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**\*579 ON PURPLE PILLS, STEM CELLS, AND OTHER MARKET FAILURES: A CASE FOR A  
LIMITED COMPULSORY LICENSING SCHEME FOR PATENT PROPERTY**

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INTRODUCTION

"We must always remember that access to medicines is a right, not something that should be determined by charity or subsidies for the poorest of the poor." [\[FN1\]](#)

Access to medicines and other healthcare goods and services should be assured through programs that are consistent with the framework of intellectual property and market-based incentives necessary for continued innovation. [\[FN2\]](#)

As we celebrate the fiftieth anniversary of the seminal case *Brown v. Board of Education*, I reflect on the status of access to pharmaceuticals (and other health-care products), which like education in *Brown*, remains separate and unequal. [\[FN3\]](#) Unlike *Brown* however, the inequalities are drawn primarily along economic, rather than \*580 racial lines. [\[FN4\]](#) Recent studies indicate that nearly two-thirds (60.9%) of non-elderly individuals in families at or below 100% of the federal poverty level (\$18,660 per year for a family of four in 2003) lacked health insurance. [\[FN5\]](#) More than half (53.5%) of non-elderly individuals in families with incomes between 100-200% of the federal poverty level (\$37,320.00 per year for a family of four in 2003) were uninsured. [\[FN6\]](#) Contrary to popular belief, these numbers reflect the working poor, since more than 4 out of 5 individuals without health insurance were employed. [\[FN7\]](#)

Because minorities make up a disproportionate number of the medically uninsured, there is a racial component to the separate but unequal access to medical products. [\[FN8\]](#) Families U.S.A. reports that lack of health insurance disproportionately affects Hispanics and African-Americans. [\[FN9\]](#) It is promising, however, that on December 8, 2003, President Bush signed into law health care legislation adding a voluntary prescription drug benefit to Medicare. [\[FN10\]](#) Unfortunately, given the bill's complexity and limited advantages to specific classes of seniors, overall access to pharmaceuticals and health products, in general, is likely to remain separate and unequal. [\[FN11\]](#)

\*581 For pharmaceutical patents, there is a period where exclusive property rights are essential to recoup ever-increasing research and development costs. [\[FN12\]](#) Yet the industry's present pricing and licensing strategies evidence that exclusive rights are being used to procure extraordinary profits while making it cost prohibitive for the poor in the United States and other countries to access these life-enhancing benefits. [\[FN13\]](#) For example, the American Association of Retired Persons (AARP) recently reported that, on average, prices charged by drug manufacturers to wholesalers for widely used brand name prescription drugs in 2003 increased three times the rate of inflation. [\[FN14\]](#) Abbot Laboratories, manufacturer of the AIDS drug Norvir, has quadrupled the price of the drug, while simultaneously vowing that no patient who needs the drug will go without it. [\[FN15\]](#) Ironically, this pledge was in response to the possibility that the National Institute of Health (NIH) would reassign licenses for the patented drug to other pharmaceutical companies under a little-used federal provision that allows NIH intervention where federal research funds were utilized in the creation of the drug. [\[FN16\]](#)

\*582 Most prescription drugs (for example, the purple pill, Prilosec), biotechnology products (for example, stem cells), and medical devices are protected by patents. [\[FN17\]](#) Thus, we cannot ignore the economic impact of the patent property right when evaluating how to make health care products, particularly pharmaceuticals, more accessible to the working poor and elderly. For certain cutting-edge or pioneering technologies, excessive social and transactional costs can create licensing bottlenecks, which in turn can create an inability to offer generic versions of these products (or even product improvements) at affordable prices. Pharmaceutical and bio-technology patents are often the subject of such technology. Here, overvaluing or undervaluing the market, market uncertainty, the desire to retain monopoly profits, and differing goals of academic and corporate research are just a few of the situations which increase the costs of negotiating licenses and marketing these inventions.

These excessive transaction costs negate the Coasean "commons" theory that in the ideal universe of private property, minimal transaction costs will motivate parties to negotiate and share exclusive rights in a manner that leads to the most economically efficient use of resources. [\[FN18\]](#) Instead, each time excessive transactional costs prevent the efficient transfer of patent property, we have a market failure that leads to an economically inefficient use of these resources. The inefficient sharing and distribution of vital patent property, such as pharmaceuticals and other health care products via monopoly pricing, clearly impede free market competition. Moreover, if the award of the patent right helps facilitate these increased transactional costs, then this puts into question whether the present patent monopoly meets the constitutional mandate of awarding patent rights for "limited times" to "Promote the Progress of Science and the useful Arts." [\[FN19\]](#)

The extraordinary profits gained from monopolizing cutting-edge technology decrease the incentive for patentees to seek socially beneficial\*583 agreements in times of national crisis. [\[FN20\]](#) One way around these bottlenecks or market failures is to amend the Patent Act to include a "fair use" provision. This would provide a defense against infringing uses which are permissible because of their overall value to society, and arguably create greater access to pioneering health-care products. [\[FN21\]](#)

As an advocate for Patent Rights being viewed as "Property" rather than monopolies, I am an unlikely proponent for creating a fair use provision for patents. However, when balancing the constitutional incentive of granting exclusive rights for "limited times" to inventors [\[FN22\]](#) against the goal of furthering innovation and providing fair access to technology and knowledge, one may find herself exploring options that provide greater leverage to accessing patented technology in a timely manner, in situations where traditional licensing arrangements are an economic impossibility. Of course, as the introductory quotes illustrate, reaching "interest convergence" on how best to preserve patent property interests while meeting a humanitarian calling is a daunting, but hopefully workable task. [\[FN23\]](#)

Intellectual property lawyers are in the unique position to understand the arguments on both sides of the issue. Indeed, our clients may resist investing in research and development to produce the best or most effective technology if their exclusive right incentive is eroded by overly broad provisions for governmental or other fair use. Should this occur, society would be further harmed by the lack of available technology at any price. On the other hand, in times of national emergency or crisis, there should be some mechanism for accessing technology in a timely manner, while providing adequate compensation to the patentee. Again, intellectual property lawyers are in the best position to serve as educated advocates for both our clients and Congress, \*584 to ensure that the solution implemented is one that protects both inventors and society as a whole.

Fair use provisions, although attractive on the surface, can lead to increased erosion of inventor incentives. This is particularly true in the area of biotechnology where start-up and research and development may become cost-prohibitive. Also, the patentee presently discloses its invention to the public to provide building blocks for inventing additional novel and non-obvious technology, thereby enhancing innovation without the need for fair use. Moreover, the reverse doctrine of

equivalents allows for infringing acts, which produce radically pioneering inventions. With this in mind, instead of attempting to mirror the Copyright Act's fair use provisions, this Article advocates implementing a limited compulsory licensing scheme which can be triggered for public health, national emergency, or market failure situations. A compulsory licensing scheme for public health or national crisis reasons is socially compelling. Many believe, however, that introducing a compulsory licensing scheme for avoiding market failures goes against our system of free market capitalism and would undercut the incentive built into the patent property scheme.

Part I of this Article outlines recent international and national events which compel a reevaluation of how we protect various types of intellectual property, particularly patentable inventions. Part II provides an overview of the idea of patents as property rights which are subject to equitable boundaries and liability limitations. Part III of this Article outlines the arguments for limiting the patent right in situations where excessive transactions costs create market failures. Here, this Article posits that for pioneering inventions and certain types of basic research, such as stem cells, the transaction costs for negotiating and enforcing patent licenses become prohibitive and the amount of exercisable market power increases exponentially, thereby creating the likelihood of licensing bottlenecks and market failures.

Part IV of this Article evaluates whether the doctrine of fair use or a compulsory licensing scheme is the most viable means of solving the market failure dilemma. This Article will argue that the most efficient option is to add a well-defined compulsory licensing provision to the Patent Act which can only be utilized in cases of national emergency or where excessive transaction costs are established. This will have the "wings-effect" of motivating parties to come to the table to effectuate the traditional free market licenses and avoid governmental intervention. Furthermore, it ensures that patent property maintains \*585 the constitutionally mandated balance of providing exclusive rights for limited times to promote the progress of science and the useful arts, as well as stimulating free market competition. In conclusion, this Article provides a model compulsory licensing statute, which includes factors to evaluate when considering whether to issue the license and the appropriate length of an exclusive monopoly period for the patentee.

## I. THE 21ST CENTURY: A TURNING POINT IN NATIONAL AND INTERNATIONAL INTELLECTUAL PROPERTY LAW

National and international public health issues have signaled a need to reevaluate the broad property rights presently granted patentees. [\[FN24\]](#) Intellectual property lawyers are in the unique position of understanding both sides of the dispute. We know the economic significance of preserving the incentive to invent, while remaining sensitive to providing timely access to technology during times of national crisis or when necessary to overcome market failure.

### A. National

The close of the twentieth century brought the realization that rapidly advancing technology mandated reevaluating how we protect intellectual property. The twenty-first century was ushered in with major amendments to the Copyright Act concerning digital transmissions, Internet Service Provider Liability and the Circumvention of Technical Protection Measures. [\[FN25\]](#) The Patent Act remains relatively intact, but a host of national and international events signal a willingness to revisit the Patent Trust and determine whether the present system, particularly for biotechnology and software, effectively stimulates innovation without inhibiting free market competition. [\[FN26\]](#)

\*586 First, the failure to provide timely access to patented technology was at the heart of the debate over the University of Wisconsin's stem cell patent portfolio. [\[FN27\]](#) The University of Wisconsin began negotiating licenses with numerous academic, governmental and private sources. Unfortunately, the Geron Corporation heavily funded this initial research and held an exclusive license to the stem cells. Geron appeared unwilling to share its exclusive rights, despite its inability to

single-handedly use the technology efficiently. The Wisconsin Alumni Foundation, holders of the Patent Trust, eventually sued Geron to prevent the corporation from interfering with the effective licensing of this technology. After extensive public backlash, Geron settled with the foundation and agreed to a broad range of licensing schemes which allow for timely access to patented embryonic stem cell technology. [\[FN28\]](#) In exchange, Geron retained exclusive rights to develop products from three of the six stem cell lines and non-exclusive licenses for the remaining lines.

The Geron situation illustrates the need for improving our exclusive rights paradigm when dealing with cutting-edge technology, which is at the apex of numerous life-saving and pioneering inventions. [\[FN29\]](#) Here, the pioneering, basic technological nature of the invention and the unlimited market potential made it difficult to conduct effective licensing negotiations. Geron was unwilling to relinquish its monopoly on extraordinary profits, even if it meant delaying the overall quality of public health. [\[FN30\]](#) Indeed, the government's moratorium on the creation of any new stem-cell lines with federal research funds **\*587** further emphasizes the need for lowering the transactions costs to facilitate further innovation. [\[FN31\]](#)

Second, the terrorist attacks of September 11, 2001 and the subsequent Anthrax scare raised the possibility of generic production of patented devices where needed, to promote bio-defense or medical progress. [\[FN32\]](#) Cipro, the leading drug treatment for Anthrax, was at the heart of the debate. Since the patentee, Bayer A.G. of Germany, could not produce enough Cipro to effectively fight a nationwide Anthrax epidemic, Senator Charles Schumer proposed that the U.S. government temporarily control the Cipro patent and allow enough generic production to stockpile Cipro. [\[FN33\]](#) Schumer was backed by several consumer advocates including Jamie Love, of the Naderite Consumer Group Project who argued that enforcing the Cipro patent meant endangering public health. [\[FN34\]](#) Opponents argued that "drug-company bashing" was an inappropriate response to fighting bio-terrorism. Instead, pharmaceutical, biotech, and genomic firms should be regarded as "strategic assets in the war against bio-terror." [\[FN35\]](#) Before such legislation passed, however, Bayer A.G. agreed to voluntarily work with the government to produce or authorize any additional Cipro production needed by the United States to fight Anthrax. [\[FN36\]](#) Large pharmaceuticals have also implemented additional programs to provide drugs to the poor and elderly for free or at a substantial discount. [\[FN37\]](#)

**\*588** Recently, Abbot Labs, the manufacturer of the AIDS drug Norvir, has committed to tiered pricing or other means to facilitate accessibility to the poor and elderly. [\[FN38\]](#) Unfortunately, this offer was in response to a National Institute of Health review on whether to reassign the license for the drug due to the manufacturer's excessively high pricing structure in the United States. [\[FN39\]](#) Physicians and other AIDS advocates argue that Norvir, whose research was subsidized with federal funds, should not be priced several times higher in the U.S. than in Canada, Australia, and Europe. Thus, NIH should invoke the "march-in" provisions of the Bayh-Dole Act (which provides for the transfer of publicly funded drugs to the commercial market and allows for the reassignment of these licenses) and reassign licenses for Norvir, which would in turn lead to a price-cut for the drug in the United States. [\[FN40\]](#) Indeed, most pharmaceutical discount programs **\*589** are offered outside the United States with few domestic counterparts. [\[FN41\]](#)

Last, but not least, a coalition comprised of the nation's governors and interested corporate citizens is presently fighting what they describe as "monopolistic" patent term extensions for pharmaceutical products. [\[FN42\]](#) Under the Hatch-Waxman Act of 1984, an automatic thirty month term extension is granted each time a patentee claims generic approval would infringe on its patents. [\[FN43\]](#) These delays were designed to give the patentee sufficient time to prove infringement in court. According to the Washington Post, extensions granted by the FDA for the heartburn drug Prilosec will cost state Medicaid programs \$300 million. [\[FN44\]](#) AstraZeneca, the patentee, collects \$5.6 million in unanticipated revenue every day that the Prilosec patent remains enforceable beyond its term. [\[FN45\]](#) Term extension opponents argue that patentees are abusing the system by "filing frivolous appeals that take advantage of the loopholes in the law to stretch out patent protection months or years longer than intended." [\[FN46\]](#) Once again, Senator Schumer (along with Senator John McCain) drafted legislation that would

eliminate many of the term extensions presently in place and shorten the approval process for generic drugs. [\[FN47\]](#)

**\*590** On December 8, 2003, President Bush signed into law the "Medicare Prescription Drug Improvement Act" which included amendments to the Hatch-Waxman Act that provide some relief for generic drug manufacturers. [\[FN48\]](#) For instance, the 180-day marketing exclusivity period awarded to the first generic manufacturer to file an Abbreviated New Drug Application (ANDA) with a "paragraph IV" certification can only be triggered by commercial marketing of the drug, and not by a court decision. [\[FN49\]](#) Abandoning the "court decision" trigger allows generics to challenge any patents surrounding a given drug whose patent recently expired without risking loss of the 180-day exclusivity period triggered by other findings of invalidity or non-infringement. [\[FN50\]](#)

The stem cell debacle, as well as the Anthrax and Prilosec debates, all signal the possibility that Congress will take a closer look at the Patent Act to determine if the public is being hurt by the broad exclusive rights presently granted patentees. Both the Federal Trade Commission (FTC) and Justice Department have held hearings to evaluate whether the Patent and Trademark Office (PTO) is granting an excessive number of patents, particularly in the areas of biotechnology **\*591** and software. [\[FN51\]](#) Since global terrorism and public health issues also remain on the horizon, it is likely that generic registration legislation may also reappear in the near future. [\[FN52\]](#) Indeed, as the discussion below indicates, other nations have narrowed patent rights for public health or national emergency purposes.

#### B. International

The World Trade Organization (WTO) has 137 member nations, which account for more than ninety percent of world trade. [\[FN53\]](#) Central to monitoring world-wide intellectual property is the General Agreement on Tariffs and Trades (GATT). [\[FN54\]](#) The most controversial portion of GATT is the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). [\[FN55\]](#) Under TRIPS, member nations agree to minimum standards of protecting intellectual property, which include protecting patents for a minimum period of twenty years and providing specific protection for pharmaceutical patents. Nations failing to provide the minimum protection are subject to trade sanctions by the WTO. [\[FN56\]](#)

TRIPS allows member nations to narrow the scope of patent protection (for example, through the use of compulsory licenses or temporary suspension of the patent right) to protect public health or in times of national crisis. [\[FN57\]](#) Both Brazil and South Africa have taken advantage of these controversial provisions. South Africa passed the **\*592** South African Medicine Act of 1997. [\[FN58\]](#) The Act's goal was to provide for the timely and affordable supply of pharmaceuticals during times of national emergency, such as the HIV crisis presently overwhelming South Africa and the entire sub-Saharan Africa area. [\[FN59\]](#) The Act broadly allowed the South African government to issue compulsory licenses to local manufacturers "upon such conditions as to the application of such acceptable assurance principles and good manufacturing and distribution practices as the council may determine." [\[FN60\]](#) The Act further provided for the parallel importation of drugs as needed by South Africa. Parallel importation allows a country to sell drugs below market price by importing the same drugs from other countries where the drug is sold at a lower price. Obviously, pharmaceutical companies firmly oppose parallel importation. In response to South Africa's Act, forty pharmaceuticals filed suit to block implementation of the Act, and the United States began pressuring the WTO to issue sanctions against the country. [\[FN61\]](#) Unfortunately, the South African Act was ripe for attack since it failed to state that compulsory licensing and parallel importation were reserved for national emergencies and public health crisis. Bowing to external pressure, South Africa agreed to amend the Medicine Act to comply clearly with TRIPS. [\[FN62\]](#)

Similarly, Brazil threatened and eventually began production of generic versions of various AIDS drugs. Initially, the United States filed a complaint with the WTO, but ultimately withdrew the complaint and began negotiating with Brazil concerning

patent protection. In addition, the availability of generic alternatives led the major pharmaceutical players to reduce pricing on the brand-name equivalents in Brazil. [\[FN63\]](#) Because developed countries such as the United States disfavor **\*593** the compulsory license option, the WTO began negotiations for a compromise deal in August 2003, which specifically addressed improving access to medicines in poor countries under TRIPS. Nevertheless, the member governments are still negotiating on the specifics of how to further amend TRIPS to balance the interest of both patentees (represented by the developed countries) and poor countries needing access to pioneering medicines to combat epidemics, such as AIDS. As a result, the deadline for negotiating these amendments was recently extended to March 31, 2005. [\[FN64\]](#)

## II. PATENT PROPERTY OVERVIEW

The right of a patent holder is negative in nature; the patent allows the owner to prevent action on the part of another. Generally, unless the owner has given consent, thereby voluntarily "licensing" use by another, use of the patented information is unlawful. [\[FN65\]](#)

Differential pricing and the protection of intellectual property rights have stood as the twin pillars of the big pharmaceutical business model, leading the [pharmaceutical] industry to high profitability and continued innovation in new drug discovery. [\[FN66\]](#)

### A. Constitutional Mandate

Any amendment to the Patent Act must begin with the U.S. Constitution. The Constitution's intellectual property clause gives Congress the power "[t]o promote the Progress of Science and the useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." [\[FN67\]](#)

**\*594** A close look at the plain language of the provision highlights two clear mandates. First, the rights granted cannot be of a perpetual nature, instead, any exclusive rights granted must be for limited times. Second, any statute passed by Congress "must promote the progress of Science and the useful Arts." Indeed, the scope and terms of protection outlined in the Patent and Copyright Acts evidence a balance between the creator's property rights, and the public's right to freely utilize ideas to develop additional creative/inventive works. [\[FN68\]](#) "One of the reasons that intellectual property rights are limited in scope, duration, and in the effect is precisely in order to balance these costs and benefits. . . ." [\[FN69\]](#) The Patent Act clearly meets the first mandate. A patentee possesses the right to exclude others from making, using or selling the claimed invention. Although this is the broadest of federal intellectual property rights, these rights are limited to a period of twenty years after the application date for the patent. [\[FN70\]](#) Also, the patent must disclose the invention to enable one of ordinary skill in the art to duplicate it upon expiration of the patent's term. [\[FN71\]](#)

The more problematic mandate is that any federal patent and copyright law must "promote the progress of Science (copyrights) and the useful Arts (patentable inventions)." [\[FN72\]](#) Arguably, the rapid technological advances of the twenty-first century in the areas of biotechnology **\*595** and pharmaceuticals create economic incentives for patentees of pioneering inventions to reject traditional licensing arrangements and attempt to single-handedly exploit their technology. Arguably, the Patent Act fails to promote the useful arts when significant market failures occur. It is, however, much easier to flush out the problem than to agree on the appropriate solution. Two viable options are to amend the Patent Act to include a fair use provision or to amend the Patent Act to include some limited compulsory licensing or patent pooling provisions. The following sections explore the merits of both options. Before evaluating each option, this Article will first explore the Property Rights model of the Patent Act, which relies on the assumption of "efficient" transactions rather than the reality that there are certain patentable inventions that trigger excessive transaction costs.

### B. Patents are Property Rights, Subject to Equitable Boundaries, and Liability Limitations

Theoretically, if patent rights are too strong, a patent could actually dissuade others from innovating or engaging in other business activities. Analysis of this 'tension' consumes the bulk of economic literature related to patents . . . . [\[FN73\]](#)

Property, in its economically neutral sense, means no more than a granting of a right to exclude. [\[FN74\]](#) Describing patents as property implies an earned right to use and exclude without impeding economic efficiency or free market competition. [\[FN75\]](#) The right to exclude creates not only the incentive to invent or "prospect," but an efficient use of inventions and creations through licensing. [\[FN76\]](#) According to Professor Edmund Kitch, having a patent property right which requires both novelty and non-obviousness gives "the patent owner . . . an incentive to make investments to maximize the value of the patent without fear that the fruits of the investment will produce un-patentable information appropriable by competitors." [\[FN77\]](#) Thus, the majority of patent \*596 rights will not create anti-competitive monopolies, but instead should enhance commercialization and free market competition through the use of efficient licensing and pricing schemes. [\[FN78\]](#) This Coasean paradigm assumes an economic world without transaction costs and where private property rights prevent an over-use of "common-property." [\[FN79\]](#) Zero or minimal transaction costs will also motivate intellectual and other private property owners to negotiate and purchase property from each other, as needed. [\[FN80\]](#) In theory, these "mutually beneficial" licenses or sales should continue until each piece of property is "put to its best possible use." [\[FN81\]](#)

As noted by scholars Lemley, Merges, and Nelson, however, there are instances, particularly in the case of basic research or pioneering inventions, that a patentee may be alone in the market and set higher monopoly prices for goods or refuse to license technology. [\[FN82\]](#) This operates to the detriment of consumers and the general social welfare. [\[FN83\]](#) Thus, patent property rights must include certain boundaries and limitations since "property rights that are too narrow will not \*597 provide enough incentive to develop the asset, while overly broad rights will preempt too many competitive development efforts." [\[FN84\]](#) Arguably, for patent property in general, the enabling disclosure requirements of Section 112, [\[FN85\]](#) novelty requirements of Section 102 [\[FN86\]](#) and non-obviousness requirements of Section 103 [\[FN87\]](#) build in a set of limitations which balance the need for free market competition against the public's right to the free dissemination of information. Since patents are disclosed as early as eighteen months after application and in every case after issuance, the public is free to utilize patented information to build upon and create additional novel and non-obvious inventions. For example, providing an enabling disclosure for the latest generation antibiotic patent enables competitors to use this information as building blocks to develop and patent stronger, more effective antibiotics. [\[FN88\]](#) This prevents any single patentee from gaining monopoly power from its patent portfolio. [\[FN89\]](#) Also, the reverse doctrine of equivalents allows one with a radically pioneering improvement to escape patent liability and practice the improvement without a license. [\[FN90\]](#) Despite the well thought out limitations presently in the Patent Act, the Act still fails to address the present reality. There are situations where high or excessive "transaction costs" block the efficient transfer of intellectual property, thereby creating a bottleneck in the marketplace. [\[FN91\]](#)

### \*598 III. ARGUMENTS FOR LIMITING THE PATENT RIGHT WHERE MARKET FAILURES OCCUR

The pharmaceutical industry is motivated by competitive and economic factors. From a competitive standpoint, research and development (R&D) intensive firms are continuously under pressure to differentiate discoveries from that of competitor firms . . . . With profitability so closely linked to sales of patented drugs that are not challenged by generics or substitutes, the pharmaceutical industry uses its influence to delay patent expiration whenever possible. [\[FN92\]](#)

#### A. Situations Involving Excessive Transaction Costs and Uncompensated Positive Externalities Require Further Limitations of the Patent Property Right

Transaction costs are those tangible and intangible costs associated with implementing the transfer of property rights. These

costs are as simple and tangible as the costs involved in locating the property's source/owner, negotiating price and other terms, the physical transfer of the property, and the future enforcement of the property rights obtained. [FN93] There are, however, many intangible transaction costs involved with property transfers such as each party's valuation of its property, the economic or other goals of the party's, personalities of the parties (which create high negotiation costs), and concreteness of the existing market for the goods and services.

Intellectual property licenses are particularly costly since they are more complex than the simple purchase of goods. [FN94] Here, lawyers are needed to help evaluate the boundaries of the property and help monitor their ongoing relationships. Also, in cases where parties have not obtained patents or copyrights, the search for the true owner or source of the property may be costly and difficult. [FN95] Although costly, many intellectual property licenses are worked through privately and \*599 yield an efficient use of resources. For example, in the improvements context, the party who possesses one or more blocking patents [FN96] motivates individuals having improvement technology to negotiate some type of license or cross-license since the improvement cannot be carried out without infringing the blocking patent. [FN97] We are still left, however, with special situations where the efficient transfer of patent property is problematic due to potentially high transaction costs which are: (1) the radically pioneering invention that singly dominates the market, and (2) inventions which constitute the building blocks or basic research for expansive technological innovation (for example, stem cells). In these cases, the presence of excessively high transaction costs may eliminate the potential surplus from a license, thereby impeding negotiations between patent holders and would-be licensees. [FN98]

#### \*600 1. The Radically Pioneering Invention

Radically pioneering inventions are cutting-edge and the first or the most effective at filling a societal need. [FN99] Historical examples include the light bulb, the telephone, and Penicillin. Modern examples include the AIDS drug AZT, the digestive drug Prilosec, and MP3 technology. Unquestionably, the patent property right provides the inventor of a radically pioneering invention with a cost advantage that provides an excessive return on its investment, even after taking the high risk of the investment into account. [FN100] Although society reaps the optimal benefit from a patentee making the invention available to the public at a reasonable price, one feasibly close to marginal cost, there is no incentive to approach this social ideal unless the inventor is faced with competition. [FN101] Typically, patented technologies face competition, and, thus, pricing is kept closer to marginal cost. What separates radically pioneering inventions from the typical patented product, however, is their unique ability to fill a societal need which has a standardizing effect on the market. The radically pioneering invention is the only or most efficient way of treating symptoms of a disease, communicating or carrying out some other utilitarian function. [FN102] The patent right alone does not confer the market power. Instead, it is the exclusionary right of the patent, coupled with the "standard setting" capacity of the radically pioneering product, that enables the patentee to have market power and extract monopoly prices for pioneering technology. [FN103]

Indeed, the pharmaceutical market is replete with examples of monopoly pricing for cutting-edge drugs such as Prilosec, Zithromax, or most recently the AIDS drug, Norvir. [FN104] The pharmaceutical lobby \*601 argues that patent protection without any type of pricing control is essential to future pharmaceutical research and development. [FN105] Estimates on the cost to develop a drug and bring it to market range from \$100-500 million. [FN106] Only 1 in 250 chemical compounds that go into the laboratory makes it to the pharmacy shelves, and of every 5,000 medicines tested, on average, only 5 are tested in clinical trials and 1 of these is approved by the Federal Drug Administration (FDA) for public use. [FN107] The pharmaceutical industry notes that only 3 of 10 marketed drugs produce revenues that match or exceed average research and development costs. [FN108] Also, higher profits can provide an incentive for the manufacturer to make a wider range of samples and donated drugs available. Because radically pioneering drugs will be in great demand and lack competition, they can and must be priced significantly beyond marginal cost to absorb the research and development cost for future



cutting-edge and basic drugs. [FN109] Industry \*602 advocates also argue that Big Pharma (large pharmaceutical companies) utilizes monopoly profits to provide capital to start-up biotechnology firms. Thus, without such profits, socially-beneficial genomic research might come to a standstill. [FN110] Last, but not least, Big Pharma stockholders and research scientists expect both costly and aggressive research and development programs, which increase the likelihood of producing pioneering and high profit-yielding products. [FN111]

Nonetheless, recent financial data indicates that the pharmaceutical industry remains one of the most profitable industries in the United States, with median profits of about 18% of revenue. [FN112] This is one of the highest median returns for new economy industries, such as computer software, savings institutions, real estate, and commercial banks. [FN113] The 18% median return is also significantly higher than the median profits among the most competitive industries such as Food and Drug Stores (2%), General Merchandisers (3%), Computer Hardware (7%) and Beverages (7%). [FN114] Thus, it appears that, to \*603 some degree, the pharmaceutical industry takes advantage of the pricing leverage obtained with radically pioneering drugs to obtain significant profits. As to the financing of biotechnological companies, research indicates that while pharmaceutical companies are investing in biotech research, state governments and venture capitalists also play a significant role in genomic research. [FN115]

Despite the likelihood that pioneering patents motivate varying degrees of monopoly pricing by pharmaceutical companies, on the surface this industry appears competitive and thus arguably less prone to market failures. No single drug company has more than 7.2% of overall market share. [FN116] Arguably, the 18% median returns merely reflect high consumer demand for the most effective drug, coupled with effective brand marketing, in other words, free market capitalism operating at peak efficiency. [FN117] Nevertheless, one cannot ignore the fact that each pharmaceutical company's patent portfolio, particularly for cutting-edge drugs, creates the type of barrier to entry that facilitates monopoly pricing and creates a disincentive to embrace competition and bargain for improvement technology. Often, part of the patent procurement strategy for large pharmaceuticals is to obtain complementary method and product patents to supplement the main pharmaceutical patent. Thus, when the primary pharmaceutical patent for a cutting-edge drug expires, generic manufacturers will be blocked from producing the pharmaceutical since generic production and use by consumers would infringe one or more of the complementary "blocking" patents.

For example, AstraZeneca (the manufacturers of the "purple pill" Prilosec) as part of their marketing strategy obtained several blocking methods patents prior to the expiration of Prilosec's patent term. Astra obtained methods patents for combining Prilosec with antibiotics to cure ulcers, including a double-coating on the drug's active \*604 ingredient to improve intestinal absorption, along with a product patent for a substance that briefly forms in the human body when Prilosec is swallowed. Astra then claimed that generic versions of Prilosec would infringe some or all of the blocking patents. Thus, Astra was strategically able to use their blocking patent portfolio to delay the entrance of generic drug manufacturers into the market. [FN118] Clearly, the choice by large pharmaceuticals to utilize blocking patents to artificially extend a drug's patent term and extract monopoly profits creates the excessive transaction cost scenario that prevents either timely entry by generic competition or efficient bargaining with legitimate holders of improvement patents. Another level of market power is also created because the improvement patentee and the original patentee now each has its own own separate market power to exercise. [FN119]

Moreover, the pioneering patentee is capable of using its monopoly or status as an industry standard to delay or block the entrance of competition, both horizontally and vertically. [FN120] In the operating system context, Maureen O'Rourke provides an example using Application Programming Interfaces (APIs). APIs are the connectivity components of operating systems that specify how a particular operating system and its applications communicate. She notes that APIs, the former favorite of copyright protection, are now more frequently the subject of patent property protection, thanks to recent copyright

court decisions. [FN121] She correctly posits that if a software firm owns a patent on its operating system API, no competitor will be able to offer a \*605 horizontally compatible product without infringing it. Additionally, no unlicensed application developer is likely to be able to write a vertically compatible application without reverse engineering the operating system which would constitute patent infringement. [FN122] The reverse doctrine of equivalents fails as a viable defense here since the reverse engineering will not rise to the level of radical improvement necessary to eliminate liability for infringement. [FN123] Thus, the API patentee has an economic incentive to overvalue its technology (refuse even economically efficient licenses because it is more profitable to do so) and refuse to license any improvement technology, with the hopes of remaining the industry standard and extracting monopoly profits. [FN124]

Mark Lemley further notes that with computer software in general, competition itself creates "an uncompensated positive externality in a property rights model." [FN125] This type of market failure is particularly prevalent where the proposed licensee will be a direct competitor of the pioneer patentee. [FN126] As noted above, to produce a competitive product, a software engineer will often need to reverse engineer the existing API software. Thus, the potential competitor must obtain a license to avoid infringing on the pioneer's patents. However, excessive transaction costs and positive externalities create a bottleneck or market failure here. Although reverse engineering leads to maximizing the social benefit by creating competition in a market previously dominated by the pioneer, "the enhanced consumer surplus associated with a move from monopoly to competition by definition cannot be captured by the competitor, and so the competitor cannot possibly offer to pay the original creator the full social value of the license." [FN127] As a result, the standard-setting pioneer retains an undesirable dominance over product-market and R&D competition and reduces the opportunity to maximize social welfare by opening the standard to competition "under circumstances in which it is reasonable to conclude that the patentee's incentive will not be unduly harmed." [FN128] These market failures call for further limitations such as fair use or \*606 compulsory licensing, which will serve to motivate the patentee to license the pioneering technology, thereby removing the bottleneck to free market competition created by the market failures.

## 2. Basic Research or "Building Blocks" for Expansive Technological Innovation

The opportunity for market failures due to excessive transaction costs and uncompensated positive externalities is also present with basic research patents. Basic research is the building block technology upon which "further path-breaking research and inventions can be built." [FN129] As noted in the introduction of this article, embryonic stem-cell production is the basic research or "building-block" for curing a host of ailments, including Alzheimer's and Parkinson's diseases. It is imperative therefore that scientists around the world gain timely access to this technology. Because basic research is the foundation for a wide-range of technological development, some argue that it should not be patentable, but remain in the public domain. [FN130]

Nevertheless, basic research is patentable if it meets the statutory requirements of novelty, utility, and non-obviousness. [FN131] In fact, in a quest to enhance basic research and innovation, Congress now permits nonprofit organizations and universities to patent technology developed while using federal financing. [FN132] This fueled what some might deem "unholy marriages" (colloquial), or partnerships between academic \*607 scientists and private industry. The resulting patents may cover research so basic that there is no direct product and much additional research and development is required before useful end-products are produced. [FN133] This often requires the patentee to license the technology to "downstream innovators who conduct further research to turn it into a commercial end-product." [FN134] The earlier referenced partnership between the University of Wisconsin and Geron for embryonic stem cell research is a prime illustration of such a union as well as the potential for market failures to occur. Here, differing goals and values about the use of the technology, personality conflicts and Geron's desire to control all commercial exploitation, created excessively high transaction costs. As a result, Wisconsin and Geron were in a licensing stalemate until Wisconsin sued Geron for breach of contract. The threat of

costly litigation motivated both parties to reach a settlement agreement which split the stem cell lines between the University and Geron and allowed royalty free licensing to non-profit research entities. [\[FN135\]](#)

What is so unique about basic research that it exponentially increases the opportunity for market failure? There are several factors at play, according to Professor Clarisa Long. She cites excessive transaction costs as a factor that cannot be ignored. [\[FN136\]](#) As illustrated in the stem cell example, the transaction costs of negotiating a license can be insurmountable. Also, search costs become prohibitive where the patentee is unknown or the technology is the subject of trade-secret. Here, determining whether one needs a license becomes as difficult as searching for a needle in a haystack. [\[FN137\]](#) Finally, even if parties agree on technology transfer, the cost of enforcing a patent is the "the most flagrant aspect of patent costs." [\[FN138\]](#) Long further notes that often downstream researchers get impatient with the licensing process and working through the "legalese" of the various contracts. [\[FN139\]](#) Thus, even the most basic and straightforward licensing arrangements involving \*608 basic research may drag on indefinitely or sometimes fail altogether. [\[FN140\]](#)

Although excessive transaction costs often block technology transfer of basic research, uncertainty may be an equally driving force for market failure. [\[FN141\]](#) According to Long, uncertainty is a powerful factor, often overlooked in scholarly writings on this subject. She argues that as one approaches the basic or building-block end of the research spectrum, the ability to predict accurately the commercial viability of the technology and its future uses becomes speculative, at best. [\[FN142\]](#) Since both parties lack the data to determine the true future value of the technology, it is difficult for them to negotiate effectively a technology transfer agreement for future innovation of basic research. [\[FN143\]](#)

Of course, the upstream or earlier basic researcher has greater leverage because it has the original building block and can attempt to innovate further and commercially exploit the invention itself if negotiations fail. [\[FN144\]](#) Nevertheless, academic patentees and small or start-up corporations with limited patent portfolios often lack the resources to develop fully basic research technology. [\[FN145\]](#) Indeed, the lack of developmental\*609 resources prompted the University of Wisconsin to enter into its initial stem-cell partnership with the Geron Corporation. [\[FN146\]](#) Here, Geron was in the position to help mitigate downstream innovation cost, but excessive negotiation costs still led to an inability to conduct efficient licensing negotiations.

As illustrated by the stem cell case, for basic research, uncertainty and high transaction costs often operate in tandem to create bargaining breakdowns or market failures. Long notes that as the number of basic research patents increases, we will see an increase in market failures due to bargaining breakdowns. [\[FN147\]](#) Thus, we must explore other mechanisms for preventing market failures and facilitating the efficient transfer of basic research to stimulate downstream innovation.

#### IV. FAIR USE VERSUS COMPULSORY LICENSING AS THE MOST VIABLE MEANS OF ADDRESSING PATENT MARKET FAILURES

"Because the right [copyright] is narrower-in contrast to patents, independent creation does not infringe-there is less likelihood that a copyright will restrain competition." [\[FN148\]](#)

A. Fair Use is a Viable Limitation to Handle Excessive Transactions Costs for Copyright Property, but Patent Property is More Problematic

##### 1. Copyright Fair Use

Unlike utility patent protection, which requires both novelty and non-obviousness, a copyright subsists for "original works of authorship fixed in a tangible medium of expression." [\[FN149\]](#) There is no preliminary review required to obtain copyright protection. Instead, copyright is created upon fixation without having to register the work with the Copyright Office. [\[FN150\]](#)

While copyrights enjoy a much longer term of protection (presently life of the author plus seventy years), they have a much narrower scope of exclusive rights and are subject to \*610 a host of limitations. Under Section 106, the copyright owner has the following exclusive rights: (1) reproduction; (2) preparation of derivative works; (3) distribution; (4) public performance; (5) display; and (6) public performance of sound recordings. [FN151] There are numerous limitations, with the most important being the prohibition against copyrighting ideas and fair use. [FN152] Limiting copyright property to one's creative expression correctly leaves ideas in the public domain where they should be available to all as the building blocks for additional creative expression. [FN153] Patent Law contains analogous boundaries by limiting patentable subject matter to novel and non-obvious material and prohibiting the patenting of physical phenomena and abstract ideas. [FN154]

Section 107 of the Copyright Act codifies the equitable doctrine of fair use by providing a defense for infringing uses which are permissible because their overall value to society outweighs the copyright owner's interest in enforcing its property boundaries. Section 107's preamble outlines uses of copyrighted work for criticism, comment, news reporting, teaching, scholarship, or research as examples which provide the requisite level of social benefits to warrant a "royalty free" license. [FN155] In every case, however, a court must still balance four factors to determine whether the use made of a copyrighted work merits the fair use defense. The four factors include: (1) the purpose and character of the use (for example, commercial v. non-profit); (2) the nature of the copyrighted work (factual v. fiction); (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work. [FN156]

\*611 Copyright uses are most likely labeled fair by courts when the use is both socially desirable and will not cause the copyright owners considerable economic harm or disincentives (for example, unauthorized home-taping of copyrighted material by consumers). [FN157] Professor Maureen O' Rourke notes that these market failures fall into the following three categories: (1) high transaction costs that frustrate private bargaining; (2) positive externalities that prevent the infringer from being able to pay the copyright owner's price for a license; and (3) the failure of any market for the particular use to develop. [FN158] Of these three, the strongest case for royalty-free fair use is the large number of positive externalities that are created through the use of creative/copyrightable subject matter. Positive externalities are those social benefits that flow from a work but cannot be capitalized upon by the work's owner.

In the copyright context, home taping of copyrighted programs or music is socially beneficial to consumers, but any type of licensing arrangement is economically unfeasible to the copyright owners since it seeks to make consumers happy and consumers have no basis for recouping any cost of licensing fees. Thus, the copyright owner may be willing to turn a blind-eye to home taping unless and until he perceives that there is another viable source of licensing revenue, such as the manufacturers of home taping equipment. [FN159]

\*612 Transaction costs are all costs that the copyright owner must entail in order to either (a) license the copyrighted work or (b) enforce its copyright against alleged infringers. [FN160] Of the three areas of intellectual property, copyrightable expression covers the broadest range of protectable property. Copyrightable expression includes literary works, movies, music, choreography, art, architectural works, and computer programs. Thus, this expression is much more pervasive throughout the United States and indeed the world than patented inventions. [FN161] Because of sheer volume, the transaction costs involved in enforcing every public or private infringement of copyright is prohibitively high for even the wealthiest copyright owners. Given the broad range of copyrightable property and their different markets, it is equally inefficient and costly to set up some type of fair use fee system in lieu of enforcing rights through litigation. [FN162] As such, liability lines must be drawn to curb the transaction costs associated with enforcement. One way to accomplish this is by limiting liability for uses that either the author or general public deems socially beneficial or economically harmless. [FN163]

For example, before digital technology and the Internet, there was no economic incentive to sue individuals for reading infringing books, watching infringing movies, or listening to infringing music in the privacy of their homes. Consequently, this type of infringement was generally overlooked. [\[FN164\]](#) It was also socially beneficial to allow \*613 one who lawfully obtained a copy of a copyrighted work to lease, sell, or otherwise allow another to use that non-infringing copy. This is the basis for public and private library systems and the ability to give copyrighted works such as books, music, and art as gifts without paying royalties to authors. Section 109 of the Copyright Act codifies this social benefit by terminating the author's exclusive right of distribution once an individual has lawfully obtained a copy of a copyrighted work. [\[FN165\]](#) Also, the compelling First Amendment concerns surrounding one's right to provide social commentary and criticism, as well as the need to promote non-profit research and education, are some of the uncompensated positive externalities that drive limiting liability once an otherwise infringing act is determined to be a fair use under Section 107 of the Copyright Act. [\[FN166\]](#)

Computer software is one type of copyrightable expression that, like most patentable inventions, fails the uncompensated positive externality justifications for allowing the fair use and first sale limitations on liability. [\[FN167\]](#) For most software (excluding radically pioneering operating systems or encryption technology), there is the market, incentive, and opportunity for private bargaining to occur without excessive transaction costs. Also, unlike hard-text literary works and non-digital copies of movies, art, and so forth, software can be reverse engineered and copied to create competing products which negatively impact the copyright holder's market. With regard to copying, particularly digital copies, the same is true for sound recordings. As a result, \*614 computer programs and sound recordings (except for video games) are exempt from the First Sale limitation. [\[FN168\]](#) Although alleged software infringers can assert the defense of fair use, courts provide inconsistent guidance and often inequitably find fair use to facilitate a newcomer's entry into the software market. [\[FN169\]](#) Because the utilitarian nature of software makes it more like patentable subject matter than creative expression, such as literary works or music, the social benefit and public accessibility arguments are far weaker for allowing liability limitations such as fair use. The problems with allowing the fair use defense for software mirror the problems we will explore in the next section evaluating patent fair use.

## 2. "Fair Use" Is Not an Economically Viable Option for Patent Market Failures

There is no statutory or common law equivalent for the fair use doctrine in patent law. Patent law, however, does include other scope limitations which courts use such as validity evaluations under Section 102 and 103 of the Patent Act, the reverse doctrine of equivalents, experimental use, blocking patents (when markets are working efficiently), and the Shop-Right Doctrine. [\[FN170\]](#) These statutory and equitable limitations serve to define more accurately and fairly a patent's \*615 property boundaries. Professor O' Rourke argues that in addition to the existing limitations, patent law needs to incorporate a fair use defense which "explicitly balances the patentee's exclusive rights against overall social welfare." [\[FN171\]](#) Fair use is most helpful for industries with high rates of innovation and where high transaction costs and broad basic and blocking patents threaten further innovation. [\[FN172\]](#)

O'Rourke proposes the following five-factor test to evaluate patent fair use:

(1) the nature of the advance represented by the infringement (the more significant the advance, the more likely the public welfare would be substantially advanced if it were made available, thus major technological leaps such as stem cells would weigh in favor of fair use, while a minor advance would weigh against it); (2) the purpose of the infringing use (non-commercial v. directly or indirectly commercial); (3) the nature and strength of the market failure that prevents a traditional licensing arrangement (courts should identify the relevant market defect, such as high transaction costs, and externalities, and explain how it negatively impacts the market, particularly for innovation as this goes to the heart of the constitutional mandate to "promote the progress of the useful Arts."); (4) the impact of the use on the patentee's incentives and overall social welfare (necessitates balancing the public benefit against the patentee's incentive with use leading to

competitive rather than 'transformative' products cutting against fair use); and (5) the nature of the patented work (broadening fair use rights for relatively small advances over the prior art and narrowing fair use for major advances over prior art). [\[FN173\]](#)

At first blush, Professor O'Rourke's proposal is both compelling and straightforward. There are some practical impediments to evaluating fair use under these factors, however. First, significant tension appears to exist between factor one, the nature of the advance, and factor five, the nature of the patented work. Under factor one, public welfare is significantly advanced by pioneering inventions and this favors fair use, while factor five argues that fair use should be narrowed for "major advances over prior art." [\[FN174\]](#) Which factor gets greater priority? If the proposed statute includes a requirement that no one factor \*616 carries any particular weight and each case must be evaluated on its merits, then factor one would dominate in scenarios where public health or national emergency trigger a need to provide immediate and timely access to the patented technology. On the other hand, where there is no compelling social need, such as in the area of operations software technology, factor five may carry greater weight. As seen in copyright law, courts left to their own devices may manipulate the O'Rourke factors and the law to reach the perceived equitable result. This leads to a lack of consistent precedent for courts to rely on when evaluating similar cases in the future.

Also, for biotechnology and pharmaceuticals, the prohibitively high cost of research and development makes factor four (balancing of public benefit against inventor's incentive) the dominant factor, which compels finding very limited or no fair use to preserve the inventor's incentive to produce this much needed technology. [\[FN175\]](#) Indeed, the reverse doctrine of equivalents will already protect the would-be infringer where the transformative use is also radically pioneering. As noted in the Introduction, society sustains the greater harm if eroding the incentive to invent leads to the unavailability of technology at any price even where the infringement would be an improvement or transformative use which would greatly benefit society. In these cases, a series of royalty-free fair use licenses would greatly reduce the value of the company's patent portfolio, which ultimately reduces the overall net worth of the company. This devaluation would deter both further innovation (less investment dollars available) as well as future investment dollars. Indeed, the constitutional mandate is also defeated under this paradigm since the cessation of innovation also prevents progress or promotion of the useful arts. O'Rourke suggests that courts award royalties in situations where the patentee stands to sustain great economic harm from the alleged fair use. Once the court determines a use is fair, it then determines whether royalties are necessary as well as the amount of the royalty. [\[FN176\]](#) This sounds plausible in theory, but without further guidance, courts may inconsistently and unfairly apply the royalty versus royalty-free fair use analysis. Here, compulsory licensing provisions accompanied with a neutral royalty tribunal may lead to more equitable results.

\*617 Finally, the utility, novelty, and non-obviousness requirements of the Patent Act ensure that material outside of the inventor's innovative contribution remains in the public domain to enhance the innovative process. The written description requirement of Section 112 serves to ensure that accurate boundaries for the invention are articulated in the patent claims, while the enabling disclosure requirement serves to place the patented technology into the public domain for others to utilize this information to invent (and subsequently patent) their own novel and non-obvious improvements or new technology. Moreover, the reverse doctrine of equivalents is a powerful common-law doctrine for limiting infringement liability where the infringing act produces a radically pioneering invention. [\[FN177\]](#)

Should Congress choose to pursue a fair use limitation for the patent, royalty-based fair use would be the best option since it helps preserve the incentive to invent socially desirable technology. However, fair use should be limited to national emergency/health crisis scenarios where the positive externalities mirror those which triggered the fair use limitation in Copyright law. In cases of national crisis (such as an Anthrax epidemic), there is a tremendous demand for the patented pharmaceutical (Cipro, for Anthrax) needed to combat the disease. Unfortunately, many consumers would be unable to pay

the market price for the patented drug. Also, even if market pricing is underwritten by the federal government, it is highly unlikely that the patentee alone could manufacture the requisite amount of the drug in the needed time-span (immediate for most health epidemics). Thus, the patentee would need to license generic manufacturing of the drug to meet societal demand. [\[FN178\]](#)

Like many types of copyrightable subject matter, in a national health crisis, the patented product is socially beneficial (life-saving in \*618 the case of Cipro, or the HIV/AIDS drug Norvir), but any type of licensing arrangement is unfeasible to the patentee. The patentee wants to provide the product to the masses, but many consumers are unable to pay market price nor have any means for recouping licensing fees for generic manufacturing. Here, a royalty-based fair use provision would allow the courts to excuse the infringement associated with generic manufacturing of the patented drug and set a reasonable royalty that the generic manufacturer would pay the patentee. The royalty must be adequate to compensate the patentee and retain its incentive to invent additional life-saving products without limiting the generic manufacturers' ability to make a reasonable profit.

The problem remains that courts have inconsistently applied fair use when evaluating copyright infringement, indicating that patent cases may face the same fate. [\[FN179\]](#) Furthermore, although courts frequently determine royalty rates as damages in patent infringement cases, they are not the most efficient tribunal to evaluate reasonable royalties for market failures in the fair use context. Instead, this type of economic analysis is better accomplished by an independent tribunal made up of industry-specific experts. Thus, I propose looking to a limited compulsory licensing scheme similar to those found in the Copyright Act. [\[FN180\]](#)

#### B. Compulsory Licensing Is the More Viable Limitation for Patent Property Where Excessive Transaction Costs Prevail

In the ideal free market capitalist paradigm, there is no need for compulsory licensing of technology. Theoretically, market incentives should motivate patentees to utilize their patents in the most economically efficient manner. This may include single-handedly commercializing the technology if the patentee possesses adequate resources, but more often includes licensing the technology to others in the same field. [\[FN181\]](#)

\*619 Unfortunately, the reality is that market failures exist, particularly in areas of cutting-edge technology where there is significant market demand for the best, fastest, or most efficient product. Such demand motivates monopolistic pricing strategies as well as obtaining blocking or basic patents (which the patentee will refuse to license or exploit) for the sole purpose of precluding competitive entry into the market. This behavior is most prevalent in the areas of software, biotechnology, and pharmaceuticals. [\[FN182\]](#) In theory, blocking patents should facilitate cross licensing. With rapidly advancing technologies, however, it is often difficult to reach a consensus on valuation with internal biases leading patentees to overvalue their inventions and undervalue another's. Furthermore, technology is spread between academics and private institutions, thereby creating differing interests in negotiating. This creates disincentives for the cross-licensing of blocking and improvement patents as well as traditional licensing arrangements. [\[FN183\]](#) Thus, we are faced with high transaction costs leading to market failures and an inhibition of free market competition. This compels looking at compulsory licensing to create incentives to stimulate free market competition and provide the timely access to technology necessary to promote further innovation. [\[FN184\]](#)

When evaluating the current health care product crisis, any pressing need for this technology must be balanced against preserving the incentive to invent critically needed drugs and other health care products. [\[FN185\]](#) Some scholars advocate that a "win-win" approach is for Big Pharma to adopt a social marketing strategy. Under this paradigm, alliances are formed between major pharmaceuticals, non-governmental public-interests organizations (NGOs) and the U.S. government to

develop a "mega-marketing" scheme whose goal is to underwrite the costs for equal drug access, utilizing tax-incentives from the government, \*620 NGO time/dollars, and voluntary licensing/donation from the pharmaceuticals. [\[FN186\]](#) I agree that it is unduly burdensome and unfair to make Big Pharma solely responsible for ensuring equal access to medicines, thus making the team approach of social marketing the quintessential "win-win" scenario. [\[FN187\]](#)

Unfortunately, in the United States there are several reasons that make social marketing problematic. First, pharmaceuticals are priced higher in the United States because our market will bear this pricing structure and we have relatively few legislative provisions to control excessive pharmaceutical pricing. [\[FN188\]](#) Second, the working poor who cannot afford cutting-edge health care products remain relatively voiceless in the political arena. Last but not least, since the Anthrax scare of 2001/2002, many do not perceive that AIDS or any other health crisis has reached pandemic proportions in the United States. [\[FN189\]](#) As a result, there may not be sufficient "stake-holder" (for example, pharmaceutical or governmental) interests to bring all parties willingly to the table to effectuate equal access to medicines and other health-care products. [\[FN190\]](#) Adding a compulsory licensing provision to the Patent Act may create the "wings-effect" of motivating major pharmaceuticals or other health care product patentees to initiate social-marketing or voluntary licensing schemes, which in turn, will increase access to these essential products. [\[FN191\]](#)

\*621 Indeed, the patent system is no stranger to compulsory licensing. Although disfavored by courts unless there is patent misuse, other federal statutes include compulsory licensing provisions. [\[FN192\]](#) For example, the Atomic Energy Act allows for compulsory licensing of patents by the Atomic Energy Commission where necessary for the development of nuclear material or atomic energy. [\[FN193\]](#) The Clean Air Act also allows for compulsory licensing of patents relating to the control of air pollution. [\[FN194\]](#) Every proposed amendment to the Patent Act to require compulsory licensing for public health or other special circumstances (such as suppression or non-use by the patentee) has failed, however. [\[FN195\]](#) Opponents of compulsory licensing argue that since pharmaceutical research and development is a "lengthy, risky and expensive enterprise," full patent protection is essential to retaining the incentive to create new pharmaceutical and health care products. [\[FN196\]](#)

It is easiest to accept compulsory licensing in situations where the patentee misuses, suppresses or obtains blocking patents for technology \*622 which has great social value, such as to public health. [\[FN197\]](#) As discussed, the high transactions costs surrounding pioneering technology often lead to market failures which prevent traditional licensing that would efficiently disseminate technology and further innovation. For example, despite the current international and domestic HIV/AIDS crisis, anti-retroviral drugs remain at the center of a pricing and accessibility debate, with only small movement in the direction of voluntary licensing. [\[FN198\]](#) In reality, the mere presence of a compulsory licensing provision should have the aforementioned "wings effect" of motivating parties to work through their bargaining and valuation issues, rather than face the cost and uncertain outcome of governmental intervention. In cases where the "wings effect" fails and bargaining breakdown occurs, compulsory licensing will guarantee timely access to patentable technology. There are still two problems, however. First, what entity is best suited to handle evaluating compulsory licenses and fees? Second, should there be some delay in the availability of compulsory licenses to preserve the incentive to invent?

I propose that rather than leave this to courts, Congress should amend the Patent Act to include specific compulsory licensing provisions for situations of patent misuse, suppression, and blocking (where market failure occurs). Unlike many commentators, I also advocate mirroring the TRIPS compulsory licensing provisions for public health or other national emergencies. [\[FN199\]](#) I further advocate that the Commissioner of Patents and Trademarks be required to form a Patent Arbitration Royalty Tribunal (PART), similar to the Copyright Royalty Arbitration Panel (CARP). [\[FN200\]](#) Unlike CARP, whose primary purpose \*623 is to evaluate and set royalty rates, PART would have the additional responsibility of evaluating applications for compulsory licenses to determine if they are warranted after balancing the property and health interests



factors. [\[FN201\]](#) Parties would be allowed to bring in expert testimony to support their relative positions. Experts could also provide guidance concerning the reasonable royalty rate. Joseph Yosick argues for a maximum royalty that would "enable the patentee to realize profits as large as if he still retained a monopoly." [\[FN202\]](#) Unfortunately, in cases of public health or national crisis, this ideal may be impossible. Thus, we must look to other mechanisms, such as blocking out a period of total exclusive rights for the patentee to address any potential disincentives. PART decisions could be appealed directly to the Federal Circuit. As the mandatory circuit for patent appeals, the Federal Circuit would be best equipped to review the tribunal's conclusions.

The remaining issue is whether Congress should build in a delay in the availability of compulsory licenses. In other words, should patentees retain some period of absolute exclusive rights? Opponents of compulsory licensing argue that in addition to being socialism in disguise, compulsory licensing robs the patentee of any incentive to invent because compulsory license royalties will not make up for the deficit created by ever-increasing research and development costs. [\[FN203\]](#) Patentees would be allowed a three-to-five-year period (depending on the product's development cost) of exclusive rights. [\[FN204\]](#) The period could begin when the patent issues, or after a drug or device obtains FDA approval for sale in the case of pharmaceuticals. After the "exclusionary" \*624 period, petitions could be filed with PART to obtain a compulsory license. Of course, part of the application process must include documentation of a reasonable attempt to procure a cost effective traditional license. Also, a section should be added which mirrors Section 3 of former House Bill 1708 and mandates that all pharmaceutical companies submit an annual report of costs and profits to help ensure a fair and balanced royalty calculation and exclusionary period. [\[FN205\]](#) I propose the following framework for a "model" compulsory license which is a hybrid of the Compulsory Licensing Provisions of the Copyright Act of 1976 and House Bill 1708 (which died in Committee in 2002): [\[FN206\]](#)

### C. Model Health Care Product Compulsory License

#### 1. Scope of Exclusive Rights in Certain Patented Inventions: Compulsory license for Making, Using, or Selling Patented Inventions Relating to Health Care.

In the case of certain patentable inventions, the exclusive rights provided for in Section 271, to exclude others from making, using, and selling the patented invention during its term, are subject to compulsory licensing under the conditions specified by this section.

##### a. Availability of Compulsory License

When a health care product patented invention has been used by the inventor for a period of three years (the exclusionary period) and made available to the public in the United States under the authority of the inventor, an application may be made to the Patent Arbitration Royalty Tribunal for a compulsory license from the patentee, contractor, licensee, or assignee. The exclusionary period may be extended \*625 beyond three years if the tribunal determines that the patentee has not adequately absorbed the costs for developing the invention.

A person may obtain a compulsory license by showing clear and convincing evidence of one of the following:

(1) A national crisis which warrants immediate access to the patented product in greater quantities than the patentee or its authorized licensees can produce; or

(2) A market failure or anti-competitive situation which warrants the intervention of the royalty tribunal because of insurmountable transactional costs or valuation uncertainty. In determining whether a "market failure" or "anti-competitive" situation exists, the tribunal may consider the following:

(A) whether the patented invention is priced excessively relative to the median price for developed countries or by other reasonable standards, and such pricing contravenes the public interest; or

(B) whether the patented invention is an essential component of a health care product that involves patents and the licensing terms for the patent on the invention are not reasonable and deter innovation or product development contrary to the public interest; or

(C) whether the invention covered by a patent (the "second patent" cannot be exploited without infringing upon the patent that is the subject of the dispute the "first patent"), insofar as the invention claimed in the second patent involves an important technical advance [Blocking scenario];

(D) whether the invention claimed in the patent is needed for research purposes that would benefit the public health, and is not licensed on reasonable terms and conditions.

(3) A public health crisis requiring immediate access to the patent for further research and development or to provide sufficient access and distribution of the product; or

(4) the patentee, contractor, licensee, or assignee has not taken, or is not expected to take within reasonable time effective steps to achieve practical application of the subject invention in a field of use.

#### b. Factors for Determining Availability of Compulsory License or Extension of Exclusionary Period

In exercising the right under Part 1(a) to issue a compulsory license or extend the exclusionary period of the patent, the tribunal shall evaluate the following non-exhaustive list of factors:

(1) the risks and costs associated with the invention claimed and the commercial development of products that use the invention;

\*626 (2) the efficacy and innovative nature and importance to the public health of the invention or products using the invention;

(3) the degree to which the invention benefited from publicly funded research;

(4) the need for adequate incentives for the creation and commercialization of new inventions;

(5) the interests of the public as patients and payers for health care services; and

(6) the public health benefits of expanded access to the invention.

#### c. Notice of Intention to Obtain Compulsory License

Any person who wishes to obtain a compulsory license under this section shall before or within thirty days of failed licensing negotiations with the patentee, serve notice of intention to do so on the patent holder. The notice shall comply in form, content, and manner of service, with requirements that the Commissioner of Patents shall prescribe by regulation.

#### d. Royalty Payable/Remuneration Under Compulsory License

After evaluating the evidence presented by all parties, a reasonable royalty or remuneration shall be determined by PART. The royalty must reflect an amount which adequately compensates the patentee, while allowing the licensee to conduct

effectively further innovation or generic manufacturing. In cases of national emergency or health crisis, the tribunal retains the discretion to go below a reasonable royalty rate if necessary to facilitate timely dissemination of the patented product.

e. Consistency with TRIPS

The PTO and Secretary of Health and Human Services may adopt regulations jointly to implement the purposes of this section, consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in Section 101(d)(15) of the Uruguay Round Agreements Act.

f. Definition

In this section, the term "health care product" means any drug or device (as those terms are defined in section 201 of the Federal Food, Drug and Cosmetics Act), any biological product (as defined in section 351 of the Public Health Service Act), or technology or process to \*627 the extent the technology or process is applied to health or health care.

### CONCLUSION

Social marketing or the team involvement of corporate, government, and non-profit interests is the ideal solution for broadening access to health care products since it keeps large pharmaceutical interests from shouldering the burden alone and adequately spreads both risks and rewards. Given the unique monopoly power and increased potential for market failures triggered with pioneering drugs and other health product technology, a federal compulsory licensing scheme may provide the added "wings effect" or motivation for a patentee (corporate interest) to come to the negotiation table and avoid governmental intervention.

Once the statutory guidelines are met, a compulsory license should serve to: (1) adequately compensate the patentee; (2) overcome the market failure that previously blocked access to technology; and (3) promote further innovation by all parties in the technology area. The reduction of market failures and more efficient technology transfer will stimulate innovation and bring us more aligned with the constitutional mandate of awarding exclusive rights for "limited times" to inventors to "Promote the Progress of . . . the useful Arts."

[FN4]. Simone A. Rose, Professor of Law, Wake Forest University School of Law. I would like to thank Professor Alan Palmiter, Professor Ahmed Taha, Professor Mark Hall, Professor Marcia Baker, Ginny Gilbert, Edward Erginzinger, Wesley Sheffield, and Taylor Arnold for their invaluable assistance with this piece.

[FN1]. Richard Elliott et al., Patents, International Trade Law, and Access to Essential Medicines 12 (3d ed. 2003) (quoting Mira Shiva, All India Drug Action Network) (emphasis added).

[FN2]. Bruce N. Kuhlik, The [Assault on Pharmaceutical Intellectual Property](#), 71 U. Chi. L. Rev. 93, 109 (2004) (emphasis added).

[FN3]. 347 U.S. 483, 495 (1954). One issue which I should highlight, but not presume to answer definitively, is whether access to health care should be evaluated with the logic of Brown, or with the logic of [San Antonio Ind. School Dist. v. Rodriguez](#), 411 U.S. 1 (1973). Under either analysis, I would suggest that access to health care is a fundamental right, unequal access thereto being potentially unconstitutional.

[FN4]. See, e.g., Associated Press, Survey: U.S. Families Struggle to Pay for Drugs, Many Americans Cut Dosages to Deal with Crunch, Poll Finds, Feb. 23, 2004, available at <http://msnbc.msn.com/id/4354033/> (noting that almost one third of

Americans polled indicated that the cost of prescription drugs is a problem in their families, and many are cutting dosages to help them cope with the costs).

[FN5]. See Kathleen Stoll & Kim Jones, Families USA, One in Three: Non-Elderly Americans Without Health Insurance, 2002-2003, at 6 (2004).

[FN6]. Id.

[FN7]. Id. at 5. The study further indicates that, in sharp contrast, the likelihood of being without health insurance decreases considerably as income increases. Id. at 6 tbl.5.

[FN8]. Id. at 6 tbl.6; see also Marie C. Reed et al., Center for Studying Health System Change, Issue Brief, Unequal Access: African-American Medicare Beneficiaries and the Prescription Drug Gap 1 (2003) ("African[ ]American Medicare beneficiaries age [sixty-five] and older are more than twice as likely as elderly White beneficiaries to report that they could not afford to fill at least one prescription in the last year...").

[FN9]. Stoll & Jones, supra note 5, at 13 ("Although only 23.5[%] of [W]hite, non-Hispanic people were uninsured, nearly three out of five non-elderly Hispanics (59.5[%]) and more than two in five of all non-elderly African Americans (42.9[%]) are uninsured.").

[FN10]. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, [Pub. L. No. 108-173, 117 Stat. 2066 \(2003\)](#).

[FN11]. See Associated Press, Discount Drug Law Goes to High Court, Greensboro News & Rec., Jan. 20, 2003 (highlighting aspects of Maine plan which allows for importation of drugs from Canada); William M. Welch & Julie Appleby, Medicare Bill May Benefit Seniors, but Not Taxpayers, USA Today, June 9, 2004, available at [http://www.usatoday.com/news/washington/2003-11-24-medicare-cover\\_x.htm](http://www.usatoday.com/news/washington/2003-11-24-medicare-cover_x.htm); Ctrs for Medicare & Medicaid Servs., Overview, Medicare Prescription Drug Discount Card and Transitional Assistance Program (2004), available at <http://www.cms.hhs.gov/discountdrugs/overview.asp>; NewsHour with Jim Lehrer: Medicare Changes (PBS television broadcast, Dec. 8, 2003), transcript available at [http://www.pbs.org/newshour/bb/health/july-dec03/medicare\\_12-08.html](http://www.pbs.org/newshour/bb/health/july-dec03/medicare_12-08.html); NewsHour with Jim Lehrer: Rx for Medicine (PBS television broadcast, Nov. 25, 2003), transcript available at [http://www.pbs.org/newshour/bb/health/july-dec03/medicare\\_11-25.html](http://www.pbs.org/newshour/bb/health/july-dec03/medicare_11-25.html); see also Stoll & Jones, supra note 5, at 12, 18 (noting that one of the reasons for lack of insurance is that "contrary to popular belief, Medicaid does not provide coverage to most workers in low-wage jobs" and further that "in response to fiscal crises... six states... also stopped enrolling eligible children in their State Children's Health Insurance Programs.").

[FN12]. Some economists note that while research and investment averages 12% of pharmaceutical sales industry-wide, for large research-oriented pharmaceutical companies the investment increases to almost 21% of sales. During the past decade, research and development spending by the top pharmaceutical companies tripled to more than \$30 billion annually. See Charles R. Kennedy et al., Integrating Public Policy and Public Affairs in a Pharmaceutical Marketing Program: The AIDS Pandemic, 23 J. Pub. Pol'y & Marketing 128, 130 (citing Cynthia Challener, Finding the Bright Spots in the Vanishing Pharma Pipeline, 263 Chemical Market Rep. 4 (2003)).

[FN13]. As noted by other scholars, affordability is only a single component of the accessibility problem particularly on the international front. Adequate health care systems, trained medical personnel, prevention and follow-up programs are additional pieces of this puzzle, which must be addressed. See Kelley A. Friedgen, Comment, [Rethinking the Struggle](#)

[Between Health & Intellectual Property: A Proposed Framework for Dynamic, Rather Than Absolute, Patent Protection of Essential Medicines](#), 16 *Emory Int'l L. Rev.* 689, 692 (2002).

[FN14]. See David J. Gross et al., AARP Public Policy Institute, Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans 2000-2003 11-12 (2004), available at [http://research.aarp.org/health/2004\\_06\\_drugprices.html](http://research.aarp.org/health/2004_06_drugprices.html) (stating that the average estimated increase in the annual cost of therapy due to higher manufacturer prices for widely used brand name drugs doubled, rising from \$33.76 to \$60.38 between 2000 and 2003. For a typical older American who takes three drugs, the average increase in annual cost increased from \$101.00 and \$150.00 and 6% with annual increases between \$151 and \$313.).

[FN15]. Catherine Hollingsworth, NIH Weighs Whether to Issue License for Lower Priced Norvir, Patent, Trademark & Copyright L. Daily, June 2, 2004, available at [www.bna.com](http://www.bna.com).

[FN16]. See *id.*

[FN17]. See generally Kuhlik, *supra* note 2. The patent for Prilosec has expired, and it is presently available in both prescription and non-prescription form.

[FN18]. Robert P. Merges, Of [Property Rules, Case, and Intellectual Property](#), 94 *Colum. L. Rev.* 2655, 2656-57 (1994).

[FN19]. U.S. Const. art. I, § 8. Note that the quid pro quo for granting exclusive rights for "limited times" for patent and copyright property is that such grant "promote the progress of Science (copyrights) and the useful Arts (Patents)." *Id.* The National Academy of Sciences has created a project on whether patents are deterring innovation and competitiveness. See <http://www.nap.edu/books/0309089107/html>.

[FN20]. See Maureen A. O'Rourke, [Toward a Doctrine of Fair Use in Patent Law](#), 100 *Colum. L. Rev.* 1177, 1178 (2000); see also Mark A. Lemley, The [Economics of Improvement in Intellectual Property Law](#), 75 *Tex. L. Rev.* 989, 1065 (1997) ("Producers will price at marginal cost only if they are forced to by existing competition. A producer who controls a market will cut output and raise prices, increasing its profits but reducing both consumer and aggregate social welfare.").

[FN21]. See O'Rourke, *supra* note 20, at 1187.

[FN22]. U.S. Const. art. I, § 8 ("To promote the Progress of Science and Useful Arts, by securing for limited Times... the exclusive Right ....").

[FN23]. See Derrick Bell, [Brown v. Board of Education and the Interest-Convergence Dilemma](#), 93 *Harv. L. Rev.* 518, 523 (1980). I believe that Derrick Bell is responsible for coining the term "interest convergence," which basically means that for socially/legally charged areas where opposing views are polar opposites, social change will not be implemented (for example, integration of schools) until there is a converging of the interests of both sides. *Id.*

[FN24]. Indeed, several scholars have recently addressed this issue. See, e.g., Friedgen, *supra* note 13; John A. Lee, The [Ownership and Patenting of Inventions Resulting from Stem Cell Research](#), 43 *Santa Clara L. Rev.* 597 (2003); Tracy Collins, Note, The [Pharmaceutical Companies Versus AIDS Victims: A Classic Case of Bad Versus Good? A Look at the Struggle Between Intellectual Property Rights and Access to Treatment](#), 29 *Syracuse J. Int'l L. & Com.* 159, 171-81 (2001).

[FN25]. 17 U.S.C. § 1201 (2001); 18 U.S.C. 2319 (2001).

[FN26]. See Evan P. Schultz, *Federal Officials Are Probing the Patent Trust*, *Legal Times*, Mar. 4, 2002 (discussing FTC and Justice Department hearings which began last November to evaluate the intersection of Patent Law and Antitrust and included a detailed inquiry into the increase of patents issued in the areas of biotechnology and software); see also James Bradshaw, [Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the U.S. Patent System?](#), 37 *Willamette L. Rev.* 637 (2001) (arguing the need for timely access to genetic information and promoting the patent, noting the widespread concern that gene patents will block access to genetic information, which will inhibit the development of genetic technology, thereby negatively impacting public health. However, the author ultimately supports the U.S. patent system as the best mechanism to promote scientific progress in this area.); Brenda Sandburg, *Judge Calls for Patent Reform Commission*, *Recorder*, Mar. 5, 2002, at 4.

[FN27]. This is further complicated by the Bush administration's limits on federal research money for pre-existing lines, which inhibit the creation of additional lines even with appropriately licensed technology from the Wisconsin Foundation. See [Exec. Order No. 13,237, 66 Fed. Reg. 59,851 \(Nov. 28, 2001\)](#), available at <http://www.bioethics.gov/reports/executive.html>.

[FN28]. See Associated Press, *U.S. Stem Cell Litigant Settles*, Jan. 10, 2002, available at <http://www.jsonline.com/alive/ap/jan02/ap-stem-cell-lawsu011002.asp> (discussing the settlement giving Geron exclusive rights to develop products from three of the six cell types developed by the University of Wisconsin and non-exclusive rights to the other three cell types. In exchange, "Geron and the foundation agreed to grant research rights for existing cell patents and patent filing to academic and government researchers without royalties or fees. Other companies can form collaborations with Geron or buy licenses to Geron's intellectual property.").

[FN29]. See Lee, *supra* note 24 (discussing patenting issues relating to stem cell research).

[FN30]. *Id.*

[FN31]. [Exec. Order No. 13,237, 66 Fed. Reg. 59,851 \(Nov. 28, 2001\)](#); see also Mark Voorhees, *Cellular Divide*, *IP Law & Bus.*, Feb. 11, 2003, available at <http://www.law.com/jsp/article.jsp?id=1044059452918> (noting that BresaGen Ltd., a small Australian biotechnology company, announced that it was planning to buy rights to a different set of stem cell patents covering research at Vanderbilt University, claiming that these patents are older than the Wisconsin patents).

[FN32]. See Grace K. Avedissian, Note, [Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of Super Terrorism](#), 18 *Am. U. Int'l L. Rev.* 237 (2002).

[FN33]. See Robert M. Goldberg, *The War Against Cipro: Schumer's Biofoolishness*, *Nat'l Rev. Online* (Oct. 25, 2001), at <http://www.nationalreview.com/comment/comment-goldbergprint102501.html>.

[FN34]. *Id.*

[FN35]. *Id.*

[FN36]. *Id.*

[FN37]. See Pfizer, Inc., *Sharing the Care*, at <http://www.pfizer.com/subsites/philanthropy/access/sharing.care.index.html> (last visited June 22, 2004) ("Through Sharing the Care, Pfizer donates its most advanced medicines to low-income, uninsured patients through a network of over 380 federally-qualified community, migrant and homeless health centers across

(Cite as: 48 How. L.J. 579)

the U.S."); see also Eli Lilly & Co., Direct Patient Assistance, at [http://www.lilly.com/products/access/direct\\_patient.html](http://www.lilly.com/products/access/direct_patient.html) (last visited June 22, 2004) ("The health care needs of people throughout the world are diverse - from those of societies seeking to increase the effectiveness of health care through sophisticated, innovative technology to the needs of communities concerned with securing basic health care to help keep people alive. In 2001, Eli Lilly and Company donated pharmaceutical products with a market value of more than \$200 million to patients in need throughout the world."); GlaxoSmithKline, Inc., Global Community Partnerships, at <http://www.gsk.com/community/about.htm> (last visited June 22, 2004) ("GSK donates essential products for humanitarian relief efforts. Donations are made at the request of governments and major charitable organizations and are made on a planned production basis. Non-governmental organizations complete a needs assessment then order the product needed in their international communities. This ensures that the right product reaches the right person at the right time."); Pfizer, Inc., Connection to Care, at <http://www.pfizer.com/subsites/philanthropy/access/connection.care.index.html> (last visited June 22, 2004) ("For more than 30 years, Pfizer has worked directly with physicians on a case-by-case basis to provide medications to patients in need. In 2003 alone, Pfizer donated more than \$600 million in medicine, helping 1.5 million patients across the United States. Connection to Care provides free medications to eligible patients, with little administrative work for physicians. This program provides access to Pfizer's leading medicines, including Lipitor®, Norvasc® and Zolofit®.").

[FN38]. Hollingsworth, *supra* note 15.

[FN39]. *Id.* (discussing the NIH's evaluation of the quadrupling of the price of the AIDS drug Norvir to assess whether to reassign the drug license under the Bayh-Dole Act, which provides for the transfer of publicly funded inventions to the commercial market and allows for the reassigning of these licenses if the product is: 1) not made available to the public or 2) made available on "unreasonable terms"); see also Kennedy et al., *supra* note 12, at 129 (noting the ever-increasing pricing structure in the U.S. for anti-retroviral (AIDS) drugs which are continuously redesigned to attack drug-resistant HIV strains, "[f]or example Trimeris and Roche introduced Fuzeon in early 2003 at twice the price of any previous AIDS therapy (\$23,000 per annum), which sparked immediate protests in the United States and Europe."); Progress on Pills, *N.Y. Times*, May 18, 2004, at A22 (editorial) (noting that the Bush administration agreed to a streamlined way to provide inexpensive AIDS drugs to people in Africa and the Caribbean).

[FN40]. [Pub. L. No. 96-517, 94 Stat. 3015 \(1980\)](#), amended by [Pub. L. No. 98-620, 98 Stat. 3335 \(1984\)](#) (known commonly as the Bayh-Dole Act); see also Hollingsworth, *supra* note 15 (noting that the NIH recently rejected the march-in provision relating to the AIDS drug Norvir). The actual NIH decision is available at [http://www.autm.net/announcements/NIH\\_March-InDecision.pdf](http://www.autm.net/announcements/NIH_March-InDecision.pdf).

[FN41]. International programs include Abbott Access, Tanzania Care, AstraZeneca-Red Cross TB Program, Viramune Donation Programme, Accelerating Access Initiative, Global Alliance to Eliminate Lymphatic Filariasis, Merck Mectizan Donation Program. See PhRMA, *Global Partnerships: Humanitarian Programs of the Pharmaceutical Industry in Developing Nations* (2003), at <http://world.phrma.org/partnerships.html>. Such programs are desperately needed in the United States.

[FN42]. Ceci Connolly, *Coalition Seeks to Curb Drug Patent Extensions*, *Wash. Post*, Mar. 25, 2002, at A1. For articles evaluating how various states are taking a closer look, see, for example, Associated Press, *High Court Considers Drug Plan by Maine*, *Winston-Salem J.*, Jan. 29, 2003 (highlighting factors the Supreme Court is evaluating in examining Maine's attempt to cut prescription costs for its residents); Monica Davey, *Illinois Considers Buying Drugs in Canada*, *N.Y. Times*, Sept. 16, 2003 (describing that state's governor's attempts to evaluate feasibility of prescription drug importation, despite possible legal conflicts with the FDA); Kelly Greene, *Get Those Tests - Medicare Helps Pay*, *Winston-Salem J.*, Oct. 26, 2003, at D5 (lamenting the reluctance of Medicare patients to get basic health care for which they qualify).

[FN43]. Drug Price Competition and Patent Term Restoration Act of 1984, [Pub. L. No. 98-417, 98 Stat. 1585 \(1984\)](#) (codified as amended at [21 U.S.C. § 355](#), [28 U.S.C. §2201](#), and [35 U.S.C. §§ 156, 271, 282](#)) (commonly known as the Hatch-Waxman Act).

[FN44]. Connolly, *supra* note 42.

[FN45]. *Id.*

[FN46]. *Id.*

[FN47]. Greater Access to Affordable Pharmaceuticals Act of 2001, S. 812, 107th Cong. (2001); see also Elizabeth White, Generic Rx Group Hails Medicare Plan Provisions to Speed up Drug Competition, *Pat., Trademark & Copyright L. Daily*, Nov. 20, 2003 (chronicling efforts to close loopholes in Hatch-Waxman and the cautious responses of interested parties); Generic Pharm. Ass., Drug Patent Expiration List (2003), available at [http:// www.gphaonline.org/news/expiration.phtml](http://www.gphaonline.org/news/expiration.phtml) (The List notes that expiration dates of widely used brand name drugs such as Cipro, whose patent expired in December of 2003. Singulair's patent was scheduled to expire in February 2003, and Xenical's patent for an obesity drug was scheduled to expire in June 2004.).

[FN48]. [Pub. L. No. 108-173, 117 Stat. 2066 \(2003\)](#).

[FN49]. Hatch-Waxman allows a generic manufacturer to file an ANDA if it makes one of four certifications. The certification that the relevant patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug is known as a "Paragraph IV" certification. After a generic manufacturer files a paragraph IV certification, the brand name manufacturer (holder of the patent) has 45 days to file a patent infringement suit against the generic manufacturer. See [21 U.S.C. § 355\(c\)\(3\)\(C\)](#); see also FDA Issues Guidance Clarifying Latest Changes to Hatch-Waxman Under MMA, *Pat., Trademark & Copyright Law Daily*, Nov. 9, 2004, available at <http://pubs.bna.com/ip/BNA/ptd.nsf/is/A0B0A0K4T1>; U.S. Food and Drug Administration, Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Questions and Answers, (2004), available at <http://www.fda.gov/cder/guidance/6174dft.pdf>. For an excellent publication providing an overview of Hatch-Waxman and outlining the amendments covered by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, see Alston & Bird, Life Sciences Advisory, Changes to Hatch-Waxman Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (2004), available at [www.alston.com](http://www.alston.com).

[FN50]. Alston & Bird, *supra* note 49, at 6. As noted by the authors, the Act also includes the following changes to Hatch-Waxman: 1) A definition of bio-equivalence ("The FDA may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect."), 2) provisions governing 30 month stays, 3) the ability of generic companies to seek declaratory judgments concerning listed patents, and 4) the ability of an ANDA applicant to counterclaim to remove a patent from the "Approved Drug Products With Therapeutic Equivalence Evaluations" (also known as The Orange Book, where under FDA requirements, brand name companies submit patent information to the FDA on any drug or method of using the drug). *Id.* at 3-4.

[FN51]. Constance K. Robinson et al., Kilpatrick Stockton LLP, U.S. Antitrust Enforcement Agency Proposes Changes to Patent Law (2004), available at <http://newsletter.kilpatrickstockton.com/KSBrief/Vol2?story.aspx?ID=139>. The FTC issued its final report last year. See also [http:// www.ftc.gov/os/2003/10/innovationrpt.pdf](http://www.ftc.gov/os/2003/10/innovationrpt.pdf).



[FN52]. In 2002, two compulsory license bills, House Bills 1708 and 3235 were pending before Congress. Both bills would have led to amendments to the Patent Act and both satisfied the conditions for compulsory licensing outlined in Article 31 of TRIPS. Unfortunately, both Bills died in committee. H.R. 1708, 107th Cong. (2001); H.R. 3235, 107th Cong. (2001). As an interesting side note, House Resolution 4815, introduced a year later and providing for compulsory licensing for genetically engineered animals and crops, met a similar fate in committee. H.R. 4815, 107th Cong. (2002).

[FN53]. See Herman Reinhold, *Patients v. Patents*, IPL Newsletter, (Summer 2001), at 1-6.

[FN54]. William Drozdiak & Paul Blustein, *Serious Conflicts Threaten Trade Talks; Battle of Rich, Poor Nations Could Kill Planning for New WTO Discussions*, Wash. Post, Nov. 6, 2001, at A1.

[FN55]. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Ann. 1C, Legal Instruments-Results of the [Uruguay Round vol. 31, 33 I.L.M. 81 \(1994\)](#) art. 27 [hereinafter TRIPS Agreement].

[FN56]. *Id.*

[FN57]. Article 31(a) of TRIPS requires that a country obtain permission from the patentee before allowing compulsory licensing. However, Article 31(b) provides that "this requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." TRIPS Agreement, *supra* note 55, arts. 31(a)-(b).

[FN58]. Kennedy et al., *supra* note 12, at 129-33.

[FN59]. *Id.* (noting the 30 million cases and 2 million deaths from HIV/AIDS in sub-Saharan Africa in 2002); see also Collins, *supra* note 24, at 171-81.

[FN60]. Patrick Marc, [Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?](#), 21 N.Y. L. Sch. J. Int'l & Comp. L. 109, 111 (2001) (citing Article 22C(1)(b) of the Medicine Act of 1997); see also Trading Needed Medicine, N.Y. Times, Aug. 29, 2003 (editorial) (reporting that the U.S. is dropping its opposition to providing poor countries relief from patent restrictions, thus permitting them to import cheaper medicines); Developing Countries Prepared to Use New WTO Accord to Import Cheap Medicines, Pat., Trademark, & Copyright L. Daily, Sept. 8, 2003 (focusing on actions taken on the African continent).

[FN61]. See Marc, *supra* note 60, at 120-22; Reinhold, *supra* note 53, at 5.

[FN62]. See Marc, *supra* note 60, at 121-22.

[FN63]. See David Haskel, *Argentine Senate Clears Patent Legislation Reflecting U.S. Property Rights Demands*, Pat., Trademark, & Copyright L. Daily, Sept. 22, 2003 (reporting that the Argentine government enacted reforms of its intellectual property laws desired by the United States); Reinhold, *supra* note 53, at 5; Ed Taylor, *Presidential Decree Aims to Let Brazil Break Patents on AIDS Medicines, Others*, Pat., Trademark, & Copyright L. Daily, Sept. 10, 2003 (noting that by declaring a public health emergency, Brazilian lawmakers can buy low-priced versions of drugs).

[FN64]. See, e.g., Daniel Pruzin, *WTO Members Extend Deadline for Incorporating Medicines Deal into TRIPS*, Pat., Trademark, & Copyright L. Daily, June 17, 2004 (noting June 16 agreement of WTO member countries to extend negotiating deadline "in principle" from June 30, 2004 to March 31, 2005 to give governments more time to "hammer out an

agreement"); Kathleen McLaughlin, Pfizer Signs MOU with China to Crack Down on Drug Knock-Offs, Pat., Trademark, & Copyright Law Daily, May 24, 2004 (noting a singular example of a domestic non-governmental organization negotiating directly with a foreign government); Daniel Pruzin, WTO Chairman Circulates Text to Break TRIPs/Medicines Deadlock; Agreement Seen, Pat., Trademark, & Copyright L. Daily, Aug. 28, 2003.

[FN65]. Friedgen, supra note 13, at 64 (emphasis added).

[FN66]. Kennedy et al., supra note 12, at 128 (emphasis added).

[FN67]. [U.S. Const. art. I, § 8, cl. 8](#) (emphasis added).

[FN68]. See Simone A. Rose, [Patent "Monopolyphobia": A Means of Extinguishing the Fountainhead?](#), 49 Case W. Res. L. Rev. 509, 516 (1999); see also Lemley, supra note 20, at 997 ("Because intellectual property rights impose costs on the public, the intellectual property laws can be justified by the public good argument only to the extent that they do on balance encourage enough creation and dissemination of new works to offset those costs.").

[FN69]. Lemley, supra note 20, at 997. For example, cost includes exclusivity, higher pricing, and the benefits include dissemination of creative and inventive material to the public.

[FN70]. See [35 U.S.C. § 271 \(a\) \(2003\)](#) (detailing rights of a patent holder); [35 U.S.C. § 154\(a\)\(2\) \(2002\)](#) (detailing twenty-year patent term).

[FN71]. [35 U.S.C. § 112 \(2000\)](#). For example, the NIH is presently debating how to handle Abbot Labs' recent quadrupling of the price for the drug Norvir. Norvir's research/patent was funded by the U.S. Government and licensed to Abbot. Abbot argues that it will ensure equal access to the drug, despite its pricing structure. Since Norvir is a publicly funded invention, under the Bayh-Dole Act, NIH has the right to initiate "march-in" provisions and reassign licenses where the product is not "reasonably available" to the public. AIDS activists, physicians, and other groups argue that the poor will no longer have access to Norvir at its present pricing, so NIH should intervene and reassign product licenses to generic manufacturers in order to make cheaper versions of the drug available. Interestingly, Norvir, whose research was funded by the U.S. Government, is sold in the United States for ten times the price that it is sold for in Canada, Australia, and Europe. Hollingsworth, supra note 15.

[FN72]. Paul Goldstein, Copyright, Patent, Trademark and Related State Doctrines 2 (5th ed. 2004) (citing Carl B. Lutz, Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution, 18 Geo. Wash. L. Rev. 50 (1949) (providing historical semantics breakdown of Patent and Copyright clause and links Copyrights to "Science" and Patents to the "useful Arts")).

[FN73]. Daniel R. Cahoy, [Changing the Rules in the Middle of the Game: How the Prospective Application of Judicial Decisions Related to Intellectual Property Can Promote Economic Efficiency](#), 41 Am. Bus. L.J. 1, 11 (2003) (emphasis added).

[FN74]. Rose, supra note 68, at 516 (citing [In Re Etter](#), 756 F. 2d 852, 859 (Fed. Cir. 1985)).

[FN75]. Id. at 513.

[FN76]. Lemley, supra note 20, at 1043, 1046 (discussing Edmund Kitch's "Patent Property Rights Theory," wherein the patent property right is analogized to "prospecting," which "increases the efficiency with which investment in innovation can

be managed") (citing Edmund N. Kitch, *The Nature and Function of the Patent System*, 20 *J.L. & Econ.* 265, 276 (1977)).

[FN77]. *Id.*

[FN78]. See, e.g., Rose, *supra* note 68, at 518 (noting that on its face the granting of the right to exclude others from making, using, and selling gives the patentee some unique capability to dominate the market or control pricing at a competitive disadvantage during the patent's term. However, the reality is that a majority of patents are not commercialized and derive their value from a series of complementary factors such as manufacturing and distribution facilities, workforces, advertising, and other items of intellectual property); see also Kenneth W. Dam, *The Economic Underpinning of Patent Law*, 23 *J. Legal Stud.* 247, 250 (1994) (noting that "in the great bulk of instances, no significant market power is granted [from the patent right]"). But see Lemley, *supra* note 20, at 1045 (pointing out that if the property owner is alone in the market, as is the case with certain pioneering inventions, he may be expected to set a higher monopoly price for his goods, to the detriment of his consumers (and social welfare)).

[FN79]. Lemley, *supra* note 20, at 1043 ("The fundamental economic bases of this [Kitch's Patent Property Rights Theory] approach are the... hypothetical Coasean world without transaction costs.... The economic solution to the tragedy of the commons is private property. If everyone owns a small piece of land (or lake), and can keep others out of it (with real or 'legal' fences), then the private and public incentives are aligned. People will not over-graze their own land, because if they do they will suffer the full consequences of their actions.").

[FN80]. See, e.g., Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case for Blocking Patents*, 62 *Tenn. L. Rev.* 75, 77 (1994) ("[T]he large and thriving market for patent licenses is proof enough that parties can and do engage in private patent transactions, presumably in the interests of both parties.").

[FN81]. Lemley, *supra* note 20, at 1043 ("Further, if dealmaking between neighbors is costless, as Coase postulated but did not believe, transactions will allow neighbors with large cattle herds to purchase grazing rights from others with smaller herds. Such transactions should occur until each piece of land is put to its best possible use."); see also Merges, *supra* note 18, at 2656. ("The [Coase] Theorem says that in a world with zero transaction costs, initial rights allocations are unimportant; they will be transferred to their highest-value use through private bargains."). Merges also points out that Coase conceded that transactions costs exist and must be factored in when allocating property rights, including intellectual property rights (IPRs).

[FN82]. Dam, *supra* note 78, at 260-70.

[FN83]. *Id.*

[FN84]. See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *Colum. L. Rev.* 839, 875 (1990) (arguing that Kitch's prospect theory must be supplemented to take into account this important limitation on the breadth of property rights).

[FN85]. See 35 U.S.C. §112 (2004) (requiring a written enabling disclosure that includes the best mode of producing the claimed invention and a set of claims, which along with the specification, defines and notifies the public of the metes and bounds of the invention).

[FN86]. 35 U.S.C. § 102 (2004).

[\[FN87\]](#). [Id. § 103](#).

[\[FN88\]](#). See Rose, *supra* note 68, at 521.

[\[FN89\]](#). *Id.*

[\[FN90\]](#). See, e.g., [State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1236 \(Fed. Cir. 1985\)](#) (noting that the patent system assures the steady flow of innovations to the marketplace, providing an incentive via the doctrine of equivalents to develop one's own pioneering product); see also Lemley, *supra* note 20, at 1064 ("In the small subset of cases where the improver's invention is such a major advance over the original invention that its value is much greater than the original, the incentive theory of intellectual property suggests that we should be more concerned about encouraging improvements than we are about encouraging original inventions." Lemley goes on to note that the losses are small in this context and are outweighed by the encouragement of improvements which are themselves more valuable than the original); see also O'Rourke, *supra* note 20, at 1197 ("By sheltering the radical improver, the reverse doctrine of equivalents helps to ensure that the public will receive the benefit of major advance.").

[\[FN91\]](#). Lemley, *supra* note 20, at 1062; O'Rourke, *supra* note 20, at 1179.

[\[FN92\]](#). Kennedy et al., *supra* note 12, at 130 (citing William Reisel & Linda Sams, *The Distribution of Life-Saving Pharmaceuticals: Viewing the Conflict Between Social Efficiency-Economic Efficiency Through a Social Contact Lens*, 108 *Bus. & Soc. Rev.* 365, 368-69 (2003)) (emphasis added).

[\[FN93\]](#). See Clarisa Long, [Proprietary Rights and Why Initial Allocations Matter](#), 49 *Emory L.J.* 823, 827-28 (2000) ("Transactions Costs are composed of many elements. In the context of licensing a patent they include: the costs of searching for licensees by the patent holder or licensors by the would-be licensee; the costs of negotiating a license, sometimes with multiple licensees or patent holders; and the costs of enforcing the terms of the license and protecting against infringement by nonlicensees.").

[\[FN94\]](#). Lemley, *supra* note 20, at 1053.

[\[FN95\]](#). See *id.*; O'Rourke, *supra* note 20.

[\[FN96\]](#). An example of a blocking patent arrangement would be where A has developed and patented a new pharmaceutical product along with a method for manufacturing the drug. If B develops an improved method of manufacture which is novel and non-obvious, B is also entitled to a patent for its method. However, B cannot carry out its patented process without infringing on the rights of A's method and product patents. Thus A's method and product patents serve as "blocking patents," preventing B from making, using, or selling its invention without license from A. Since B has invented a more efficient method of producing A's product, society would benefit from B's ability to market or carry out this method. B's improvement patent provides it with property rights in its discrete improvements which will benefit A. A's blocking patents will motivate B to approach A for a license since it cannot carry out the invention without infringing A's patents. Ideally, the patent property right is thus structured to "encourage improvers to approach pioneers with licensing proposals." See Merges, *supra* note 80, at 81 (noting the significant social welfare gains from pioneer-improver transactions and illustrating that ideally providing property rights to both the blocking and improvement technology facilitates the pioneer-improver transaction.); see also O'Rourke, *supra* note 20, at 1197 ("The blocking patents doctrine increases the probability that the public will profit from substantial improvements. Those minor improvers unable to obtain a patent will be held infringers. But the cost of keeping a minor advance from the public may be justified to maintain the original patentee's incentive.").

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However, Merges further notes that despite the ideal that blocking patents facilitate most patent licensing, there are problematic situations where it does not. These will be discussed further in the next section. Merges notes that three questions remain in this context: 1) whether these bilateral monopolists (the pioneer and improver) are more likely than others to reach an impasse in a given "round" of bargaining; 2) whether their impasse is likely to be more harmful in terms of social welfare loss; and 3) whether there are any reasons to believe that an impasse in an early round will make an ultimate agreement unlikely. Merges, *supra* note 80, at 83.

[FN97]. Blocking patents do not guarantee efficient transactions with minimal transactions costs. In areas of rapidly evolving technologies and pioneering inventions, the blocking patentee may overvalue its technology to the point where it cannot conduct realistic licensing negotiations with the improvement patentee. Alternatively, as we see in the pharmaceutical context, the blocking patentee has such a monopoly on the patented product and consumers are content with the product "as is," that there is little economic incentive to alter or engage in improvements, thus blocking any hope for developing the improvement technology during the term(s) of the blocking patents.

[FN98]. See, e.g., Long, *supra* note 93, at 829 ("Because transaction costs reduce the surplus that would be gained from a license, their very existence can deter patent holders and would-be licensees from negotiating.").

[FN99]. See Rose, *supra* note 68, at 519; see also Lemley, *supra*, note 20, at 1066-67.

[FN100]. See Rose, *supra* note 68, at 522-23; see also Dam, *supra* note 84, at 250-52 (Dam explores the economics of Patent Law and suggests that rather than labeling profits as monopolistic, they are better characterized as "economic rent." Economic rent is defined as the difference between the patentee's per-unit costs and competitor's per-unit costs (to the extent attributable to the patented innovation) multiplied by the patentee's volume. For pioneering inventions, the exclusive right to exclude others from making, using and selling the claimed invention provides the pioneering inventor with a cost advantage that allows her to reap greater profits/economic rent than her competitors.).

[FN101]. See Lemley, *supra* note 20, at 1047 ("If the property owner is alone in the market, he may be expected to set higher monopoly prices for his goods, to the detriment of consumer and social welfare.").

[FN102]. See *id.* at 1067; Rose, *supra* note 68, at 519.

[FN103]. See Lemley, *supra* note 20, at 1067.

[FN104]. As noted previously, Abbot Labs has quadrupled the price for the drug Norvir, while insisting that it will provide equal access. As discussed, this seems particularly problematic since Norvir's research was conducted with federal funds. See Gross et al., *supra* note 14, at vi; Hollingsworth, *supra* note 15.

[FN105]. See Elise Tanouye & Robert Langreth, Time's Up: With Patents Expiring on Big Prescriptions, Drug Industry Quakes-Top Firms Gird for Onslaught from Generics, Scramble to Develop New Product-Bet on Fewer Blockbusters, *Wall St. J.*, Aug. 12, 1997 at A1 ("Patent protection is the financial fulcrum of the drug industry, emboldening makers to invest billions of dollars in development ...."); see also Pharmaceutical Research and Manufacturers of America-Backgrounders and Facts, Do Price Controls Hurt Pharmaceutical Research ?, Recent History Says, Yes (2004), available at <http://www.pharma.org/publications/backgrounders/development/pricingfact.phtml> (noting that companies are testing more than 600 medicines to meet the needs of our aging population and price controls, or even the threat of price controls, can push down research spending just when we need new treatments most); Kuhlik, *supra* note 2, at 109 (noting the dependency of the pharmaceutical industry on patent protection and arguing that "access to medicines and other healthcare goods and services

should be assured through programs that are consistent with the framework of intellectual property and market-based incentives necessary for continued innovation."); Susan R. Miller, *Tactical Moves: Success of Pharmaceutical Company Ivax Depends As Much on Legal Strategy As It Does on Developing Effective Drugs*, Law.com, Mar. 19, 2002 (highlighting the litigation-related costs of new drug development for those assaulting and those protecting patent rights).

[FN106]. See Sarah Lueck, *Drug Industry Exaggerates R&D Costs to Justify Pricing, Consumer Group Says*, Wall St. J., July 24, 2001, at B6 (noting the consumer group Public Citizen's estimate of \$100 million); PhRMA, *One New Drug = \$500 Million and 12-15 Years of R&D* (2004), available at <http://www.phrma.org/publications/quickfacts/01.03.2001.34.cfm> (noting the trade group PhRMA's estimate of \$500 million figure and assertion that this cost includes the cost of research failures as well as interest costs over the period of investment).

[FN107]. See PhRMA, *Why Do Pharmaceutical Companies Make Too Much in Profits?* (2002), available at <http://www.phrma.org/publications/publications/brochure/questions/toomuchprofits.phtml>; Merril J. Matthews, PhD, Center for Technology Freedom, *Policy Report: Prices, Profits and Prescriptions: The Pharmatech Industry in the New Economy* 157 (2000).

[FN108]. See Henry G. Grabowski et al., *Returns on Research and Development for 1990's New Drug Introductions*, 20 *Pharmacoeconomics Supp.* 3, 11 (Dec. 2002).

[FN109]. For example, in 1996, four cutting-edge patented drugs, including the heart drugs Vasotec and Mavacor provided more than half of Merck's \$6.18 billion U.S. drug sales. That same year, the prescription drug Claritin contributed to 57% of Schering-Plough's \$2.61 billion prescription U.S. drug sales. See Tanouye & Langreth, *supra* note 105; see also [www.phrma.org/publications/publications/brochure/questions/whycostmuch.phtml](http://www.phrma.org/publications/publications/brochure/questions/whycostmuch.phtml) (for additional statistics).

[FN110]. See, e.g., PR Newswire Association, Inc., *Biotech Flails in 2002 While Investors 'Wait It Out'; the Biotech Industry is Feeling Big Pharma's Pain, but a Turn Around Looms In the Offing*, PR Newswire-Financial News, June 12, 2002 ("Pharma is willing to pay a big premium for a potential winner, as we saw with Bristol-Myers Squibb's original deal to acquire a 40% stake in ImClone and Erbitux for \$2 billion, but then again, Erbitux's setback is a grim reminder that drug discovery and development is one risky business." (quoting G. Steven Burrill, CEO of Burrill & Company, a San Francisco based life sciences merchant bank)).

[FN111]. Kennedy et al., *supra* note 12, at 130 (noting that to attract the best research scientist Big Pharma has to produce a "conducive" research environment and that the high profitability of research-oriented pharmaceuticals has allowed them to fund large R&D budgets. The authors further note that stockholders of Big Pharma companies "favor strong financial returns and the strategic value of aggressive R&D programs that will generate future cash flows.").

[FN112]. See Matthews, *supra* note 107 (citing 1999 Fortune Magazine data documenting pharmaceutical's median return at 18%). In 2001, Merck Pharmaceutical Corporation had a net income of \$7.3 billion. Contrast that with a typical generic pharmaceutical manufacturer such as TEVA Pharmaceuticals, which posted a net income of \$278 million and possesses few significant patents in its portfolio when compared to Merck. See also Hollingsworth, *supra* note 15 (chronicling arguments for permitting a license for cheaper versions of AIDS drug, including inexplicable price hikes in the US compared with Canada, Australia, and Europe); AARP Public Policy Institute, *Growth in Prescription Drug Prices Dramatically Outpaced Inflation 2000-2003* (2004), available at <http://www.aarp.org/legislative/prescriptiondrugs/rxprices/Articles/a2004-05-24-drugprices.html>.

[FN113]. Matthews, *supra* note 107, Fig. 2 (noting the following median returns: Computer Software at 15%, Savings

Institutions at 14%, Real Estate at 17%, Commercial Banks at 15% and Pharmaceuticals at 18%). Dr. Matthews is against any form of price control for pharmaceuticals and argues that although pharmaceuticals enjoy a relatively high median return, this is not inconsistent with the other new economy industries cited, but is greater than more competitive, traditional industries such as Food and Drug Stores at 2%, General Merchandisers at 3%, Computer Hardware at 7%, and Beverages at 7%.

[FN114]. Matthews, *supra* note 107, at tbl.4 (citing Fortune One Thousand: Ranked Within Industries, *Fortune*, Apr. 17, 2000).

[FN115]. See, e.g., Andrew Pollack, Cities and States Clamour to Be Bio Town, U.S.A., *N.Y. Times*, June 11, 2002, at C1 ("Michigan is spending \$1billion to create a "life sciences corridor" .... Cities and states across the United States are committing billions of dollars to become centers of the biotechnology industry... 41 states have some program aimed at spurring development of the life science.... At least 16 states are spending part of the money they received from the tobacco lawsuit settlement on items like research and commercial development."). Venture capitalists also continue to invest in biotech. See Lori Valigra, Venture Capitalists Cautiously Optimistic, *Bio-IT World*, Jan. 13, 2004, available at [http://www.bio-itworld.com/news/011303\\_report1820.html](http://www.bio-itworld.com/news/011303_report1820.html); Matt Marshall, Banking on Biotech: Aging Baby Boomers-and the Potential for Profit- Are Driving Breed of VCs into Biotech and Health Care, *Mercury News* (Aug. 18, 2002), available at <http://www.mercurynews.com/mld/mercurynews/3889374.htm?1c>.

[FN116]. Matthews, *supra* note 107, at 9.

[FN117]. *Id.*

[FN118]. See Gardiner Harris, Fast Relief: As a Patent Expires, Drug Firm Lines up Pricey Alternative, Prilosec's Maker Is Switching Users to a Lookalike Pill While It Thwarts Generics, *Wall St. J.*, June 6, 2002 ("Drug companies patent everything they can think of about their medicines, setting up "patent estates" that serve as legal minefields for competitors." The article goes on to cite the specific method and product patents obtained.); Gardiner Harris, 2 New Fronts in Heartburn Market Battle, *N.Y. Times*, Aug. 20, 2003 (juxtaposing the losers if generic products are allowed to come to market--the parent pharmaceutical manufacturer, with the winners, competing manufacturers, and consumers).

[FN119]. Brian Lavery, Galen and Barr Make Deal on Drug Rights and Patents, *N.Y. Times*, Sept. 12, 2003 (highlighting Galen's technique for building value by extending patent rights).

[FN120]. See, e.g., O'Rourke, *supra* note 20, at 1229 ("A patentee who seeks to control innovation in the primary and secondary markets may prefer to block the secondcomer from market entry rather than engage in a cross-license."); Reuters, Forest, Lundbeck Sue Ivax, Sept. 23, 2003, available at <http://news.findlaw.com/business/s/20030923/healthforestdc.html> (highlighting potentially precedent-setting litigation over the generic version of the antidepressant Lexapro). Black's Law Dictionary 278 (7th ed. 1999) [hereinafter Black's] defines horizontal competition as "competition between a seller and its competitors" and vertical competition as "competition between participants at different levels of distribution, such as manufacturer and distributor."

[FN121]. O'Rourke, *supra* note 20, at 1211.

[FN122]. *Id.* at 1227-28.

[FN123]. *Id.*

[\[FN124\]](#). Id.; see also Lemley, supra note 20, at 1056-57.

[\[FN125\]](#). Lemley, supra note 20, at 1058-59.

[\[FN126\]](#). Id.

[\[FN127\]](#). Id. at 1058 (noting that collective action problems prevent consumers from collectively paying for the reverse engineering in order to create competition).

[\[FN128\]](#). Id. at 1227. O'Rourke, supra note 20, at 1227, proffers Patent Fair Use as a means for "usher[ing] in such beneficial competition." Although attractive on the surface, I favor some form of limited compulsory license for this scenario.

[\[FN129\]](#). Long, supra note 93, at 824; see also Brenda Sandburg, Biotech Firms Battle over Patent, Law.com, Apr. 4, 2002 (pharmaceutical researchers debate probability of use of existing prior art and appropriateness of compensation thereof).

[\[FN130\]](#). See, e.g., Howard Markel, Patents Could Block the Way to a Cure, N.Y. Times, Aug. 24, 2001, at A14 ("[T]he notion that someone could own the rights to a lifesaving treatment remains disconcerting to those of us who cherish the ideal of the altruistic scientist searching for cures for human diseases.... Recent revelations that the Wisconsin Alumni Research Fund holds the only American patent to the human embryonic stem cell make it imperative that the nation address a fundamental question: Who should benefit from discoveries pertaining to the human body?... It does not take too much imagination to realize how tangled scientific discovery would become if every innovation were patented and controlled by the discoverers... Indeed, scientific knowledge is rarely, if ever, produced in a vacuum. And yet that is what our laws today have thoroughly encouraged."); see also Long, supra note 93, at 824 (noting that even after the Supreme Court held that products of life were patentable, many pioneer scientists in bio-technology chose not to patent their basic research in DNA-sequencing and DNA-sequencing techniques).

[\[FN131\]](#). Long, supra note 93, at 825 ("In the past several decades, the boundaries of patentability have crept inexorably closer to the basic end of the research spectrum." Professor Long credits the broad expansion of patentability to the creation of the U.S. Court of Appeals for the Federal Circuit (CAFC), as the mandatory court of patent appeals.).

[\[FN132\]](#). Id. at 826. Technology transfer from universities to industry was made possible by the Bayh-Dole Act. [Pub. L. No. 96-517, 94 Stat. 3015 \(1980\)](#), amended by [P.L. 98-620, 98 Stat. 3335 \(1984\)](#).

[\[FN133\]](#). Long, supra note 93, at 824.

[\[FN134\]](#). Id. at 826.

[\[FN135\]](#). See Associated Press, supra note 28 (The article discusses negotiating difficulties and settlement giving Geron exclusive rights to develop products from three of the six cell types developed by the University of Wisconsin and non-exclusive rights to the other three cell types. This agreement also provided for granting research rights for existing cell patents to academic and government researchers without royalties or fees).

[\[FN136\]](#). Long, supra note 93, at 824-27.

[\[FN137\]](#). See Long, supra note 93; see also Lemley, supra note 20; O'Rourke, supra note 20.

[\[FN138\]](#). Long, supra note 93, at 830.



[\[FN139\]](#). See id. at 829.

[\[FN140\]](#). See id. (quoting the National Institutes of Health (NIH) Working Group on Research Tools report: "most scientists are not skilled at reading license agreements and distilling the legal implications of their language, even in consultation with their own institutional representatives...").

[\[FN141\]](#). See id. at 831.

[\[FN142\]](#). See id. at 832 ("A patent may exist on a gene although the function of that gene fragment is unknown; the sequence and function of the entire gene of which that fragment is a part is unknown; the ways in which that gene can malfunction are unknown; the diseases that arise when the gene malfunctions are unknown; and the pharmaceutical compound that can combat the disease that arises when the gene (of which the gene fragment is part) malfunctions is unknown. In this string of unknowns, it is discovering and patenting the last that is commercially lucrative. When all that is known is the sequence data surrounding the gene fragment, the future value of a patent is difficult for the patent holder and the would-be licensee to agree on.").

[\[FN143\]](#). See id. at 834. Long argues that the reason why uncertainty does not continuously block patent licensing is that proxies are frequently used to determine the patent's anticipated value. "Such proxies include the size of the patent holder's portfolio, the licensing fees the patentee received from licensing other patents, the amount of venture capital financing the patentee has been able to attract, and the litigiousness (or expected litigiousness) of the patent holder..." Id. Thus, since larger corporations possessing large patent portfolios have a track record of this data for their other patents, they can effectuate more efficient licensing arrangements and have greater bargaining power.

I posit that in the bio-technology area proxies are a problematic substitute for uncertainty in valuation since the holders of these patents are often academic institutions or small/start-up corporations with relatively small patent portfolios and limited litigation track-records.

[\[FN144\]](#). See id. at 833.

[\[FN145\]](#). See id. at 836 ("Whenever negotiating licensing terms to basic research results breaks down, valuable time is lost. The problem will be most acute when the entities patenting the basic research results do not have the capital to develop the patented material and have no further use for it except as a source of licensing revenue.").

[\[FN146\]](#). See id. at 834-35.

[\[FN147\]](#). See id. at 835.

[\[FN148\]](#). Cahoy, *supra* note 73, at 12 (emphasis added).

[\[FN149\]](#). [17 U.S.C. § 102 \(2004\)](#). Under [Section 102](#), works of authorship include the following categories: (1) literary works, (2) musical works, (3) dramatic works, (4) pantomimes and choreographic works; (5) pictorial, graphic and sculptural works; (6) motion pictures and other audiovisual works; (7) sound recordings; and (8) architectural works. Id.

[\[FN150\]](#). Id. Nonetheless, registration is required to obtain the remedies available under the Copyright Act for copyright infringement. See also [17 U.S.C. §§ 501-504](#).

[\[FN151\]](#). [17 U.S.C. § 106 \(2004\)](#). There is also the limited "moral" right available to works of fine art under Section 106A of the Copyright Act.

[FN152]. [17 U.S.C. § 107](#); see also O'Rourke, supra note 20, at 1188.

[FN153]. See, e.g., [Feist Publ'g Inc. v. Rural Tel. Servs. Co.](#), 499 U.S. 340, 349-50 (1991) ("To this end, copyright assures authors the right to their original expression, but encourages others to build freely upon the ideas and information conveyed by the work.") (citing [Harper & Row, Publishers v. Nations Enter.](#), 471 U.S. 539, 556-57 (1985)).

[FN154]. [35 U.S.C. § 101](#). See also [Parker v. Flook](#), 437 U.S. 584 (1978); [Gottschalk v. Benson](#), 409 U.S. 63 (1972); [Funk Bros. Seed Co. v. Kalo Inoculant Co.](#), 333 U.S. 127 (1948), which all hold that abstract ideas and algorithms are unpatentable.

[FN155]. [17 U.S.C. § 107 \(2003\)](#).

[FN156]. [17 U.S.C. § 107](#). This is, however, not an exhaustive list of factors courts may consider. See, e.g., [Harper & Roe Publishers](#), 471 U.S. at 558; [Am. Geophysical Union v. Texaco, Inc.](#), 60 F.3d 913, 918 (2d Cir. 1994); [Campbell v. Acuff-Rose Music, Inc.](#), 510 U.S. 569, 575 (1994); Melville B. Nimmer & David Nimmer, Nimmer on Copyright § 13.05 [A] (1997), ("[T]he factors contained in [Section 107](#) are merely by way of example, and are not exhaustive enumeration. This means that factors other than those enumerated may prove to have a bearing upon the determination of fair use.").

[FN157]. O'Rourke, supra note 20, at 1188; see also Roger D. Blair & Thomas F. Cotter, An [Economic Analysis of Seller and User Liability in Intellectual Property Law](#), 68 U. Cin. L. Rev. 1, 31 (1999) (discussing the role of fair use to limit copyright liability "to permit valuable uses of copyrighted material in circumstances in which transaction costs or other bargaining obstacles would preclude voluntary negotiations").

[FN158]. Blair & Cotter, supra note 157, at 31; O'Rourke, supra note 20, at 1188.

[FN159]. These are essentially the facts of the infamous Sony "Fair Use" case, wherein Sony was sued by various program copyright holders under a theory of contributory infringement, since consumers were the direct infringers and the positive externalities created an impasse to suing the direct infringers. [Sony Corp. v. Universal City Studios, Inc.](#), 464 U.S. 417 (1984). Mark Lemley notes that positive externalities also exist in the copyright improvement context.

The willingness of an original copyright owner to license his work to an improver under a property rights scheme depends, not surprisingly, on the improver's willingness to pay. The improver's willingness to pay, in turn, depends (among other things) on the revenue the improver expects to receive from the improvement. Where the improver's expected revenue matches society's expected benefit, externalities do not interfere with efficient licensing between the parties. However, where the improver's work would create a significant social benefit that the improver cannot capture, the improver (and thus the original copyright owner) will undervalue that work. The result is that the improver may be unwilling or unable to pay for a license to use an original work, even though the aggregate benefit to society would more than make up for the license fee demanded.

Lemley, supra note 20, at 1056-57 (citing the law review example, noting that absent positive externalities, scholars would hold out for licensing fees for future scholars to cite their work in new law review pieces). However, since law review authors are not compensated on the basis of the value of their ideas, they are typically unwilling to pay for the right to quote prior scholars, notwithstanding the social value of the quote or information to the work. Id.

[FN160]. Lemley, supra note 20, at 1053.

[FN161]. Blair & Cotter, supra note 157, at 31.

[FN162]. O'Rourke, *supra* note 20, at 1209.

[FN163]. *Id.*; see also Blair & Cotter, *supra* note 157, at 31-33; Lateef Mtima, [Tasini and Its Progeny: The New Exclusive Right or Fair Use on the Electronic Publishing Frontier](#), 14 *Fordham Intell. Prop. Media & Ent. L.J.* 369, 428-29 (2004) (evaluating Digital Republication and Fair Use and noting that "[t]he fair use doctrine enables the copyright law to account for those situations in which the social utilities to be achieved in permitting a specific use of copyrighted material warrant a limited impingement upon the copyright holder's exclusive property rights").

[FN164]. See Blair & Cotter, *supra* note 157, at 31. Even in [Sony Corp. v. Universal City Studios, Inc.](#), 464 U.S. 417 (1984), the infamous fair use case, Columbia chose not to sue consumers who were directly infringing by home-taping copyrighted material from television shows and movies. Instead, the television and motion picture industry went after Sony, the seller of the Betamax video recording machines, under a theory of contributory infringement. Blair & Cotter, *supra* note 157, at 31. Today, with the creation of MP3 and other digital file/transfer technology, authors are not so willing to ignore private infringing uses of copyrighted material. Since a digital transmission is both a copy and a distribution, I cannot assert the defense of first sale when I digitally transmit even a lawfully obtained copy of copyrighted music, art, or movies. This is because first sale terminates the author's [Section 106\(3\)](#) right of distribution only, not its 106(1) right of reproduction. Thus, first sale is inapplicable to internet transmissions of copyrighted works. Because digital technology allows for the endless distribution and reproduction of copyrighted works, many copyright owners now go after private infringing uses in the digital context. Large music copyright holders like Sony and Columbia, have been known to anonymously participate (by creating fictitious characters with dummy e-mail addresses) in file sharing groups in an attempt to catch individuals who are illegally sharing copies of copyrighted music or movies. Sony then charges these individuals, often college students, with direct copyright infringement. Carl Bialik, *Will the Music Industry Sue Your Kid?*, *Wall St. J.*, Sept. 10, 2003, at D1; Nick Wingfield, *RIAA Targets Are Surprised by Piracy Suits*, *Wall St. J.*, Sept. 10, 2003, at B1.

[FN165]. [17 U.S.C. § 109\(a\) \(2004\)](#).

[FN166]. Blair & Cotter, *supra* note 157, at 33 ("A second likely reason for copyright to follow a different path [than patents] may be attributable to traditional notions of freedom and privacy"); see also O'Rourke, *supra* note 20, at 1209 ("[C]opyright also excuses payment when the infringing use is socially beneficial and the infringer simply cannot pay the price, usually because it cannot capture the externalities associated with its use. Certainly, educational and other non-profit uses like pure research often fall into this category.").

[FN167]. Blair & Cotter, *supra* note 157, at 35; [Adobe Sys. Inc. v. Stargate Software Inc.](#), 216 F. Supp. 2d 1051, 1059 (N.D. Cal., 2002); [Sony Computer Entm't, Inc. v. Connectix Corp.](#), 203 F.3d 596, 603 (9th Cir. 2000) (proposing that software poses unique copyright problems); Blair & Cotter, *supra* note 157, at 35.

[FN168]. [17 U.S.C. § 109\(b\) \(2004\)](#).

[FN169]. See [Adobe Sys. Inc.](#), 216 F. Supp. 2d at 1059; [Sony Computer Entm't Inc.](#), 203 F.3d at 603.

[FN170]. The Doctrine of Equivalents prevents a person from practicing a fraud on a patent by substituting obvious equivalents for elements in the claims to avoid their literal language. An accused product or process will infringe a claim, though outside its literal terms, if it does the same work in substantially the same way to accomplish substantially the same result as the patented product or process. Pioneer inventions are entitled to a greater range of equivalents than a lesser improvement. The doctrine can work in reverse, excluding an accused device that falls within the literal language of a claim but operates in an essentially different manner. Black's, *supra* note 120, at 496-97; see also [Tate Access Floors, Inc. v.](#)

[Interface Architectural Res., Inc., 279 F.3d 1357 \(Fed. Cir. 2002\)](#) (discussing additionally the Reverse Doctrine of Equivalents). Experimental Use is activity by the inventor or his assignee that otherwise would place an invention in public use or on sale but will not constitute a statutory bar through more than one year prior to the application filing date if the primary purpose of the activity is experimentation. Experimentation includes both activity with a view to development or modification and activity simply to test the utility of the invention but does not include market testing. One may use a patented invention without the authority of the patent owner if the use is for purposes of research or experimentation and not for profit. Black's, *supra* note 120, at 1540. A Blocking Patent is an invention claimed in one patent that may require for its practice use of another invention claimed in another patent. In such a case of blocking patents, common subject matter may be used only with the concurrent authority of both patent owners. The owners themselves may cross-license each other. See *supra* note 96. The "Shop Right Doctrine" is the principle that an employer is entitled to a non-exclusive free license to use an employee's invention that the employee developed in the course of employment while using the employer's materials. Black's, *supra* note 120, at 1384; see also Donald S. Chisum, *Chisum on Patents, Glossary* (2004); Associated Press, *supra* note 28 (providing additional definitions and discussion of the terms generally); Markel, *supra* note 130.

[\[FN171\]](#). See O'Rourke, *supra* note 20, at 1187.

[\[FN172\]](#). *Id.* at 1238.

[\[FN173\]](#). *Id.* at 1205-08.

[\[FN174\]](#). *Id.*

[\[FN175\]](#). Estimates range from \$360 to \$500 million to get a new pharmaceutical product to the market. Reinhold, *supra* note 53, at 4. This does not include the additional cost for researching and developing products that are ultimately deemed ineffective and thus not marketed.

[\[FN176\]](#). O'Rourke, *supra* note 20, at 1209.

[\[FN177\]](#). Of course, the would-be infringer runs the great risk that a court may not find that the infringing product is "radically pioneering." Even with the existence of the Federal Circuit as the mandatory court of patent appeals, the boundaries of the doctrine of equivalents and reverse doctrine of equivalents remain difficult to define, and cases are inconsistently decided by the courts. Thus, it is difficult to provide clear guidance to clients when rendering patentability or infringement opinions when evaluating potential licensing arrangements. Lemley, *supra* note 20; Merges, *supra* note 80.

[\[FN178\]](#). For an interesting article that proposes a dynamic framework for evaluating whether to limit or deny patent protection of health-care products, see Friedgen, *supra* note 13. Without specifically referencing "fair use," the author argues for ease or elimination of patent property interests for public health emergencies (international or domestic) "where the need of treatment is so critical and acute as to justify the denial of patent protections." *Id.* at 720. The author cites compulsory licensing, generic production, and parallel importing as actions which may be taken to solve the pressing need. *Id.*

[\[FN179\]](#). For instance, in [Sony Corp. of America v. Universal City Studios, 464 U.S. 417, 448-50 \(1984\)](#), the Court concentrated its inquiry on the first and fourth fair use factors. Conversely, in [Campbell v. Acuff-Rose Music, 510 U.S. 569, 577 \(1994\)](#), the Court explored all four fair use factors, and pointed out their being non-exclusive. Compare the subtle treatment of Circuit Judge Beezer in [A&M Records, Inc., v. Napster, Inc., 239 F.3d 1004 \(9th Cir. 2001\)](#), with the heavy-handed approach of District Judge Rakoff in [UMG Recordings, Inc. v. MP3.Com, Inc., 92 F. Supp. 2d 349 \(S.D.N.Y. 2000\)](#).

[FN180]. Copyright Act of 1976, [17 U.S.C. §§ 101-1332 \(2004\)](#).

[FN181]. O'Rourke, *supra* note 20, at 1179; see also Joseph Yosick, [Compulsory Patent Licensing for Efficient Use of Inventions](#), 2001 U. Ill. L. Rev. 1275 (2001).

[FN182]. See, e.g., O'Rourke, *supra* note 20, at 1237 ("[R]ightholders have yet to come together to form a licensing institution in the biomedical field. In biotechnology and pharmaceutical areas, patents have traditionally played an important role in securing market share, rendering firms less willing to sacrifice exclusivity by pooling their patents because some discoveries lack substitutes. By increasing the power of some, this lack of substitutes worsens holdout problems.").

[FN183]. *Id.*

[FN184]. *Id.*; see also Yosick, *supra* note 181, at 1276.

[FN185]. See, e.g., Friedgen, *supra* note 13, at 724-35 (The author acknowledges that the high cost and risk associated with health product research and development requires a more dynamic approach to patent protection in this area which balances health interests against the patent property interests and limits easing/limiting patent protection to national or international situations of public health emergencies. The author also provides an actual framework/balancing to three diseases, HIV/AIDS, Malaria, and Trachoma.).

[FN186]. Kennedy et al., *supra* note 12, at 135-38 (outlining such a paradigm for addressing the HIV/AIDS pandemic). Friedgen, *supra* note 13, at 736 also advocates such alliances without use of the term "social marketing."

[FN187]. See Friedgen, *supra* note 13, at 716 ("It is inappropriate to expect for-profit firms like pharmaceutical manufactures to shoulder the burden of providing essential medicines alone.").

[FN188]. Indeed, the Baye-Doyle Act is one of the few provisions that allow governmental intervention, but only where the pharmaceutical at issue is one created with federal research monies. Some countries, like Canada, exercise some level of control over pharmaceutical pricing. See William M. Welch, *Once Just a Trickle, Canada's Rx Drugs Pouring into USA*, USA Today, Oct. 7, 2003 at A1, available at <http://www.globalaging.org/elderrights/us/trickle.htm> (last visited Dec. 12, 2004).

[FN189]. Kennedy et al., *supra* note 12, at 129 (comparing statistics for HIV/AIDS in the United States to those of countries where it has reached pandemic proportions).

[FN190]. *Id.* at 21-25.

[FN191]. Another interesting approach favored by budding scholar Kelly A. Friedgen is to create a dynamic "Framework" where patent protection for health care products is eased or eliminated where international interests supercede the patent property interests. See Friedgen, *supra* note 13, at 718-21. On the other hand, "where the subject matter of a patent fulfills the requirements for patentability and health interests are not in issue either in a national or international context, strong patent protections are warranted and demand enforcement in all WTO nations." See *id.* For Friedgen, "health interests" include access to essential medicines, treatment for ill populations, as well as disease prevention, health infrastructure investment (for example, medical insurance), medical education and training, and endemic disease research and development. See *id.* "Property interests" include the patent or other intellectual property right, and the patentee's expectations of profitability and control. See *id.* According to the author, this triggers, "issues of risk and reward, costs of product development, and

obligations to investors." See *id.*

[FN192]. See, e.g., Cont'l [Paper Bag Co. v. E. Paper Bag Co.](#), 210 U.S. 405, 423-30 (1908) (emphasizing the privilege of patentees to exclude others from using their inventions, without question of motive); [Smith Int'l Inc. v. Hughes Tool Co.](#), 718 F.2d 1573, 1581 (1983) (reaffirming the patentee's right to exclude); see also Yosick, *supra* note 181, at 1280-81.

[FN193]. [42 U.S.C. § 2183 \(2004\)](#).

[FN194]. *Id.* § 7608.

[FN195]. For example House Bills 1708 (introduced May 3, 2001) and 3235 (introduced Nov. 6, 2001) were both brought before committee and sought to amend the Patent Act to provide for compulsory licensing of certain patented inventions relating to health care emergencies. Unfortunately, both bills died in committee in 2002. H.R. 1708, 107th Cong. (2001); H.R. 3235, 107th Cong. (2001); see also Yosick, *supra* note 181, at 1278 (discussing the Hart Bill of 1973, which proposed compulsory licensing of patents related to public health, safety or protection of the environment, plus any patent not used within a fixed period of time, or one blocking an issued patent; discussing also the Affordable Prescription Act of 1999, which proposed compulsory licensing of patents relating to human health for specific cases including where "the patented material is priced higher than reasonably expected").

[FN196]. See, e.g., Kuhlik, *supra* note 2, at 106-09 (arguing that recent legislative and regulatory initiative such as amendments to Hatch-Waxman and the Medicaid provisions "threaten the competitive dynamics of the pharmaceutical market" and will reduce Big PhRMA's investment in biotechnology.) The author further notes that only three of every ten marketed drugs generate revenues that match or exceed average research and development costs. He cites the average cost of developing a new drug as \$802 million. *Id.* at 94. However, as noted in this Article, this number is highly disputed among industry experts and is difficult to pinpoint since it is rarely disclosed by individual companies; see also Kirby W. Lee, Comment, [Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing](#), 36 *Ind. L. Rev.* 175, 196 (2003) (arguing that there are currently other available avenues for the permitted use of patented invention, such as the Experimental Use Provisions under the Patent Act and the recent amendments to the Hatch-Waxman Act: "Congress has correctly recognized the unique incentive-backed investment expectations of the pharmaceutical industry and should wisely avoid these broad, sweeping compulsory licensing bills.").

[FN197]. Yosick, *supra* note 181, at 1300-02.

[FN198]. The present domestic controversy over the AIDS drug Norvir between Abbot Labs and NIH, with NIH threatening to invoke the rarely used Baye-Doyle provisions to reassign the license is a present example of this controversy. As noted in Part I of this Article, Abbot Labs has quadrupled the price of this drug, while simultaneously pledging to make it available to anyone who needs it. See Collins, *supra* note 24; Hollingsworth, *supra* note 15; see also Kennedy et al., *supra* note 12.

[FN199]. See, e.g., Yosick, *supra* note 181, at 1301 (arguing that "[c]ompulsory licensing should not be expanded to cover food and medicine patents."). Yosick believes that the power of the pharmaceutical lobby will always block such legislation and that "pharmaceutical companies need patent protection to recoup their investment and provide incentives to develop new drugs. Any provision allowing for compulsory licensing of pharmaceutical patents would have a detrimental effect on the development of new medicines." *Id.*

[FN200]. See [17 U.S.C. § 801 \(1998\)](#) (establishing CARP.) The Librarian of Congress, upon recommendation of the Register of Copyrights, is authorized to appoint and convene such panels to make adjustments of reasonable copyright royalty rates

for cable transmissions, non-dramatic musical works, satellite and other compulsory licenses found in the Copyright Act. Congress recently abolished the Copyright Royalty Tribunal by virtue of the Copyright Royalty Tribunal Act of 1993, saying the tribunal was "underutilized" and "unnecessary." 139 Cong. Rec. H7698-01 (daily ed. Oct. 12, 1993) (statement of Rep. Hughes).

[FN201]. The Panel could also be appointed by the Secretary of Health and Human Services as proposed in former House Bill 1708, or fall under the authority of the NIH (which presently administers the Baye-Doyle provisions), or the FTC. I believe that because the PTO has the greatest understanding of the scope of "patent property," it is in the best position to deal with issues of easing or diminishing the patent right.

[FN202]. Yosick, *supra* note 181, at 1303. Yosick notes that this preserves the incentive and any rate below this would weaken incentives for innovation, and also permit strong price competition.

[FN203]. See Yosick, *supra* note 181, at 1291-92; see also Goldberg, *supra* note 33.

[FN204]. See, e.g., Katherine J. Strandburg, [What Does the Public Get? Experimental Use and the Patent Bargain](#), 2004 *Wis. L. Rev.* 81, 142-46 (2004) (arguing for a period of exclusivity for patents followed by a period where compulsory license would be available: "The initial exclusivity period would also provide an opportunity for inventors who have sunk significant research and development investments into complex research tools with simple applications to perform the research their inventions have made possible... [t]he exclusivity period would also provide some reference for the determination of a reasonable compulsory license").

[FN205]. Affordable Prescription Drugs and Medical Inventions Act, H.R. 1708, 107th Cong. § 3(a) (stating "Any person engaged in the manufacture and sale of any drug approved under [S]ection 505 or 512 of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 355](#), [360b](#)) for which a patent is still in effect shall report to the Secretary of Health and Human Services annually an audit of all financial information relevant to the pricing of that drug nationally and internationally, including, in formats specified by the Secretary, an accounting of the costs allocated to research and development of that drug, as well as costs allocated to other research and development activities. The Secretary shall transmit the reports filed under this subsection to the Congress."). Section 3 of the act also includes a \$25,000 monetary penalty for failure to submit the Report as required by subsection (a). *Id.*

[FN206]. This model follows the general format of Section 115 of the Copyright Act, the compulsory licensing provisions for non-dramatic musical works, and borrows greatly from the framework and language of House Bill 1708. [17 U.S.C. § 115 \(2001\)](#).

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