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An Introduction

Patents Versus Patients: Must We Choose?

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Are patents a tool for promoting the development of medical treatments for patients or merely a roadblock to access to health care? This is a perennial question to which there are often strenuous opinions. This Symposium Issue complements the Second Annual Beazley Symposium on Access to Health Care, “Perspectives on Patents and Patients: Can They Coexist?,” by providing a variety of perspectives on the increasingly important intersection between patents, health care access and innovation.

Whether there is any need to “choose” between patents and patients is an intriguing yet controversial question. To some, patents seem to clearly undermine the goal of providing drugs at the lowest possible costs because the exclusivity inherent with patent rights provides an incentive for profits. To others, there is no conflict at all because patents are seen as the driver of innovation that will inevitably benefit all of society and even facilitate the genesis for low-cost generic drugs. So, which view is correct, or is neither?

Prior to discussing whether a choice is necessary, it is important to understand some fundamentals of patent law. Patents are granted by national governments to applicants who establish that an invention is new, useful, and not “obvious” to someone in the same technical area as the inventor. For example, once penicillin has been discovered and publicly disclosed, no one can thereafter claim a patent on penicillin because it

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would not be “new.” If, on the other hand, the first person to create a drug to treat cancer obtains a patent on the drug, the inventor will be able to exclude all others from making the patented cancer treatment. The ability to exclude all others can enable that inventor to charge a high cost—especially if it is the only drug available for that treatment. Moreover, a patent also increases costs for researchers who want to use the patented drug as the basis for developing further innovations; some researchers and companies may strategically decide to ignore research in certain areas to avoid either patent liability or high costs in licensing the patented drug for further research.

Not surprisingly, patents are often a target of criticism concerning the price of drugs and the extent to which price limits access to medicine. The cost of medication is an issue for all countries. In the current economic climate, patients are highly sensitive to costs. Even in the United States, some consumers forego filling prescription drugs because of inadequate funds. In other countries, newer—and more expensive—drugs may also be hard to access. Moreover, although drug prices are often the focus, patents and their concomitant costs may extend far beyond traditional drug discovery because of the expansive scope of patentability to include medical tests, software, and so forth.

3. See 35 U.S.C. §271 (a) (2006) (providing the owner of a patent the ability to exclude all others from making, using, selling, offering to sell, or importing the patented invention).
4. This may not be true in all countries, but it is in the United States where there are no price controls on medicines.
5. In the United States, there is no general exception to patent liability for researchers—even academic researchers can be liable for patent infringement. See Madey v. Duke, 307 F. 3d 1351, 1361-62 (Fed Cir. 2002).
6. On the other hand, defenders of patents often note that there are many issues that may impede access, including the fact that inadequate infrastructure, as well as tariffs and taxes on imported drugs can impose costs. E.g., Roger Bate, Why Taxes and Tariffs on Medicines in Developing Nations Is a Fatal Policy, MEDICAL PROGRESS TODAY, May 5, 2005, http://www.aei.org/article/22471; Roger Bate & Richard Tren, The Real Obstacles to Sound Treatment of AIDS in Poor Countries, AEI OUTLOOK, July 2004, http://www.aei.org/outlook/20841.
7. Kevin Sack, Slump Pushing Cost of Drugs Out of Reach, N.Y. TIMES, June 4, 2009, at A1 (noting that customers are often not filling or refilling all their prescriptions because of limited funds).
9. See, e.g., COMM. ON INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECON., NAT’L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 45 (Stephen Merrill et al. eds., 2004) (noting that patentable subject matter has been expanding and is of concern to some), available at http://ww.nap.edu/html/patentsystem/0309089107.pdf [hereinafter NAT’L RESEARCH COUNCIL]. To some extent, there has since been recognition that the scope of patentable subject matter may be too broad. Indeed, the U.S. Supreme Court has granted certiorari to revisit this question. See In re Bilski, 545 F.3d 943 (Fed. Cir.)
I. ARE PATENTS ESSENTIAL FOR INNOVATION?

Some suggest that without patents, we would have no drugs. It is true that most pharmaceutical companies today have business models built around strong patent portfolios. Companies that develop new drugs suggest that patent protection is critical because drugs are simple to reverse engineer, such that another company could easily and unfairly appropriate profits without the protection of patents. Drug companies also point to the fact that the regulatory approval process required before a drug can be sold can diminish the effective patent term. They argue that since a drug cannot be sold without regulatory approval regardless of its patent situation, companies are justified in charging higher costs during the shortened patent term. In addition, they note that because generics can quickly and effectively compete once the patent term expires, the patent exclusivity is critical to recoup some of the cost of drug discovery and to provide enough financial support to enable new research. While this may sound logical, critics are skeptical of this argument because the amount of research money is actually often eclipsed by money spent on marketing and administration of drugs.

Moreover, patents are not the only driver of innovation. Even in the context of drug discovery, there have been major innovations that were made without any patent incentives. Dr. Salk, inventor of the revolutionary polio vaccine, never patented his invention. Researchers today often have less choice than Dr. Salk. Due to a 1980 law entitled the Bayh-Dole Act,
universities can claim patent rights in federally funded inventions.16 This law has had a major impact in academic culture towards patents. Now, most universities require their employees to file for patents in the hope that they too can share in the patent profits. Although such profits are elusive – few universities make money and many even lose money once the costs of patenting efforts are considered – the patent culture is nonetheless a strong one.17 Indeed, other countries seem eager to implement the Bayh-Dole Act despite the lack of concrete evidence that it has reaped true rewards.18

However, while there is a strong trend towards patenting by academic scientists, others are opposed to widespread patenting – especially with regard to research tools that might prevent other scientists from creating further innovations. The federal government initially sought to patent sequences of the human genome but subsequently withdrew its patent applications after public protests.19 Some scientists publish rather than patent their innovations, and others have collaborated in ways to ensure that their research results will be freely available.20

II. WHAT IS THE REAL IMPACT OF A PRO-PATENT CULTURE?

The lure of patent profits may have a significant impact on the path of scientific research and development. An obvious impact is that the most lucrative diseases, rather than the most devastating social diseases, attract research dollars. In some cases, the two can be the same – such as in the case of human immunodeficiency virus (HIV). However, for many diseases that primarily effect developing countries, patents provide little incentive because such countries do not have resources to pay for any potential cures; not surprisingly, there are few patents or drugs developed

for such diseases.\textsuperscript{21} In addition, even among diseases that afflict people in wealthy countries with the ability to pay, there is still a disproportionate focus on drugs that have mass appeal and have the potential to generate large profits – i.e. the blockbuster mentality. Some have suggested that this has led to an overabundance of drugs that all treat the same condition – so-called "me-too" drugs – that are very similar whether they treat acid reflux, depression, or erectile dysfunction.\textsuperscript{22} In some cases, multiple drugs within the same class give patients more options. However, often the new drugs do not demonstrate improved efficacy.\textsuperscript{23} That is not necessarily surprising since neither patent nor regulatory laws require that a drug be more efficacious than existing drugs.\textsuperscript{24}

Some are beginning to question the traditional model of using profits from patented drugs to fund research. After all, despite increasing research spending, the actual output of the pharmaceutical industry seems to be

\textsuperscript{21} See Colleen Chien, \textit{Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?}, 18 BERKELEY TECH. L. J. 853, 892 (2003) ("[A] 2001 Harvard School of Public Health survey of twenty large pharmaceutical firms found that [o]f 11 responders, eight had done no research over the past year in tuberculosis, malaria, African sleeping sickness, leishmaniasis, or Chagas disease; seven spent less than 1% of their research and development budget on any of these disorders."). The lack of attention on neglected diseases is also reflect by the efforts of the World Health Assembly to modestly increase the amount of spending on such diseases from the current level of three percent of global research to twelve percent. World Health Organization [WHO], Executive Bd. 124th Session, \textit{Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action: Proposed Time Frames and Estimated Funding Needs}, 1, EB124/16 Add.2 (Jan. 21, 2009), available at http://www.who.int/gb/ebwha/pdf_files/EB124/B124_16Add2-en.pdf. This is particularly significant since there has long been a discussion of a 10/90 gap in reference to the fact that only ten percent of research dollars go towards disease that affect 90% of the population. GLOBAL FORUM FOR HEALTH RESEARCH, 10/90 REPORT 2003-2004 35 (2004); see Michael R. Reich, \textit{The Global Drug Gap}, 287 SCIENCE 1979 (2000). However, it turns out that the reality is that even reaching ten percent is sadly just an aspiration at present.

\textsuperscript{22} ANGELL, supra note 14, at 74-83.

\textsuperscript{23} Id. at 75.

\textsuperscript{24} United States patent laws require an invention to be new, useful, and nonobvious – efficacy is not required. \textit{See generally} 35 U.S.C. §§ 101-103 (2006). In addition, regulatory laws applicable to approving a drug for sale require demonstration of safety and efficacy, but not improved efficacy. While most countries have similar patent and regulatory laws, India is attempting to use patent laws to direct research towards more innovative drugs with a new patent requirement that variations on existing drug compounds are not patentable unless they show improved efficacy. The Patents Act, No. 15 of 2005; India Code (2005), 3(d). This provision is highly controversial and may be subject to international challenge for a potential noncompliance with TRIPS; an international agreement that mandates certain patent standards, including nondiscrimination in the area of technology, such as pharmaceuticals. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1208 (1994). There was one case in India challenging this section on this ground; the Indian Supreme Court found the law to be Constitutional and declined to opine on compliance with international law. Novartis v. Union of India, (2007) 4 M.L.J. 1153.
decreasing in terms of innovative new drugs in the pipeline. In addition, the high costs of patented drugs may actually promote counterfeiting since there is a market of people looking for cheaper alternatives. Moreover, the patent system may not even be working for patent owners. Even with patents, the first market entrant in a particular class of disease, such as heartburn, typically dominates the market for only about a year before the next “me too” drug enters and potentially captures a large share of the market. In addition, once a generic enters the market, prices and profits quickly plummet.

III. BEYOND PILLS TO BIOTECH

As difficult as the questions are about patient access to traditional drugs, the issues become increasingly more complex in the area of biotechnology. Patents on gene sequences or other related products can have pernicious effects on access not only by patients, but also by other researchers. A patented gene may effectively prevent patients from access to diagnostic tests based on that gene because the patent owner has the power to price the test without limits – at least in the United States where there are no price controls on diagnostic tests. This can be further exacerbated by other areas of law beyond patents. For example, Medicare may decline to reimburse what is not necessary for treatment, so if a patented test “only” predicts predisposition, but does not actually treat the disease, a patient may have no ability to pay for this test. Even outside the Medicare context, some private insurers may be reluctant to pay what seems like exorbitant costs charged by some patent owners. Myriad Technology, owner of the isolated BRCA-1 and BRCA-2 gene patents that predicts some types of breast cancer, is one infamous example since the company


charged thousands of dollars for its predictive tests. Moreover, patented genes may impact the course of research; studies show that research has been delayed, limited or discontinued because of concern about violating gene patents.

In the past, many assumed that a wealth of diagnostic and medical treatments would quickly result from sequencing the human genome. There was once a "gold rush" mentality to patenting genes presumed to be critical in leading to new treatments, including ones that could be "personalized" on an individual level. However, the science is actually quite complex—most diseases and conditions are the result of more than one gene—such that patents on individual genes may have little if any true commercial utility. The more scientists learn, the more they realize that their initial predictions were overly optimistic. Genes may have limited value in predicting disease let alone resulting in cures of diseases. Moreover, large numbers of patients are needed to do research in this area, yet patents on genetic material that result from patient research may actually disenfranchise patients and make them less likely to participate in research.

IV. SHIFTING TIDES

The tide may be turning against patents. There are major calls for patent reform in general. One theme is that patents are issued too easily.
While a problem in all areas, an overabundance of "bad" patents in the health care field has immense implications for access to health care. In addition, there is clear concern by some about the impact of patents not only on patient access to medical treatments, but also on subsequent innovation. Recently, a group of cancer patients have challenged the validity of gene patents in the United States. The patients may lose on substantive grounds, but their challenges may represent a shift in public perception regarding patents that could herald possible reform of patents. For example, legislation has been previously proposed to amend patent laws to include more generous exceptions for scientific research, as well as clinical tests. Perhaps the time is ripe to bring back such legislation.

Some drug companies seem to understand that their former business model of primarily selling drugs at a high price to all countries is also changing. Although pharmaceutical companies assert that they provide lower prices to poor countries, voluntary discounts are actually infrequent and discounted prices are often still much higher than the cost of generics. For example, in 2003, Bristol Myers Squibb asserted that it was selling HIV treatment below cost to poor countries in Africa, but generic manufacturers thereafter marketed the same drug for a lower price. While the price at which most drugs (beyond HIV treatment) are sold is among one of the most closely guarded secrets – together with the "costs" of research and development – there are signs that companies are bowing to public pressure to engage in more differential pricing. In particular, pharmaceutical giant GlaxoSmithKline (GSK) recently announced that it would cut prices in the world’s poorest countries. In particular, GSK stated that it would cut prices for the poorest fifty countries so that they encompass no more than twenty-five percent of the price of the cost in wealthy nations. While some are critical of GSK’s price cuts as not going far enough, they

34. While legislative reform of patents is actually not primarily motivated by concern about access to medical treatment, it is implicated.
38. E.g., Jeanne Whalen, Glaxo Plans to Cut Drug Prices in Poorest Countries, WALL ST. J., Feb. 13, 2009, at D6. At the same time, GSK stated that it would invest a percentage of its profits in medical infrastructure, such as health clinics and also contribute patents to a pool for neglected diseases – excluding AIDS. Id.
39. Id.
V. INTERNATIONAL SUPPORT FOR NEW SOLUTIONS

There is also broad international support for considering new solutions. In a highly significant development, the World Health Organization (WHO) adopted a resolution for a global strategy and plan of action on issues surrounding public health, intellectual property and innovation in May, 2008. The resolution calls for new proposals for funding that would stimulate research and development (R&D) for neglected diseases typically unsupported by patents because the market is too small or uncertain. In addition, the Annex to the resolution provides specific proposals to consider, including a global R&D treaty as well as new incentive schemes to delink R&D costs from the price of drugs such as prize awards.

One proposal supported by the WHO and others is the creation of patent “pools” that would enable patents to be part of the solution. A patent pool involves an agreement by at least two patent owners to share (pool) their patents and license them to each other as well as to third parties. The patent pool provides a “one stop” shopping for patents related to a certain technology. “Pooling” together relevant patents for a particular subject matter for licensing can reduce barriers to entry and foster development of needed drugs. Historically, pharmaceutical companies were not inclined to pool patents because they stood to gain more from selling drugs on their own; prior successful patent pools often involved areas where companies clearly needed pools, such as when there was a universal standard.

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40. Brook Baker, Health Gap Global Access Project Campaigns, GSK Access to Medicines: The Good, the Bad, and the Illusory (Feb. 15, 2009), http://www.healthgap.org/bakeronGSK.htm (offering praise for extensions of price discounts to a wider scope of diseases while simultaneously offering criticisms that the discounts will not cover all countries in need and that the discounts may still be too expensive for targeted consumers).


42. The document refers to stimulating R&D for “Type II and Type III” diseases. Type II diseases occur in all countries, but a substantial proportion of cases occur in poor countries. Type III diseases overwhelmingly or exclusively occur in developing countries. By contrast, Type I diseases occur in rich and poor countries, with large numbers affected in all countries. Id. at 7.

43. WHA61.21, Annex, para 30, 2.3(c) (proposing an “essential health and biomedical R&D treaty.”)

44. WHA61.21, Annex, para 36, 5.3(a).

Despite the lack of much precedent for patent pools in the area of pharmaceuticals, there are some signs of possible pools in the near future. For example, GSK made headlines this past year when it announced that it will set up a pool for patents on neglected diseases. While some assert that GSK’s announcement is mostly a publicity move that does too little in that it explicitly excludes HIV drugs, any endorsement of patent pools by a private company is still a major departure from the past. In addition, a patent pool that applies to HIV may in fact come into being. Last summer, UNITAID, a UN supported agency that purchases drugs, announced that it supported a patent pool for medicine. The initial focus of the pool will be on pediatric anti-retrovirals (ARVs) and new combinations, both of which could be greatly aided by a pool – the majority of the 22 ARVs currently available are either not approved for pediatric use or are not available in appropriate formulations. Moreover, fixed dose combinations can increase patient adherence, reducing resistance rates, as well as overall health. However, such combinations often require multiple patents, thus making them difficult to manufacture without a pool. In addition, although HIV treatment has been recently more affordable due to extensive generic competition, the cost of treatment is rapidly escalating for both improved first-line treatments, as well as patented second-line treatments.  

46. See e.g., Sarah Bosely, Profits Before the Poor? Drugs Giant Offers an Answer to the Toxic Question Facing a ‘Heartless’ Industry, GUARDIAN, Feb. 14, 2009, http://www.guardian.co.uk/business/2009/feb/14/gsk-big-pharma-drugs. At the same time it announced its patent pool, GSK also announced that it would provide discounted prices in the 60 poorest countries of the world and also provide funding for creating infrastructure. Whalen, supra note 38, at D6. In particular, GSK promised to cap the price of drugs in the poorest 50 nations to no more than 25% of the cost of drugs in wealthy nations. Included drugs include malaria, tuberculosis, and hepatitis, as well as HIV, to the extent that HIV drugs are not already offered at this rate. GSK also promised to invest 20% of profits made in least developed countries to build health care infrastructure in such countries. Id.  


51. MSF reports that whereas the previously recommended regimen cost less than $100 per patient per year, the newer first-line treatments recommended by the WHO cost $600-1,000. Id. The difference is prices is in part attributable to the fact India must now provide
UNITAID’s goal is to implement the pool by the end of 2009.52

These proposals - an R&D treaty, prizes and patent pools - represent international endorsement for new solutions to address current problems with health care access and innovation. Some, such as patent pools, can help to minimize patent thickets that would otherwise exist and block needed innovation in developing treatments based on existing patented drugs. Similarly, prizes can work in lieu of, or alongside, the patent system to provide an additional mechanism to promote innovation that may avoid the traditional problem whereby profit margins create a bias in favor of lucrative drugs. In addition, the WHO resolution as a whole provides strong support for the need to create new solutions to promote innovation for neglected diseases. Although the patent system has long been recognized as failing to provide an adequate incentive in this area, the WHO resolution is an important milestone that may signal a major shift towards prioritizing the need to promote incentives for diseases with low profit margins.

VI. SYMPOSIUM ARTICLES

Against this backdrop of growing skepticism of patents as well as spiraling health care costs, this Symposium Issue offers some important criticisms as well as solutions to be considered. A single solution is unlikely for such a complex and charged topic as “choosing” between patents and patients - particularly since some believe that there is no choice necessary at all. A diversity of voices and perspectives are offered that extend beyond traditional legal academia. Articles are presented by globally recognized advocates for promoting better access to medical treatments, a legal academic, an academic medical researcher, and practicing lawyers with advanced degrees in scientific fields. These differing roles and dimensions of expertise help illustrate a variety of perspectives on patents and their impact on access. The articles can be broadly categorized as highlighting current problems as well as offering possible solutions.

The Symposium Issue begins with a proposal to promote innovation and

access beyond the patent system. In particular, James Love, the Symposium keynote speaker, together with Tim Hubbard, discuss the utility of prizes in stimulating medical innovation, controlling costs, and ensuring greater access to new medicines and vaccines. The idea of using prizes, which offer a cash-only reward rather than exclusivity that accompanies patents, is of growing interest to both domestic and international communities. In “Prizes for Innovation of New Medicine and Vaccines,” the authors explore four increasingly ambitious prize options, each addressing flaws in the current patent system. The first option replaces the exclusive rights to make, sell or use a product following Food and Drug Administration approval with a cash prize fund, linked to the impact of the product on health outcomes. The second option builds upon the first and utilizes prizes to offer open source dividends to reward the sharing of knowledge, data and technology. The third option introduces prizes at an earlier stage of the research and development process, and sets up multiple competitive intermediaries to award prizes for interim benchmarks and discrete technical problems. The final option suggests a system for enabling subsequent users to easily use patented material subject only to compensation, but not an injunction. This proposal is aimed at eliminating patent thickets that may otherwise block subsequent research. The authors discuss both historical support for such a system, as well as possible obstacles. The authors conclude that while a system of prizes to reward drug development is an admittedly radical approach, it is far preferable to the expense and minimal productivity of the current system.

In the second article, “Patents & Progress of Personalized Medicine: Biomarkers as Lens,” Professor Matthew Herder returns to the field of patents, but to a previously under-explored issue of the extent to which patents play a role in promoting “personalized medicine.” The term “personalized medicine” is commonly associated with the idea that science has progressed to the stage where patients will be able to obtain tailored treatments. However, as this article discusses, that idea is more of a fiction than a reality at the present time. Professor Herder focuses on “biomarkers” – biological predictors of disease - as an example of the inadequacies of patent law in fostering personalized medicine. He begins by explaining regulatory and market deficiencies in biomarkers research, but makes the broader point that patents have played a significant role in the problem of coordination among scientists, research institutions, healthcare providers, and commercial actors. He then addresses the debate surrounding patenting “upstream research,” and reviews the existing data regarding the impact of such patenting upon research and development. The author sets forth a series of questions for future research to more fully define the barriers to biomarkers research and to uncover which corrective measures may be effective. The author concludes by recommending an integration of
regulatory and patent reforms, with a call to action by scholars, scientists, representatives of the biopharmaceutical industry, and policy-makers.

Dr. Michael Tomasson provides an interesting comparative medical perspective on bottlenecks to developing genomic tests. While his article, "Legal, Ethical, and Conceptual Bottlenecks to the Development of Useful Genomic Tests," focuses on genomic tests, it shares similar issues with the area of biomarkers. This article discusses advances in genomic research and genomic testing in the context of the debate surrounding gene patent rights and the limited rights of patient-participants in translational research. Dr. Tomasson describes his research at Washington University School of Medicine to discover tyrosine kinase mutations in acute myeloid leukemia to illustrate the unexpected complexity of human genetics and the bottlenecks to practical application of genomics research. He further notes that the results of recent genetics research support an anti-pharmaceutical model, whereby genetic testing may indicate which drugs a patient should not take. In addition, he explores statutory and regulatory hurdles to advances in disease diagnosis, such the Bayh-Dole Act, Medicare Legislation, and Health Insurance Portability and Accountability Act, from the perspective of an academic medical research scientist. The author questions the effectiveness of academic research that is increasingly commercialized in the Bayh-Dole era, and the limited success of the private sector in these crucial research areas. The author concludes that future genomic research will require significantly increased numbers of patient-participants in the research process, which may necessitate a reshaping of the pharmaceutical approach to medicine and the limited stake that patients have in the breakthroughs developed through their participation in the process.

Dr. Alice Martin and Dr. Sendil Devadas’ article, “Patents with an ‘I’ = Patients,” also provides a comparative perspective – to all of the other articles in the Symposium Issue on the question of whether patents are consistent with patient interests. The authors argue that patents are inherently reconcilable with patient needs since without patents, there would be no important medical innovations. The authors assert that patent protection in the United States is often quite narrow in scope, difficult to obtain, and insufficient in duration; thus stifling research and development of potential breakthrough pharmaceuticals. The authors note that the private sector is predominantly responsible for the necessary clinical research that results in translating basic research into applied drugs and that proposals for open source sharing do not address this. Without the patent guarantee of exclusivity, companies do not have an incentive to develop necessary products. The authors further posit a correlation between patents and economic growth, suggesting that the United States’ lead in biotechnology was fostered by strong patent rights and is now an example
that other countries are following. They discuss evidence that countries with stronger patent systems experienced increases in foreign direct investment.

In addressing critics of biotechnology patents, the authors provide a series of testimonials to support their position and suggest that high profile controversies may have an undue impact on policy makers. For instance, the authors contend that the controversy surrounding Myriad Genetics’ BRCA-1 breast cancer gene patents reflect not a problem with patentability per se, but with enforcement of patents. The authors assert that there is no empirical evidence of a problem with patents impeding scientific research, including the fact that there is thus far minimal litigation for the number of gene patents issued. The authors conclude that given the substantial evidence of the patent system’s benefits, and the mere speculation that biotechnology patents have a deleterious effect on patients, policy makers should avoid unnecessary tinkering with a system that is not broken for fear of negatively impacting innovation that will benefit all patients.

The Symposium Issue concludes with a comment by Ann Weilbaecher, entitled “Diseases Endemic in Developing Countries: How to Incentivize Innovation.” This comment focuses on innovation problems – as well as solutions – for neglected diseases in developing countries. The comment begins by providing important context to the problem of historically inadequate innovation in this area and how traditional patent incentives exacerbate the problem by not only failing to provide any direct incentive, but also potentially creating difficulties for downstream research. The majority of the comment focuses on potential solutions to address this problem, using three possible themes proposed by the WHO’s recent Global Strategy as a framework – open source, patent pools, and prizes. The comment builds upon the bare bone suggestions of the WHO to include specific and current examples that have been suggested and/or implemented in each of these areas in both the domestic and international arenas. The last possible solution proposed is the concept of “wild card” patent extensions as a contrasting model that leverages the existing patent system to incentive research and development. The author concludes that a combination of solutions may provide the best framework for the creation of essential medicines for neglected diseases.

**VII. PREVIEW OF NEXT ISSUE**

Another issue beyond patents, but still related to the Symposium is the question of how to improve unequal access to new medical technologies for patients of differing socioeconomic backgrounds. While patents are the primary target of criticism concerning access to medicine, many patients may have problems achieving effective access of even unpatented
VIII. CONCLUSION

The articles in this Issue illustrate the range of perspectives on the important question of whether there is a need to choose between patents versus patients. Some authors suggest side-stepping the patent system with other alternatives, such as prizes or open source initiatives. Others focus on highlighting existing conflicts not only in the area of access to medicines, but also in the increasingly complex field of biomarkers and genomic tests. Still others suggest that the current patent system is unduly criticized and is in fact the best way to promote innovation and patient care. It is our hope that these diverse perspectives stimulate greater discussion and awareness of important controversies regarding patents and access to healthcare treatment and innovation.