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How should we support pharmaceutical innovation?

Paul Grootendorst

SEDAP Research Paper No. 246

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How should we support pharmaceutical innovation?

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Abstract:

The question as to how society should support pharmaceutical ('pharma') innovation is both pertinent and timely: Pharma drugs are an integral component of modern health care and hold the promise to treat more effectively various debilitating health problems. The rate of pharma innovation, however, has declined since the 1980s. Many observers question whether the patent system is capable of providing the appropriate incentives for pharma innovation and point to several promising alternative mechanisms. These mechanisms include both 'push' programs – subsidies directed towards the cost of pharma R&D – and 'pull' programs – lumpsum rewards for the outputs of pharma R&D, that is, new drugs. I review evidence why our current system of pharma patents is defective and outline the various alternative mechanisms that may spur pharma innovation more effectively.

Résumé:

La question de savoir comment la société devrait promouvoir l'innovation dans le domaine des produits pharmaceutiques tombe à point nommé pour diverses raisons: les produits pharmaceutiques sont un élément important des systèmes de santé modernes et tiennent la promesse de traiter plus efficacement un certain nombre de problèmes de santé débilitants. Cependant, le taux d'innovation dans le domaine pharmaceutique est en baisse depuis les années 80. Beaucoup d'observateurs se demandent aujourd'hui si le système en place d'attribution des brevets est en mesure de générer les incitations nécessaires à promouvoir l'innovation et proposent des solutions de remplacement plus prometteuses pour le financement de l'innovation pharmaceutique. Ces solutions comprennent des programmes de subventions des coûts de R & D dans le domaine pharmaceutique (push programs) et d'allocation de primes lors de la création de produits pharmaceutiques issus de la R & D (pull programs), par exemple, de nouveaux médicaments. Je passe en revue les éléments de preuve qui démontrent pourquoi le système de brevets pharmaceutiques actuellement en place est déficient et propose des solutions de remplacement qui pourraient stimuler l'innovation pharmaceutique de manière plus efficace.

JEL Classification: I18, O34

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Introduction

The development of new pharmaceutical ('pharma') drugs, coupled with advances in disease management, has undoubtedly contributed to the impressive growth in the length and quality of life observed in most developed countries since WWII (Cutler, Deaton and Lleras-Muney 2006). In the last two decades, however, the rate of pharma innovation has slowed markedly. Despite the considerable resources committed to drug discovery, most new drugs are characterized as being 'me-toos' – variants on existing molecules that offer, at best, only modest health gains (Morgan *et al* 2005). In other words, the productivity of the pharma R&D enterprise – the number of important new molecules brought to market per dollar spent – has declined markedly.

This productivity slowdown raises questions about how pharma innovation should be encouraged. To many observers, but especially those in the pharma industry, there is no question – pharma innovation requires stronger patent protection. There is a growing body of evidence, however, that patents provide only weak incentives for innovative activity in general, and the development of new drugs in particular. At worst, patents can actually stifle innovation (Bessen and Meurer 2008, Boldrin and Levine 2008, Boyle 2008, Heller 2008, Jaffe and Lerner 2006).

The question as to how society should support pharma innovation strikes me as being a pertinent and timely policy question. Pharma drugs are an integral component of medicine. They are routinely used to manage chronic conditions, prevent infectious disease, and hold the promise to treat more effectively various debilitating health problems. Private foundations and governments spend large sums on pharma R&D, both directly (R&D tax credits, research grants) and indirectly (subsidizing the purchase of patented drugs by beneficiaries of public drug plans, and by treating employer-provided drug insurance as a tax-free benefit). Providing the appropriate incentives and economic environment for drug discovery is therefore crucial. In this paper, I outline the argument against patents and identify alternative forms of public support that might yield more important new drugs per dollar spent on R&D.

The rationale for patents

The rationale for patents is well known. By granting innovators the privilege of market exclusivity, or monopoly, innovators can charge a price well above marginal production and distribution costs without fear of being undercut by competitors. This margin between price and marginal cost, i.e. 'profit' earned

on each unit of the drug sold can be used to recover sunk R&D costs. Indeed, this is the pharma industry's mantra: high margins fuel drug innovation.

Why patents may be counterproductive

Inefficiency

Economists recognize that market exclusivity incurs an efficiency cost, but most contend that this is the price of progress. This inefficiency, known as a 'deadweight loss', pertains to the non-realized sales of the drug to 'price sensitive' consumers – those who are unable or unwilling to pay the monopoly price but who are willing and able to pay the marginal cost. These sales are valued at more than their resource cost, so society gains if these sales take place. But they don't because a monopolist would lose money by doing so. Why? To make these sales, it would need to reduce its price and, by so doing, it would lose more revenues on its 'price insensitive' customers – those who are willing to pay the monopoly price – than it earns on its price sensitive customers. It *would* be profitable to sell at a lower price just to its price sensitive consumers if it could prevent resale of the product to price insensitive customers. But it is costly to prevent resale, as is clear from the controversies over pharma companies initial reluctance to sell at discounted prices AIDs drugs in low income countries.

Profit expropriation

The deadweight loss (DWL) of drug patents is widely recognized. Perhaps less well recognized is the fact that some of the potential profits conferred by patent protection are simply lost and hence unavailable to support pharma R&D. The reason is simple: Patents create high margins and high margins attract 'raiders' – those who want to expropriate these margins. The potential profits from patent protection therefore decline, both by the profits actually expropriated and by the resources expended by the innovator to fend off the raiders. Hence the threat posed by raiders dulls the financial incentive to conduct R&D in the first place.

Profit raiders include drug resellers (those who buy drugs in low price jurisdictions and sell them in high price jurisdictions), counterfeiters (those who pass off fake copies of a patented drug as the real thing), drug companies that develop therapeutically similar 'me-too' drugs (which are sufficiently differentiated

to avoid patent infringement), price regulators (such as Canada's Patented Medicine Prices Review Board) and drug insurers (which delay listing of new drugs on their formularies, and thereby reduce patent life, and impose various price controls).

Fending off these raiders is expensive. For instance, the innovator will need to secure its supply chain from attacks by drug resellers and counterfeiters. To obtain drug plan reimbursement, the innovator will need to conduct increasingly expensive and lengthy clinical and economic studies, shepherd the application through the bureaucracy and directly lobby decision makers. Price regulation is another threat and the pharma industry employs a large number of lobbyists to prevent this from happening. Despite this lobbying, Santerre, Vernon and Giacotto (2006) estimate that federal government price controls in the US pharma market have reduced pharma R&D spending by about $250 billion over the period 1962-2001.

The innovator will also engage competing drug firms in costly battles over market share. Battles with prospective me-too drugs are sometimes fought in the courts. For instance, Pfizer attempted to block Eli Lilly's market introduction of a competitor to Viagra, the first drug for male erectile dysfunction (2003 FC 1278). More commonly, however, the innovator will engage in promotion and marketing directed at prescribers and patients to defend market share from me-toos.

The moniker 'me-too' is pejorative. If patients respond idiosyncratically to any one in a group of similar drugs, it is no doubt useful having alternatives. Indeed, some me-too drugs are therapeutically superior to the pioneer. The issue is that the drug patent creates the high margins that attract more me-too drugs than would otherwise be the case. These me-too drugs, each of which incurs its own development and clinical testing costs, engage in costly battles with the pioneer over market share and dull the incentive to develop first-in-class drugs. Philipson and Lichtenberg (2002) estimate that the reduction in the present discounted value of sales from me-too competition is four times as large as the reduction in sales due to competition from generic drugs after patent expiry.

Patent extension

The innovator might also devote resources so as to extend the life of its patent using a variety of tactics. First, it might attempt to discourage generic entry by using any one of the strategies outlined in Hollis (2009) and European Commission (2008). Second, the innovator might repackage its molecule in a new dosage form or bundle its molecule with other drugs; in either case, it would gain additional patent life.

Third, it might develop a new molecule – perhaps a metabolite or isomer – derived from the original molecule; this new molecule is in effect a 'me-too' version of its original product. The issue here is that the resources expended to help extend patent protection are socially wasteful. Furthermore, to the extent that these tactics do extend patent terms, they create additional DWL.

Increased R&D costs

Patents also increase R&D costs when innovation is sequential, that is, when new products build upon patented discoveries or techniques. Consider, for instance, the challenges of developing new internet commerce software in the US. As Lessig (1999) notes, large swaths of computer code that enable such software enjoy patent protection: "Patent No. 5,715,314, for example, gives the holder a monopoly over "network-based sales systems" - we call that e-commerce. Patent No. 5,797,127 forms the basis for Priceline.com and effectively blocks any competitor. Patent No. 4,949,257 covers the purchase of software over a network." Widely diffused ownership over productive inputs makes it costly for innovators to develop new products in this area. This is what economists call the 'hold-up' problem.

How susceptible is pharma innovation to this problem? Historically, drug development was not sequential. Scientists capitalized on chance discoveries made by assessing the therapeutic properties of very large numbers of synthetic molecules or naturally occurring substances. But this hit-and-miss approach is reaching the point of diminishing returns, as is clear from the recent record of drug discovery. Increasingly, in an attempt to increase R&D productivity, drug designers exploit knowledge of human physiology. Specific building blocks include therapeutic proteins, diagnostic tests for genetic diseases, raw genomic DNA sequences, and receptors useful for screening potential pharmaceutical products (Edwards 2008). Many of the extant discoveries in these areas, however, have received patents and this increases the cost of conducting R&D (Heller and Eisenberg 1998; Boldrin and Levine 2008; Boyle 2008). Why? Firms contemplating introducing new products into such markets must anticipate the threat of legal action by patent holders. One way to deal with such threats is to pay licensing fees, assuming that the entrant can make a mutually beneficial deal with all the patent holders. Another is to simply wait until relevant patents have expired. The potential entrant might also mount a legal challenge to the validity of patents perceived as being weak. Yet another tactic is to amass a portfolio of patents so that the firm can credibly threat to counter-sue for infringement of some of its own patents. Each of these responses is costly.

There is growing evidence, then, that the pharma patent system is defective and is not serving the

interests of either the pharma industry or consumers. Whatever incentives it creates to conduct R&D into socially valuable new drugs is mitigated by DWL, unproductive battles over monopoly profits (which is what economists call 'rent seeking'), and increased costs of pharma R&D. Guell and Fischbaum (1997) estimate DWL in the U.S. market to be in the order of 60 percent of sales revenues. I am unaware of estimates of all the resources spent in profit competition; but I suspect that they are large. A recent study (Gagnon and Lexchin 2008) suggests that industry outlays on pharmaceutical promotion in the US are almost double the amount it spends on pharma R&D. Nor am I familiar with systematic examination of the hold-up problem – the increased cost of pharma R&D that builds on previous discoveries, but I suspect that the costs are not immaterial. Anecdotal reports suggest that promising avenues of research are being abandoned due to the difficulty of striking deals with multiple patent holders (Heller and Eisenberg 1998).

One remaining, putative advantage of the patent system is that they make public technological innovations. Hence even if they do not fuel R&D, pharma patents may serve a valuable disclosure role. But even this advantage is unclear. Specifically, some claim that pharma patents are written in ways that effectively disguise the essential innovation so as to protect the innovation from challenges by generic drug firms and others (Edwards 2008). In any event, given advances in methods of reverse engineering, a patent disclosure is not necessary to learn about the chemical composition of a new drug.

What are the alternatives to patents?

It is worth noting at the outset that patents are not always necessary for innovation. In many markets, firms have sufficient incentive to incur substantial R&D costs without any government assistance. Boldrin and Levine (2008) describe the mechanisms, which include first mover advantages (e.g. the innovator often enjoys a reputational advantage and also earns profits on the sale of a product until competitors' sales drive the market price down to marginal cost), learning curve advantages (i.e. the innovator is more familiar with the underlying technology than are imitators), capacity constraints (i.e. if each competitor needs to invest in productive capacity then there are limits to the number of firms that will enter the market), and the sale of complementary services (e.g. open source software developers earn profits on the sale of product support). Nevertheless, it is entirely possible that without public subsidy, there would be under-investment in pharma R&D given the considerable expense of drug development and the relatively low cost of imitation.

A number of alternative mechanisms have been proposed. These mechanisms include both 'push' programs – subsidies directed towards the cost of pharma R&D, including biomedical research and clinical trials – and 'pull' programs – rewards for new drugs, where the reward size is higher, the more socially valuable is the drug. In other words, the alternatives can be broadly distinguished by whether they subsidize the inputs of the pharma R&D process or the outputs of the process.

Pull programs

The existing patent system

Pull programs come in many flavors. One flavor is the current patent system: drugs that the market deems to be more valuable earn greater profits. But, as I have argued, patents incur significant social costs. Moreover, the standard economic measure of value – willingness to pay – is a noisy measure of a drug's value. In most markets, consumers assess whether a good or service is worth the price; consumer willingness to pay in such markets is a reasonable estimate of social value. But, as Hollis (2005) notes, pharmaceutical markets are extraordinary because the consumer neither chooses the medicine (the physician does) nor pays for it (the insurer does).

Various proposals have emerged which would see the patent system continue in its present form, but with modifications to patent terms and other parameters to address one or more of its limitations. For instance, the Commission of Inquiry on the Pharmaceutical Industry (Canada 1984), recommended that patented drugs be granted a short period of market exclusivity (four years) from the date of regulatory approval to market the drug. Thereafter, generic entrants would pay a royalty to the patentee.

One limitation with patents stems from a limitation of the market mechanism: patents will not encourage R&D in therapeutic areas where drug development costs exceed potential drug sales revenues. These include diseases affecting only small numbers of individuals (such as Paget's disease, Nephroblastoma, Creutzfeldt-Jakob Syndrome and other rare diseases, or pediatric uses of drugs that treat more common disease) and diseases prevalent in resource poor countries (such as drug resistant TB, malaria, schistosomiasis and other tropical diseases).

The US government has enacted several programs to address this issue. It provides for an additional six months of market exclusivity on a drug if the drug manufacturer submits data on the safety and effectiveness of the drug in a pediatric population. The US Orphan Drug Act provides a variety of incentives to encourage development of drugs that treat diseases affecting less than 200,000 US

citizens. These incentives include a market exclusivity provision that prevents competitors from marketing the same drug or a me-too variant for the same approved rare disease for 7 years (Yin 2008). Other proposals deal with the problem by guaranteeing drug developers a subsidy on a fixed quantity of a drug or vaccine that meets pre-specified technical requirements. This is the basis of Kremer's (2002) Advanced Market Commitment.

Alternatives to patents

Most proposed pull-type programs would give drug developers a reward or prize in exchange for forfeiting the privilege of market exclusivity. The benefits are clear: allowing other firms to produce and sell the drug should move prices closer to marginal costs, and the reduction in margins will reduce profit competition and DWL. Placing new drugs in the public domain may, or may not, deal with the hold-up problems created by the proprietary ownership of therapeutic proteins, raw genomic DNA sequences, and the other 'building blocks' of drug discovery. This depends on whether the building blocks come 'bundled with' the new drug or whether they are separate. If they are bundled together, then placing the new drug in the public domain will automatically place the building blocks in the public domain. If not, then the hold-up problem will remain.

The prize/reward proposals can be categorized along several dimensions. First, they can be distinguished by the amount of discretion afforded the agency disbursing the rewards in setting research directions. Some argue for highly targeted research. Stiglitz (2006), for instance, proposes that the agency offer prizes for new therapies for specific diseases, such as malaria. Other proposals would see the agency follow rules that would reward all comers in proportion to the extent they meet some predefined social objective. Hollis (2005) and Hollis and Pogge (2008) would reward a new drug in proportion to its measured impact on population health. Others assess social value by using firms' assessments of the profitability of the new drug, either with the privilege of market exclusivity (Guell and Fischbaum 1995, Kremer 1998) or without this privilege (Levine 2009). DiMasi and Grabowski (2007) would appear to favor a formulaic reward. They express concern that under a discretionary system, 'political rent seeking' and lobbying may distort research directions. Moreover, they suggest that for-profit drug developers are best able to identify and pursue the scientific opportunities that will lead to socially valuable products.

The proposed reward programs also differ in the division of the social surplus of the new drug between consumers and the innovator. (The social surplus is the dollar value of the health gains created by the

drug less the costs of developing, producing and distributing the new drug.) Some would set the reward amount at a level that makes both consumers and the innovator better off relative to the current system. In other words, the reward amount exceeds the patentee's monopoly profits, but is smaller than the social value of the innovation. Hollis and Pogge (2008), for instance, propose a scheme whereby developers can elect to exercise their patent privilege or relinquish this privilege in exchange for a series of lumpsum rewards from an agency called the Health Impact Fund (HIF). By making the scheme optional, developers can earn at least their monopoly profits. Guell and Fischbaum (1995) and Kremer (1998) propose schemes whereby innovators would receive the present discount value of their anticipated monopoly profits; the former would estimate monopoly profits by selling the new drug for a limited time in a test market, the latter would use an auction format.

Other formulae provide developers with rewards that are less than their monopoly profits but greater than their opportunity costs. As an example, Levine (2009) proposes that firms bid for the rights to drug candidates. Bids consist of royalty rates that would accrue to the winner from all firms selling the drug, should the drug clear all the clinical trials and gain regulatory approval. The lowest bidder earns royalty income but is responsible for covering the trial costs.

Levine (2009) is one of two proposals that advocate an auction format to reward new drugs. Kremer (1998) is the other. Kremer proposes that patent rights to a new drug be put up for auction. Unlike a standard auction, however, the winning bidder would not be guaranteed the patent. Instead, at the conclusion of the auction, a coin is tossed. If it comes up heads, the highest bidder pays his bid and gets the patent. If the coin comes up tails, the government pays the highest bid and places the discovery in the public domain. This auction mechanism is a useful way to elicit private information on value. The problem is that half of the new drugs remain under patent. However, as Landsburg (2007) notes, this problem can be easily mitigated. One merely throws "a biased coin that comes up tails, say, 90 percent of the time. Then 90 percent of all patents end up in the public domain, which is not as good as 100 percent but far better than none at all. We do have to give the private bidders some hope of winning so they'll take their bidding seriously." The Kremer auction also has provisions to help avoid bid rigging.

Firms participating in the Hollis and Pogge (2008) scheme would be required to sell their product worldwide at an administered price near the average cost of production and distribution. In exchange, following market approval, the HIF would issue 10 annual payments based on the assessed global health impact of its drug. Each payment represents a share of a reward fund; the reward fund share for drug x in a given year is equal to drug x's share of the global health produced by all participating drugs in that

year. For example, if all participating drugs were estimated to have saved twenty million 'Quality-Adjusted Life Years' (QALYs), and if drug x had saved two million of these QALYs, then it would receive ten percent of the fund. The rewards accruing to drug x are therefore greater the more effective is the drug, and the more people who use it. Conversely, rewards are lower, the greater is the health impact of other drugs competing for HIF funds.

Although all new drugs could participate in the HIF, it would likely attract those drugs whose potential health impact is large relative to the sales revenue it could earn should the developer elect to exercise its patents. In other words, it would likely attract drugs for tropical disease, drugs that confer large positive externalities, such as vaccines, and drugs that are inherently unpatentable. The HIF might also attract me-too drugs that elect to compete with existing patented drugs on the basis of price.

There is one final distinction between the schemes: how the reward funds are financed. All proposals, except Levine (2009), require public finance. Public finance has both pros and cons. On the one hand, the technology to produce a new drug is a classic public good whose cost should be borne collectively by all the jurisdictions in which the drug is used or tested. Also, contributions to a prize fund would be more transparent than the current system of patents governed by the TRIPs agreement (World Trade Organization 2009). Although TRIPS standardizes nominal patent terms among member countries, the actual contribution to pharma R&D by members depends on several factors. One of these is the time required for regulatory review of the new drug as this review period eats into a drug's patent life. Another factor are the price and reimbursement controls imposed by governments, as well as public and private drug plans; these reduce the monopoly rents that are ostensibly there to recoup R&D costs. Another pro of public finance is that drug prices will be lower than in reward schemes financed by royalties from imitators to innovators.

Public finance also has various drawbacks. One is the uncertainty over the rewards. The success of publicly-funded pull programs depends critically on the credibility of the sponsoring organization. Innovators are unlikely to commit resources if they suspect that the sponsor will renege on its promise to pay. Another is the DWL of the taxes required to raise the prize funds. The total public outlays under a rewards scheme, however, should not be that much more than outlays under the current drug patents system. Most prescription drug expenditures in developed countries are already publicly funded, either directly or through tax subsidies for private drug insurance. Under a rewards scheme, drug prices would drop markedly – likely by a larger percentage than the percentage increase in unit volume. Publicly

funded drug spending should therefore decrease, and the savings could be directed towards the reward fund.

Push programs

Proposals have been advanced to subsidize the cost of conducting pharma R&D, both pre-clinical research and clinical trials. Some proposals have come to fruition: The US Orphan Drug Act subsidizes both R&D components, including research grants and tax credits on the cost of clinical trials. The US National Institutes of Health have run some landmark clinical trials, including the ALLHAT study of the efficacy of different anti-hypertensive drugs[1] and WHI study of postmenopausal hormone therapy[2]. Baker (2008) argues for the public subsidy of all post-Phase II clinical trials. Public funding of clinical trials does have several merits. Industry-funded trials are often placebo-controlled, focus on surrogate endpoints and are conducted for a relatively short period of time; moreover trial results are proprietary (Angell 2004, Baker 2008). (This is not intended to be a criticism of the industry. Indeed, this is rational economic behaviour given the regulatory environment and behaviour of competing firms.) Publicly funded trials, conversely, could disclose the evidence on comparative drug effectiveness needed by prescribers to make informed choices. Government spending on clinical trials could also be modest, for two reasons. First, public funding may temper the tendency of regulators to impose additional rules and conditions on the conduct of clinical trials: regulators would face the full cost of adhering to the rules that they impose. Second, governments likely face a cost of capital less than that faced by the pharma industry. According to Grabowski, Vernon and DiMasi (2002), the pharma industry's cost of capital is 11%. Moreover, drug R&D expenses are incurred up to 12 years prior to regulatory approval, so that capital costs account for about half the $802 million cost of drug development estimated by DiMasi, Hansen and Grabowski (2003). Public funding of clinical trials would thus markedly reduce firms' sunk R&D costs and hence address pharma firms' standard justification for patent protection. One drawback of public trial funding, echoing concerns raised by DiMasi and Grabowski (2007) of prize-based schemes, is that the public agency may not be well informed of the most promising drug candidates and may be subject to undue political interference.

Clinical trials account for about 55% of the cost of drug development; the remaining 45% is the cost of pre-clinical research, wherein candidate drugs are identified and selected for testing (Adams and

[1] http://www.nhlbi.nih.gov/health/allhat/facts.htm
[2] http://www.nhlbi.nih.gov/whi/

Brantner 2006). Edwards (2008) presents a compelling case for public subsidy of the basic scientific research necessary to identify drug candidates. Only through a better understanding of the underlying biological mechanisms, he argues, can scientists develop drugs that stand a good chance of being clinically useful. He further argues no one pharma firm has the resources necessary to mount such an ambitious program of research. Instead, this research enterprise is best funded by both public and private sectors and conducted in partnership between academic and industrial scientists, so as to capitalize on their respective skill sets. Moreover, he argues that it is imperative that all research results be placed in the public domain, with no restrictions placed on their use. The reason is that the transactions costs associated with sorting out 'ownership' of discoveries are so high that the only feasible solution is for the work to take place in an IP-free zone. Placing results in the public domain would make it easier to conduct downstream research.

There are several examples of successful research partnerships. One is the Single Nucleotide Polymorphism (SNP) Consortium, funded by a consortium of pharma firms, IBM, Motorola and the Wellcome Trust. On a budget of $44 million, scientists working at four academic institutions: (Sanger Centre, Stanford University, Washington University (St. Louis) and Whitehead Institute) have discovered more than 1.8 million SNPs. Another example is the Structural Genomics Consortium (SGC), an initiative financed by private foundations, governments and the pharma industry. On a budget of only $25M per year, the SGC has purified over 1,500 human proteins and has determined the structures of over 500 new human proteins, accounting for about 20% of all the human protein structures over the past 4 years. Both examples illustrate that industrial and academic scientists can collaborate in ways that satisfy both the goals of academic scientists and the goals of the project sponsors.

Push-pull hybrids

Another option is to combine aspects of both push and pull programs. For instance, one could imagine public subsidies of research initiatives like the SNP and SGC and other initiatives that develop and identify drug candidates. The mechanism proposed by Levine (2009) could then be used to select the most promising candidates, and finance their clinical trials. Recall that rights to these candidate drugs would be auctioned. The firm that bids the lowest royalty rate covers the trial costs but receives the royalty from all firms selling the drug, should the drug receive regulatory approval.

This mechanism has several attractive properties. First, it allows for competition in the final dosage form drug market, reducing margins and hence DWL and wasteful profit competition. Second, because

the cost of these trials is privately financed, there is perhaps less scope for political interference than if trials were reliant on public funds. That being said, a public agency could in principle specify the parameters of the trial (e.g. comparators, endpoints, duration) so that the information gained could be useful to clinicians. Finally, the mechanism capitalizes on the expertise of the pharma industry in identifying promising drug candidates, coordinating clinical trials and marketing and distributing drugs. Indeed, the auction format would favor the firm that is most efficient in running the trial.

Conclusion

The patent system does not appear to be a particularly effective way to encourage pharma innovation. In theory, the profits earned on the sale of a patented drug allow the innovator to recoup R&D costs. Patents do result in DWL, but the theory says that this is the price of progress. The textbook theory, however, appears to be incomplete. The presence of monopoly profits attracts raiders – counterfeiters, resellers, me-too drugs, price regulators, drug insurers – and some, perhaps most, of these profits are lost in the ensuing battle. Moreover, patents on upstream discoveries increase the cost of pharma R&D. The result is that the incentives for drug discovery are muted. Several alternatives ways to encourage drug discovery have been advanced. These include public subsidy of the cost of pharma R&D, lumpsum rewards for new drugs, and royalty payments paid to innovator firms. Although much more work is needed to operationalize and compare the merits of these alternative approaches, my sense is that they hold the promise to increase the productivity of the pharma R&D enterprise and decrease social costs and therefore deserve serious consideration.

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