

The University of Akron
IdeaExchange@Uakron

Akron Intellectual Property Journal

Akron Law Journals

March 2016

IP and Health Care: New Drugs Pricing and Medical Mistakes

Jay Dratler Jr.

Please take a moment to share how this work helps you [through this survey](#). Your feedback will be important as we plan further development of our repository.

Follow this and additional works at: <https://ideaexchange.uakron.edu/akronintellectualproperty>

 Part of the [Health Law and Policy Commons](#), and the [Intellectual Property Law Commons](#)

Recommended Citation

Dratler, Jay Jr. (2014) "IP and Health Care: New Drugs Pricing and Medical Mistakes," *Akron Intellectual Property Journal*: Vol. 7 : Iss. 1 , Article 1.

Available at: <https://ideaexchange.uakron.edu/akronintellectualproperty/vol7/iss1/1>

This Article is brought to you for free and open access by Akron Law Journals at IdeaExchange@Uakron, the institutional repository of The University of Akron in Akron, Ohio, USA. It has been accepted for inclusion in Akron Intellectual Property Journal by an authorized administrator of IdeaExchange@Uakron. For more information, please contact mjon@uakron.edu, uapress@uakron.edu.

IP AND HEALTH CARE: NEW DRUGS PRICING AND MEDICAL MISTAKES

*By Jay Dratler, Jr.**

Sixth Annual Akron IP Forum, October 26, 2012

I.	Introduction: IP Law and Health Care.....	1
II.	Pricing Patented New Drugs Globally.....	5
	A. The Basics.....	5
	B. The Variables.....	6
	C. The Formula.....	7
	D. Some Results.....	8
	E. International markets.....	12
III.	Keeping Medical Outcomes Secret.....	15
IV.	Conclusion.....	18

I. INTRODUCTION: IP LAW AND HEALTH CARE

IP law is economic law. It restrains and prohibits unauthorized copying. But why? The answer is built right into our Constitution: “[t]o promote the Progress of Science and useful Arts”¹ When our Framers drafted that document, they understood “Science” as knowledge generally, as embodied in books, and “useful Arts” as what we call “technology” today – the subjects of copyrights and patents, respectively.

How does IP “promote” these things? Our IP Clause answers that question, too: “by securing to Authors and Inventors for limited Times the exclusive Right to their respective Writings and Discoveries.”² When our Founders wrote “exclusive Right,” they meant what we mean today when we say “legal monopoly.”

* Goodyear Professor of Intellectual Property, Emeritus, University of Akron School of Law.

1. U.S. CONST. art. I, § 8, cl. 8.

2. *Id.*

Similar rationales for trade secrets and trademarks came much later, through organic common-law development. Legal protection of trade secrets encourages advances in technology that cannot or will not be patented,³ and trademarks encourage investment in convenient and reliable brand identifiers that high-population consumer societies like ours (which our Founders never knew) need to avoid chaos in the marketplace.⁴

Our Framers were not ignorant of how monopolies work. They did not use modern economic terminology because much of it had not yet been invented. And they certainly did not use quantitative methods. Adam Smith had just published *An Inquiry into the Nature and Causes of the Wealth of Nations* in 1776, as we were starting to fight for our independence.

But our Framers knew all about how monopolies raise prices, stifle commerce, and impede innovation. The lawyers among them, who were many, knew from the old English Statute of Monopolies.⁵ That venerable statute already had prohibited monopolies, with an exception for patents on “new Manufactures,” for a century and a half.⁶ The businessmen, like Ben Franklin, knew these things from practical experience and from reading.

That is why they inserted the words “for limited Times.” We do not know for sure, but this phrase probably arose from a famous colloquy, by letter, between Thomas Jefferson and James Madison when Jefferson was our ambassador to France.⁷ Ever the populist, Jefferson hated monopolies because they raised prices and hurt the people.⁸ He wanted to include a prohibition against them in our Bill of Rights.⁹ Madison convinced him that, as Jefferson himself later put it, “ingenuity should receive a liberal encouragement.”¹⁰

The result was our IP Clause with its time limitation. That limitation curtails the bad effects of monopolies by putting the subjects

3. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 485 (1974) (“Trade secret law will encourage invention in areas where patent law does not reach, and will prompt the independent innovator to proceed with the discovery and exploitation of his invention.”).

4. 1 JAY DRATLER, JR. & STEPHEN MCJOHN, *INTELLECTUAL PROPERTY LAW: COMMERCIAL, CREATIVE, AND INDUSTRIAL PROPERTY* § 1.02[5] (2014); 3 *id.* § 9.02[1].

5. See Jay Dratler, Jr., *Does Lord Darcy Yet Live? The Case Against Software and Business-Method Patents*, 43 SANTA CLARA L. REV. 823, 829-30 (2003) [hereinafter *Darcy*].

6. *Id.* at 826-28.

7. See generally *Graham v. John Deere Co.*, 383 U.S. 1, 7-8 (1966) (for citation to, discussion of, and quotations from this correspondence).

8. *Id.* at 7.

9. *Id.* at 7-8.

10. *Id.* at 8.

of copyright and patent protection in the public domain, eventually. There they can be copied freely, so that others can use them to innovate or make their own “riffs,” after the short period of monopoly has done its job: providing economic incentives for innovation or creativity.

Jefferson, to whom we owe our IP Clause, was smart enough to keep two seemingly contradictory things in his mind at the same time. He probably drafted the Clause that authorizes IP law, but he also knew how important copying was to the progress of knowledge and technology.

He had no idea how important copying would be in a modern consumer society where millions of people daily enrich their lives with identical machine-manufactured products, or (today) bits and bytes copied automatically and identically and transmitted electronically. But he understood the principle. In a famous passage in one of his letters,¹¹ he described how knowledge propagates in our species by a process of sharing from person to person, which he analogized to one candle being lit from another. If he had thought about it, he probably would also have mentioned the flowering of baroque music, whose composers all copied shamelessly from each other and their own earlier works.

So our basic law and our Framers’ wisdom recognize that IP law is economic law. Where it outlaws copying, copying becomes *malum prohibitum* – wrong because outlawed, for economic reasons – not *malum in se*, or wrong in itself.

That is why I wince when I hear the RIAA (Recording Industry Association of America) and its public-relations people analogizing unauthorized downloading to stealing. We may need to outlaw it in order to have any music industry at all, and we may need to have harsh sanctions in order to get that point across (the jury is still out on the latter point, often literally).

But it is not “stealing.” An illegal downloader takes nothing but hoped-for revenue from the copyright owner, and nothing at all from other music listeners. She is like the borrower of Jefferson’s “taper” (candle), who uses it to light her own so she can grow wiser but leave the other candle still lit brightly.¹² We prohibit downloading for economic reasons, nothing more.

Our Founders wrote succinctly and with a broad brush, on IP as on everything else. They left it for future generations to flesh out the details

11. See Scott Carpenter, *Thomas Jefferson on Patents and Freedom of Ideas*, MOVING TO FREEDOM (Oct. 6, 2006), <http://movingtofreedom.org/2006/10/06/thomas-jefferson-on-patents-and-freedom-of-ideas/>.

12. *Id.*

and make necessary adjustments from time to time. But they left no doubt that economics – not some moral command or prohibition – is the motivating force behind and the lodestar for IP law. We should take these basic principles, so clearly enshrined in our Constitution, to heart as we continue to apply IP law to rapidly changing technology in a rapidly changing global economy.

Perhaps belatedly, the Supreme Court and Congress are starting to do just that. They are beginning to question whether patents on abstractions and basic research are good things¹³ in a global economy where innovation in ideas proceeds at light speed, often over the Internet, and where we now know that the basis of life itself is abstract information, which we can store in electronic databases. They are beginning to take seriously the question whether we should encourage non-practicing “troll” corporations,¹⁴ often set up by lawyers who know little or nothing about engineering or science, to use stale patents to bleed and impede innovators who do.

As we address these important questions, we must rely more and more on economic analysis and economic studies, as “dismal” as that science may be. We must do so not just because our Framers left clear signals that that is what they intended. We must do so because we now live in a fiercely competitive global economy. If we do not get our economics right, others will get theirs right and surpass us, more quickly than we can imagine.

So how do we apply these principles to healthcare? I propose to address briefly two important IP questions from an economic perspective: patented drug pricing in an international context and trade secret protection for health care outcomes. The first will involve some algebra; the second involves a bit of common sense that so far seems to have eluded us.

13. For a nine-page mathematical demonstration why this is generally not a good thing, see Jay Dratler, Jr., *Combinatorial Mathematics and the Problem of Early-Stage Patents in Biotechnology* (Univ. of Akron Sch. of Law Legal Studies Research Paper Series, Paper No. 07-02, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=959462 [hereinafter *Combinatorial*].

14. The operative word here is “beginning.” After years of effort, and with apparent prospects for success, an anti-troll bill failed in Senate maneuvering due to opposition from “big pharma,” some universities, and other risk-averse stakeholders that prefer the status quo. See Dan D’Ambrosio, *Patent reform fight ends in retreat — for now*, USA TODAY (July 9, 2014, 11:14 AM), <http://www.usatoday.com/story/money/business/2014/07/08/patent-troll-legislation-fight/12392453/>.

II. PRICING PATENTED NEW DRUGS GLOBALLY

A. *The Basics*

Everyone who studies IP, including those like me¹⁵ who have become skeptical of ever-broadening patentable subject matter, knows that patents are a *sine qua non* of pharmaceutical innovation. They are essential for a simple and compelling reason: developing new drugs is extremely expensive.¹⁶

Not only do drug innovators have to create something new, safe, and effective, they also have to prove it is safe and effective in large-scale clinical trials that are among the most complex, tricky, and expensive things that any industry does. If copiers could take the results of this long, risky, and expensive process and copy the pills, incurring only manufacturing and distribution costs, they would drive innovators out of business and investors in drug innovation away. Then we would not have any pharmaceutical research or innovation at all. So the pharmaceutical sector is the paradigm of a patent-driven industry.

But that is just the beginning of the analysis. The pharmaceutical industry is also a matter of life and death, or at least longevity and quality of life, for millions of patients with various diseases and conditions. The more widely we can distribute safe and effective new drugs, and the cheaper we can make each pill, the more lives we can save and the more patients we can benefit.

This is a classic case of “tension” between fundamental values: innovation and its human benefits, which would not be possible without the innovation.

As we now know, when values are in tension, the best approach is not to pick one or the other as the one you like best. The best approach is to dig deeper and see if you can discern in more detail how the tension between values actually works in practice. Then you may discover where and how to adjust the system, and whether and when you need to compromise the two values, in order to produce optimal benefit, or at least minimally acceptable results.

15. See generally Jay Dratler, Jr., *Fixing Our Broken Patent System*, 14 MARQ. INTEL. PROP. L. REV. 47, 56-57 (2010); *Combinatorial*, *supra* note 13; Jay Dratler, Jr., *Invention is a Process, or Why the Electronics and Pharmaceutical Industries are at Loggerheads over Patents* (Univ. of Akron Sch. of Law Legal Studies Research Paper Series, Paper No. 06-13, 2006), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=899924 [hereinafter *Process*]; Jay Dratler, Jr., *Alice in Wonderland Meets the U.S. Patent System*, 38 AKRON L. REV. 299 (2005); *Darcy*, *supra* note 5.

16. For my own recognition of these points, see *Process*, *supra* note 15, at 1-2 & n.3, 17-19.

In the case of new pharmaceuticals, that digging requires a little math and an arithmetic table. But that is a good way to see the relationships between the key economic variables that drive pharmaceutical innovation.

B. The Variables

In abstract principle, it is easy to see what factors help patents drive innovation in pharmaceuticals and effect patient benefits. Patents are vital because innovation is so expensive. So the key variable for justifying patent protection is development cost, including the cost of clinical trials.

A Tufts University study about a decade ago put this cost at \$ 0.8 billion per new drug.¹⁷ The study is a bit outdated, and the cost has probably risen. Since \$1 billion is a nice round number and we are interested primarily in rough quantitative trends, not detailed economics or business analysis, we will use it.

Another study estimates that, for every five developmental new drugs that make it to clinical trials, only one succeeds.¹⁸ It is not clear whether this point refers to large-scale clinical trials, which are by far the most expensive stage of drug development. So as a rough educated guess, assume a total development cost, including begun but failed development projects, of \$ 2.5 billion for each new drug. For abstract use in formulas, designate this cost as “D,” the development cost.

That is a lot of money. In order to invest it, investors must expect not just to recover the development cost, but to get what economists call a “risk premium” as well. To put it another way, if investors did not get more than their development cost back, they would earn nothing and would not make the investment in the first place.

In modern business terms, what they require is a positive annual “rate of return” on their investment, which we will designate by the letter “R.” It is often expressed as a percentage, but in calculations the corresponding decimal fraction is used. (You can think of R as an

17. Press Release, Tufts Ctr. for the Study of Drug Dev., Tufts Univ., Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at \$802 Million (Nov. 30, 2001), (on file with author).

18. See Henry Grabowski, *Pharmaceuticals: Politics, Policy and Availability: Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUB. POL'Y REV. 7, 9 (2003) (citing Joseph A. DiMasi, *Success Rates for New Drugs Entering Clinical Testing in the United States*, 58 CLINICAL PHARMACOLOGY & THERAPEUTICS 1-14 (1995) (“[o]nly 20 percent of the compounds entering clinical trials survive the development process and gain FDA approval”)).

interest rate that a bank would pay if it paid as well as a risky investment in new drugs. It fixes what the development money would return if invested in such a bank account, drawing interest at the rate of return for twenty years – the patent term – compounded annually.) For the moment, keep R abstract, a dependent variable.

The independent variables are easier to identify. The drug company must incur the cost of manufacturing and distributing the pills, which we will lump together into a single independent cost variable, “ C .” For ease of handling, we will consider this cost to be the per-patient annual cost of treatment, so we do not have to keep track of dosage, the number of pills used per year, or their individual cost.

Finally, we have a very important independent variable: the number of patients, “ N ,” who need the drug. Pharmaceuticals are unique products in one respect: *medicine*, not marketing, largely determines their market size, because only patients who have a particular disease or condition and are likely to benefit will buy the drug. Marketing and customer preferences, which are important for other types of products, are negligible in comparison. (Some people will not endure the side effects or will not take the pills for religious, personal or other reasons, but we can ignore them for now.)

The two *dependent* variables are the rate of return, R , and the per-patient price in dollars, “ P ,” of a yearly course of treatment. We want to see how their relationship varies depending on the size of the market, N , and the per-patient manufacturing and distribution cost for an annual course of treatment, C .

The patent term is twenty years, and we assume the drug maker is clever enough to begin making and selling the new pills just as it starts. That assumption is unrealistic, but not wildly so. Anyway, it disadvantages the investors, but it compensates for the fact that we are not going to consider the impact of post-patent-expiration sales of the generic drug, which advantage them. (We do not know that these two effects actually cancel each other, but at least they cut in opposite directions.)

C. The Formula

With this introduction and explanation, we can now derive a simple formula for pharmaceutical investment. Over the twenty-year period of patent protection, the revenue coming back to the pharmaceutical company is as follows:

$$\text{Patent term revenue} = 20 * N * (P - C) \text{ [Equation 1]}$$

That is, the pharmaceutical innovator's revenue from selling the new drug over the patent's term is twenty times the number of patients needing it, times the difference between the annual price charged for the drug and the annual cost of its manufacture and distribution. (This analysis neglects likely changes in those variables over the course of the patent's term; but, again, we are looking for general quantitative trends, not precision in any particular case.)

Money is neither created nor destroyed, except by bankers. So the revenue or money coming in must equal the money going back to investors, or the investors' development cost, D , inflated exponentially by their annual rate of return, R . Thus,

$$D * (1 + R)^{20} = 20 * N * (P - C) \text{ [Equation 2]}$$

(For ease in typography and format-free electronic transmission, we use computer programming symbology, in which $*$ denotes multiplication and $**$ denotes an exponent, here taking $(1+R)$ to the twentieth power.)

This formula shows how the investors' rate of return, R , depends on the price charged for the new drug, P (for an annual course of treatment), the annual cost of making and distributing it, C , the size of the patient market, N , and the cost of development D , which we assume to be \$2.5 billion.

This formula is general but not entirely accurate. It neglects the effect of economic price inflation on both sides of the equation. That is not too bad for R , for you can think of R as an inflation-adjusted rate of return, i.e., a rate of return reduced by the rate of inflation. It does neglect the effect of inflation on the cost C , plus the fact that the seller might increase the price to compensate for cost inflation. But the formula is still not too bad, as P will usually be quite a bit larger than C in order to recoup the huge development expense, let alone at a decent rate of return.

D. Some Results

If as a math-hating law professor you have not fallen asleep yet, you are now in for a treat. We can get to the fun part: the results.

We are not going to do much with the manufacturing-and-distribution cost, C , so let us assume a constant \$100 for all our results. That is $\$100/365 = 27$ cents a day, or per pill if patients take one pill a

day. That is high today, but it may be more realistic as we get more into “personalized medicine” with differing, personalized formulations designed for each patient’s genome. Now our formula becomes:

$$\$2.5 \text{ billion} * (1+R)**20 = 20*N*(P-\$100) \text{ [Equation 3]}$$

You cannot tell much just by looking at this formula, so we will study a table of results.

Table 1 shows how the annual per-patient price of treatment P (in dollars, rounded to the nearest whole dollar) varies with the market size N and the rate of return R. Our minimum R, 5%, is about the lowest any investor in pharmaceutical innovation would accept today. Riskless Treasury bills for twenty-year terms, if they existed, would now pay around 2% to 2.5%, so the “risk premium” for our huge twenty-year investment would be only 2.5% to 3%. That is small. (We have also tried to account for the risk of development failure by inflating the successful single-drug development cost D 2.5 times to account for failed projects. But there is always more risk in estimating risk, and savvy investors would demand compensation for it.)

Table 1: Annual Treatment Price as Function of Rate of Return and No. of Patients

Annual Rate of Return	N=500,000	N=1 million	N=5 million	N=10 million	N=50 million
5%	\$763	\$432	\$166	\$133	\$107
10%	\$1,782	\$941	\$268	\$184	\$117
25%	\$21,784	\$10,942	\$2,268	\$1,184	\$317
50%	\$831,414	\$415,757	\$83,231	\$41,666	\$8,413

Two things are apparent from the table. First, the treatment price depends dramatically on the market size: the larger the market, the cheaper the pills. As you get to markets of fifty million patients, the cost of treatment comes close to the cost of manufacture and distribution, which we assume to be \$100. It even comes close to cost for a relatively high rate of return of 25% – a rate that investors in today’s flat market would kill for (as long as the risk of no return is properly accounted for).

On the other hand, as the number of patients N gets low, especially

as low as 500,000, the cost of treatment soars, even for low rates of return. That is why, among other things, we have special legislation on “orphan” drugs, providing beyond-patent exclusivity to induce their development and sale.¹⁹

In a free-market system, that is not a matter of corporate greed, but simple business economics. The only realistic alternatives are a government subsidy of research on orphan drugs, financed by taxes,²⁰ or development financed by private philanthropy.

The second thing evident from Table 1 is how the annual price of treatment depends even more dramatically on the rate of return on investment. That is due to the exponential rise in total dollar return with rate of return. As the rate of return goes up, the incentive to invest goes up, but so does the treatment price, dramatically.

If patients must pay for pills themselves, some get priced out of the market and suffer or die. If insurance pays, the patients get saved, but premiums go up and everyone pays more.

Our Supreme Court has rightly recognized that patent (or copyright) protection confers only a *legal* monopoly, not an economic monopoly.²¹ But new drugs differ from other patented products. If (as is often the case) they are the only effective way to treat a particular disease, the patent confers an economic as well as legal monopoly, for patients have to buy from a single source (the lone pharmaceutical innovator) or suffer or die. That is pretty strong market or monopoly power.

Coupled with Table 1, these facts put the policy question in stark relief. Should government intervene and limit or control the maximum rate of return that investors can get, and thereby limit new-drug prices?

In a free-market system, the traditional answer is, “no, let the market decide.” But with new drugs, moral considerations inevitably intrude. If patients pay themselves, some will suffer or die if the price is too high. If insurance pays, everyone will pay more.

Market economics cannot answer these questions because there is no right or ability to “take it or leave it,” as with ordinary commodities. If we (or they) want to save patients, we *have* to take it. So for a

19. See Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in relevant part at 21 U.S.C. §§ 360aa-360ee (2012)).

20. The Orphan Drug Act permits such grants but does not require or appropriate funds for them. See 21 U.S.C. § 360ee(a).

21. See *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44-46 (2006) (“[A] patent does not necessarily confer market power [upon the patentee] . . . and therefore [we] hold that, in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product.”).

uniquely effective new drug, the new-drug patent monopoly gives investors the power to raise prices as high as their pocketbooks demand and their consciences allow. (The law of supply and demand imposes some limitations, discussed below, but only after some patients cannot afford the new drug and so suffer or die.)

In a paper this short, there are only two observations worth making. First, these issues are essentially issues of public policy, outside the traditional sphere of IP. Lawyers cannot solve them just by applying the law.

Second, and even more important, economics is also of no help here. There is no way for economics to decree a “right” rate of return, any more than the law can determine a “just price.” The market is supposed to fix those things, but, as we should know by now, the market is amoral and lacks human values.

There are lots of scientific, medical, chemical, engineering, and manufacturing risks in new-drug development and production that this simple model cannot take into account. The higher those risks, the higher the rate of return rational investors will demand, and the higher the drug price will be. And we know of no way, at present, of estimating, let alone quantifying, what fraction of their demand comes from reasonable risk assessment and what fraction comes from sheer greed.

At the margins, where risks and prices get high and people start to die, the only known solutions are: (1) private philanthropy, (2) government subsidy, (3) or government price controls, which inject politics into economics and, if too crude, risk killing the research goose that lays the golden eggs of new drugs.

This analysis shows why we will not ever have relief from interminable political squabbles about drug prices, unless our plutocrats get so rich that their philanthropy can pick up the entire tab – an unlikely prospect. With our guesstimated \$2.5 billion development cost, D , even Bill Gates’ or Warren Buffet’s \$30 billion dollar gift would support only a dozen new drugs.

As genomics and personalized medicine advance, science is likely to make hundreds of new drugs possible and useful in the next two decades. Someone will have to decide which ones get developed and which do not. If policymakers do not decide, private investors will. Private philanthropy, while helpful, simply cannot fill the gap. As these formulas and tables show, the two most important determinants of pricing will be the number of patients who need a new drug and their ability to pay, as perceived by investors.

The most basic law of economics is “there is no such thing as a free lunch.” *Someone* has to pay the enormous costs of new drug development, which will only get higher as advances in medicine and medical technology bring with them enormous demand for personalized drugs. And *someone* has to decide where to put the money we can spare. If we do not develop rules, or at least guidelines, for deciding rationally, powerful people’s personal preferences – or what conditions their kids have – will determine haphazardly which of us will suffer or die although modern medicine could, in theory, save us.

E. International markets.

This brings us to the cause célèbre of the last few years: international markets in new pharmaceuticals. Sixteen years after the TRIPS Agreement’s adoption, all the transition periods have passed.²² Now every country – whether least developed, developing, or developed – is supposed to have patent protection for pharmaceuticals, both products and processes.²³

Almost all do, and “big pharma” has the money and the incentive to file for patents in every market it deems important. In every such market, the TRIPS Agreement obligates the relevant jurisdiction to recognize and enforce patent protection, unless a few rarely-used exceptions for public order and public health apply.²⁴

In this context, the possibilities for investors in new drugs to recover their investment with an attractive rate of return are nearly endless. They can pick and choose from 160 different markets in which to manufacture and distribute,²⁵ or to license manufacture and distribution of their new drug. In some of those markets, they may have to leap new regulatory hurdles for the drug itself or (more likely) its local manufacture. These hurdles impose new development costs, while each market creates a new source of revenue.

Our simple formula in Equation 2 obviously will not suffice for the general case. But we can expand it with a few restrictive but often realistic assumptions.

22. See Agreement on Trade-Related Aspects of Intellectual Property Rights art. 65, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994) [hereinafter *TRIPS Agreement*].

23. *Id.* at art. 27(1).

24. *Id.* at art. 27(2). For enforcement procedures, see *id.* at art. 41-61.

25. As of July 24, 2014, the TRIPS Agreement had 160 signatory nations. *Understanding the WTO: The Organization, WORLD TRADE ORG.*, http://wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited July 24, 2014).

Suppose that a single entity, the drug developer, owns the patents and all the manufacturing and distribution facilities in countries 1 through M, including the home country of original development. And suppose the regulatory costs outside the home country are negligible in amount compared to the regulatory costs at home. Since the TRIPS Agreement demands uniform patent terms of twenty years,²⁶ our formula becomes:

$$D*(1+R)**20 = 20 * \sum [N_i*(P_i-C_i)], \text{ [Equation 4]}$$

where the “ \sum ” term is the sum from $i = 1$ to M of the revenue from the various countries, namely, $20*N_i*(P_i-C_i)$, assuming the patient market, price and cost will differ in each. (For typographical reasons, I do not show the range limits for the variable “ i ” in the usual places, at the bottom and top of the capital sigma.)

As this formula suggests, the international context multiplies both the humanitarian opportunities and the policy choices. Suppose, for example, that the home country, $i = 1$, has a rich enough and big enough patient population to support drug prices there that provide an ample rate of return, “ R_1 ,” by themselves. Then:

$$D*(1+R_1)**20 = 20*N_1*(P_1-C_1) \text{ [Equation 5]}$$

In that case, the other nations, 2 through M, need not add anything to the investors’ return, thus:

$$\text{For } i = 2 \text{ through } M, 20*N_i*(P_i-C_i) = 0, \text{ or } P_i = C_i \text{ [Equation 6]}$$

That is, our hypothetical single entity could then sell the new pills in every country in which it does business outside the home country at cost, i.e., at a price no higher than the manufacturing and distribution cost in that country. In our example we assumed that to be 27 cents per day for the home country, but in less-developed countries it might well be less. This strategy could save millions of lives around the world and still give the single entity’s investors a satisfactory rate of return.

But of course life is seldom so simple. No home country is so rich that all patients who need a drug can afford it. If insurance pays, everyone pays. So our strategy that seems so simple from the investors’ viewpoint would probably generate lots of pushback from patients and insurers in the home country.

26. *TRIPS Agreement*, *supra* note 22, at art. 33.

There are other options the single entity and/or its investors could take. They could charge higher prices in other countries and enjoy a higher rate of return on their investment. They could raise prices in the home country, sell the pills below cost in other countries and still make a reasonable rate of return. They could sell the pills at the same price in all countries, pricing many patients out of the market in many countries, and make a huge rate of return. (We assume here that the home country is highly developed and relatively rich and the other countries more populous and relatively poorer. For example, think of a two-country model with the United States as the home country and India as the chief foreign market.)

Nothing in market economics can decide among these models. In a free market system, investors decide based on their pocketbooks, consciences, and business resources, and patients influence their decisions through collective action (remember the street marches by and for AIDS sufferers?), economic pressure, and political pressure.

In administrative systems, administrators might make or influence the decisions. But the TRIPS Agreement gives them little legal leeway to deviate from free-market principles. And if they are smart, they will not stray too far from good economic principles anyway because doing so would discourage operations inside their borders. (If one country offers a higher local rate of return on investment than another, guess where investors and their hired factories and expertise will go.)

So again we have a set of moral and public-policy questions. They are really outside the purview of IP law, although their parameters and limits depend on it. In a global free-market system, now with enforceable IP law under the TRIPS Agreement, investors who fund pharmaceutical innovation are free to charge what the market will bear, to gouge some markets and coddle others, and to make as big a rate of return as their greed demands and consciences allow.

The only *economic* limit on investors' rate of return is the law of supply and demand. As the rate of return increases, so does the price of treatment. As it rises, it may force some patients and/or insurers from the market. At some point, the increasing price per pill and decreasing N may cause total revenue to drop, thereby also dropping the rate of return. But because we are talking about life-saving pills, not jelly beans, social and political pushback will probably come long before that point.

To my knowledge, there is no framework of international law, or even custom, that comes close to resolving these issues. There are only the few exceptions in international conventions, including the Paris

Convention²⁷ and the TRIPS Agreement,²⁸ for public order and public health. And they are seldom used, simply because it is one thing to decree a patent forfeiture or commandeered license and quite another to find a competent firm that will manufacture and distribute a commandeered drug safely and effectively and at a price set by politics.

In an ideal world, there would be some international consensus on international manufacture and sale of important new drugs, providing guidelines that maximize both returns for investors and relief for patients. The international effort to distribute retroviral drugs to slow the HIV epidemic in Africa might be a model, or at least a starting point, for such guidelines. Economics can be helpful in showing the various stakeholders what the effects of different models might be, but it cannot resolve the moral, ethical, and public-policy questions. Nor can IP law. Only bargaining through a political process can do that.

III. KEEPING MEDICAL OUTCOMES SECRET

Another point of intersection between IP law and health care is a case study in the transition from common law to statutes. That is the increasing use of trade secret law to keep medical outcomes and records of success or failure secret.

Take a simple example. Suppose a leading health-care provider has a poor record of success with a particular standard surgical procedure.²⁹ Its rates of mortality and morbidity are above average, and it has a far higher than average rate of nosocomial (hospital-acquired) infection.

Accrediting organizations like JCAHO³⁰ have access to this information by virtue of their accrediting power. If they do not get it, they will not accredit the provider, with obvious adverse effects.

But what about the public? What about admitting doctors, patients and prospective patients? What about other providers? What about newly-minted doctors in the field who are deciding where to practice?

27. See Paris Convention for the Protection of Industrial Property art. 5A(2)-(5), 21 U.S.T. 1583, 828 U.N.T.S. 303 (as last revised at the Stockholm Revision Conference July 14, 1967).

28. *TRIPS Agreement*, *supra* note 22.

29. The observations that follow do not apply to innovative procedures and experiments. Publishing their results prematurely might inhibit innovation by drying up research funds or producing inappropriate political or professional pressure. The type of "procedure" I have in mind here is a routine surgical operation covered by widely available best practices guidelines. There are many such in medicine today.

30. JCAHO, the Joint Commission on Accreditation of Health Care Organizations, is a nonprofit corporation that reviews and accredits health-care providers. See *Definition of JCAHO in the Medical Dictionary - JCAHO*, THE FREE DICTIONARY, <http://medical-dictionary.thefreedictionary.com/JCAHO> (last visited July 24, 2014).

Can they get this information?

Today, the answer is often no. One reason given is that these data are “trade secrets” of the hospital, medical group or even doctor in question. But does this reason make sense?

If you look only at the wording of the Uniform Trade Secrets Act, which nearly all 50 states have adopted – 47, to be exact³¹ – you can make a good argument that it does. The definition of “trade secret,” which I quote verbatim in the footnotes, has three elements: (1) relative secrecy, (2) economic value by virtue of secrecy, and (3) reasonable efforts to keep the secret.³²

Any health-care provider with the poor records assumed would probably satisfy this statutory definition, literally interpreted. To preserve its reputation and avoid bad publicity, it probably keeps the bad data relatively secret, or, as the statute says, not “generally known” and not “readily ascertainable.” If it did not, it would lose patients and doctors and probably not be doing that procedure much longer. For the same reason, it probably devotes *more* than reasonable efforts to keep the secret. Thus it probably satisfies prongs (1) and (3) of the definition of “trade secret.”

But is the poor performance record *really* a trade secret? From a statutory perspective, the bodies are buried (literally!) in the second requirement: economic value by virtue of secrecy.

Again, a literal interpretation of the words alone seems to fit. If the secret gets out, the provider and alleged trade secret owner will suffer economically. For the provider, it is better off if the secret stays secret. Competing providers would benefit by getting the information and making it public, because terrified patients would come to them. So at first glance the secret has competitive value, too – the touchstone of prong (2).

But does that mean the secret has the kind of “value” that trade secret law recognizes? To the provider trying to keep it, it has value only in a negative sense. It is well known that negative results in *science or engineering* – the fact that an experiment or line of inquiry did not

31. See 2 DRATLER & MCJOHN, *supra* note 4, § 4.01[3][b] (table of adopting jurisdictions, with citations).

32. UNIF. TRADE SECRETS ACT § 1(4) (1985) (“‘Trade secret’ means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.”).

work – can be a trade secret.³³ But is this the same sort of negative information?

I think not. The negative result of an experiment can be a trade secret because experiments cost money. The alleged trade secret owner's investment in the experiment has "economic value" because it provides knowledge of something that cost money to discover, and because he can now pursue alternative lines of inquiry, or drop the whole line of research without wasting more.

While keeping the secret from competitors might encourage them to invest in duplicative and useless experiments, allowing them to steal the secret with impunity would let them reap where they have not sown. Doing *that* would discourage everyone, at the margins, from investing in high-risk experiments, i.e., those with a high probability of a negative outcome. It would thus discourage research that ultimately leads to innovation after a few false starts.

The purpose of protecting trade secrets is much the same as for patents. Protection encourages investment in innovation and prevents what economists call free-riding on someone else's investment.³⁴

But that is not what protecting our hypothetical bad-performance secrets does. Poor medical performance of the type we are discussing is not the result of investment in innovation. Often it derives from a *failure* to innovate or a simple failure to follow standard procedures, such as having doctors wash their hands.

And protecting the secret encourages precisely the wrong behavior: sloppy and substandard health care. In this case *releasing* the secret would have a better result: encouraging poorly performing providers and doctors to clean up their act (through loss of custom and public pressure, if nothing else), and giving patients and admitting doctors an incentive to seek better results elsewhere until they do. *Cessante ratione legis, cessat et ipsa lex*.

If trade secret law were still common law, as it was in the beginning,³⁵ no competent judge would entertain this claim for long. But something – including judicial flexibility – was lost in the translation from common law to statute. The rigidity of the statutory language at issue permits credible arguments that mistakes can be hidden

33. See 2 DRATLER & MCJOHN, *supra* note 4, § 4.02[2][b].

34. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 485 (1974) ("Trade secret law will encourage invention in areas where patent law does not reach, and will prompt the independent innovator to proceed with the discovery and exploitation of his invention.").

35. See *Tabor v. Hoffman*, 23 N.E. 12 (N.Y. 1889) (paradigmatic common law, trade secret case).

behind a veil of legal secrecy. Closer examination suggests an obvious truth: that trade secret law, like IP law generally, is there to encourage innovation, not hide mistakes.

That is why, among other things, we will always have and need human judges and at least a residue of the old common law. The ambiguity and other limitations of human tongues preclude statutory drafters, no matter how provident or clever, from ruling out in advance all the specious arguments that lawyers may later make based on statutory language once set in print. Only judges can make sure the process of putting policy principles into words does not transgress common sense.

IV. CONCLUSION

This short paper deals with two very different issues. The first is how to spread the benefits of exorbitantly expensive pharmaceutical research in a globalized economy based on free-market principles and IP law. The second is whether doctors can hide their mistakes and poor performance behind the IP law of trade secrets.

As unlike as they first appear, the two issues have some things in common. Both address the unintended consequences of laws that, in the abstract, are good and well founded. Both reflect the fundamental nature of IP law as economic law, and the crying need for economic and competitive analysis.

And both suggest that the law alone is not enough. In order to reach the law's abstract and theoretical objectives in practice, courts and policy makers must focus on how it actually works in the real world. In many cases – certainly in getting new drugs to patients who need them – that means knowing something about economics and how it impacts patient care. In some cases – as in refusing to let doctors keep their mistakes secret – it means not losing sight of common sense.

Old common-law judges used to do the latter pretty well, but they were often unversed in economics. Now judges and policy-makers have to do both – tasks that the density and rigidity of detailed statutory language often make difficult. If Congress (with its own economic staff and hired experts) cannot or will not do the job, perhaps it should appropriate money for judges to hire economic experts beholden only to them.³⁶

36. See FED. R. EVID. 706. This rule allows courts to appoint their own experts, as European courts often do. Our own courts do not lack the authority, just the money.