Policies that ensure access to medicine, and promote innovation, with special attention to issues concerning the impact of parallel trade on the competitive sector, and a trade framework to support global R&D on new health care inventions.

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1. This position paper will examine several issues related to the creation of a global system that will accommodate the interests of the poor, while also supporting investments in R&D for new health care inventions. I will begin by briefly discussing problems in the "strong" IP regime, address issues relating to parallel trade, and then describe a proposal for a new global convention on R&D. In brief, I believe developing countries should be permitted to embrace weak levels of intellectual property protection on medicines, and specifically either exempt essential medicines from patent protection (certainly for the WTO's "least developed" countries), or use compulsory licensing liberally. The policy would ensure that prices for essential medicines would be close to marginal costs, a key policy objective, and one that I believe will only be achieved under this approach. Also, in the richer countries, there is a need to restrain pricing of medicines in order to extend treatment to uninsured groups and to expand access to medicines on formularies, and perhaps less appreciated, to address the growing problems of excessive levels of protection in new biomedical technologies, as well as the growing problem of evergreening of patents on older products. The combination of these policies would likely decrease big pharma drug company profits, at least to some extent. Moreover, at any level of company profits, there are still many important underfunded R&D projects, and much controversy over who should pay for R&D, even among the developed countries. I therefore review proposals for a global R&D convention, an issued raised by CPT, MSF and HAI in previous occasions, including for example the Amsterdam Statement.

Problems with the IPR system

2. The IPR system is a system of government regulation, and like any other system of government regulation, it looks better in theory than it does in practice. I think that everyone understands that patents create monopolies, and that this leads to high prices, which is the expected cost of the patent system and of course, and one way to pay for R&D. In 1999 Glaxo claimed to have re-invested 14.6 percent of its revenues in R&D, so for every dollar of drug sales, the global R&D budget increased by 15 cents, which is why we permit Glaxo to charge thousands of dollars per year for drugs that cost much less to manufacture. The WHO reckons that most patented medicines are sold at 20 to 100 times their marginal costs, so this is a fairly expensive way to pay for R&D, but it works. That is, it works if you can afford it. But as we also know, many cannot afford such an expensive mechanism to fund R&D, and we are here in Norway to consider the 90 percent of the global population that cannot afford to pay, including for example the 20,000 persons per month dying in South Africa of AIDS, while Glaxo and other big Pharma companies sue the South Africa government to keep cheaper generic AIDS drugs off the market.
3. There are also huge problems with the new medical technologies. Here big pharma itself is a consumer, because it licenses most of its technologies from the competitive sector, including universities and other government funded researchers. In the past, in a one patent one product world, this was not a huge problem, because big Pharma was needed to put marketing muscle behind a new invention, and it could license inventions for reasonable terms. However, in the new world of lower standards for patentability and the broader scope of new biotechnology patents, big pharma is facing growing problems in obtaining and consolidating intellectual property rights. When Columbia University tried to extend its biotech Cotransformation Patent, big pharma lobbied against the patent extension. They were paying royalties to Columbia University. When

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
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> LOS ANGELES TIMES -- WASHINGTON
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> In one of the landmark cases dealing with the controversy involving human gene patenting, researchers at the University of Pennsylvania argue that patent holder Myriad Genetics, a Utah company, used its ownership claims on two genes to stifle development of new tests and treatments for breast cancer.
>
> Early work on the genes, called BRCA1 and BRCA2, followed what used to be a familiar pattern. Scientists at several institutions raced to locate and decode the genes, which are linked to families with high rates of breast and ovarian cancers. Myriad, collaborating with the National Institutes of Health, got to BRCA1 first and later claimed it was first to BRCA2 as well.
>
> Researchers, including Pennsylvania University's lab research director Arupa Ganguly, followed up by developing tests for variations in the genes that can signal susceptibility to disease. By 1998, the Penn lab was performing more than 700 tests a year.
>
> That's when Myriad used its patent to pull the plug. It notified Ganguly and her colleagues that they could no longer do more than a handful of tests. The company also required the genes' co- discoverer, former NIH collaborator Phillip Futreal, to pay Myriad for tests he needed for his research. And it set a $2,580 fee for the test, more than twice that charged by most other labs, including Penn's.
>
> Recently, after a furor over the fee, the company relented and agreed to charge only $1,200 when federally funded research such as Futreal's is involved.

5. Another set of concerns are those relating to the practical issues in running a patent system. The first issue concerns what it costs to run a patent office. In the United States, it is $1 billion per year and growing. Not many developing countries can afford to spend a $1 billion to examine patents.
6. Despite these massive expenditures, the quality of US patent examination is poor. According to a study by Lemley and Allison of patents litigated to judgment, 54% were found to be valid, and 46% were invalid.[1]
7. Critics of US patent examinations believe a much larger number of issued patents are not valid under any reasonable tests of utility and invention, and would be busted if the patent owners sought enforcement. Patent examinations in developing countries, if they exist at all, are under staffed, under trained and have less access to research materials on prior art.
8. The costs of litigation are not trivial. In (December 27) 1998, the New York Times reported the median cost of US patent litigation was $1.2 million, per side, and the costs of litigation in complex cases is much higher. In Polaroid v. Kodak, each side reportedly spent over $100 million. Consider this quote from a Judge in the AZT patent dispute. [2]

> In the twenty-five months transpiring between the filing of the initial complaint in this consolidated patent infringement action on May 14,

> 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 patent system, and how reasonable is it to expect poor patents to be busted in developing countries? I believe the best evidence suggests that as in the Thai ddI patent case, bad patents will keep cheaper medicines off the market for years. The policy consequences are bad. The poor will face more IPR protection that the rich, because they will lack the ability to reject or bust bad patents.
11. I have written elsewhere that poor countries should adopt compulsory licensing or government use laws that are consistent with the TRIPS, but that suit the needs of the poor. They should be easy to use, nearly automatic in terms of getting the licenses or authorizing public use, and they should not permit the drug companies to tie matters up in court for years. Fortunately, the TRIPS permits this. Unfortunately, WIPO and the WTO give poor countries really bad legal advice. Indeed, I think the technical assistance on IPR issues borders on legal malpractice, because the advice benefits the big pharma companies, but not the poor who live in these countries. My own recommendations are on the web here: http://www.cptech.org/ip/health/cl/recommendedstatepractice.html. Compare my advice to the model laws that countries get from WIPO, and then ask yourself, who benefit the most from the WIPO versions? The poor or big Pharma? If the developing countries wanted to change things, they should give Carlos Correa a top job at WIPO.
12. Competition is what drives prices to marginal costs. If the global community wants the poor to have access to essential medicines at close to marginal costs, then there should be lots of compulsory licensing. You can have interesting discussions about the compensation to the patent owners under a compulsory license, but at the end of the day, public policy should not be a barrier to access. In the least developed countries, they should just not have patents on medicines. If you want to kill the competitive generics sector, then you force everyone to buy from big pharma, you link donor aid to purchases from big pharma, you subsidize big pharma exports to poor countries, you impose IPR systems that big pharma can manipulate, you do all of these things and more, and there are people in the WHO Commission for Macroeconomics and Health who are pushing this

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. WTO rules generally restrict the grounds under which countries can restrict cross border trade, and some legal scholars say that the provisions in the GATT obligate countries to permit cross border trade in pharmaceuticals. In any case, parallel trade in pharmaceuticals is only done to a limited extent.
22. Restrictions on cross border trade in pharmaceutical drugs are typically enforced though regulatory barriers. For example, in the US, the barriers to cross border (parallel) trade in pharmaceuticals are not based upon intellectual property rules, but rather on FDA health and safety regulation.[4]
23. The possibility of parallel trade can restrain pricing, and in general consumers in any one country benefit from the opportunity to seek out alternative sources of supply. There are arguments that the global free trade in pharmaceutical drugs (parallel imports permitted in every country) would lead to prices that are higher for some consumers, and there are other undesirable aspects to parallel trade as well, including problems with quality control and maintaining distribution systems. The reasons to consider parallel trade are to benefit from better prices in more competitive markets.

24. Competition is the single most important force to protect consumers on pricing issues, and consumers who live in countries with small internal markets or inefficient or monopolistic distribution systems can obtain very significant benefits from parallel trade, for some products. This is true for both government and private sector buyers of medicines.
25. If "big pharma" companies were to face extensive global parallel trade, a situation that is not the case outside of the European Union, they would be faced with choices when products are not protected by patents, sui generis or regulatory regimes in some countries, but are in others, or for whatever other reason there was more competition in some markets than others. If they lower prices in the competitive market, they face parallel trade back to the less competitive markets. The existence of parallel trade would restrain big pharma ability to lower prices. This would benefit the competitive sector, including the smaller domestic generics companies. To the extent that the competitive sector would achieve larger market shares on popular products coming off patent or other exclusivity restrictions, it would be larger and ultimately more efficient.
26. We support restrictions on parallel trade from poor countries to the United States, the European Union, Japan and other wealthy counties, and this is currently illegal in each of these countries. However, even if such trade was legal, poor countries would have options to protect consumers in the event that big pharma set a single global price for the rich countries. The poor countries could issue compulsory licenses to the competitive sector. This too would strengthen the generic sector in the developing countries. Extensive use of compulsory licensing the poor countries would drive prices closer to marginal cost, which is a good result from an ethical standpoint. Concerns about the appropriate burden sharing for global R&D would be addressed explicitly in the setting of compensation for the licenses. This would be a transparent and direct approach to the issue of supporting R&D.

Production for Export

27. Under the WTO TRIPS accord, the general rule is that compulsory licenses will be predominately for the domestic market. There are several provisions in the TRIPS that would permit exports. One way concerns Article 31.k, regarding anticompetitive practices. The US government uses Article 31.k extensively, and several developing countries are looking at Article 31.k as they revise their patent laws. The TRIPS council may also examine "production for export" exceptions to patent rights under Article 30, an issue that will be discussed in Brussels in the May TACD meeting.

Global convention on R&D

28. There are real concerns that downward pressures on pricing would lead to inadequate private investment in R&D, and even with higher rather than lower IPR protections, there is still too little invested in many important public health projects, including for example basic research, neglected diseases, adverse effects, health and the environment, appropriate technology, health care delivery systems, vaccines and many other important public health concerns. There are also concerns about the fairness of global burden sharing for R&D. What is needed is a global convention to obligate member countries to provide adequate contributions to R&D.
29. The WTO TRIPS accord was a response to IP owner lobbying efforts, and it addresses their concerns. But it is not about R&D, it is about the rights of property owners. The whole framework for the TRIPS is minimum property owner rights and maximum public rights. There are no obligations to fund R&D, just to enforce one mechanism that is a highly imperfect way to fund R&D.
30. Governments can and do mandate investments in a wide range of areas. For example, in the employment area, there have been various proposals for mandated investments in worker training. A recent example is the US H-1B program for temporary workers in the technology sector. Under this program the employer pays a fee of $500 for each employee, which is used for training and scholarships for US citizens. In the US banking sector, there is the "Community Reinvestment Act," which requires US banking institutions to invest in low income neighborhoods. This law was first passed in the 1970s, in response to criticisms that banks were "redlining" poor neighborhoods.
31. The government can also raise money from one part of the economy to address entirely different needs. For example, in 1997 US Senator Specter sponsored legislation (S. 435) to create to create a "Healthy Children's Trust Fund," to provide funds so that eligible children could get vouchers to

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