One source of the difficulty is that some people are likely react to an increase in their tax burdens in precisely the opposite way – by working harder or longer to offset their loss of income and thus maintain their standard of living. Most economists think that the diminution in labor of the former group will be larger than the increase in labor of the latter group, but economists disagree sharply concerning the magnitude of the net effect – and specifically concerning the magnitude of the welfare loss caused by this distortion. The majority think that it would be modest,[16] but not all agree.[17]

The issue is further complicated by the uncertain normative footing of economists' depiction of this effect as a "distortion." A distortion of what? Presumably, the overall pattern of labor and investment that existed prior to the imposition of the extra taxes necessary to run the prize system. But why should we consider that pattern

[16] See ARTHUR SNOW & RONALD S. WARREN, JR., *The Marginal Welfare Cost of Public Funds: Theory and Estimates*, 61 Journal of Public Economics 289, (1996). (review article); BAKER & CHATANI, 7 n.4. Louis Kaplow argues persuasively that, in one context, the diminution in labor would be zero – namely, when the distribution of tax burdens precisely matched the distribution of benefits from the innovation induced by those taxes. See LOUIS KAPLOW, *The Optimal Supply of Public Goods and the Distortionary Cost of Taxation*, 49 National Tax Journal 513, (1996); LOUIS KAPLOW, *A Note on the Optimal Supply of Public Goods and the Distortionary Cost of Taxation*, 51 National Tax Journal 117, (1998); LOUIS KAPLOW, On the (Ir)Relevance of Distribution and Labor Supply Distortion to Public Goods Provision and Regulation (2004). This insight would provide a powerful justification for a prize system for drugs that addressed the diseases common in the United States, insofar as the set of beneficiaries of such a system would closely resemble the set of taxpayers. Unfortunately, a prize system of the sort we are considering, which would most benefit the residents of developing countries while imposing most of its burdens on the residents of developed countries, would not benefit from the feedback effect identified by Kaplow.

[17] See MARTIN FELDSTEIN, *How Big Should Government Be?*, 50 National Tax Journal 197 (1997).

optimal, and regret deviations from it? The usual response is that we have no reason to doubt its optimality.[18] Perhaps, but that seems a weak foundation. Until it is shored up, we will have trouble assessing the magnitude of this problem.

The bottom line is that the benefits we would reap in the form of reduced "deadweight losses" by replacing the patent system with a prize system would likely be partially – but not completely – offset by an increase in the welfare losses caused by a reduction in the output of labor in developed countries.[19]

A second potential disadvantage of a prize system is that it could foster inefficient "rent seeking." Pharmaceutical firms already spend substantial sums on campaign contributions and lobbyists, seeking to persuade government officials to modify the patent system to their advantage.[20] From the standpoint of aggregate social welfare, such

[18] See DOUGLAS GARY LICHTMAN, *Pricing Prozac: Why the Government Should Subsidize the Purchase of Patented Pharmaceuticals*, 11 Harvard Journal of Law and Technology 123, (1997); BARTON H. THOMPSON, JR., *The Endangered Species Act: A Case Study in Takings & Incentives*, 49 Stanford Law Review 305, (1997).

[19] See MICHAEL ABRAMOWICZ, *Perfecting Patent Prizes*, 56 Vanderbilt Law Review 115 (2003).

[20] The following chart (current as of October 22, 2008), showing total U.S. campaign contributions by pharmaceutical firms during the past two decades, was created by the Center for Responsive Politics, relying on information from the Federal Election Commission:

Election Cycle	Rank†	Total Contributions	Contributions from Individuals	Contributions from PACs	Soft Money Contributions	Donations to Democrats	Donations to Republicans	% to Dems	% to Repubs
2008*	18	$22,462,731	$10,230,644	$12,232,087	N/A	$11,034,755	$11,410,100	49%	51%
2006*	15	$19,414,800	$6,920,128	$12,494,672	N/A	$6,065,172	$13,040,480	31%	67%
2004*	21	$17,824,366	$8,583,959	$9,240,407	N/A	$6,019,855	$11,779,136	34%	66%
2002	10	$29,651,261	$3,424,600	$6,957,382	$19,269,279	$7,703,282	$21,922,972	26%	74%
2000	13	$27,087,280	$5,867,187	$5,649,913	$15,570,180	$8,319,347	$18,704,853	31%	69%
1998	16	$13,219,634	$2,723,785	$4,107,068	$6,388,781	$4,748,779	$8,426,010	36%	64%
1996	16	$14,032,842	$3,568,762	$3,584,217	$6,879,863	$4,884,915	$9,119,373	35%	65%
1994	20	$7,966,783	$2,075,830	$3,477,146	$2,413,807	$3,528,138	$4,433,468	44%	56%
1992	23	$7,424,841	$2,513,802	$2,589,241	$2,321,798	$3,188,167	$4,223,127	43%	57%
1990	28	$3,276,017	$812,446	$2,463,571	N/A	$1,517,129	$1,756,673	46%	54%
Total	16	$162,360,555	$46,721,143	$62,795,704	$52,843,708	$57,009,539	$104,816,192	35%	65%

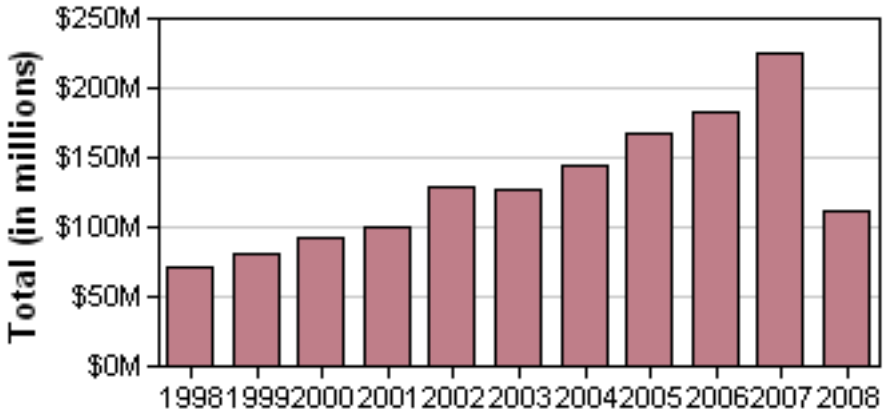
"Pharmaceuticals/Health Products: Long-Term Contribution Trends," http://www.opensecrets.org/industries/indus.php?ind=H04.

Total spending by the industry on lobbyists, as reported by the Center for Responsive Politics, was substantially more:

expenditures represent pure waste. Unfortunately, under a prize system, the amount spent on efforts to influence government – specifically, to affect the ways in which the prizes are calculated and allocated – could increase.

A third problem is that prize systems are clumsy in dealing with sequential innovation.[21] Suppose Firm A develops a breakthrough product. Firm B, building on A's research, develops a slightly improved version of the product. What should be the magnitude of the prize awarded to each? The answer is far from clear, and on that answer depends the capacity of the system to provide optimal incentives for innovation.

A fourth potential disadvantage of a prize system is that distrust of government may increase its costs. In the past, governments have not always made good on their promises to award prizes to successful innovators. For example, the British government long delayed awarding a promised prize to the developer of a device or technique that would enable mariners to determine longitude.[22] Such breaches of faith may make pharmaceutical firms hesitate to commit huge sums of money to new research ventures in reliance on a government's commitment to reward them if successful. To overcome that



"Annual Lobbying on Pharmaceuticals/Health Products," http://www.opensecrets.org/lobby/indusclient.php?lname=H04&year=2008.

[21] For discussion of the difficulty of designing a system that will deal effectively with situations in which innovation is cumulative, see NANCY GALLINI & SUZANNE SCOTCHMER, *Intellectual Property: When Is It the Best Incentive System?*, UC Berkeley Working Papers, Department of Economics, 16-20 (2001).

[22] See DAVA SOBEL, Longitude (Walker & Company. 1995).

hesitation, the government may need to increase the magnitude of the promised prize. Bonuses of that sort would plainly increase the cost of the program.[23]

The implications of the last of the differences between a prize system and the patent system are more ambiguous. The carrot of a patent commonly leads multiple firms to pursue a particular research goal simultaneously and to keep their work secret from one another. Whether such a "patent race" is socially beneficial is unclear. On one hand, it can increase the likelihood that the goal will be achieved or the speed with which it is achieved, which both benefits the consumers of the patented innovation and may accelerate socially beneficial follow-on innovation.[24] On the other hand, it may lead to truly duplicative and thus plainly wasteful research, and it may engage minds and money that could be better applied to other projects.[25] Some level of duplication is probably socially advantageous, but how much is uncertain.[26]

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[23] See STEPHEN M. MAURER, The Right Tool(s): Designing Cost-Effective Strategies for Neglected Disease Research (2005).

[24] See RICHARD R. NELSON, *Uncertainty, Learning, and the Economics of Parallel Research and Development*, Review of Economics and Statistics (1961).

[25] See STEVE CALANDRILLO, *An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System*, 9 Fordham Intellectual Property, Media & Entertainment Law Journal 301, 329 (1998).

[26] Efforts by economists to resolve these extraordinarily difficult issues include F.M. SCHERER, *Parallel R&D Paths Revisited*, Kennedy School of Government, Faculty Research Working Paper Series (2007). F.M. Scherer, "Research and Development Resource Allocation Under Rivalry," 81 Quarterly Journal of Economics 359, 364-66 (1967); Yoram Barzel, "Optimal Timing of Innovations," 50 Review of Economics & Statistics 348 (1968); Partha Dasgupta, "Patents, Priority and Imitation or, The Economics of Races and Waiting Games," 98 Economics Journal 66, 74-78 (1988); Partha Dasgupta and Joseph Stiglitz, "Uncertainty, Industrial Structure and the Speed of R&D," 11 Bell Journal of Economics 1, 12-13 (1980); Drew Fundenberg, Richard Gilbert, Joseph Stiglitz, and Jean Tirole, "Preemption, Leapfrogging, and Competition in Patent Races," 77 European Economic Review 176 (1983); Michael L. Katz & Carl Shapiro, "R & D Rivalry with Licensing or Imitation," 77 American Economic Review 402 (1987); Steven A. Lippman & Kevin F. McCardle, "Dropout Behavior in R&D Races with Learning," 18 Rand Journal of Economics 287 (1987); Glenn C. Loury, "Market Structure and Innovation," 93 Quarterly Journal of Economics 395 (1979); Pankaj Tandon, "Rivalry and the Excessive Allocation of Resources to Research," 14 Bell Journal of Economics 152 (1983):; Brian D. Wright, "The Resource Allocation Problem in R & D," in The Economics of R & D Policy 41, 50 (George S. Tolley, James H. Hodge & James F. Oehmke eds., 1985). Efforts by legal scholars, building on the economics literature, include Peter Menell, "Intellectual Property: General Theories," Encyclopedia of Law & Economics, available at http://encyclo.findlaw.com/1600book.pdf; Louis Kaplow, "The Patent-Antitrust Intersection: A

Some scholars have tried to provide us better guidance on this question with respect to pharmaceutical products. A recent study by Joseph DeMasi and Cherie Paquette confirms the prediction that multiple pharmaceutical firms often work independently on the same problem – as evidenced by the frequency with which breakthrough drugs are succeeded by other drugs in the same therapeutic categories more quickly than would be possible if the later entrants were building on the work of the pioneer.[27] F.M. Scherer has argued that this practice may be socially beneficial. When all possible projects that have the potential to generate a particular therapeutic outcome are risky, Scherer argues, a given firm will maximize its profits by pursuing in parallel several such projects – or, more subtly, by undertaking a series of groups of parallel projects. The lower the probability that any one path will succeed (and the more lucrative the goal) the greater the number of paths the firm will rationally pursue simultaneously. The same principle, Scherer suggests, may justify, from the standpoint of aggregate social welfare, the pursuit of parallel research paths by many firms within the pharmaceutical industry as a whole.[28]

Scherer's analysis neglects, however, some differences between the profit-maximizing behavior of a single firm, and the pattern of behavior induced by the patent system in the industry as a whole. First, an individual firm is unlikely to ask two or more teams to pursue two identical paths at the same time. Rather, it will (rationally) explore

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Reappraisal," 97 Harvard Law Review 1813 (1984); Edmund Kitch, "The Nature and Function of the Patent System," 20 Journal of Law and Economics 265 (1977); idem, "Patents, Prospects, and Economic Surplus: A Reply," 23 Journal of Law and Economics 205 (1980); Mark F. Grady & J.I. Alexander, "Patent Law and Rent Dissipation," 78 Virginia Law Review 305 (1992); Robert Merges & Richard Nelson, "On the Complex Economics of Patent Scope," 90 Columbia Law Review 839 (1990); and Mark Lemley, "The Economics of Improvement in Intellectual Property Law," 75 Texas Law Review 993 (1997).

[27] JOSEPH A. DIMASI & CHERIE PAQUETTE, *The Economics of Follow-on Drug Research and Innovation*, 22 Pharmacoeconomics 1 (2004).

[28] See F.M. SCHERER, *Markets and Uncertainty in Pharmaceutical Development*, Kennedy School of Government, Faculty Research Working Paper Series, 10-16 (2007).

simultaneously several different possible routes to the same end – for example, several different molecules, each of which has a chance of achieving the desired outcome. By contrast, patent races may result in two or more firms pursuing identical projects.[29] Moreover, an individual firm will likely encourage its various teams to share information in order to avoid reinventing wheels. Competitive firms, by contrast, do not share such information. The likelihood of waste at the industry level is thus significantly higher.

Another potentially important source of waste is obscured by Scherer's argument. Under the patent system, individual firms have an incentive to invest more resources into the development of me-too drugs than would be justified by the profits attributable solely to the therapeutic advantages (by definition, modest in amount) of those drugs. The reason: they can appropriate some of the market for the pioneer drug. As a result, each firm may be less discouraged from entering a crowded field than it would be under a truly winner-take-all regime by the fear of losing the patent race. It is not certain that this effect would occur. The prospect of earning substantial profits from a me-too drug depends upon the ability of the pioneer and the follower(s) to engage in oligopolistic pricing, which might be difficult. And the prospect that one would have to share one's gains with a follower plainly reduces the incentives of the pioneer, which may diminish the number of firms willing even to start races. In short, many factors are at play here.

[29] Michael Kremer and Rachel Glennerster provide a hypothetical example that shows how this inefficient duplication might occur even if each firm is aware of what the others are working on. Suppose that "there are two promising ways to develop a vaccine." One has a 60% chance of success, the other a 25% chance of success. Each of two firms is considering working on the project. From a social welfare standpoint, we would want one firm to pursue the first route, the other firm to pursue the second. But both may instead choose to pursue the first route, figuring that they each have a 50% chance of winning the resultant race and thus a 30% chance of obtaining a patent on the vaccine – better odds than those associated with the second route. See MICHAEL KREMER & RACHEL GLENNERSTER, Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases 66 (Princeton University Press. 2004). A possible response: the two firms could and should strike a deal in which they pursue separate routes, and the firm taking the promising road compensates the other in some way. In any event, the likelihood that firms acting independently will engage in an inefficient pattern of research are much greater – and opportunities for such corrective deals are much scarcer – when they don't know what each other is doing.

And we may be able, through adjustment of other legal doctrines, such as antitrust law, to affect some of those factors. But the data offered by DeMasi and Paquette suggest that, under the present patent regime, the amount of research devoted to the development of what will become me-too drugs is higher than optimal. Especially telling is that fact that many losers of patent races initiate clinical trials – the most expensive phase of the research – even after it is clear that they have been beaten to the punch and that the incremental health benefits of their own products are slight.[30]

The complexity of the issue makes it very difficult to determine whether a prize system would be better or worse in this respect than the current patent system. The fact that the levels of duplication under the present regime appear to be too high creates at least the possibility that a well-designed prize system could achieve significant social gains. On the other hand, anecdotal evidence suggests that some prize systems are even worse than the patent regime in this regard.[31] An extreme example: Netflix recently offered a prize of $1 million to the creator of a computer program that was better (by a specified amount) than Netflix' own "recommendation engine" (a piece of software that suggests movies that a person might enjoy based on the movies that she has already seen and enjoyed).[32] The contest attracted more than 27,000 competitors, organized into more than 2,500 teams.[33] It is hard to believe that that number is optimal. Less troubling are the fruits of a prize system aimed at problem more closely analogous to the kinds of pharmaceutical research with which we are concerned: The J. Craig Venter Science Foundation recently joined forces with the X Prize Foundation to offer a $10 million

[30] See DIMASI & PAQUETTE, ---.
[31] For the argument that prize systems are worse on this score than the patent system, see Newell & Wilson.
[32] See KATIE HAFNER, *And if You Liked the Movie, a Netflix Contest May Reward You Handsomely*, New York Times October 2, 2006. 2006.
[33] See TIM HARFORD, *Cash for Answers*, FT Magazine, (2008)., available at http:/timharford.com/.

prize to "the first Team that can build a device and use it to sequence 100 human genomes within 10 days or less, with an accuracy of no more than one error in every 100,000 bases sequenced, with sequences accurately covering at least 98% of the genome, and at a recurring cost of no more than $10,000 per genome."[34] As of September 20, 2008, seven teams had registered to compete in the competition.[35] Redundancy on that scale is much less worrisome.

In short, whether a prize system is more or less likely than the patent system to foster socially excessive levels of research redundancy seems to depend, in significant part, on how the prize system is designed. To such matters we now turn.

[34] See http://genomics.xprize.org/genomics/archon-x-prize-for-genomics/prize-overview.
[35] See http://genomics.xprize.org/genomics/teams/registered-teams.

B. Optimal Design

Plainly, in constructing and administering a prize system, one should strive to capitalize on the potential advantages and minimize the disadvantages just reviewed. This section relies on that guideline in considering what sort of prize system would be most effective in alleviating the health crisis in the developing world.

1. Defining the Contest

The first question we must consider is what the prizes would be awarded for. A wide variety of frameworks has been proposed or might be imagined. The most tightly focused approach would involve a government agency identifying a specific neglected disease and offering a prize to the first person or firm to develop a vaccine for it. Historically, most prize systems have taken this form. A government official, foundation, or private firm has identified a specific pressing problem and has offered a reward to anyone able to solve it. Examples include a prize offered by Napoleon for the best method of extracting sugar from beets, a series of prizes offered by the industrialist, Hemry Kremer, for human-powered flying machines, and the prize offered recently by regional governments in Australia for the best method of trapping poisonous cane toads.[36]

The influential proposal for "advanced market commitments" (AMCs), which has been made by Michael Kremer and Jeffrey Sachs (separately and in tandem) employs the same general approach.[37] Kremer and Sachs urge coalitions of governments and private

[36] A comprehensive list of such prizes can be found in KNOWLEDGE ECOLOGY INTERNATIONAL, *Selected Innovation Prizes and Reward Programs*, KEI Research Note 2008:1 (2008). For a large catalogue of current prizes of this highly focused sort, visit the website of Innocentive: http://www.innocentive.com/.

[37] *See* Jeffrey Sachs, Michael Kremer & Amar Hamoudi, *The Case for a Vaccine Purchase Fund* (Center for International Development, Harvard); Jeffrey Sachs, *Helping the World's Poorest*, 352 THE ECONOMIST 17 (1999); KREMER, *Creating Markets, Part I*; KREMER & GLENNERSTER, Strong Medicine; RACHEL GLENNERSTER, et al., *Creating Markets for Vaccines*, Winter 2006 Innovations (2006); MICHAEL R.

foundations to commit[38] to purchasing a particular number of doses (at a particular price) of a vaccine that effectively prevents contraction of a particular disease – say, malaria. [39] Their proposal has several other important dimensions, some of which we will consider shortly, but its key feature, for present purposes, is that it would target specific diseases.[40]

The principal strength of this strategy is that it is likely to be politically attractive. The misery associated with a specific disease is easier to understand and to explain to potentially skeptical officials (or constituents) than the general problem of neglected diseases. It is thus unsurprising the Kremer/Sachs proposal has gained significantly more traction to date than any other prize-system idea. In 2007, the governments of Britain, Italy, Canada, Norway, and Russia, along with the Gates Foundation, committed $1.5 billion to purchase doses of a successful vaccine for pneumococcal disease, which currently kills roughly 700,000 children per year in developing countries.[41] Senator

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KREMER, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Quarterly Journal of Economics 1137, (1998); MICHAEL R. KREMER, *Creating Markets for New Vaccines, Part II: Designing Issues*, NBER Working Paper #7717 (2000).

[38] How could such commitments be made credible? Kremer advocates the use of legally enforceable contractual obligations, pointing to cases where courts have held that public commitments to reward winners or to purchase specified goods constitute legally binding contracts, holding governments to them in cases where changed circumstances motivated attempts at reneging. See KREMER & GLENNERSTER, Strong Medicine, Chpt. 12.

[39] The tax credit proposed by Lawrence Summers when he was Secretary of the Treasury in the United Sates would have taken the same general form. *See* Lawrence H. Summers, Testimony Before the Senate Appropriations Committee Subcommittee on Foreign Appropriations (6 April 2000). The credit would have applied to sales of vaccines for malaria, TB, HIV/AIDS "or any infectious disease that causes over one million deaths annually worldwide." It would have allowed the seller of a qualified vaccine to claim a credit equal to 100 percent of the amount paid by any nonprofit organization, such as UNICEF, selected for the program by US AID. The effect of the credit would have been to double the purchasing power of such organizations, with US AID setting the total amount eligible for the program (the figure of $1 billion for all vaccines from 2002 to 2010 was suggested). The aim was to "provide a specific and credible commitment to purchase vaccines", one that would be further bolstered if other governments made similar commitments, in an effort to "ensure a future market" for innovators' products. The proposal also contained two other prongs: an increase in direct funding of NIH research on AIDS vaccines and a 30% tax credit, akin to the orphan drug tax credit, for qualified clinical testing expenses for certain vaccines.

[40] See also Davis 2002.

[41] See GAVI Alliance, "Five nations and the Bill & Melinda Gates Foundation launch Advance Market Commitment for vaccines to combat deadly disease in poor nations," (February 7, 2007), http://www.vaccineamc.org/news_launch_event_01.html; NICK TIMIRAOS, *Push to develop vaccines for poor*, The Globe and Mail December 31, 2007

Kerry has urged the United States to join the effort.[42] If this initial, "pilot" version of the AMC system works, backers hope to extend it to other diseases.

This approach does, however, have two serious weaknesses. First, it risks drawing research funds away from fields where greater health benefits could be reaped per dollar invested. Recall that, although government officials have good information concerning the potential welfare gains associated with preventing or curing particular diseases, they have poor information concerning the costs and the probability of success of the various lines of research that might generate those gains. Would we get more bang for our research buck by focusing on diarrhea or malaria? Government officials have no way of knowing. Awarding prizes for addressing particular diseases thus risks inducing firms to put their time and money into suboptimal zones.

The second problem is that the specific-disease approach exacerbates the hazard of research redundancy. Even if malaria research would provide us the greatest bang per research buck, we may not want to encourage all pharmaceutical firms to focus on it. It would be better if some concentrated their energies on other diseases. (The pneumoccocal AMC is not particularly vulnerable to criticism on this ground, because two firms – GlaxoSmithKline and Wyeth – have already progressed far down the line toward developing an effective vaccine, and other firms are unlikely to enter the field.[43] But, for the same reason, the pneumococcal pilot project is not a good test of the AMC stategy; in effect, it more closely resembles a procurement contract than a prize.)

Both of these problems could be avoided if we framed the contest more broadly. For example, we could follow Joseph Stiglitz' lead in offering prizes to the developers of

[42] See , *Kerry Provisions on Vaccines, Anti-Discrimination Included in PEPFAR*, Congressional Documents and Publications March 13, 2008.
[43] See TIMIRAOS.

pharmaceutical products that address any neglected disease.[44] For the reasons just sketched, this would be better than the AMC approach, but it may not go far enough. Medical innovations pertaining to neglected diseases that do not involve new products – for example, better delivery systems for existing drugs, better diagnostic procedures, and new non-pharmaceutical infection-prevention systems[45] – might reap larger health gains per research dollar than some new drugs. A sensible prize system presumably should encompass them as well.[46]

But why stop with neglected diseases? The same considerations presumably should prompt us to extend the competition to all new pharmaceutical projects, or all medical innovations. For that matter, why not include all kinds of potentially patentable innovation – or even innovations of sorts traditionally managed by the copyright system, such as musical compositions or sound recordings, as one of us has elsewhere proposed?[47]

Although a prize system that broad might indeed be socially optimal, two considerations argue against its adoption. First, medical innovations – and pharmaceutical products in particular – tend to be relatively discrete. In many other technological fields, this is not true. Consumer electronic products, for example, commonly incorporate hundreds or thousands of innovations. A well developed system of patent licensing currently enables us to allocate the profits generated by such composite products among the myriad innovators who have contributed to them – not

[44] See Stiglitz 2007.
[45] For a thorough review of the relative efficacy of such nonpharmaceutical strategies – some of them novel, others quite old – in reducing the incidence of diarrhea, see ALIX PETERSON ZWANE & MICHAEL R. KREMER, *What Works in Fighting Diarrheal Diseases in Developing Countries? A Critical Review*, World Bank Research Observer (2007).
[46] See SCHWARTZ & KIM, 48.
[47] See WILLIAM W. FISHER, III, Promises to Keep: Technology, Law, and the Future of Entertainment chapter 6 (Stanford University Press. 2004). See also CALANDRILLO.

very precisely, perhaps, but satisfactorily. A prize system, by contrast, would require a government official to manage the allocation. Problems of the sort highlighted by Gallini and Scotchmer probably would be severe. Confining the system to health care would reduce this hazard.

The second, more important consideration has already been mentioned: political palatability. It's hard enough to imagine Congress (or any other national legislature) adopting in the foreseeable future a prize system that would encompass all medical innovations pertaining to the diseases that currently ravage developing countries. The unpopularity of tax increases, coupled with the widespread sentiment that the patent system, outside the sphere of neglected and global diseases, is not yet "broken," make it extremely unlikely that Congress would be willing to reach even further.

2. The Nature and Size of the Prize

What should be the form and magnitude of the prize awarded to the developers of effective vaccines or cures? This is the issue that, thus far, has attracted the most attention in the literature on prize systems. Myriad plans have been proposed, but they can be grouped into five clusters.

In proposals of the first type, the prize would consist of enhanced patent protection for some other drug, presumably a lucrative drug that addresses a disease common in developed countries.[48] The enhancement might be achieved in various ways. The simplest, proposed by GlaxoSmithKline and by the late Jonathan Mann, would extend the life of the patent on the lucrative drug. Another variant would allow the

[48] See HANNAH E. KETTLER, *Narrowing the Gap Between Provision and Need for Medicines in Developing Countries*, Office of Health Economics, 49-50 (2000). (referring to this approach as "roaming market exclusivity")

applicant for a patent on a potentially lucrative drug to obtain "priority review" by the FDA, rather than "standard review."[49] The former procedure is ordinarily only available for drugs that offer "significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease," while latter is employed in situations in which "[t]he drug appears to have therapeutic qualities similar to those of one or more already marketed drugs."[50] Thus, the prize essentially would consist of the right to obtain expedited review of a "me-too" drug.

In most proposals within this family, the enhanced rights would be transferable. Thus, if firm A succeeded in developing a malaria vaccine, it could sell to firm B the right to obtain priority review of a new drug for erectile dysfunction or high cholesterol.

Congress recently adopted a system of this sort. As part of the FDA Amendments Act of 2007, it authorized a firm that obtains FDA approval for a novel drug that addresses one of a set of specified tropical diseases to obtain a transferable "priority review voucher" that can be employed to obtain accelerated review by the FDA of any other drug.[51] In a recent paper, Henry Grabowski, David Ridley, and Jeffrey Moe argue persuasively that such vouchers could be highly valuable.[52] They point out that, in the past few years, priority review by the FDA has been roughly seven months faster than standard review. Even if the overall life of the patent on the drug for which the priority

[49] See Ridley 2004; DAVID B. RIDLEY, et al., *Developing Drugs for Developing Countries*, 25 Health Affairs 313, (2006).. Cf. Moran 2005.
[50] See Food and Drug ADMINISTRATION, available at http://www.fda.gov/cder/rdmt/pstable.htm.
[51] 21 U.S.C. 360n. The diseases, specified in the statute, that, when addressed, will give rise to such a voucher are: Tuberculosis; Malaria; Blinding trachoma; Buruli Ulcer; Cholera; Dengue/dengue haemorrhagic fever; Dracunculiasis (guinea-worm disease); Fascioliasis; Human African trypanosomiasis; Leishmaniasis; Leprosy; Lymphatic filariasis; Onchocerciasis; Schistosomiasis; Soil transmitted helmithiasis; Yaws; and "any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary."
[52] See HENRY GRABOWSKI, et al., Priority Review Vouchers to Encourage Innovation for Neglected Diseases (2008).

review was obtained remained the same, the ability to start collecting money seven months earlier could be worth a great deal. First-mover advantages – the ability to establish a reputation and a market before competitive drugs enter the field – would add to that benefit. Last but not least, Grabowski and his colleagues show that the interaction of the new system with the complex provisions of the Hatch-Waxman Act governing permissible extensions of the terms of pharmaceutical-product patents will, under some circumstances, have the effect of accelerating the date on which the patentee may begin to collect money, without accelerating the termination date of the patent – thus effectively extending the patent life. The bottom line: in the right hands (and getting it into the right hands is, of course, made possible by its transferability), such a voucher is likely to be worth $100 million and possibly much more.

A system of this sort has the obvious merit of channeling substantial resources into the development of new drugs that address neglected diseases. For that reason, Congress' action should surely be applauded. But such a system has four drawbacks, which, in combination, make it the least attractive of the design options. First, the new statute contains no requirement that the novel drug addressing tropical diseases be made available inexpensively in the countries in which those diseases are rampant. In other words, the new system is cumulative; it in no way alters the background rules of patent law. The upshot is that a firm might develop a new treatment for Buruli ulcer, rely upon that accomplishment to obtain priority review for its next anti-depression drug, and then sell both drugs at profit-maximizing prices, in developing countries as well as developed countries. The availability of this option means that the new system promises to address the "incentive" problem – the fact that too few financial carrots currently exist for the

creation of drugs focused on neglected diseases – but will do nothing to solve the "access" problem – the fact that the drugs that do exist are often priced out of the reach of most developing-country victims.

This first drawback, though very serious, could be redressed easily. The statute could be modified to require the patentee on the tropical-disease drug to grant royalty-free licenses to generic firms, permitting them to manufacture the drug and to distribute it on whatever terms they wish in developing countries. The result, of course, would be to drive the cost of the drug in those regions down close to the cost of production.

The other drawbacks of this approach, unfortunately, could not be remedied so easily. The most serious of the problems involves the pattern of incentives it creates. Suppose that a firm wishing to obtain a priority review voucher for an upcoming cholesterol drug might earn that right by successfully completing one of three projects currently on its drawing boards: the development of a palliative treatment for yaws, a serious but nonfatal disease currently afflicting roughly 500,000 people;[53] the development of a vaccine for dengue fever, which causes roughly 19,000 deaths per year and a loss of 528,000 DALYs (disability adjusted life years); and the development of a vaccine for leishmaniasis, which causes roughly 51,00 deaths per year and a loss of 1,757,000 DALYs.[54] Assume, for simplicity, that the three projects would cost the same amount and (as is likely) would generate little or no profit for the firm because most of the beneficiaries are too poor to pay for them. Plainly the firm will choose the project with the greatest chance of success – i.e., the greatest chance of earning the firm a

[53] See ASSOCIATED PRESS, *WHO: Flesh-Eating Disease Making Comeback*, FoxNews.com January 25, 2007.
[54] See PIERRE CATTAND, et al., *Tropical Diseases Lacking Adequate Control Measures: Dengue. Leishmaniasis, and African Trypanosomiasis, in* Disease Control Priorities in Developing Countries 454-55, (Dean Jamison, et al. eds., 2006).

valuable voucher – and will ignore the radical differences in their potential health benefits. (Conversely, if the projects have the same chance of success, the firm will choose the cheapest, even if its health benefits are modest.) The bottom line: the system fails to direct research and development toward areas that will most efficiently improve public health.

The third drawback is that the new statute will increase the already excessive degree to which pharmaceutical firms are induced to concentrate R&D resources on "me-too" drugs. All of the drugs upon which the vouchers will be used are "me-toos"; otherwise they would already be entitled to priority review. By permitting firms to introduce those drugs into the market sooner, and then to protect them against competition longer, the statute will prompt firms to shift even more resources toward them – precisely the behavior we don't want to induce.

Finally, the new statute may increase the risk that drugs will be commercially deployed before their long-run side effects become evident. This is a controverted issue; Grabowski and his colleagues argue strenuously that priority review is not correlated with any increased in the frequency of adverse events. We are not in a position to assess that claim here. We merely observe that, if they were correct, then the appropriate response would be to institute priority review for all drugs, not merely for those for which firms can obtain a voucher.[55] In other words, the pace at which the FDA evaluates all applications should be increased, thereby enabling all people to gain access to all

[55] An objection: the FDA has limited resources and cannot afford to provide accelerated review for all drugs. Of the possible responses, the most plausible would be simply to generalize the approach recommended by Grabowski et al. and embodied in the new statute: a firm not otherwise entitled to priority review would simply pay the agency the extra costs – currently, roughly $1.1 million.

beneficial drugs more quickly, and we should look for other ways to provide incentives for the development of drugs focusing on neglected diseases.

The second family of proposals would tie the size of the prize to the value of the patent that the drug developer could obtain. This might be achieved in various ways. The simplest would be to require the drug developer to obtain a patent in the ordinary course, after which the government would acquire the patent, either by purchasing it for a mutually acceptable price, or by exercising its power of eminent domain. The government would then release the invention governed by the patent into the public domain, enabling generic manufacturers to make and sell the drug in question at close to the marginal cost of producing it.

The practical problem that besets all proposals of this type is how much money the government should pay. If it uses its power of eminent domain to compel the patentee to surrender the patent, then the government is obliged, both by the Constitution and by the arguably pertinent federal statute,[56] to pay the patentee the fair-market value of the patent – i.e., the net present value of the profit that the firm could have earned through sales of the patented drugs during the duration of the patent.[57] To induce the patentee to sell the patent voluntarily, the government will have to offer at least that much. But how is that amount to be determined? Scholars have suggested various

[56] 28 USC 1498(a) provides that "[w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture." It is not clear that this provision could be construed to permit the government to authorize third parties (i.e., generic firms) to make and distribute the drugs at issue. If not, then implementation of this approach could be achieved with by an amendment of section 1498 or by the exercise of the government's authority to engage in so-called "straight condemnation." See Kirby Forest Industries v. United States, ___ U.S. ___ (1984).

[57] In proceedings brought under section 1498(a), the patentee is typically awarded a "reasonable royalty." For a persuasive argument that the award should also include lost profits, see Cahoy 2002.

solutions. Robert Guell and Marvin Fischbaum propose that the drug be test marketed in a small geographic area, enabling the government to extrapolate the profits that the firm might earn globally. Michael Kremer has suggested a more complex and ingenious scheme, the heart of which is an auction. In brief: Firm A develops a drug and patents it. The government invites Firm A to submit the patent for valuation. If Firm A accepts, the government solicits bids from other firms (most of which are likely to be other pharmaceutical firms). In 10% (selected at random) of the cases of this sort, the government offers to buy the patent for the price named by the highest bidder and then, if the patentee agrees to sell, resells the patent to the highest bidder for the same amount. In the other 90% of the cases, the government offers to buy the patent for the price named by the highest bidder and then, if the patentee accepts, releases the technology into the public domain. The 10% chance of actually obtaining the patent is what induces the other firms to participate in the auction.[58]

Each of these approaches has difficulties, most of which are thoroughly discussed in a recent paper by Michael Abramowicz.[59] For example, the technique suggested by Guell and Fischbaum would result in a significant delay, while the test marketing occurred, and would require the drug developer to spend substantial sums on marketing, in order to stimulate demand for the drug and simulate a real market. Kremer's system would encounter other problems. To induce firms to invest the substantial resources necessary to prepare bids, the frequency with which the government resold the patent to the highest bidder would probably have to be well above 10%, which would of course reduce the coverage (and thus the efficacy) of the system. In addition, Firm A would

[58] See KREMER, *Patent Buyouts.*
[59] See ABRAMOWICZ, 128-36, 148-58.

have an incentive to collude (explicitly or implicitly, through repeat behavior) with one or more of the bidders, which would then result in misleadingly high auction prices. The system would result in an excessively low price if both of two substitute drugs were submitted (because of the high probability that one of them would end up in the public domain), and an excessively high price if both of two complementary drugs were submitted (again, because of the high probability that one would end up in the public domain, which in this context would enable the holder of the patent on the other to reap all of the monopoly profits on the cocktail). Last but not least, because the system requires many firms to expend substantial resources preparing bids (most of which have no chance of winning), the system would be socially wasteful. There are techniques – some proposed by Kremer, others by Abramowicz – for mitigating some of these problems, but none would be perfect.

The principal drawback of all members of this family of approaches is not, however, the difficulties associated with valuation; it's rather that tying the size of the prize to the value of the patent that it would displace fails to generate a socially optimal pattern of incentives. It would do a decent (not perfect) job of getting the drugs that would be developed anyway into the bodies of people who desperately need them. But it would do nothing to redirect the research activities of the pharmaceutical firms toward neglected diseases.[60]

Michael Kremer recognizes this problem. To solve it, he suggests that the government pay Firm A, not the magnitude of the winning bid, but the magnitude of the winning bid multiplied by some number. (He suggests a markup of somewhere between

[60] See AIDAN HOLLIS, *An Optimal Reward System for Neglected Disease Drugs* (2005).

2.5 and 3.33.)[61] That would indeed alter the incentives of pharmaceutical firms, but in an arbitrary way. The underlying problem is that, for the reasons explored above, there is little relationship between the social value of a drug and its market value. Simply multiplying estimates of market values, no matter how accurate those estimates are, by a fixed number in thus unlikely to create a pattern of prizes that would draw firms into the most socially beneficial lines of research.

The third approach is very different in form, but in the end founders on the same rock. Douglas Lichtman has proposed that, instead of purchasing (or expropriating) a pharmaceutical patent by paying the developer its market value, the government should leave the patent in the hands of the developer, and pay poor potential consumers enough to enable them to buy the drug. If the government had very good information concerning the demand for the drug, this strategy would have much to recommend it. Each consumer could be given a coupon, redeemable by the government, equal in value to the difference between that consumer's willingness and ability to pay for the drug and the price of the drug as set by the patentee. As a result, the recipients of the coupons would no longer be priced out of the market. Indeed – and this is the most striking aspect of Lichtman's proposal – the ability of the drug company to reach this new group of subsidized consumers should make the developer willing to reduce the price of the drug for all consumers. The government can prompt the company to reduce the price by capping the value of each coupon. The establishment of such a ceiling would have two beneficial effects: enhancement of the consumer surplus reaped by the unsubsidized consumers (who would have bought the drug at the original, higher price), and a

[61] See KREMER, *Patent Buyouts*.

reduction in the amount of money that the government would have to spend to redeem the coupons. Clever.

Two circumstances unfortunately deprive this proposal of most of its potential for alleviating the health crisis in the developing world. First, the demand curves for pharmaceutical products in developing countries are typically, to use the economists' jargon, "convex to the origin."[62] In other words, there exist a small number of consumers able and willing to pay quite high prices for access to the drug in question, a very large number able to pay very little, and not very many in between. The cost (to the government) of the coupons necessary to achieve the leveraging effect identified by Lichtman would be higher when demand curves are shaped in this fashion than when the curves are linear (as, for simplicity, he assumed).[63] Second and more seriously, the governments of developing countries typically have even poorer information concerning each potential consumer's ability and willingness to pay for a given drug than do the governments of developed countries.[64] If the government had that information, it should supply it to the patentee and encourage it to engage in precise, "first-degree" price discrimination – the economic effects of which would be even better than Lichtman's proposal. Lacking it, the government would be forced either to issue coupons to some people who don't need them or deny coupons to some people who do, or both. As Abramowicz observes, errors of the first sort will cause the patentee to raise the market price (or at least be less willing to reduce the price to reach poor consumers, thus

[62] For clarification of the sometime confusing terminology, see ADOLF KOZLIK, *Note on Terminology Convex and Concave*, 31 American Economic Review 103, (1941).
[63] This effect is illustrated by the following graphs: _____.
[64] The kinds of things that, Lichtman argues, would enable a government to estimate individual consumers ability and willingness to pay for drugs – such as income-tax returns or health-insurance applications – are unlikely to be available to the governments of developing countries.

increasing the cost of the program to the government), whereas errors of the latter sort will reduce the efficacy of the program.[65]

The bottom line: In the context of developing countries, Lichtman's approach is likely to be worse, not better, than a straightforward patent-purchase program of the sort we just considered. But even if this were not true, his proposal would share with patent-purchase program a fundamental flaw: it fails to shift research incentives in beneficial directions.

The fourth and fifth families of proposals both seek to remedy this problem by tying the amounts of the prizes issued to drug developers to the social value of their products, measured by the DALYs they would save. The two families differ in one main respect: proposals of the fourth type would have the government allocate a fixed sum of money to be distributed in a given year to drug developers; that pot would then be divided among the participating firms in proportion to the relative social value of their inventions. Proposals of the fifth type, by contrast, would have the government pay each participating firm a specified amount of money for each DALY saved through the distribution of its products. Both approaches have important strengths; the choice between them is not easy. We will suggest that, on balance, the fifth approach is superior, but adoption of the fourth approach would not be irresponsible.

Assessment of their relative merits is complicated by the fact that, within each family, there are several variants, each of which has pros and cons. The simplest version of the fixed-pot approach would give each participating firm a share of the pot proportional to the number of DALYs saved as a result of the creation and administration

[65] See ABRAMOWICZ.

of its drugs.[66] And how, exactly, would we ascertain those numbers? The task, though formidable, would not be as daunting as one might imagine. The World Health Organization, as previously noted, already gathers and publishes data concerning the disease burdens (measured in DALYs) associated with particular diseases. Many governments, including the United States, already employ reasonably sophisticated pharmacoeconomic assessment systems to determine the efficacy of particular drugs in curing or preventing those diseases.[67] The piece of the analytical puzzle that would be hardest to obtain would be data concerning, not just sales, but consumption of the drugs in question. That data would have to include, not just versions of the drugs manufactured by the inventor, but also versions manufactured and distributed by generic firms. Impediments to getting the necessary numbers would include the notorious reluctance of pharmaceutical firms to release information concerning their operations and the fact that many of generic manufacturers would not operate in the United States and thus would not be subject to American licensing requirements. Note, however, that the numbers we would need do not include prices, costs, or profits. All we would need are retail sales data (which the generic firms would have no incentive to exaggerate). In the end, that could probably be obtained – if necessary, by paying the firms in question a fee.[68]

Once the numbers had been assembled, it would be reasonably straightforward to ascertain the relative health benefits of each innovation.[69] That information could then be used to determine the size of the prize given to each of the innovators.

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[66] See, for example, HOLLIS.
[67] See MICHAEL DICKSON, et al., *Survey of Pharmacoeconomic Assessment Activity in Eleven Countries*, OECD HEALTH WORKING PAPERS NO. 4, (2003).
[68] Cf. HOLLIS. (suggesting that licensees could be required to submit sales data).
[69] As Hollis points out, ideally the measures of health benefits should be net of the cost of manufacturing the drugs at issue. Accommodation of this principle would, however, be difficult for two reasons: First it would require converting DALYs to dollars – a task we will take up shortly, but which is obviously fraught

The obvious advantage of this procedure is that it would draw R&D resources into fields where they would provide the greatest health-care benefits. However, Jamie Love and Tim Hubbard argue, plausibly, that this variant has two related drawbacks: it ignores the fact that drug development costs are often unrelated to the number of people served by the drug at issue, and it fails to provide adequate incentives for the development of orphan drugs. In other words, this procedure will direct too much money to the developers of drugs that address common diseases and too little to the developers of drugs that address rare diseases.

To correct these biases, Love and Hubbard propose that the pot should be divided on the basis of multiple factors. The Medical Innovation Prize Fund Act, a bill recently introduced by Senator Sanders, who in turn relied heavily on advice from Love and Hubbard, provides a good illustration of the method they prefer. It would create an annual fund equal in amount to 0.6% of the gross domestic product of the United States during the preceding year. (In fiscal year 2008, that would come to roughly $83 billion.) The money would be divided among the firms that developed new "drugs, biological processes, and manufacturing processes for drugs or biological processes" during the year in question or during any of the preceding ten years. The criteria for making the division would be set by a Board of Trustees, composed partly of government officials and partly of persons drawn from specified subsets of the private sector. In setting the criteria, the Board would be obliged to take into account (and weight) the following factors: the number of people who would benefit from each drug or process; the incremental

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with controversy. Second, it would require obtaining data concerning manufacturing costs from the generic firms, which would likely be a good deal harder than obtaining sales data. Thus, ignoring Hollis' point is probably necessary as a practical matter. Because of the low costs of producing most drugs, it is probably tolerable as well.

therapeutic benefit of each drug or process; the degree to which each drug or process addressed priority health-care needs, including global infectious diseases, rare severe illnesses, and neglected diseases that primarily afflict the poor in developing countries; and finally the improved efficiency of each manufacturing process. In designing and administering the distribution system, the Board would be required to ensure that minimum amounts were applied to three areas of special need: 4% for innovations addressing global diseases; 4% for global infectious diseases and other public-health priorities; and 10% for orphan drugs. Finally, in a given year no one drug or process could earn its creator more than 5% of the pot.[70]

Adoption of this bill would indeed address the two problems identified by Hubbard and Love. It would, however, have a major disadvantage: As Marlynn Wei observes (when commenting on a predecessor proposal), the ambiguity of the factors used to determine each firm's share, plus the discretion enjoyed by the administrative tribunal in balancing them, plus the large stakes of the game, would give rise to many disagreements among the potential claimants, the resolution of which would consume considerable resources.[71] In other words, this approach would likely give rise to especially severe forms of the rent-seeking and dispute-resolution problems that Section A suggested potentially afflict prize systems. To avoid this outcome, some way of making the distribution of the funds more mechanical and predictable seems imperative.

How might this be achieved without undercompensating the developers of orphan drugs? One technique, also suggested by Hubbard and Love, would be to divide the pot into two parts. The money in the first sector would be allocated to drug developers on the

[70] S.2210, Medical Innovation Prize Act (2007).
[71] See MARLYNN WEI, *Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005*, 13 Boston University Journal of Science and Technology Law 25, (2007).

basis of the DALY benefits of their creations; the money in the second would be allocated to all "successful new drugs."[72] Unfortunately, this strategy fails to differentiate optimally among the developers of orphan drugs.

A better approach, we suggest, would be to maintain a focus on the DALYs saved through the distribution of each eligible drug, but to use a nonlinear formula for taking them into account. For example, each developer might be given a share of the pot proportional to the square root of the total number of DALYs saved by its products. More elaborate nonlinear formulae can of course be imagined. Adoption of this variant would have the effect of reducing the returns to the developers of "blockbuster" drugs and enhancing the returns to the developers of orphan drugs, while still giving firms of all sorts incentives to direct their resources toward areas with greater potential health benefits. To be sure, the returns available to a firm considering pursuing a drug aimed at a disease that afflicted a truly tiny group of people might still be insufficient to justify the cost,[73] but to us that seems acceptable.[74]

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[72] See JAMES LOVE & TIM HUBBARD, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, Knowledge Ecology International, 17-19 (2007). A more elaborate version of the two-part approach can be found in JAMES PACKARD LOVE, *Modeling Prize Fund Rewards*, Drug Development (2006). ("One can imagine, for example, that the rewards for QALYs should follow a simple decay function, such as: Reward = a + b * (QALYs ^ k) , where k (less than 1) is the decay parameter, and a and b are parameters that reflect the fixed and variable value of new products, both determined within the context of a budget constraint.").

[73] To illustrate, consider the following hypothetical example, an extension of an example offered by Love and Hubbard to explain their own approach. Suppose that "the risk-adjusted cost of drug development is fixed at $200 million, the size of the prize fund is $2 billion, and there are 5 potential candidates for R&D, expecting to yield 1,000; 2,000; 3,000; 7,000 and 25,000 QALYs." LOVE & HUBBARD, *The Big Idea: Prizes to Stimulate R&D for New Medicines*.___. Love and Hubbard point out that, "[i]f the prizes were allocated with a strictly proportional payout per share of QALYs, … only two the projects would be brought to market. If the prize fund were allocated half on the basis of QALYs and half for bringing a new product for market, all five projects would be brought to market." By contrast, if the fund were allocated on the basis of the square root of the QALYs saved by each candidate, four of the five projects would be brought to market and one would not.

The calculations that lead to these outcomes are summarized in the following chart:

To summarize, the variant of the fixed-pot approach that seems most attractive is one in which the pot were divided in proportion to some nonlinear function of the number of DALYs saved by each eligible. Now let's step back from these details and consider the strengths and weaknesses of this family as a whole. As Love and Hubbard point out, its great advantage is that it enables government officials to know, in advance, how much the program will cost. 83 billion dollars is a lot of money, but at least it's a known quantity. Legislators considering adopting such a plan would know its cost, and the tax laws could be adjusted to raise the necessary revenue.

Love and Hubbard argue that the fixed pot approach has another benefit as well: "[B]y fixing the size of the prize fund, the developers of products will have an incentive to lobby for fair and efficient methods of valuing inventions. If too much money is given to one inventor, prizes available for everyone else are smaller."[75] This strikes us as overly optimistic. To be sure, each participating firm would have an incentive to challenge the

Drugs	QALYs	Approach #1: Rewards proportional to QALYs ($millions)	Approach #2: Half allocated proportional to QALYs; half to successful projects ($millions)	Approach #3: Rewards proportional to square root of QALYs ($millions)
A	25000	1,316	858	849
B	7000	368	384	451
C	3000	158	279	295
D	2000	105	253	241
E	1000	53	226	172

Note that, under the first approach, the prizes available to the developers of drugs C, D, and E are less than the costs of producing them ($200M). Under the second approach, all of the projects are cost-justified. Under the third approach, the prize available to the developer of drug E is less than its cost.

[74] Our judgment on this issue is rooted in the views that: (i) each person has a legitimate claim – a right, if you will – to a portion of society's resources necessary to protect that person from a serious illness, even if it is rare; (ii) such a claim should prevail over the interest of many people to a share of society's resources necessary to relieve them from a minor ailment (e.g., the common cold), even if the total suffering caused by the ailment afflicting the many exceeds the total suffering caused by the serious illness affecting the few; but (iii) there is a limit to such a claim – in other words, at some point a disease becomes so rare or the costs of preventing or curing it become so high, that the interests of its victims may, indeed must, be ignored. Explaining and defending this composite argument will take many pages in Chapters 11 and 12 of our book.

[75] See LOVE & HUBBARD, *The Big Idea: Prizes to Stimulate R&D for New Medicines*.

data concerning the public-health benefits of its competitors' drugs. But this is more likely to lead to assaults on the competitors' data than an effort to establish "fair and efficient" valuation techniques. Thus, what Love and Hubbard see as a strength we see as a weakness: even variants of this approach that use mechanical distribution formulae will be beset by the kind of rent-seeking and waste of resources highlighted by Wei.

An even more serious drawback of the fixed-pot approach is that it renders highly unpredictable the amount of money that a firm could earn by developing a drug aimed at a particular disease. The problem is especially severe with discretionary, multi-factored variants, like the proposed Medical Innovation Prize Fund Act. But it would be serious even if the distribution formula were mechanical and stable. The reason is that the amount of money that a firm could earn for a given drug depends upon what other drugs qualify for participation in the fund and the health benefits of each. Suppose, for example, a firm is considering investing in the development of a malaria vaccine. The amount that it stands to earn, if successful, would depend heavily upon whether, during the ten-year window in which the vaccine were eligible for prizes, another firm developed an effective HIV vaccine. Why? Because the health benefits of a malaria vaccine, large as they are, would pale in comparison to the health benefits of an HIV vaccine, and thus the latter would get the lion's share of the prize fund. This problem could be mitigated if, as in the Medical Innovation Prize Fund Act, the amount that any one drug could earn its maker were capped, but the imposition of such a cap would undermine the ability of the system as a whole to draw R&D resources into areas of

greatest social need – such as HIV/AIDS. And, at most, caps could mitigate, but not eliminate the problem.[76]

Approaches within the fifth family would avoid these problems – although, as we will see, they would have some difficulties of their own. The feature common to the members of this family is that the government would commit to paying the inventors of new drugs a certain amount of money for each DALY saved as a result of their inventions. Somewhat more specifically, under these systems the inventor would be paid a certain amount of money per DALY for the incremental health benefits of the new drug as compared to drugs already on the market at the time the new drug is introduced.

As several scholars have suggested, it would make most sense, not to try to predict the DALY benefits of a drug at the time it is first introduced, but rather to measure them over time. Each year, the government would collect sales, consumption, and pharmacological efficacy data of the sort described above[77] pertaining to each registered drug, derive from that data a total number of DALYs saved through administration of the drug, multiply that number by the promised fee, and issue a prize to the inventor of the drug. To keep making such payments forever would be unwieldy and unnecessary; a limited term would suffice. Following Love and Hubbard, we might select, for simplicity, a term of 10 years from the date the new drug is first introduced to the market.

How would such a system deal with cases of so-called "sequential innovation"? Suppose, for example, that in 2010, Firm A introduces to the market a malaria vaccine. Each year for the next five years, it is administered to 1 million children, resulting in a

[76] A less serious, but not trivial, related drawback: In a lean year for innovation, the government could end up paying a great deal for modest technological advances.
[77] See supra page ___.

total savings of 10 million DALYs. In 2015, Firm B, relying on Firm A's breakthrough, develops and introduces into the market an improved vaccine – improved in the sense that it has fewer side effects. Vaccine B supplants vaccine A entirely. Each year it is administered to 1 million children, resulting in a total savings of 11 million DALYs – the increase representing the reduction of side effects. How much should each firm be awarded? To create the right pattern of incentives, it would seem that we should give Firm A credit each year (until 2020) for 10 million DALYs, and Firm B credit each year (until 2025) for 1 million DALYs.

A refinement: What if Firm B developed its vaccine without relying upon A's research? Firm B should still be entitled to credit for only 1 million DALYs per year. That, after all, is the incremental health benefit of its drug. But what of Firm A? Arguably, it does not "deserve" credit for 10 million DALYs per year after 2015. But two considerations counsel giving Firm A credit anyway. First, to created sensible incentives for innovative activity, we would want to avoid exposing all firms to the risk that the markets for their creations will be destroyed soon thereafter by newcomers. Second, we should avoid, if possible, the need to resolve tangled questions concerning when one firm relied upon the work of another.[78]

The issue that most plagues and divides the proponents of this fifth approach is how much the government should pay per DALY. Plainly, the higher the amount, the more innovation we will stimulate and the more quickly we will alleviate the health crisis in the developing world. On the other hand, the higher the amount, the more expensive the program and the greater the difficulty of securing its adoption.

[78] [This issue requires more work. A precondition for a more refined analysis is some empirical investigation of the frequency with which different scenarios occur, what it means in practice to rely on the work of a predecessor, how much cost is saved thereby, etc.]

The range of options is considerable. At one extreme, we might strive, as Professors Shavell and van Ypersele suggest, to select a number that will generate prizes equal in amount to the total social-welfare benefits of each invention. That might, as they argue, generate optimal incentives for innovative activity – although the fact that we don't pay innovators in any other sector of the economy the full social value of their innovations casts doubt on that judgment.[79] But, in any event, it would be prohibitively costly. To illustrate, in the United States, when assessing safety or pollution-control proposals, we commonly implicitly use cost-effectiveness thresholds of between $50,000 and $100,000 per DALY.[80] If we relied upon that number when selecting a prize for an effective, widely-used vaccine for malaria, which currently has a global annual disease burden of 44,716,000 DALYs, we would have to pay the developer between 2 and 4 trillion dollars per year. Clearly, this is out of the question. Even if we could afford such a sum, the rent dissipation it would generate would likely be prohibitive

Another possible approach: We might try to pick a number that, in practice, would provide the developer of a drug focused on a neglected disease a stream of revenues comparable to the stream that it could earn from a drug aimed at a non-neglected disease – adjusted upward or downward depending upon whether we thought that the technical challenges associated with solving neglected diseases were either greater or lesser than the challenges associated with the typical commercial drug.

A variant of this approach is employed by Kremer and his colleagues in calculating the magnitude of the AMCs that would be necessary to induce the

[79] See FISHER, Promises to Keep chapter 6.
[80] See ERNST R. BERNDT, et al., *Advance market commitments for vaccines against neglected diseases: estimating costs and effectiveness*, 16 Health Economics 491, (2007); P.J. NEUMANN, *Are Pharmaceuticals Cost-Effective? A Review of the Evidence*, 19 Health Affairs, (2000). [Insert additional data from Viscusi.]

development of vaccines for malaria and similar diseases. Their conclusion: "a commitment to pay $13-$15 per person immunized for the first 200 million people" would be necessary and sufficient.[81] If they are right, and if such a commitment led to the development of an effective malaria vaccine, we would reap health benefits of (coincidentally) roughly $15 per DALY. If similar commitments led to development of an HIV/AIDS vaccine and a tuberculosis vaccine, we would reap health benefits of $17 per DALY and $31 per DALY, respectively.[82] If, for the reasons discussed above, we were skeptical of AMCs for specific diseases, and wished simply to offer drug developers prizes consisting of a certain amount of money per DALY saved as a result of the administration of their drugs, we could employ an average of the last set of numbers produced by Kremer and his colleagues: $21 per DALY.

There are reasons to be uneasy about this strategy, however. Most importantly, it takes as given the current costs of commercial drug development and seeks to offer the pharmaceutical firms similar returns for working on neglected diseases. To their credit, Kremer and his colleagues do not simply accept the profits levels that the firms themselves claim they achieve (or need), or the oft-criticized estimates of the costs of drug development generated by Grabowski, but seek to derive more realistic numbers. They also make an effort to adjust the figures downward to take into account the savings in firms' marketing costs that implementation of their system would enable. But they still aspire to match "the net present value of the revenues earned by a sample of recently launched commercial pharmaceutical products."[83] Unless one believes that the R&D

[81] The complex set of calculations that underlie this conclusion are set forth in BERNDT, et al., 492. See also KREMER & GLENNERSTER, Strong Medicine 86-90 (similar methodology and result).
[82] BERNDT, et al., 502.
[83] Id. at 495.

systems that have arisen under the extant patent-based regime are ideal,[84] that number is excessive.

A radically different approach would ask, not how much is necessary to stimulate innovation, but how much are "we" (the residents of developed countries who would have to approve of and pay for such a program) willing to pay to save a year of the life of a resident of a developing country. An answer might be obtained from a loosely democratic political procedure: We could set the figure at a low level in the first year of the program – say, $10 per DALY – and then gradually increase it in subsequent years. The overall cost of the program would of course rise over time, not just because we would be paying more per DALY, but because more firms would be opting for prizes rather than patents, and because more and more projects aimed at neglected diseases would come to fruition. At the same time, the health benefits of the program – the lives and pain saved in developing countries – would become increasingly concrete and visible. At some point, median public sentiment (reflected in the miscellaneous collection of polls, grass-roots campaigns, lobbying initiatives, etc., that – for better or worse – we rely upon for gauges of public attitudes) would deem us to have gone far enough to satisfy our moral obligations. Thereafter, we would hold the number steady – until such time as our collective altruism increased a notch.

One advantage of this approach is that it would catalyze public discussion of the underlying public-health problem and our responsibilities to address it. The global health crisis currently does not figure prominently in political conversations in developed countries. For example, as of this writing, it has not yet surfaced in the Presidential campaign in the United States. (During the debate on October 7, both candidates insisted

[84] Reasons to doubt this assumption are explored in Chapter 2 of our forthcoming book.

that the United States would never again sit by while a holocaust occurred – without acknowledging that we are in effect doing so now.) One of the many reasons for our collective inattention is that the magnitude of the problem and the scale of our contributions to efforts to solve it are difficult to grasp. The procedure sketched above, by reducing the issue to a single question – how much are we willing to pay to save a year of the life of a person in a developing country? – should facilitate debate and foster more serious reflection on our duties.

A complication: But wouldn't such a procedure encourage firms to "game" the system? Knowing that the reward per DALY will increase over time, wouldn't they hold off either beginning research projects or submitting successful drugs for prizes, hoping in later years to get a better "price"? Probably not, because such strategic delays would increase sharply the risk that they would be beaten out by competitors and thus would get nothing. If this proved to be a serious problem, it could be mitigated (although not eliminated) by applying each increased fee not merely to drugs first submitted during the year in which the increase occurred, but also to drugs that were first submitted during previous years but are still within the ten-year prize-distribution window.

A final complication: The approach outlined above is vulnerable to the same objection raised by Love and Hubbard in the context of a fixed-pot system that relied solely upon DALYs to determine the relative social value of innovations – namely, that it would overpay the developers of drugs that addressed common illnesses and underpay the developers of orphan drugs. To meet this objection, one could make an adjustment closely analogous to the adjustment discussed above: instead of paying a flat fee for each DALY saved by each drug, one could pay a declining fee. In other words, the developer

would be awarded (each year) a certain amount of money for the first DALY saved as a result of the distribution and consumption during that year of a particular drug, a slightly smaller amount for the second DALY saved, a slightly smaller amount for the third, and so forth. Various nonlinear formulae could be imagined. Unfortunately, this response would have one significant drawback: it would reduce the simplicity and clarity of the system, thus undermining somewhat its capacity to facilitate public conversation concerning "our" moral obligations.

In sum, a dollars-for-DALYs approach of the sort we have outlined would not be perfect. But, on balance, it seems the best of the five approaches.

3. The Relationship between the Prize System and the Patent System

Currently, we rely almost entirely on the patent system to stimulate and channel drug research. What should become of the patent system if a prize system were introduced?

There are three possible answers to this question. This first is: nothing. Neither the content nor the coverage of the patent system should be altered at all. The prize system would thus be cumulative, offering drug developers rewards in addition to those they could receive by patenting their creations.

Several of the proposals we have already encountered take this general form. For example, the Advance Market Commitments advocated by Michael Kremer and others – and recently adopted by the G-8 countries – presume that the developer of a qualifying vaccine would patent it and then earn both the revenues guaranteed by the AMC and revenues from traditional sales of the patented product. Similarly, the new federal statute

that will give "priority review vouchers" to the developers of drugs aimed at tropical diseases presume that those drugs would be patented in the usual way. Finally, Doug Lichtman's ingenious proposal seeks to supplement, not supplant, the patent system.

The major benefit of this approach is political feasibility. Pharmaceutical firms can be expected to endorse proposals of this kind, for the obvious reason that all such proposals provide the firms new sources of revenue without affecting their old sources of revenue. The pharmaceutical firms have enormous political power. It is thus unsurprising that the only prize systems that thus far have made much headway have been cumulative systems of this general sort.

The major disadvantage of this strategy is equally obvious: it is very expensive. All of the costs of the present patent system are retained. To them are added the new costs associated with the prize system. Thus, if possible, we should strive to avoid this approach.

The second answer is that a prize system should replace the patent system with respect to all innovations eligible for the new prizes. The premier example of this approach is the Medical Innovation Prize Fund Act, which grows out of the work of Love and Hubbard. As we have seen, that Act would create a new prize system available to the developers of all new "drugs, biological processes, and manufacturing processes for drugs or biological processes." It would also withdraw patent protection from eligible drugs or processes.[85] Pharmaceutical firms (and the inventors of eligible

[85] The pertinent section of the bill provides: "Notwithstanding title 35, United States Code, relevant provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (including amendments made by the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417; referred to as the ''Hatch-Waxman Act'')), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), and any other provision of law providing any patent right or exclusive mar keting period for any drug, biological product, or manufacturing process for a drug or biological product (such as pediatric extensions under section 505A of the Federal Food, Drug, and

nonpharmaceutical innovations) would thus have no practical choice but to apply for one of the new prizes; patent protection would not longer be available. Guell and Fischbaum's proposal, under which the government would expropriate some drug patents, would lead to the same outcome on a smaller scale. Proposals of this type are commonly referred to as "mandatory."

The third approach would leave the patent system in place, but would force a drug developer to choose between obtaining a patent or obtaining a prize. The simplest variant of this so-called "optional" approach would require the developer of a particular drug to decide, prior to introducing it to the market, whether to apply for a patent or for a prize, and would not permit him to change his mind later. The prize and patent systems would thus be two mutually exclusive paths.

As a practical matter, a fixed-pot distribution system, of the sort considered in the preceding section, would have to be mandatory. If it were optional, there would be too many opportunities for firms to collude or otherwise to game the system. Suppose, for example, that in a particular year, Firm A and Firm B have each developed a blockbuster drug. If both opted for prizes, they would have to split the pot. It is plainly to their advantage to come to an agreement under which only one of them seeks a prize and the other seeks a patent. Explicit or tacit agreements of this general type would seriously distort the operation of the system. It is thus no accident that Love and Hubbard, the principal advocates of the fixed-pot approach, also support a mandatory system.

Cosmetic Act (21 U.S.C. 355a) or orphan drug marketing exclusivity under subchapter B of chapter V of such Act (21 U.S.C. 360aa et seq.)), no person shall have the right to exclusively manufacture, distribute, sell, or use a drug, a biological product, or a manufacturing process for a drug or biological product in interstate commerce, including the exclusive right to rely on health registration data or the 30-month stay-of-effectiveness period for Orange Book patents under section 505(j) of such Act (21 U.S.C. 355(j)). Section 5(a).

So which approach is better? The main advantage of a mandatory regime is that it could be much less expensive to fund, because it would not have to compete with the patent system. Unfortunately, a mandatory system would have three drawbacks. First, as Shavell and Ypersele point out, it would contain no safeguard against valuation mistakes by government officials. Under an optional system, if the prize formula were set too low, firms could opt out and continue to pursue patents instead. In a mandatory system, this would not be possible. As Shavell and Ypersele suggest, the result is that a mandatory system could be worse, from a social welfare standpoint, from the current patent regime, with all of its faults.

Second, pharmaceutical firms would fiercely oppose a mandatory system, for the obvious reason that it could leave them worse off. The only reason why they have not mounted an attack on the Medical Innovation Prize Fund Act is that they don't think it has any chance of passage.[86]

Finally, a mandatory system would likely violate the TRIPS Agreement, which binds the United States as well as the other 152 member countries of the World Trade Organization. Specifically, it would appear to violate Article 27, which provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" and in particular that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[87]

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[86] Check for any pharma commentary on the bill.

[87] Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization), Article 27(1), available at http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm.

This conclusion is not free from doubt; various arguments have been made that a mandatory prize system for pharmaceutical products patents is compatible with TRIPS. The most plausible of those arguments runs as follows:[88] The mandate of Article 27 is not absolute; it is qualified by Article 30, which permits member countries to make "limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Because a prize system would provide drug developers an alternative source of revenue, its interference with their ability to exploit their patents should not be deemed "unreasonable."[89] Moreover, it bears emphasis that a prize system – at least one structured is the fashion proposed by Love and Hubbard – would not prevent the acquisition of patents on drugs; it would merely curtail patentees' ability to enforce the patents after the drugs to which they pertain have been offered for sale.[90] In that sense, it is equivalent (or at least analogous) to a compulsory licensing system, which Article 31 of the Agreement permits, provided that certain conditions are satisfied. The most important of those conditions is that "the right holder … be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization"; the prizes awarded to drug developers would

[88] A less plausible argument than the one summarized in the text would rely on Article 27(2), which permits member countries to "exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health." The weakness of this argument is readily evident: To invoke 27(2), one would be obliged, not merely to withdraw patent protection from pharmaceutical products, but also to prohibit their "commercial exploitation." That a prize system would not do. See ROBERT WEISSMAN, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Alternatives Available to Third World Countries*, 17 University of Pennsylvania Journal of International Economic Law 1069, 1100 (1996).

[89] This is the lead argument made by James Love in defense of his proposal. See JAMES LOVE, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D*, 40 U.C. Davis Law Review 679, 704 (2007).

[90] In this respect, it is similar to the compulsory licensing system of section 115 of the copyright statute.

constitute such substitute remuneration. Finally, the Doha Declaration, which construed (or, in the judgment of some observers, modified) the TRIPS Agreement, allows member countries considerable latitude both in defining and in responding to "national emergencies" within the meaning of subsection 31(b).[91] Among the germane provisions of the Declaration are paragraph 7, which reaffirm[s] the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members," and paragraph 4, which provides that "the Agreement can and should be interpreted . . . in a manner supportive of WTO Members' right to . . . promote access to medicines for all."[92] A prize system designed to increase the development and distribution of drugs that address communicable diseases in developing countries is surely compatible with those aspirations.

Although colorable (and appealing), this argument would likely in the end fail, for the following reasons. First, it would be difficult to characterize a mandatory prize system for pharmaceutical products as a "limited" exception "to the exclusive rights conferred by a patent," within the meaning of Article 30.[93] The legislative history of that provision suggests that it was designed "to exempt from infringement the use of patented inventions for (1) private, noncommercial purposes, (2) academic research, (3) experimentation for testing or improvement, and (4) educational purposes" – not to

[91] Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WTO Doc. T/MIN(01)/DEC/2, ¶ 5(c).
[92] Id. at ¶ ¶ 7, 4.
[93] See ANDREW W. TORRANCE, *Patents to the Rescue: Disasters and Health Care Law*, 10 DePaul Journal of Health Care Law 309, 332 (2007). (arguing that "Article 30 does not authorize either compulsory licensing or patent breaking, but rather, it allows member nations to stipulate that some specified uses of patented inventions do not constitute infringement."); ALIX WEISFELD, *How Much Intellectual Property Protection Do the Newest (and Coolest) Biotechnologies Get Internationally?*, 6 Chicago Journal of International Law 833, 844 (2006).

permit member countries to refuse to enforce patents on an entire category of products.[94] The most pertinent of the Dispute Resolution Panel reports interpreting Article 30 confirms the foregoing interpretation, holding that that "[t]he term 'limited exception' must . . . be read to connote a narrow exception - one which makes only a small diminution of the rights in question."[95] It is especially unlikely that a future dispute-resolution panel would adopt a more expansive reading of the critical phrase in the context of pharmaceutical-product patents – the field of technology that Article 27 was primarily designed to reach.[96]

Efforts to rely on Article 31 are also problematic. To begin with, the characterization of a mandatory prize system as a compulsory license is something of a stretch. Assuming that characterization passed muster, one would still have to argue that a prize system covering *all* pharmaceutical products (not merely products necessary to address "HIV/AIDS, tuberculosis, malaria and other epidemics") was necessary to address "national emergencies";[97] not only does that seem implausible on its face,[98] but an interpretation of subsection 31(b) that would have reached that far was considered and

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[94] THOMAS A. HAAG, *TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?*, 84 Journal of the Patent & Trademark Office Society 945, 960-61 (2002). See also DANIEL R. CAHOY, *Confronting Myths and Myopia on the Road from Doha*, 42 Gerogia Law Review 131, 150 n.78 (2007).

[95] Report of WTO Dispute Settlement Panel, Canada-Patent Protection of Pharmaceutical Products, ¶ 7.28, WT/DS114/R (March 17, 2000) [hereinafter Canada-Pharmaceuticals Panel Report]. As Love points out, limitations on patent rights have been upheld by other dispute resolution panels. For example, the so-called "Bolar" provision, which permits generic drug manufacturers to "use" patented pharmaceutical products for the purpose of obtaining regulatory approval to begin distributing the drug once the patents in question expire was upheld on the basis of Article 30. *See Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited October 21, 2008). But the challenged provision seems precisely the sort of "limited" exception that the Canada-Pharmaceuticals panel had in mind.

[96] Canada-Pharmaceuticals Panel Report, *supra* note ___, at ¶ 7.90.

[97] For an interpretation of 31(b) that would sweep this broadly, see DEBJANI ROY, *In Search of the Golden Years: How Compulsory Licensing Can Lower the Price of Prescription Drugs for Millions of Senior Citizens in the United States*, 52 Cleveland State Law Review 467, (2004).

[98] See BRYAN C. MERCURIO, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 Marquette Intellectual Property Law Review 211, 239 (2004).

rejected during the deliberations that issued in the Doha Declaration.[99] Finally, Article 31 contains various requirements in addition to "adequate remuneration," which a prize system could not satisfy.[100] For example, subsections (i) and (j) permit "use of the subject matter of a patent without the authorization of the right holder" only if "the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member" and "any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority."[101]

In sum, it is highly likely that, if push came to shove, a mandatory prize system would be deemed to violate the TRIPS Agreement. Thus, before adopting such a system, the United States would have to seek and then secure an amendment to TRIPS. Insofar as Article 27 was the most hotly contested provision in the agreement, and the provision that the United States regarded as its most important accomplishment, the chances of such a reform seem remote.

In our judgment, these three drawbacks of a mandatory system, in combination, are decisive. That same judgment reinforces our preference for a dollars-for-DALYs approach, as opposed to a fixed-pot prize system, insofar as the latter would likely have to be mandatory.

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[99] See KEVIN J. NOWAK, *Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in TRIPS Article 27*, 26 Michigan Journal of International Law 899, 915 (2005).
[100] See MARKUS NOLFF, *Compulsory Patent Licensing in View of the Ministerial Conference Declaration on the TRIPS Agreement and Public Health*, 84 Journal of the Patent & Trademark Office Society 133, 140 (2002).
[101] A narrower additional problem: at least under the Love-Hubbard plan, prizes would sometimes be awarded, not to the holder on the patent for a drug, but to the first firm "to receive market clearance." MIPA § 9(b)(1). Plainly, under such circumstances the patentee would not receive "adequate remuneration."

To be sure, an optional system would itself have some drawbacks. The most important is that it would require the government to offer innovators rewards that exceed the profits they could make under the patent system. That constraint would not significantly hamper the flexibility of the government with respect to neglected diseases, because the patent-based revenues that the firms could earn by developing drugs that addressed them are so low. But it would substantially affect its flexibility with respect to global diseases, such as HIV/AIDS, that afflict both large populations of poor residents in developing countries and significant populations of more prosperous residents of developed countries. To persuade the developers of drugs focused on the latter to opt for prizes rather than patents, the government would have to offer more substantial sums.

In the previous section, we sketched a possible way of rolling out a dollars-for-DALYs approach: begin with a low figure and gradually increase it over time. If, as we now suggest, such a system were optional, in the sense that drug developers could eschew it in favor of patents, then the likely result would be that, in early years, prizes would be given only to the developers of drugs focused on neglected diseases. Gradually, as the potential prizes increased, one would see more prize applications from the developers of global diseases. If, as we have argued, the prize system would, on balance, be superior to the patent system, then the resultant delay in extending its reach to global diseases would of course be regrettable. But we are not unduly troubled by the fact that the system would initially redound only to the benefit of the victims of neglected diseases, which to date have attracted the least research.

4. Reducing Redundancy

As we suggested at the outset of this paper, both patent systems and prize systems lead to redundant research. Some of that redundancy is socially beneficial; some of it wasteful. Plainly, we should strive, when tuning a prize system, to reduce bad redundancy, while preserving good redundancy. This is hard, in part because we have poor information concerning how much is optimal.

One aspect of the variant of a prize system that we have defended on other grounds also, fortunately, seems helpful on this front as well – namely, the fact that prizes would be awarded only for incremental health benefits. The aspect of the current patent system that is most clearly undesirable is the excessive incentive it creates for the development of me-too drugs – in other words, the incentive that exceeds the modest health benefits of those drugs but rather arises out of the opportunity to appropriate a share of the market enjoyed by the drug or drugs already on the market. By paying developers a certain number of dollars for the DALYs saved by their products – in other words, the DALYs that wouldn't have been saved by drugs already on the market – the system we have outlined eliminates this socially undesirable carrot.

That's already a big benefit. But perhaps we can go further. One possibility would be to incorporate into the prize system a registration requirement. Various versions could be imagined. Here's one: Suppose that a firm that anticipated applying for a prize were obliged to register at two stages. When it first commenced research directed toward a particular disease, it would have to so notify the FDA, which in turn would add its name to a publicly available list of firms pursuing the disease in question. Next, when the firm commenced clinical trials on a particular drug, it would have to

notify, both the FDA and the public at large.[102] The penalty for failure to register in a timely fashion would be disqualification for the prize system. The resultant increase in awareness of just how crowded is the field pursuing a particular goal would help each potential new entrant make more informed decisions concerning whether it made economic sense to join the competition.

But what if the combined effect of many such privately rational decisions were to attract more than a socially optimal number of firms into a given field? For the reasons explored above, it is unclear whether that would indeed occur. If it did, we could use the levers of the prize system to bring the numbers down. For example, we could cap the number of firms permitted to register projects aimed at a particular disease. In the extreme case, we could reduce the number to one. New entrants would be permitted only when an initial registrant acknowledged failure and pulled out.

But wouldn't such a system produce an Oklahoma land rush? Pharmaceutical firms would quickly register for every conceivable disease, not just to preserve their options, but also to exclude competitors. Such abuse could be checked with a reporting requirement. Periodically, each registrant would be obliged to describe what it had done or is doing on a particular research venture. Failure to continue would result in delisting. Failure even to undertake a project would result in denial of the right to register for future projects.

Using these tools, the government could bring the total number of participants down to optimal levels. The levels would likely vary by field. As F.M. Scherer has shown, the optimal number increases as the probability of success decreases. Thus, for diseases with respect to which the science was still primitive and the likelihood that any

[102] Explore extent to which this tracks extant requirements.

given project would succeed were low, the government could not impose any ceiling. For diseases, such as pneumoccal disease, where the science was well advanced and the probability of success were higher, the government could set lower caps.

Plainly, crucial to this strategy would be good information concerning the optimal levels of redundancy. Such information is currently lacking – and we are not in a position to offer it. But, if and when we obtain it, the prize system could be adjusted to take advantage of it.

5. Geographic Scope

Thus far, we have been assuming, vaguely, that the prize system would be global in coverage. In other words, the magnitude of the reward made to the developer would reflect the number of DALYs it saved (per year) throughout the world, and the drugs to which the system applied would not be subject to patent protection anywhere in the world. But implementation of a system on that scale would be far from simple. Formally at least, innovation policies are set at the national level;[103] within the limits set by the TRIPS Agreement and the Paris Convention, each country decides for itself how to stimulate research and development. The creation of a global reward system would thus require coordinating reform efforts in over 150 separate countries.

The obvious difficulty of persuading so many countries to move in parallel would be exacerbated by a collective-action problem. Each country would have an incentive to rely upon other countries' willingness to institute a prize system, funded by taxes on their own residents.

[103] But cf. Mossinghoff and Kuo (predicting that, in foreseeable future, we will shift to a global patent system).

Suppose that, despairing of achieving global consensus, the United States were to implement a prize system unilaterally. More specifically, suppose that it adopted an optional reward system of the sort sketched above and then (building on a proposal by Jean Lanjouw)[104] required prize applicants to forego patent protection for their products, not just in the United States, but in all developing countries.

Although feasible, this option is not terribly realistic. It would have the practical effect of imposing on residents of the United States the entire burden of financing the development of drugs that meet the health needs of the developing world. The United States has long been unwilling to shoulder even its fair share (on a per capita basis) of the costs of foreign aid or other humanitarian efforts.[105] The likelihood that the federal government would be willing to move to the opposite extreme seems slim.

A route somewhere in between these poles seems the most promising. Instead of either seeking to secure a global consensus, or of going it alone, the United States could collaborate with a small number of other developed countries to institute an optional reward system. The G-8, under whose auspices the pilot AMC program is being deployed,[106] might be a congenial institutional home. Each participating country would agree to bear a share of the total financial burden of the program (the cost of the prizes themselves plus the administrative costs) proportional to its population – or, perhaps, to its GDP. Prize recipients would be required to forego patent protection for the discoveries at issue throughout the world.

[104] That proposal is discussed at length in FISHER & SYED, Drugs, Law, and the Health Crisis in the Developing World chpt. 8.
[105] [Document the dismal record on foreign aid.]
[106] See the text accompanying notes ___, supra.

Implementation of the prize system at the level of the G-8 or a similar organization unfortunately would complicate the process, proposed above, for setting the dollars-to-DALYs formula. The rate would have to be set – and then periodically adjusted – by a tribunal of some kind, created as part of the agreement among the participating countries. The governments of the participating countries, each responsive to their own residents, would vary in their tolerance for rate increases. The tribunal would have to balance their competing demands, turning the dial fast enough to satisfy the more altruistic, without causing defections by the less altruistic. Tricky, but possible.

Conclusion

To summarize, the prize system that holds the greatest promise for alleviating the health crisis in the developing world would have the following features:

- Prizes would be available for all drugs and medical innovations that addressed neglected or global diseases.
- Prize recipients would be awarded, once a year for 10 years, a sum of money for each DALY saved anywhere in the world during the preceding year as a result of their innovations. The rate would initially be set at a low level, then gradually increased.
- The system would be optional, not mandatory or cumulative.
- Firms considering applying for a prize would be obliged to register both when they initiated a research project and when commencing clinical trials. The FDA might cap the number of firms permitted to work simultaneously on a particular disease.

- The system would be created and implemented by a small consortium of developed countries.

A system thus constituted would be superior to the current patent-based regime in several respects.

How does a prize system of the sort we have outlined here compare to other possible reforms of the current regime – such as a much-expanded system of compulsory licenses or a system of regulations designed to channel the research efforts of pharmaceutical firms in more socially beneficial directions? Might it be combined in some way with such alternatives? Those questions must await other essays.