

**Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for
Financing Pharmaceutical R&D**

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INTRODUCTION

A recent paper by Hubbard and Love (2004) questions the value of the patent system as a mechanism for funding pharmaceutical R&D relative to a number of other frameworks. The authors suggest that current levels of pharmaceutical R&D can be maintained along with lower costs for medicines if one or all of the alternative mechanisms that they promulgate replaced the patent system wholesale. This paper examines the feasibility of putting into place these alternative systems and the problems that would be engendered if they were to be adopted.

The belief that patents are problematic because they create market inefficiencies is a concept that has long been noted. From an economic perspective, the issue is framed in terms of pricing and output with and without a patent monopoly. The argument goes as follows. With patent protection, price will be set above marginal cost (the price that would prevail in a perfectly competitive market [i.e., a scenario with no patent protection]) and, as a result, the quantity consumed will be below that which would result under perfect competition. The less than optimal (in a purely static sense) consumption of the good during the period of patent protection results in a net loss to society.

However, the rationale for patents needs to be understood in a dynamic context. In industries where patents are important, as is the case with pharmaceutical products, innovators would lack the incentive to innovate if there were no patent protection, since the volumes and prices that they would receive would not be sufficient to cover the costs of discovering and developing innovations. The dynamic benefits created by patents on pharmaceuticals can, and almost surely do, swamp in significance their short-run inefficiencies (Philipson and Mechoulan, 2003).

Even though a world in which there are no patent protections for pharmaceutical products, and no other means by which innovators can expect to recoup their R&D costs, is clearly inferior to a world in which there are meaningful intellectual property protections, one can consider whether there are other means to achieve a given level of innovation with fewer inefficiencies than those supposedly engendered by a patent system. This is an issue that has been debated for as long as patents have existed. There are two major alternatives to patents that have been discussed in the literature. One is a system in which successful innovative effort is compensated with a prize (award) upon completion of the innovation, or after some relatively short time on the market, and the innovation is subsequently put in the public domain. The other main approach is one in which a government authority procures R&D effort (through, for example, contract grants). Completed innovations are then used by the procurer or put in the public domain.

There have been real world cases that illustrate the operation of the two approaches. For example, the old Soviet Union rewarded inventors with prizes, and governments frequently use a procurement system for national defense R&D. In the case of the Soviet Union, the rewards to innovators were far less than the values of the innovations, and the record of innovation was not impressive (Scherer, 1980, p.458). In the case of government contracting for defense systems, the informational problems that would severely limit the ability of governments to properly assess the potential benefits of directed R&D for most kinds of product innovations are mitigated substantially since the consumer in these cases is the government agency itself. The R&D grants process is also generally beset with numerous issues resulting in perverse incentives that are discussed further below.

The Hubbard and Love paper (2004) paper presents a proposal for radically altering the intellectual property rights environment for new drugs. The scheme eliminates patent protection for pharmaceuticals so that new drugs are sold at generic prices immediately after regulatory marketing approval. R&D is financed via a tax or tax-like mechanism that is required to raise predetermined amounts at the national level. The national global R&D budgets are determined according to a treaty and are a fixed percentage of a nation's Gross Domestic Product (GDP). The actual mechanism by which R&D funds are disbursed is left open to a number of possibilities, with no real detail on any of them. We outline the major problems that we see with the Hubbard and Love proposal (hereafter referred to as HL) in the next section.

POINTS TO CONSIDER

- **General funding:**
 - The HL proposal requires that every government set aside a fixed percentage of its national output to finance pharmaceutical R&D (they suggest 0.1% of GDP on the argument that 1% of GDP is spent on pharmaceuticals now and 10% of that is invested in R&D). This is to be accomplished through a treaty. They argue that the countries would be better off funding national R&D budgets of comparable magnitude as a quid pro quo for abolishing patents and gaining access to drugs at generic prices. For this to work, all, or nearly all, countries must agree to tax (directly or indirectly) their constituents year-in and year-out to fund the system.
 - It is not the case, however, that most countries are currently contributing to the fixed costs of R&D in an amount that is proportional to their GDP. There are large differences in drug prices across countries as a result of drug price controls

and regulations. As a consequence, many countries currently contribute little to fixed R&D costs. These countries would have little incentive to enter into the national R&D budget treaties proposed by HL. Thus, it seems highly implausible that one could get all of these parties, each with their own needs and priorities and with incentives to free ride, to agree to such a framework.

- HL does not discuss how these national R&D budget commitments would be enforced. In particular, what penalties would free riders or violators incur? HL indicates that if a country refused to sign the treaties, it would remain subject to the existing system of patent rights. However, it is difficult to see how a mixed system across countries could be sustained and provide adequate incentives to innovators.
- There is no reason to believe that it would be optimal to have the same annual percentage national contribution each year. Changing scientific opportunities or medical needs can argue for a greater or lesser contribution at any point in time. Thus, the agreement would have to be constantly renegotiated, or all of the nations would have to cede authority for this financial obligation to some central authority. These complicating factors further argue against the practicality of this proposal.
- Even without changes in the scientific and medical landscape, the economic circumstances of individual countries can diverge over time. At some points, some countries may be in a recession while others may not, some may have dire national emergencies or military needs while others may not. Thus, the willingness to pay into the system would vary differentially over time. The risk

of having to meet unforeseen needs would therefore argue against countries signing the treaty in the first place.

- Even if one considers only the U.S. case, it is problematic that one could get the public sector to replace a large portion of the existing private R&D spending on pharmaceuticals. The main beneficiaries in the short run would be private insurers and public sector purchasers of pharmaceuticals. The costs would fall on general taxpayers (or possibly employers and individuals in their dedicated R&D intermediators variant). Governments and insurers are focused myopically on managing health care costs. They are not likely to be strong advocates for funding new drug development that can increase individual quality of life and productivity, but also increase their long-term budgets through expanded drug utilization.
- Economic history studies suggest that as countries develop and gain a domestic capacity to innovate, they become stronger advocates of intellectual property protection systems. Japan went through such an evolutionary development after World War II (Grabowski, 2002). India may be following a similar evolutionary pathway today.
- National R&D budgets would also likely lead to strong protectionist pressure to perform R&D locally. Currently, the location of R&D activity is based on scientific excellence and capacity, costs of R&D personnel and equipment, tax structures, regulatory factors and other demand and supply side factors. If nationalistic and protectionist motives become a key driver in the allocation of a

country's mandated expenditures on R&D, this would politicize the process and lead to potentially large inefficiencies in R&D productivity.

- **Direct Funding of R&D:** HL suggests that governments use directed funding of drug development as a possible mechanism for compensating R&D effort. They speculate that current academic funding (via, for example, the NIH structure) could be expanded or that specific work be contracted for with existing pharmaceutical companies (thereby turning innovator firms into contract research organizations [CROs] supplying research services to the government). There are a number of well-known problems with directed R&D funding in general (Kremer, 1998; Shavell and van Ypersele, 2001), and at least one that can be particularized to pharmaceutical R&D.
 - As discussed in the economic literature, R&D contracts are subject to asymmetric information and principal–agent problems. In particular, R&D organizations are not only likely to have better information about scientific opportunities, but may also possess different motives and agendas than politicians and program administrators. This, in turn, can lead to moral hazard (a misalignment of incentives) and adverse selection problems.¹
 - Adverse selection can occur both in terms of what disease categories are funded and what organizations are selected to undertake the projects. Program administrators are likely to have difficulties in assessing which scientific

¹ Moral hazard is the risk that one party to an agreement can change its behavior to the detriment of the other party after the agreement has been reached. Adverse selection occurs when, because of asymmetric information between the parties, an entity inefficiently selects individuals or groups with which to come to an agreement. The classic examples of moral hazard and adverse selection can be found in health insurance markets, where asymmetric information between insurers and the insured can be prevalent. Here the insured may have better knowledge of his/her current and future health needs than does the insurer.

opportunities are the most promising and what groups are best at doing the R&D projects. These opportunities are subject to significant uncertainties and costly investment outlays before one can ascertain whether effective drug products can be developed. In such an environment, decision makers may end up funding programs with very low chances of success or alternatively failing to fund promising programs because they do not conform to established theories and paradigms.

- Adverse selection can also result, due to political rent-seeking² and related considerations. Under a centralized government system of research expenditures, lobbying by those groups that are better organized politically can distort the direction of research to better suit their particular needs. The history of weapons research and procurement is filled with numerous examples of cost inefficiencies related to this and other factors. See, for example, Klein (1962), Marschak, et al (1967), and Peck and Scherer (1962). Moreover, once programs are in place, it becomes difficult to shut down failed or inefficient projects due to local job market and other political considerations.
- One particularly instructive example of these adverse selection problems is the U.S. and Anglo-France experience with the supersonic transport (SST) aircraft programs. This was an attempt to apply the military procurement model to the development of commercial aircraft (Eads and Nelson, 1971). The U.S. program was faced with numerous technical and commercialization problems as well as

² Political rent-seeking is the expenditure of resources to effect a transfer of goods, services or income from one party to another without proper compensation as a consequence of a political process.

environmental concerns. This ultimately led Congress to abandon the U.S. program in 1971.

- The Anglo-French joint development of the Concorde achieved some significant technical successes, but was beset by escalating government costs from its outset. After nearly three decades of losses, the two governments recently terminated commercial flights. Mowery and Rosenberg (1982) reflect on this case example of government supported R&D, and draw the following lessons: “The Concorde experience, which proved to be a financial disaster, forcefully underlined the importance of the exercise of commercial judgments, and of bolstering the incentive to exercise such judgments in high-technology industries such as aircraft. Establishing the purely technical feasibility of an aircraft is very different from establishing its commercial feasibility. It is clear that the early phases of the SST design paid no attention to prospective operating costs. (34) That was, of course, also true of the Concorde, which had to be developed at a joint cost to the French and British governments of several billion dollars.(35) It is arguable that the poor British performance in the aircraft industry in the post-World War II years was aggravated by the availability of large government subventions that dulled the commercial judgment of development decision makers. (36)”
- Kremer (2002) has cited a U.S. Agency for International Development (USAID) 1980’s program to develop a Malaria vaccine that is also illustrative of these incentive and adverse selection problems. USAID funded three research teams and spent over \$60 million to develop a new malaria vaccine beginning in 1980 as

a direct result of the overly optimistic view of one of its research directors, and despite the skepticism of some external evaluators. The program experienced numerous problems including the personal use of grant funds and other accounting irregularities. Nevertheless, in 1984, USAID announced that there had been “a major breakthrough in the development of a vaccine against the most deadly form of malaria in human beings. This vaccine should be ready, especially in developing countries, within five years” (Desowitz, 1991). However, two decades later, it is fair to say this program contributed little of value to the development of an effective malaria vaccine.

- Since governments will likely value some innovations differently than will firms responding to consumer needs, it is probable that a number of innovations that many consumers would find useful will not be funded because the authority directing research will not share the preferences of consumers (e.g., convenience of use or increased quality of life may be valued more by consumers than by the government research czars).
- A substantial expansion of academic funding is not likely to be very helpful in getting drugs that have been discovered through the testing process and past regulatory oversight. Academics are not likely to be very interested in doing many of the routine and scientifically uninteresting (to them) testing that must be done to gain regulatory approval, and the need for patients is so great in many phase III trials that community physicians must be engaged.
- If all R&D activities are treated as inputs purchased by government contract, then some inefficiencies can arise as a result of incentive problems related to what

economists have called yardstick competition (Tirole, 1988). Since the effectiveness of R&D activities can be difficult to measure, control and compare (particularly on the research side), some shirking may result (either through reduced effort or the pursuit of what is of purely scientific interest). On the other hand, if contracts have a high degree of specificity, then they may discourage thinking outside of the box.

- **Prizes:** An alternative mechanism that HL envision for funding R&D is a prize (award) system. Rather than paying for R&D inputs, here the government pays an innovator a lump sum amount for its innovation that is then placed in the public domain. There are also well known problems with prizes. Although its origins are in the very distant past, the award system has been used very infrequently.
 - As is the case for direct funding of R&D, serious problems arise because the government is unlikely to be able to value innovations properly. The incentives for innovators depend crucially on how the government values innovations. Generally, private firms will be better informed about the potential value of innovations to consumers and providers.
 - In the HL system, the differences between government and private valuations are likely to be more pronounced than in the typical prize system, as they propose valuations that would overtly substitute a central authority's vision of what is socially useful innovation for what the market would value. As was the case with direct government funding of R&D, the potential for political rent-seeking is great.

- Prize systems are subject to what economists have called the hold-up problem. The awards would typically be determined after an innovator has invested in developing an innovation. The temptation is great for the award granting authority to offer prizes that are much lower than the true value of the innovation. Since the innovator's costs are sunk,³ the innovator has little choice but to accede to the expropriation of value. Such behavior by the award granting authorities, however, will greatly diminish the incentives for innovators to engage in future R&D activities.
- Under the current patent system, competition from closely substitutable products (i.e., products in the same chemical family) often quickly emerges, providing gains to patients in terms of both quality and price. It is difficult for a prize system to allocate shares of the market to follow-on competitors based on their value to individual patients. In effect, one substitutes a regulatory process for a market-oriented one with all the inefficiencies that can entail.
- Overall, there is much less international experience with prizes as a means of encouraging innovation than patents or research contracts. As noted, the old Soviet Union used prizes as a standard method of motivating individuals in lieu of patents. The Soviet experience was characterized by low levels of monetary compensation and poor innovative performance (Scherer, 1980, p.458; Artemiev, 1974; Hughes, 1946; Hughes, 1945).
- A more relevant example to the issues posed by HL involves awards to innovators under the U.S. Atomic Energy Act of 1946. Under that Act, military uses of atomic energy were not patentable. Instead, the Act empowered a Patent

³ Sunk costs are costs that have already been incurred and cannot be reversed.

Compensation Board to award monetary compensation to individuals making inventions that had military applications to atomic energy.

- In evaluating this experience, F.M. Scherer draws the following conclusions.

“There is an inherent conservative bias in the prizes granted by administrative and quasi-judicial bodies. Munificence is a rare committee virtue. For example, the Atomic Energy Commission’s Patent Compensation Board awarded the assignee of Enrico Fermi’s basic patent on the reproduction of radioactive isotopes— forerunner of the methods for producing plutonium—a sum of \$300,000 when the patent was dedicated to the public. In an analogous case, the federal government agreed to pay \$1 million as compensation for utilizing Robert H. Goddard’s basic liquid rocket engine patents. During the life of the Goddard patents, U.S. expenditures on liquid-propelled rockets amounted to roughly \$10 billion. Compared to the value of the inventions and the profits that might have been earned if exclusive patent rights could have been enforced, the Fermi and Goddard awards were miserly. They were certainly not what Schumpeter had in mind in describing “spectacular prizes...thrown to a small minority of winners.” It is doubtful whether a generalized reward system administered in this conservative tradition would motivate as much risk bearing as the patent system presently does” (Scherer 1980, p.458).

- **R&D Financing Intermediaries:** What seems to be HL’s primary choice for a R&D financing mechanism is one in which what they call R&D investment intermediators are created, licensed, and regulated. It is not entirely clear whether their function would be to

develop drugs themselves, or simply finance the innovation of selected innovators. At one point they state that “Intermediators would compete to attract funds to invest in R&D based on their prowess for drug development and upon their priorities.” This would suggest that they actually develop drugs themselves. On the other hand, they discuss “intermediators experimenting with prize systems, direct investments in profit or nonprofit entities, open collaborative public good models, or other approaches.” This would suggest that the intermediators decide how to allocate to innovators the funds that they obtain from individuals or employers. The latter scenario is likely the one that they intended. There are substantial problems here as well.

- If the actual compensation of innovators in this scenario follows a prize system or direct contracting, then the same problems noted above would be relevant. The novelty here is not in how innovators are compensated, but merely in the presence of the intermediary entities.
- According to HL, individuals or employers would have to make mandatory contributions to R&D intermediators of their choice. They tell us nothing about how the contribution amounts would be determined. For example, they are silent on whether the contributions are constant or dependent on income. If they are fixed per capita, then this amounts to a regressive tax. If they rise with income, then higher income individuals effectively get more votes for setting the R&D agenda.
- Since the pharmaceutical R&D process is complex, obscure, and very lengthy, and outcomes depend to a significant extent on luck, it is unlikely that individuals or employers will be able to rationally allocate their funds based on the prowess

of the organizations that the various R&D intermediators fund, even if they had sufficient incentive to investigate the possibilities. Thus, it is likely that R&D intermediators would specialize in different health priorities, and that is the basis upon which individuals would allocate funds. While sick individuals have strong incentives to “vote” with their contributions for intermediators that direct funds to innovators that target their conditions, it is unclear, though, how much incentive healthy individuals have to pay much attention to how their contributions get allocated.

- Given the weak interest on the part of healthy individuals in choosing among alternative intermediators, patient advocacy groups have strong incentives to engage in political rent-seeking by attempting to influence the allocative choices made by the general healthy population. This can lead to substantial “marketing” expenditures and a potentially serious distortion of research agendas as the best organized and funded groups succeed the most in influencing allocative choices.

- **Diffusion of Information:** HL notes that their scenarios eliminate the need for private firms to market their products. However, innovations do not diffuse widely and quickly on their own. Some mechanism would be required to inform physicians and patients about new products and their characteristics. HL makes no mention of this need, but any mechanism that promotes widespread and rapid diffusion of new therapies would have to come at some (not insignificant) cost.

SUMMARY

The HL proposal for a new R&D funding paradigm actually puts forth not one, but a number of distinct alternatives to the patent system. These mechanisms have largely been rejected over the centuries as wholesale alternatives to the patent system by academics and governments. What may be novel here are the mechanism for global budgeting (mandatory national fixed contributions based on GDP) and the introduction of R&D intermediators to allocate R&D funds. As noted above, both concepts have serious problems of their own, beyond the well-known problems associated with the usual alternatives to the patent system.

Our main concern with HL's proposals centers around the compulsory termination of the patent system, given the strong role that patents have played in encouraging drug R&D and innovation. Our analysis should not be construed as a critique of supplements to the patent systems, including prizes and R&D partnerships, which are designed to increase R&D activities for particular socially meritorious ends. For example, the U.S. Orphan Drug Act has successfully employed various push and pull incentives to encourage research on rare diseases (Grabowski, 2004). This is a case where the market potential for rare diseases was generally too small to support the costly and risky investments required. The incentives in the Orphan Drug Act include R&D grants, tax credits, and market exclusivity rights.

At the current time, various public and private initiatives are being developed to encourage increased R&D on the treatment of diseases endemic to developing countries (e.g., malaria and tuberculosis), as well as on vaccines for bioterrorism agents like anthrax (Kremer, 2002). Like orphan drugs for rare diseases, these are situations where markets do not presently exist or resources are too limited by themselves to support long-term costly R&D programs. In such circumstances, proposed guaranteed purchase funds ("pull" programs) and R&D alliances

(“push” programs) operate as supplements to the existing patent systems. These public and private initiatives increase overall R&D incentives. These programs are in strong contrast to HL’s compulsory elimination of the patent system with its expected adverse consequences for pharmaceutical R&D.

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