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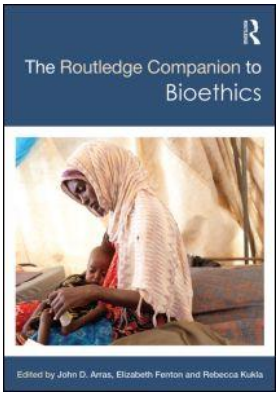

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Intellectual Property In The Biomedical Sciences

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Part III

INTELLECTUAL PROPERTY AND COMMODIFICATION

In June 1980, the Supreme Court handed down its decision in the landmark case of *Diamond v. Chakrabarty*. In a close 5–4 ruling, the court upheld a patent initially granted to the General Electric Company for a genetically modified organism created in its labs by Ananda Chakrabarty. Living things had previously been thought outside the realm of patentable subject matter; but in *Chakrabarty* the court ruled that the modified genome of a bacterium, *Pseudomonas putida*, was no different than any other invented "composition of matter" and thus was eligible for a patent. The decision was (and still is) a landmark; the *Chakrabarty* case opened up a whole set of items—genetically modified organisms, cell lines, and genes, among others—to patenting, and made what were previously thought to be research tools into valuable commercial properties. Biomedical scientists doing research on, for example, cell lines extracted from patients with cancer were no longer working with "merely" biological materials; they were now working with resources worth (potentially) millions of dollars.

Changes to law and policy over the last 30–40 years like the *Chakrabarty* decision have had big effects on the conduct of biomedical research. The upshot of these changes has been a steady process of commercialization of medicine, with profound consequences for research in the biomedical sciences as well as the practice of medicine. How best to understand commercialization, as well as the evaluation of its effects, are hotly contested topics. Commercialization raises a number of questions that overlap with many of the traditional concerns of bioethics: access to health care resources, exploitation in the doctor–patient relationship, the treatment of research subjects, and the use of human biological materials in research, among others. It also generates questions at the frontiers of work in research ethics and the ethics of the life sciences.

This section explores ethical questions about intellectual property and commercialization in medicine and biomedical research, focusing on the potential harms of commercialization. Biddle surveys ethical questions about the role of intellectual property in the biomedical sciences. He focuses on two problems in particular, each of which has been the subject of intense debate: the potentially negative effects of intellectual property on access to health care resources (especially medicines), and the possibility that increased patenting of upstream research tools (such as cell lines) will have a

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chilling effect on research activity. Biddle views these two problems as objections to the dominant (consequentialist) justification for patents, the incentives argument. The central function of intellectual property, according to this argument, is to generate incentives for investment in certain kinds of costly productive activity (such as biomedical research) that otherwise would be very difficult to profit from (due to the difficulty of excluding others from—and charging a price for access to—their products, such as medicines). In exchange for the welfare-decreasing effects of patents (due to the high prices patent holders can charge), there is (allegedly) a net benefit over the long term in the form of more and better medical innovation. But, as Biddle points out, if there is reason to doubt whether patents generate this benefit, then there is reason to doubt whether the incentives argument offers a sufficient justification for intellectual property rights in biomedical research.

Biddle explores the two problems in depth, and surveys a great deal of existing commentary on these two issues; he also discusses some of the potential solutions. Ultimately, he concludes that the potential harms patents pose are serious enough to warrant a revision of current patent criteria (at least as they pertain to biomedical research). Biddle's concern is with the impacts of the biomedical sciences: with the ways in which research and its results in these disciplines affect the health and wellbeing of consumers of medicine. Resnik, however, is concerned with the way commercialization will affect the conduct of research itself. Scientists, as Resnik points out, are bound by standards of research integrity, and adherence to those standards is required not only to ensure that research is ethically above board, but also to maintain the credibility of scientific expertise and public trust in science. Resnik makes a distinction between two sorts of threats to scientific integrity posed by interactions with commercial interests: the possibility of biasing research, and outright misconduct. Whereas bias is unintentional and largely unconscious, misconduct involves the deliberate intent to deceive through, for example, the fabrication of research results. Because of the potential harms of both of these sorts of behaviors, Resnik argues that dealing with both should be a top priority for those institutions responsible for regulating research.

Like Resnik and Biddle, Brody discusses issues in research ethics, but his contribution also deals with a topic of longstanding interest to bioethicists: the ethics of the doctor–patient relationship. Brody's subject is the influence of the pharmaceutical industry on both medical research and patient care; he explores a number of questions about the potential for interaction with the pharmaceutical industry to generate conflicts of interest for physicians and medical researchers. Brody considers the available evidence that financial and other relationships with pharmaceutical companies creates conflicts of interest, and analyzes the arguments for and against different harms associated with these. He also discusses where primary responsibility for dealing with these harms lies (for example, whether it is industry or physicians who are responsible), and what the proper response to these harms should be.

Together these entries survey a wide range of issues and work on commercialization and intellectual property in medicine and the biomedical sciences. Given the sheer amount of money, brain power, and resources—not to mention hopes and dreams—invested in the biotechnology and pharmaceutical industries, and the real potential of work in the biomedical sciences to greatly alter (for better or worse) the human condition over the coming decades, this topic area will only increase in importance, and should be one that will generate worthwhile issues for bioethicists to explore for the foreseeable future.

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INTELLECTUAL PROPERTY IN THE BIOMEDICAL SCIENCES

Justin B. Biddle

Introduction

Since the late 1970s and early 1980s, intellectual property rights (IPRs) have become increasingly important in many areas of science, including (and perhaps especially) biomedical research. This is evidenced by a dramatic rise in patenting activity. Between 1983 and 2003, the number of patents issued to U.S. universities rose from 434 to 3,259 (Walsh et al. 2007: 1184); patenting in biotechnology has also risen significantly, from 2,000 in 1985 to over 13,000 in 2000 (Walsh et al. 2003: 293). Other countries have witnessed similar trends (American Association for the Advancement of Science (AAAS) 2007a).

While there are a number of factors that have contributed to the increase in patenting, three are particularly important. The first is the development of recombinant DNA technology by Stanley Cohen and Herbert Boyer in the early 1970s, which allowed scientists to isolate specific segments of DNA and transfer them into the DNA of other organisms. This development, which ushered in the age of biotechnology, also laid the groundwork for the patenting of living organisms, as it created the possibility of engineering living organisms that are not "naturally occurring." The second factor is a legal development concerning the patentability of living organisms. In 1972, Ananda Chakrabarty applied to the U.S. Patent and Trademark Office (USPTO) for a number of patents on a genetically engineered bacterium—including a patent on the process of engineering this organism and a patent on the organism itself. The USPTO granted the process patent but initially argued that the organism itself is not patentable because it is a product of nature, and living. Chakrabarty appealed the case to the Supreme Court, which ultimately granted the patent (*Diamond v. Chakrabarty*, 447 U.S. 303 (1980)). The Court argued that Chakrabarty had engineered a bacterium that does not occur naturally, and it claimed that the fact that the organism was living was irrelevant to the question of patentability; the relevant distinction is between products of nature and human-made inventions, not between the living and non-living. In the U.S., this decision provided legal groundwork for the patenting of life. Subsequent to this decision, the

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European Patent Office reached a similar conclusion, in part to ensure that the U.S. biotech industry, which could patent living organisms, did not have a competitive advantage over its European counterpart (Brody 2007).

The third factor that contributed to the rise in patenting is a series of U.S. legislative initiatives passed in the early 1980s, especially the *Bayh–Dole Act* of 1980 (PL 96-517) and the *Stevenson–Wydler Technology Innovation Act* of 1980 (PL 96-480). Prior to these enactments, inventions resulting from privately funded research could be privately appropriated, whereas inventions resulting from publicly funded research typically remained in the public domain. The *Bayh–Dole Act* allowed universities and private corporations to patent the results of publicly funded research, while the *Stevenson–Wydler Act* allowed for the patenting of results obtained in government laboratories. The explicit intention behind these acts was to encourage patenting in order to facilitate the transfer of research results into the marketplace (Biddle 2011).

The growing importance of intellectual property (IP) in the biomedical sciences raises a number of important philosophical issues. As will be discussed in the next section, one of the most important moral justifications of IPRs, especially patents, is that they incentivize research and development (R&D) that ultimately benefits society. Patents give patent holders the right to exclude others from making, using, or selling patented entities; as such, they give patent holders a temporary monopoly over those entities. One of the most important arguments in favor of patents is that these temporary monopolies facilitate the production of knowledge, which in turn benefits society. However, there are reasons to doubt that patents in biomedical research have this effect; this essay will examine some of these reasons.

Intellectual Property and Its Justifications

There are four types of IP: patents, copyrights, trademarks, and trade secrets. The subject of this essay is IP in the biomedical sciences, and because the type of IP that is most relevant to the sciences is patents, this essay will deal exclusively with them. In the U.S., patents cover inventions and discoveries that are: statutory, novel, useful, and non-obvious. Most other patent systems, including the European Patent Office, have similar requirements. To be statutory, an invention or discovery must be the kind of thing that is patentable; while different countries interpret this requirement in different ways, all require that patentable objects be "non-natural"—e.g., not an abstract idea or law of nature. Novelty requires of an invention that it not be known publicly prior to the submission of the patent application. Usefulness requires that an object be capable of being utilized in a practical context for the attainment of specific goals. Finally, to be non-obvious, the discovery or invention cannot be obvious to a person with ordinary skill in the art. Clearly, each of these requirements is open to interpretation and has been the object of a long legal and policy debate. Excellent narrative histories of recent debates in the U.S. and in Europe have been provided by Brody (2006a, 2006b) and Brody (2007), respectively.

The recent increase in patenting activity in science raises philosophical questions about the moral and epistemological justifiability of IP. There are at least three types of justifications: labor based, personality based, and incentive based (Hughes 1988). The labor-based account begins with the premise that every human being has a property right over herself, including her labor. When an individual mixes her labor with a previously unowned object, she thereby acquires a property right over it (subject to certain restrictions).

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This account, which derives from John Locke (1980 [1690]), has been defended more recently by Nozick (1974), Moore (2001), and others.

According to the personality-based account, property provides a particularly suitable means for self-actualization and personal expression (Hughes 1988: 330). The process of self-actualization requires that we maintain some degree of control over our external environment, both tangible and intangible; personality-based justifications argue that property rights are the most effective means of maintaining such control. This view, which derives from G.W.F. Hegel (1991 [1821]), is discussed in detail by Hughes (1988).

According to the third type of account, IP is justified on the basis of its incentivizing effects. This justification includes both an epistemic and a moral component. IPRs are thought to incentivize R&D that would otherwise not get done, or not get done as quickly, and thereby facilitate the development of useful knowledge (the epistemic component). In facilitating the development of useful knowledge, IPRs thus quicken the transfer of research into the marketplace, which ultimately benefits society (the moral component). This justification, which is associated with the utilitarian tradition in moral philosophy, is widely accepted in the arena of science and technology policy, and it has been used to justify initiatives aimed at increasing patenting activity in science, such as the *Bayh–Dole Act*.

While the labor-based and personality-based accounts might provide plausible justifications for some kinds of IP, they face serious obstacles as justifications of patenting in science. Scientific research is a communal enterprise. Advances in science and technology require not just teams of researchers working toward particular developments but also prior generations of researchers who provide the requisite groundwork for those advances. Cohen and Boyer's work on recombinant DNA technology, for example, would have been impossible without Watson and Crick's earlier discovery of the structure of DNA. The communal nature of research presents serious difficulties for both labor-based and personality-based accounts, as such accounts would seem to require that we be able to draw a sharp line between those who have contributed their labor or their "personality" toward an advance and those who have not. While it is easy enough to draw a line for pragmatic reasons, it is difficult if not impossible to draw it in a principled way. Personality-based accounts face the additional problem that they seem incapable of justifying property rights over objects that are useful but that have little of their developer's "personality" in them (Hughes 1988). It is perhaps plausible to argue that an individual has a property right over a poem that she wrote, on the grounds that it is an expression of her personhood; this argument is much less plausible when the object in question is a genetically modified microorganism.

The incentive-based, consequentialist justification of patenting is arguably the most plausible of the three, at least with respect to biomedical research—and, as noted, it is the most commonly maintained justification in science and technology policy. The remainder of this essay will examine two important sets of criticisms of patenting in biomedical research, both of which call into question the consequentialist justification. The first is the "tragedy of the anticommons" thesis, which concerns the effects of patenting items of basic research, while the second pertains to the effects of patenting in pharmaceutical research, especially for the developing world.

Tragedy of the Anticommons?

Many have argued that the proliferation of patenting in science—particularly in basic, or upstream, research—is obstructing the flow of information, which in turn impedes

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progress in science and technology (Nelson 2004). One of the most important of these arguments is the "tragedy of the anticommons," put forward by Heller and Eisenberg (1998). The tragedy of the anticommons thesis is a play on Garrett Hardin's "tragedy of the commons," according to which common ownership of scarce resources leads, by way of a series of individually rational decisions, to overexploitation (Hardin 1968). The solution to this problem, according to Hardin, is private appropriation of the commons. According to Heller and Eisenberg, however, too many property rights can lead to underutilization and impede the development of potentially beneficial technologies. A "proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development" (Heller and Eisenberg 1998: 698).

An example that Heller and Eisenberg provide in support of their thesis is patents on concurrent gene fragments. In situations in which the development of a product requires access to multiple concurrent gene fragments, patents can slow down, and even stop, the development of a product. For example, the development of DNA diagnostic tests can require access to multiple patented DNA segments; obtaining access to these segments can be either so complex or so expensive that, in many cases, researchers will cease developing these tests and turn their attention elsewhere. While Heller and Eisenberg do not explicitly defend a particular solution to this problem, I interpret them as maintaining that patents on the results of upstream scientific research—and particularly research inputs—should be prohibited.

The anticommons thesis has generated much controversy. Several studies have been conducted to test the thesis empirically, and many hold that these studies effectively falsify the thesis. One of the most commonly cited of these studies is that of American Association for the Advancement of Science's Project on Intellectual Property in the Public Interest (AAAS-SIPPI), one of the conclusions of which is that there is "very little evidence of an 'anticommons problem'" (AAAS 2007a: 12). In order to reach this conclusion, the authors surveyed over 8,000 randomly selected members of the AAAS from a variety of different fields and asked them about their experiences acquiring IP-protected materials. Many of the results provide grounds for concern. Thirty-three percent of respondents reported that they had experienced difficulties acquiring IP-protected material, including 25 percent of academic respondents and 40 percent of industry respondents (AAAS 2007b: 24). Of those who reported difficulties, 60 percent stated that licensing negotiations were "overly complex" and 38 percent reported a "breakdown of licensing negotiations" (AAAS 2007b: 24). Given these results, it is at first difficult to see why the authors would conclude that there is very little evidence of an anticommons problem; the basis for this conclusion is that only 1 percent of all respondents reported abandoning their projects (AAAS 2007b: 25, 61). The study authors have thus interpreted "anticommons problem" rather narrowly, which is how they could reach the conclusion that they did. While the results of this study do not suggest that IPRs are leading to widespread project abandonment, they do provide reason to worry that IPRs are inhibiting research in a number of ways.

Perhaps the most important of the studies cited in response to the anticommons thesis are those of J. Walsh, W. Cohen, and colleagues (e.g., Walsh et al. 2007). One of these surveyed over 1,000 researchers in genomics and proteomics—two fields with extensive patenting activity—in order to determine the effects of patenting on the choice of problems to address and the decision not to pursue a project. To determine the former, the authors listed a variety of potential reasons for choosing a project and asked

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respondents to rate the importance of each. While "scientific importance" and "interest" were widely reported to be "very important" or "moderately important" reasons for choosing a project (by 97 and 95 percent, respectively), only 7 percent reported that "inputs patent free" was an important reason for choosing a project, with the same percentage reporting that the patentability of results was an important reason (Walsh et al. 2007: 1188). With respect to the decision not to pursue a project, only 3 percent of respondents reported that too many patents upstream was an important reason for not pursuing a project. These results cohere well with those of the AAAS-SIPPI study in finding that IPRs—at least in some areas of research—do not seem to be leading to widespread project abandonment.

The results reached by Walsh et al. are curious: In the patent-rich fields of genomics and proteomics, patents do not appear to be doing what they are designed to do—i.e., exclude others from using patent-protected objects. Walsh et al. investigate this issue and argue that scientists have developed "working solutions" to the problem of obtaining access to IP-protected materials; perhaps the most important of these is infringement. The authors ask how often scientists believe they require access to other people's IP-protected materials, and of those who responded, 8 percent believed that they had, within the past two years, used knowledge or information covered by someone else's patent, but only 5 percent of respondents reported that they regularly check to see if the information they are using is patent protected (Walsh et al. 2007: 1189). Given the frequency of patenting activity in these fields, and given the infrequency with which scientists report checking for patents, it is hard not to conclude that infringement is widespread.

It is common to believe that these studies provide evidence against the anticommons thesis. The AAAS-SIPPI study states this explicitly, and it is often cited to this effect (e.g., Gold et al. 2010). However, a closer examination reveals that the evidence presented in the AAAS-SIPPI study and in the studies of Walsh et al. is largely irrelevant to an evaluation of the anticommons thesis (Biddle 2012; Eisenberg 2008: 1069). The anticommons thesis, recall, states that a proliferation of patenting and licensing *upstream*—i.e., in more basic research—is inhibiting *downstream* research and product development. The aforementioned studies, however, do not examine the effects of patenting and licensing in upstream research on downstream research and product development. The AAAS-SIPPI study focuses upon research scientists and did not ask which patented materials were being acquired or how these materials were being used (AAAS 2007b: 19); as a result, it is not relevant to the question of how patents upstream effect downstream research and product development. The studies of Walsh et al. examine the effects of patenting and licensing upon the sharing of information among academic researchers, the vast majority of whom are engaged in basic research (Walsh et al. 2007: 1086). The data in these studies, as a result, are also irrelevant to the anticommons thesis. In this regard, it is worth noting that, despite the fact that the studies of Walsh et al. are sometimes taken to disconfirm the anticommons thesis, the authors themselves never make this claim. Rather, they claim that, at the present time, access to patents "rarely imposes a significant burden for academic biomedical researchers" who are engaged in basic research (Walsh et al. 2007: 1191).

There are other empirical studies that do provide data that are relevant to the anticommons thesis, and these studies support the thesis—though the data they provide are limited to a small number of fields. DNA diagnostics is one area in which we do seem to be witnessing anticommons problems. Mildred Cho et al. surveyed 132 directors of

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diagnostic laboratories; 75 percent of respondents held patent licenses, 65 percent had been contacted by a patent or license holder regarding potential infringement, *25 percent had stopped performing a clinical genetic test as a result of a patent or license, and 53 percent had decided not to develop a new clinical genetic test as a result of a patent or license* (Cho et al. 2003: 5, emphasis added). This is exactly the sort of problem anticipated by Heller and Eisenberg.

While it is not clear why we are witnessing problems in this area and not in the areas of more basic research examined by Walsh et al., one can hypothesize a plausible explanation in terms of a simple cost–benefit analysis (Walsh and Cohen 2008). The burden of enforcing IPRs falls on the patent holder, and in many areas of basic research, there is little incentive to enforce these rights, as the development of a marketable product is typically a long way away. In these areas, the expected benefits of enforcement are typically negligible. The situation is different, however, in areas of research that straddle the line between basic research and product development—areas such as DNA diagnostics. In DNA diagnostics, a significant part of the research is isolating genes and determining their functions in disease processes; but once this is done, one is not far from having a marketable product—namely, a test for the gene(s) in question. In areas such as this, the benefits of enforcement can be great.

These empirical investigations have important implications for the questions of the moral and epistemic justifiability of patenting in the biomedical sciences. Patents increase the cost and complexity of research, and while they do not seem to be leading to widespread project abandonment in academic research, this is in large part due to the prevalence of patent infringement. And while there are relatively few data concerning the effects of patents over items of basic research on downstream research and product development, the data that we do have provide reason to believe that patents are having an inhibiting, rather than an incentivizing, effect. More specifically, patents in areas such as DNA diagnostics appear to be inhibiting the development of certain kinds of knowledge and certain technological capabilities that have the potential to save lives. Thus, with respect to patents on items of basic biomedical research, the consequentialist justification of IPRs is on shaky ground.

Intellectual Property and Pharmaceutical Innovation

The pharmaceutical industry is ostensibly an area in which IPRs play a crucial role in incentivizing research and development. Putting a new drug on the market is a long and expensive process; some have estimated the cost at $800 million per drug (DiMasi et al. 2003), though others argue that this figure is highly inflated (Angell 2004). Nonetheless, it is clear that commercial enterprises will be reluctant to invest in drugs unless they have reason to believe that they can recoup their investments—and patents provide a mechanism for doing so. For many commentators, cases like this—in which the outcomes of research are uncertain and the costs of developing a product prohibitive—are paradigm examples of why patents are necessary.

The claim that patents incentivize *innovative* pharmaceutical research is, however, questionable. Much of what the pharmaceutical industry produces are duplicative drugs—or "me-too" drugs—that are sufficiently different from already-existing medicines to obtain a separate patent, but that have therapeutic effects that are the same as, or very similar to, drugs already on the market. For example, between 1990 and 2004, 77 percent of drugs approved by the U.S. Food and Drug Administration were duplicative

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in this sense (Angell 2004: 75). Developing "me-too" drugs is profitable for industry; it can charge monopoly prices because the drugs are patent protected, and the risk involved in R&D is much lower than in the case of truly innovative drugs. All of this suggests that while IPRs might be necessary for innovation, they are not sufficient, and that at present, they are not adequately incentivizing the development of innovative pharmaceuticals. The consequentialist justification of patenting requires that patents incentivize not just any research, but research that benefits society. In this respect, the consequentialist justification of patenting is again on shaky ground.

While the innovativeness of the pharmaceutical industry in the developed world is debatable, it is unquestionable that IPRs are failing to incentivize the development of innovative medicines for the developing world. Nearly 2 billion people, or almost 30 percent of the world population, do not have access to potentially life-saving medicines; as a result, roughly 10 million people die needlessly every year, most of whom live in the developing world (Grover 2009: 7). This situation represents one of the greatest collective moral failures of our time, and IP is at the center of it. Discussions of this tragedy focus upon two problems. The first is the problem of gaining access to medicines that already exist (the "problem of access"); the second is the problem of developing new drugs to treat diseases that afflict primarily or exclusively the developing world (the "problem of availability").

There are a myriad of factors that contribute to the problem of access to essential medicines; one of them is the high cost of medicines that are patent protected. By granting legal rights to exclude others from making, using, or selling patent-protected materials, patents provide temporary monopolies; this gives patent holders and licensees the ability to sell their products at whatever price the market will bear. The vast majority of inhabitants of developing countries cannot afford to purchase life-saving medicines at these prices (or their impoverished health systems cannot afford to buy them on their behalf). Other factors that contribute to the problem of access include inadequate infrastructure in developing countries, which makes storing and distributing medicines difficult, and extreme poverty, which prohibits some people from affording *any* drugs, even those that are no longer patent protected.

The problem of access has been exacerbated by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This agreement, which was negotiated in 1994 at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), set minimum standards for IP policies for all World Trade Organization (WTO) members. One of these standards requires all WTO members to grant product patents. Prior to this agreement, some developing countries (such as India) granted patents on processes but not products. This allowed generic drug makers to reverse engineer new drugs that were still patent protected in other countries, allowing them to be sold in the developing world for prices much lower than their patented equivalents. Once the TRIPS agreement took effect, WTO countries could no longer produce generics for many medicines.

While IPRs represent only one contributing factor among many to the problem of access, they are by far the most important contributing factor to the problem of availability. Pharmaceutical R&D, as noted, is expensive, and it is conducted almost exclusively by industry; because for-profit corporations must be profitable in order to survive, and because inhabitants of the developing world cannot afford medicines at monopoly prices, there is little incentive for firms to invest in medicines that treat diseases that afflict primarily or exclusively the developing world (or type II or type III

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diseases, respectively). Thus, for example, of the 1,393 drugs approved for sale between 1975 and 1999, only 13 specifically treated tropical diseases (Trouiller et al. 2002). Between 2000 and 2004, an additional 163 new chemical entities were marketed, and only five were for neglected diseases (Chirac and Torreele 2006).

Potential Solutions

While the problems discussed thus far (the anticommons problem and the problems of access and availability) are recognized to varying degrees—the anticommons problem is still much debated, and the problems of access and availability are widely acknowledged—there is little consensus about how best to solve them. Potential solutions can be placed into one of three mutually exclusive categories:

1. Maintain the current system of IPRs (perhaps supplemented with additional rewards).
2. Eliminate IPRs.
3. Revise the current system of IPRs.

The vast majority of proposals for solving the problems of access and availability fall within (1). One proposal that has already been implemented is governmental and non-governmental donations and bulk buying, which involves governments, sometimes in combination with one another, targeting particular diseases and donating drugs that treat these diseases, or negotiating with pharmaceutical companies to sell drugs for particular diseases at lower prices. These programs address the problem of access by ensuring that (at least some) medicines are sold at either a lower cost or at no cost at all, and they address the problem of availability by providing a market for drugs for (at least some) neglected diseases. The overall effect of these programs, however, is modest, due to the fact that they tend to target diseases that have well-organized lobbying groups. Thus, they have had some success with regard to HIV/AIDS medications but are unlikely to have much of an effect in the treatment of type III diseases such as African sleeping sickness (Ravvin 2008). There are a number of other proposals that work entirely within the current system of IPRs—including differential pricing and compulsory licensing—but none is likely to serve as a general solution to either the problem of access or the problem of availability (Ravvin 2008), and none addresses the anticommons problem.

Others have proposed supplementing the current system of IPRs by offering additional financial incentives to firms that develop vaccines or medicines that treat neglected diseases. One such proposal, which is already in effect, is Advanced Market Commitments (AMCs). On this proposal, sponsors (e.g., governments, non-governmental organizations) incentivize the development of new vaccines by guaranteeing that they will purchase vaccines that meet predetermined technical specifications. The purchase price is predetermined, and once the vaccine is purchased, they are sold at predetermined, affordable prices. AMCs thus have the potential to alleviate both the problems of availability and access; but while they have had some successes, there are a number of drawbacks, which make them unlikely to serve as a general solution to either problem. Perhaps most significantly, AMCs require of innovators that they create vaccines that meet technical specifications that are predetermined by a committee. Medical research, by its very nature, is uncertain, and it is difficult to know ahead of time whether a particular intervention will meet predetermined specifications; the demand

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to meet such specifications thus places significant limits on the incentivizing effect of AMCs (Ravvin 2008).

Arguably the most promising of the proposals to supplement the current system of IPRs is the Health Impact Fund (HIF), developed by Aidan Hollis and Thomas Pogge (Hollis 2008; Pogge 2005). Under this proposal, innovators would have the choice of selling a drug or vaccine under the current IP system or registering it with the HIF. If the latter option were chosen, the innovator would be rewarded on the basis of the extent to which the innovation actually reduced the global burden of disease (GBD). This proposal has a number of advantages. Depending upon the size of the prize (Hollis (2008) suggests somewhere between $2 and 20 billion per year), it could provide a significant incentive to develop treatments for neglected diseases. Moreover, because the innovator would be rewarded on the basis of the extent to which the treatment *actually* reduced the GBD, the HIF provides incentive not just to develop treatments, but also to ensure that the treatments are affordable, that they reach targeted populations, and that they are taken properly. The proposal also has the benefit of being acceptable to the pharmaceutical industry; it leaves the current IP system completely intact. Perhaps the most significant problem with the proposal is the technical one of determining the extent to which an intervention actually reduces the GBD. Determining the causal effect of an intervention upon the GBD is difficult for both theoretical and practical reasons; this is especially so when multiple interventions are introduced simultaneously (Selgelid 2008). Neither the HIF nor AMCs is intended to address the anticommons problem.

The second class of proposals recommends eliminating IPRs in medical research. Brown (2008) defends a version of this, which he calls "scientific socialism." Under this proposal, patents in medical research should be eliminated, and public funding for research should be adjusted to appropriate levels. Brown argues that patents are not necessary for incentivizing medical innovation; recognition within the scientific community has been a sufficient incentive to innovate for most of the history of science, and it still can be (cf. Hollis 2008; Reiss 2010). Moreover, taking research out of the hands of private corporations would allow scientists the freedom to investigate treatments for all diseases—not just those that afflict the wealthy—and the lack of monopoly pricing would help to solve the problem of access. Furthermore, while Brown does not emphasize this consequence, the proposal would solve the anticommons problem.

The proposal to eliminate IPRs in medical research is a radical one, which would have profound repercussions not just for the entire complex of biomedical research, but for the global economy as well. The radical nature of the proposal brings with it a practical problem of political feasibility: Even if it were advisable in the ideal to eliminate IPRs in medical research, it is unlikely that this proposal would garner much political support. The radical nature of the proposal also, however, brings an epistemological problem of knowing precisely how such a change would affect our systems of knowledge production. Given this, it is perhaps wiser—both practically and epistemically—to proceed in a piecemeal and iterative fashion, by examining the current system of IPRs, predicting the effects of adjusting components of this system, making adjustments, examining the actual effects of these adjustments, and beginning the iterative process anew. This strategy of "adaptive management" has been defended by Mitchell (2009) in the context of policy-relevant research and by Reiss (2010) in the context of biomedical research.

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In the remainder of this section, I will analyze the current system into five different components, for the purpose of illustrating the variety of ways in which the current system could be revised, and I will discuss briefly a few possibilities for revising the current system.[1] The focus is on the U.S.; the European system is very similar, with one exception, which I will highlight below.

The first component of the current system of IPRs is the permissibility of patents on products as well as processes. In other words, it is not only possible to patent something for use in a particular specified process; it is also possible to patent something for any usage whatsoever. This has not always been the case; as I noted earlier, some countries have refused to allow patents on products (e.g., India prior to the TRIPS agreement).

The second component is that patents are granted to the first to file a patent application, as opposed to the first to invent. Most countries operate under a first-to-file system; the U.S. previously operated under a first-to-invent system, but changed to first-to-file with the *America Invents Act* of 2011.

The third component is extensive rights of exclusion. Patents, again, provide legal rights to patent holders to exclude others from making, using, and selling patented inventions—but these rights can be weaker or stronger, and they can apply to different ranges of activities. The term "use," for example, is open to different interpretations. The U.S. legal system has traditionally allowed that non-commercial research falls outside the range of activities that patent holders can exclude; however, in the important Federal Court of Appeals decision, *Madey v. Duke University* (2002), the concept of a non-commercial activity was interpreted so narrowly that almost no activity falls within it. Another issue that is open to interpretation is the limits to the demands that patent holders can place to grant access to patent-protected materials. At present, there are no limits upon the demands that can be placed—even in cases where inventions were made through the use of public funds. Finally, there is the issue of the duration of rights to exclude, which is currently placed at 20 years.

The fourth component is the full sufficiency of meeting the USPTO requirements for obtaining a patent. (A discovery or invention, again, must be statutory, novel, useful, and non-obvious in order to be patentable.) There are other patent systems—for example, that of the European Union—in which these four requirements are not sufficient; according to Article 53(a) of the European Patent Convention, discoveries or inventions that are "contrary to the 'ordre public' or morality" are not patentable. The full sufficiency of these requirements in the U.S. does not allow any exceptions, such as for items of basic research or research tools. It also does not allow for exceptions for living organisms. There are some patent systems that place restrictions upon the types of living organisms that can be patented; Canada, for example, does not grant patents on "higher life forms" (such as plants and animals)—though it does allow for patents on single-celled organisms.

The fifth component is the liberality of USPTO requirements. As noted, the notions of novelty, usefulness, and non-obviousness are open to interpretation, as is the question of whether or not an invention or discovery is statutory. There is a long history of decisions by the USPTO and cases within the U.S. legal system that have dealt with these issues of interpretation, and most of these, especially since 1980, have sided on behalf of those seeking stronger IP protection (Brody 2006a, 2006b). For example, the question of whether isolated and purified DNA segments are statutory is one that is currently making its way through the U.S. legal system; the outcome could have significant implications for the extent to which upstream biomedical research can be shared openly (e.g., *Association for Molecular Pathology et al. v. USPTO* (2010)).

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Given this analysis, what kinds of revisions to the current system might alleviate the anticommons problem and the problems of access and availability? I will briefly highlight a couple of different possibilities. One would be to revise the first component by allowing patents on processes but not on products. This would have the effect of weakening IP protection, which in turn would facilitate the free flow of information, so much so that the anticommons problem would be greatly alleviated, if not solved completely. It would also reduce the problem of access to essential medicines, as it would allow firms to reverse engineer new drugs and create generics. However, in a pharmaceutical system dominated by industry, this reduction might come at the cost of exacerbating the problem of availability, as it would decrease the financial incentives of firms to develop new drugs (Schroeder and Singer 2011).

A different possibility would be to continue to allow product patents but to restrict the rights that patent holders have over these products (the third component). Creating a more robust research exemption by interpreting "non-commercial use" more broadly could have the effect of alleviating the anticommons problem. Placing limits on prices that patent holders can charge for access, especially in cases in which inventions were made through the use of public funds, could help to reduce the problem of access. Shortening the duration of patent rights from 20 years would also help to reduce the problem of access, while arguably still providing sufficient incentive to develop new medicines (Reiss and Kitcher 2009).

Revising the third component in the ways just suggested could be supplemented by a revision of the fourth component, by granting exceptions to the full sufficiency of the four requirements for obtaining a patent. One such potential exception could be for research inputs, which could help to alleviate the anticommons problem. Finally, supplementing the revisions of the third and/or fourth components with targeted, market-based proposals such as AMCs and the HIF could further incentivize the development of new, low-cost drugs that target type II and III diseases, thereby increasing both access and availability.

Conclusion

According to the consequentialist justification, IPRs are both epistemically and morally justifiable, because they incentivize innovative research that leads to social benefits. The preceding discussion has highlighted a number of respects in which IPRs in biomedical research are not adequately incentivizing R&D. The tragedy of the anticommons thesis holds that the proliferation of patenting and licensing in upstream biomedical research is actually *impeding* downstream research and product development. In the area of pharmaceuticals, IPRs might be incentivizing innovation in the developing world (though this is questionable), but they do not incentivize the types of innovations that, on the global scale, are most necessary from a moral perspective. The fact that the current system of IPRs is not adequately incentivizing innovative research, and in some cases is inhibiting the ability of the poor to obtain access to life-saving medicines, poses a serious problem for the consequentialist justification of IPRs in biomedical research.

I have argued that the best strategy for solving these problems is to revise the current system of IPRs. I have provided a framework for examining the ways in which this might be done and have discussed the following possibilities: prohibiting product patents; placing greater restrictions on the rights of patent holders, and allowing exceptions to the full sufficiency of the four requirements for obtaining a patent. The second and third of these

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revisions could be supplemented by market-based proposals such as AMCs and the HIF in order to increase the incentive to innovate, as well as lower costs further. Determining which, if any, of these revisions and supplements would be most successful is a project for further investigation.

Related Topics

Chapter 13, "Influence of the Pharmaceutical Industry on Research and Clinical Care," Howard Brody

Note

1 This analysis is a slightly modified version of Brody's (2006a, 2006b).

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