the University of Rochester was awarded a patent for a new class of drugs known as Cox-2 inhibitors, big pharma was concerned. There are lots of these stories.

4. Big pharma has been concerned about patents on genes, and this is also a huge problem for the competitive research community itself, as reported in this LA Times story.

Aggressive Patenting May Stifle Gene Discovery Benefits

> 1991, and the commencement of the trial on June 28, 1993, approximately five hundred forty-one pleadings have been filed and dozens of hearings on motions and discovery matters have been conducted by the court. The court has entered eighty- eight written orders and numerous bench rulings. Thus, the court is intimately familiar with the facts of this case and the legal contentions of the parties. To state that the case has been hotly contested would be an understatement. The parties have amassed learned, experienced and sizable trial teams who have represented their clients zealously and competently. The administrative complexity [of] conducting a trial of this magnitude has been enormous for the court and the parties. The sixty-year- old courtroom in New Bern, North Carolina, has been converted into a contemporary high tech facility utilizing real time court reporting and six computer-integrated video display monitors. It is highly conceivable that the cost of this trial for the parties exceeds $100,000 per day, in addition to the time and expense associated with this court and the jury. As the case enters its fourth week of trial, the parties estimate, somewhat conservatively the court suspects, that the trial will last an additional six to eight weeks.

9. See also this quote by Professor Michael Meurer: 3

> First of all, frequency of litigation and the cost of litigation for biotech patents is very high. Drug and health patents are litigated more than any other kind of technology. There is one empirical study that showed that six lawsuits are spawned by every 100 corporate biotech patents. There is also research that shows that most of the start-up companies are spending a comparable amount on legal costs to what they are spending on research. So this is a very big concern for start-up companies.

10. Given these facts, one has to ask how realistic it will be for poor countries to administer a good

big pharma agenda. Which is odd, because the WHO is supposed to be helping the poor, not protecting big pharma profits.

Considerations concerning parallel trade

13. Sellers of pharmaceutical drugs routinely engage in price discrimination. Differences in prices are typically a response to market issues, on the supply and demand side. Supply side issues include differences in marketing and distribution costs, including in some cases, taxes or tariffs. Not to be overlooked are the wide differences in financing arrangements, and the lack of confidence that purchasers pay timely, if at all.
14. Demand side issues include such items as (a) the income and ability of consumers to pay, (b) competition from generics or therapeutic alternatives, and (c) government price controls.
15. While most people think it would be better if the poor would pay less for medicines, often the contrary is true. In the USA, for example, the unemployed or uninsured pay much higher prices for medicines than do those who are insured and benefit from the ability of insurance companies and HMO's to use formularies to negotiate lower prices.
16. Many differences in prices are explained by the inefficiencies in the distributions systems. This is true for products that are on or off patent. Consider for example, the December 31, 1998 report in the Wall Street Journal, which indicated that US pharmacies routinely impose enormous mark-ups on retail prices of generic products (see the data tables at the end of this presentation). For example, Atenolol, a drug for high blood pressure, was sold by the generic manufacturer for $.62, and retailed by the pharmacy at $14.68, a 2,368 percent increase. In some countries pharmacy margins are regulated, but this too can introduce distortions. In Bangladesh low cost generic suppliers complain that pharmaceutics are reluctant to sell the least expensive products, because the retail mark-ups are smaller. There are also many perverse incentives at the point of prescription. In some countries, such as South Africa, doctors also dispense products, and earn substantial income from prescribing expensive brand name products. And of course there are countless stories all over the world of manufacturer kick-backs and gifts to doctors who prescribe products.
17. Methods of funding pharmaceutical drugs vary of course. In states with a large public sector role in paying for medicines, the government can and do negotiate, solicit bids or engage in other strategies to obtain favorable prices on products. The ability to speak for larger quantities is a plus in obtaining good prices.
18. Price controls are used in some countries, with very different methodologies and outcomes.
19. Intellectual property rules vary from country to country; particularly during the period before WTO rules are in place, but even within the WTO framework. The WTO rules in general provide minimum and mandatory rights for IP owners, and maximum and voluntary rights for the public. Rules on the scope and term of patents, and on a wide variety of sui generis rights, including those that are presented as regulatory measures, vary from country to country. As a consequence, products may be marketed as a monopoly in one country, and face competition in another.
20. As a consequence of any number of the above factors, prices for pharmaceutical products, brand name or generic, on patent or off patent, differ, between countries, and often within countries.
21. The price differences between countries create opportunities for cross border (parallel) trade.

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24. Competition is the single most important force to protect consumers on pricing issues, and

purchase state health insurance. The funding for the trust fund was to come from an auction of spectrum for wireless telecommunications.

32. In early 1995, Senator Specter introduced S. 18, the "Health Care Assurance Act," which, among other things, would have created a "Trust Fund for Medical Treatment Outcomes Research." This R&D fund would have been funded by a tax of .1 percent of the premiums on private health insurance. Later the same year, Senators Hatfield, Harkin, Boxer, Inouye, Simon, Kerrey, Mikulsk and Moynihan sponsored S. 1251, "the `National Fund for Health Research." The money for the fund would have come from an increase in the excise taxes on tobacco products. This bill also would have created a voluntary check-off system, whereby taxpayers could designate $1 of their tax refunds be donated to medical research.
33. In 1997, Senator Specter and others proposed, at the urging of Bristol-Myers Squibb, that the US government's Hatch/Waxman "data exclusivity" protections be extended from 5 to 10 years, in return for the government receiving 3 percent of a drug's revenues to be used for research, and a commitment that the company would spend another 3 percent on R&D.
34. Other countries have explored similar approaches. In the United Kingdom, the government permits higher reimbursement prices for pharmaceutical when companies have above average R&D expenditures. In several countries, including Canada, the drug companies have negotiated promises for increased R&D levels, in return for changes in public policy. In India, the government has tried to push for minimum levels of R&D investments, but has meet resistance. In Argentina, there are proposals in the domestic industry for a tax on pharmaceutical sales to fund an Argentine R&D program.
35. In the 1999 "Amsterdam statement to WTO member states on access to medicines," CPT, HAI and MSF called for a global agreement on R&D, and also endorsed the use of "compulsory research obligations, such as requirements that companies reinvest a percentage of pharmaceutical sales into R&D, either directly or through public or private sector R&D programs."
36. The advantages of mandates or strong linkage are many, including:
    1. Governments can determine by policy the aggregate level of R&D funding.
    2. Governments can determine the composition of R&D funding.
    3. It is possible to increase access to medicines and increasing R&D at the same time.
    4. The system can be as transparent as policy makers wish.
    5. Mixed funding models are possible. Governments can decide if R&D funds are invested by governments or companies or a combination of both.
    6. Mandates and strong linkage can be use in combination with other approaches, including intellectual property rights and direct public investment via general tax revenue.
37. Our general proposal for the global convention is one that would replace the TRIPS as it relates to medicine, and give countries direct obligations to fund R&D, according to their ability and stage of development, through the policy instruments that make sense for them. Any combination of high IPR and high consumer prices, public funding of R&D or mandatory R&D requirements could satisfy the obligation, so long as the member country actually did something to fund R&D. Others have proposed a convention that only deals with funding diseases for the poor, or just deals with a specific issue, such as the funding of vaccines for malaria, TB or AIDS. Some WTO officials think it should work within the TRIPS framework, and some public health groups think it should be a replacement for TRIPS. It would not have to be the convention that I would draft, but it is something that should be done, on some level. We have to begin to think about pro-active globalization initiatives to address the needs to the public, including the poor, rather than the needs of firms that are global. Even if we fail to adopt the best convention, we should try, because it is our job to try to do what is best for the poor, and also because the effort will help us put into perspective the value of alternatives. We can at a minimum create a yardstick to measure where we should be going. And with time, enough hard work and good will, we might surprise ourselves and change the world
38. Thank you for the invitation to address this gathering.

Attachment on Ramsey Pricing

The WTO paper discusses price discrimination for drugs in terms of Ramsey pricing, and others have addressed this. Ramsey is a term used first to describe issues in public utility regulation,

where there were big fixed costs and low marginal costs, and hence increasing returns to scale, and departures from marginal cost were necessary to recoup the fixed costs. Since marginal cost pricing would not meet the budget constraint of the enterprise, Ramsey and others (before him) examined the issue of how best to price the good or service. In particular, he focused on classic notions of economic efficiency, as measured by consumer surplus, and like most such analysis, ignoring distributional issues.

Ramsey's insight (he was not the first it turns out), was that pricing similar to a monopolist was economically efficient, if both could engage in price discrimination. The less elastic the demand for the good (the higher the willingness to pay), the less consumer (social) surplus that was lost. The Ramsey solution was not the monopolist solution, however, because Ramsey limited the increases over marginal cost to only that necessary to pay for the fixed costs. Ramsey would price according to what the market would bear, but only up to a point when the enterprise met its budget constraint. The Ramsey solution is often used to some degree by regulators, but with some limitations, because it has some problems.

One illustration of this is from the optimal tax theory, where it was quickly shown that a ramsey solution would involve shifting taxes away from many luxury goods, and more problematic, to things like life saving medicines. For example, under ramsey pricing, one would have *very* high taxes on insulin, and use this revenue to say pay for roads. Any medicine that treated a severe illness was a target for a Ramsey tax. The demand was "inelastic" because people really needed it. Not very many people thought this was a great way to design taxes. It turns out people do care about distributional issues.

Monopolies of one sort or another were fascinated with Ramsey pricing, because it provides a nice rationale for behavior that looked a lot like what a monopolist wanted to do. Thus, for example, in the early 80s the railroads claimed that deregulation of "captive" shippers of coal and grain, was "Ramsey efficient," because they were recouping fixed costs from those who had no alternatives, and hence, were relatively price inelastic. The railroads even got Ken Arrow to sign a letter on this. Price gouging (whoops, I mean Ramsey efficient pricing) of captive airline markets also leads to similar claims that this is just an efficiency justified pricing scheme (not a true statement, of course).

The big problem with Ramsey pricing is that everyone loves to push the price discrimination part, which is pricing according to what people are willing to pay, but there is considerably less enthusiasm for the other part, which is the budget constraint. And, without the government regulation of the budget constraint, you just have monopoly pricing, which is not in fact efficient, in most cases, not to mention the ethical issues, or the rather messy empirical realities of industry pricing practices.

So it is somewhat ironic that at the center of a debate over how to help the poor, we are showcasing theories of why letting big pharma engage in monopoly like price discrimination, without any price controls, is the answer.

Footnotes

1. 26 AIPLA Quarterly Journal 185 (1998)
2. Burroughs Wellcome Co. v. Barr Lab., 828 F. Supp. 1208, 1209 (E.D.N.C. 1993).
3. http://www.bu.edu/law/scitech/volume6/Panel2.htm. The text referred to studies by Josh Lerner, The Importance of Trade Secrecy: Evidence from Civil Litigation, paper presented to the Conference on the Economics of Intellectual Property Rights, ICARE Institute, University of Venice, Italy (October 6-8, 1994), and Jean O. Lanjouw & Mark Schankerman, Stylized Facts Of Patent Litigation: Value, Scope And Ownership 3 (National Bureau of Economic Research Working Paper No. 6297, 1997) (noting that crowded fields and new fields of technology generate more patent litigation); Jean O. Lanjouw & Josh Lerner, The Enforcement Of Intellectual Property Rights: A Survey Of The Empirical Literature 13 (National Bureau of Economic Research Working Paper No. 6292, 1997) (correlating number of times that a patent is cited in future applications to the value of the patent and noting that innovative technology patents are cited with increased frequency).
4. The US legislation on "reimportation" of pharmaceutical drugs, a limited and so far unused provision authorizing parallel imports, did not change US patent law.

Tables