Essays on IPR and Health, Part 5

Nonoy Oplas
May 29, 2009

Introduction

Below are five of my recent short discussions on the subject, posted in my blog, http://funwithgovernment.blogspot.com. With A(H1N1) scare still on-going, there are lots to read and write on IPR and health these days.

Meanwhile, I tried searching in google the subject "IPR and health" because I wanted to read other materials on the subject, I was surprised that my two recent papers, "Essays on IPR and Health, part 4" and "Essays on IPR and Health, part 3" were in the top 5 of google's list! ☺

(1) IPR and Liberal economics

May 10, 2009

A German friend commented on my posting on "Drug price control and the LP". He said that some liberal economists believe that IPRs are used to suppress competition and hence, can discourage innovation.

He is right, there is indeed an on-going debate even among classical liberals (or libertarians) about whether IPR encourages or kills innovation and competition. I am among those believe that IPR protection promotes competition and innovation.

In my article below, "Swine flu and medicine innovation", I discussed a philosophical situation, company A developed drug A from mango extracts; company C developed drug C from chicken liver, etc. So there are many "patent monopoly" from many

drugs by many innovative (not generic) pharmaceutical corporations to cure just a single disease.

This is a case of "monopolistic competition" industry structure, and not a classic "monopoly". Not a single pharma company has a "monopoly" to treat any disease. Thus, if there are 50 different medicines and vaccines -(and all are patented) from 50 pharma companies to keep AIDS at bay, then there are 50 monopoly patents from 50 companies trying or attempting to cure AIDS alone. And if IPR protection + prospect of huge profit -- by curing diseases and helping patients -- are the incentives for pharma companies, then it should be given to them. Isn't IPR therefore, a wonderful tool that must be encouraged and protected, not restricted and abrogated?

The parallel importation scheme is lousy and dangerous to patients. I explained why this is so in my recent papers below on BFAD.

If the real goal is to increase competition among manufacturers and distributors of effective and safe medicines, then there is one time-tested tool: free trade. Abolish all tariff and non-tariff barriers (import tax, import processing fee, import documentary stamp tax, VAT, etc.). Parallel importation retains all those taxes, importers need the blessing and accreditation (and political patronage?) by the state corporation PITC. That is why parallel importation as a tool to bring down drug prices is a hypocrisy, and a smoke screen to cover up trade protectionism.

If we are to summarize the "cheaper medicines law" (RA 9502) in terms of advancing liberal economics, then it is a big failure. That law advanced huge government intervention, wider State restrictions, while retaining s heavy government taxation, of medicines and the manufacturers of innovative medicines.

This is not to attack Sen. Mar Roxas per se. It is his inconsistency with liberal economics considering that he is the head of the Liberal Party (LP). If it is politicians from Lakas, Nacionalista, Bayan Muna, and other political parties for big and even bigger government, then they were simply being consistent in advocating for wider government intervention through the "cheaper medicines law".

About drug "maximum retail price" (MRP), maximum price = price control. The price of something cannot go beyond the maximum level set by the State.

I reviewed Senate Committee Report No. 6 (dated October 1, 2007), the substitute and final Senate bill on then "cheaper medicines bill". Its Section 10 was entitled "Drug or medicine price regulation by the President of the Philippines". So there was a price regulation provision in the Senate version. The House version was indeed more populist and explicit about price control.

My earlier posting with a news report on it explicitly reported Sen. Mar lambasting the DOH for not implementing the drug price control provision. I mean, for a Liberal politician, I thought he need not insist on a price control provision, perhaps keep silent

on it even if it's in the law already, since price control philosophy is clearly anti-Liberal because there is no existing national health emergency.

(2) Medicine patents and politics

May 11, 2009

Recently, a health industry alliance in the US, the Pharmaceutical Research and Manufacturers of America (PhRMA) repeated its call for the Philippine government to be careful in implementing patent confiscation provisions of the "Cheaper medicines law" (RA 9502). Here's the news report today.
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http://www.bworldonline.com/BW051109/content.php?id=004

Monday, May 11, 2009

US lobby group seeks more talks on patent row

AMERICAN pharmaceutical companies are calling for more dialogues with the Philippine government to settle differences regarding drug patent protection.
The talks are needed to forge policies that will make medicine more accessible but also ensure patents are respected, the Pharmaceutical Research and Manufacturers of America (PhRMA) said.

The lobby group's call came as the US government said it would be monitoring Manila's copyright policies this year, including the recently passed cheaper medicines law which relaxes patent rules to allow the importation and local production of less expensive drug versions.

The US Trade Representative's office, in its annual Special 301 report issued earlier this year, criticized the law, saying it "significantly weakens patent protection for pharmaceutical products".

The report kept the Philippines under the copyright piracy watch list and tagged the country as among those whose intellectual property protection policies would be monitored....

From what I observe here, there seems to be no huge public pressure to utilize the IPR abrogation provisions of the law and its implementing rules and regulations (IRR). There is no "national health emergency" that will warrant the utilization of such provisions. AIDS, malaria, dengue, cancer, are not on a "national emergency" level. The closest health "emergency" that could be invoked in the country would be the influenza A(H1N1) virus, previously called "swine flu". But the incidence in the country as of today is almost zero. Besides, vaccine that can combat such virus has not

been invented yet, according to the WHO. The nearest anti-viral drugs that can fight the disease are said to be Tamiflu (by Roche) and Relenza (by GSK), but I don't read any government in the world rushing for the issuance of compulsory licensing (CL) of such patented drugs yet.

The sectors that are calling for the issuance of CL are some international health NGOs. It is very unlikely that such move will be adopted since the countries that have relatively high incidence of patients suffering from the said new disease are rich countries – US, Canada, a few European countries – and these countries have strong rule of law political culture. IPR confiscation for important and safe medicines is not in their laws.

In the absence of a real health emergency in the country, perhaps PhRMA should be more worried of a "political emergency". Some politicians and Presidential aspirants in the May 2010 elections, just one year from now, might become desperate for political and public attention in order to increase their ranking in the "Presidentiable" surveys. And such politicians can exaggerate a simple disease into a "national emergency" situation to allow the Philippine government, through the Department of Health (DOH), to declare drug price control and/or issue CL.

Another possibility can be political extortion. Some of those politicians, especially in the administration party and coalition, may demand huge amount of campaign money from the big multinational pharmaceutical companies in the country and threaten, "We will declare drug price control (or issue CL) of your most popular medicines, unless you pay us up…" Presidential and Senatorial elections are very expensive in this country and some politicians are capable of selling their souls to the devil – from monopolists to gambling lords to drug pushers.

It is important that various stakeholders, consumer groups in particular, should be vigilant of the threats that can spank them anytime. In the case of medicines, the threats are the entry of cheap but counterfeit or sub-standard medicines, and the non-availability of important medicines and vaccines to future or emerging diseases. After H5N1 (avian flu), H1N1 (swine flu), what could be next – H9N1, H101N1, H1N500, etc.? And the preliminary R&D for medications to reduce the damage, if not totally kill those potential diseases, may not be around the corner, if the pharmaceutical companies that are capable of inventing such medications are gripped by fear of drug price control, CL and related intervention and IPR confiscation by the State.

(3) GSK-Pfizer union in AIDS treatment

May 15, 2009

A friend from a our local coalition here in Manila, the Coalition for Health Advocacy and Transparency (CHAT), posted this news story in our discussion the other day:

GSK Joins Forces with Pfizer to develop HIV/AIDS drugs

Britain's biggest pharmaceuticals firm will pool resources with American rival in £250m joint venture Company Britain's biggest drugs company, GlaxoSmithKline, is to pool resources for treating HIV/AIDS with US rival Pfizer in a bid to reinvigorate financial returns from tackling the global epidemic.

GSK and Pfizer announced today that they intend to create a new company, headquartered in London but as yet unnamed, to manage their HIV operations with initial working capital of £250m.

The lion's share of the business will be owned by GSK, which will take 85 per cent to reflect its portfolio of big-selling HIV drugs such as Combivir and Kivexa. The other 15 per cent will go to Pfizer, which will contribute potentially promising new treatments.

GSK's chief executive, Andrew Witty, said the "clear focus" of the joint venture would be in delivering new drugs to build on what he described as the drugs industry's remarkable success in tackling HIV over the last two decades.

The new company will have 11 drugs on the market and a further six in clinical development. It will have a market share of 19 per cent and annual sales of £1.6bn.

Once the global leader in HIV drugs, GSK has slipped to second place behind a US rival, Gilead, and has seen sales stutter. Revenue from GSK's HIV treatments fell by 5% to £1.5bn last year, while sales of the company's entire pharmaceuticals portfolio slipped 3% to £20.3bn.

Pfizer has a relatively newly launched HIV drug, Selzentry, and is working on several more in trials....

Source: The Guardian (UK), 16 April 2009

I think this is a good and welcome development. Competing companies have to set aside their corporate rivalry in some cases to pool resources in order to develop more revolutionary treatment to some pressing diseases.

Medicine innovation, or discovery of new medicines and vaccines for new and emerging diseases, will remain to be a very important function of innovator pharma companies. Generics pharma firms have little or zero capability to develop revolutionary drugs. They can only copy and make slight improvement or new marketing ideas on old and previously innovator drugs whose patents have expired, or still patented but governments will come in to issue a compulsory licensing (CL).

The current flu virus A(H1N1), the WHO says there is no existing vaccine to fight it yet. The earliest vaccine to come out will be 5 to 6 months from now.

Before we have H5N1 (avian flu), today we have H1N1 (swine flu), tomorrow we may have H105N501 or H302N203 or whatever new disease. Diseases keep on evolving and mutating, so that old and existing medicines cannot deal with the new "cousin" diseases of the old ones.

I think GSK and Pfizer are looking at new or evolved strands of AIDS that they see will emerge in the next couple of years, on top of current strands of AIDS virus that need urgent and quick medications.

My understanding is that all anti-AIDS medicines that are currently existing can only keep AIDS virus at bay, but not really kill it. Sort of just helping boost the immune system of the patients, keep them alive longer until such time that their natural immune system has fully recovered. But the virus that depletes the immune system in the patients' body cannot be killed yet by existing anti-AIDS medicines.

(4) A(H1N1) virus, CL and Tamiflu

May 15, 2009

Here's one case of possible issuance of compulsory licensing (CL) in Mexico. Import from India the drug Antiflu, a copycat of Tamiflu, still on patent in Mexico. Tamiflu is the only existing effective anti-influenza A(H1N1) medication. But the real "killer" of said virus, a vaccine, has not been invented yet. WHO announced on May 2 that it will take 5 to 6 months for such vaccine to hit the drug stores worldwide. So Tamiflu and its copycat, Antiflu, are more of stop-gap measures and not the real cure to the virus.

The same drama and debate repeated over and over: Patients need a good medicine to cure a particular dreaded disease. But an existing medicine is still on patent and is sold expensively. Pharma company A, the medicine inventor, says they need to sell at a high price to recover the huge costs in researching, developing and marketing the medicine (industry average cost is around $1 billion per effective and successful medicine) . Comes pharma company T, did not spend a single centavo in innovation R&D, only in copycat R&D and announces to sell the copycat at a much lower price. The government and the public side with company T and go ahead with CL issuance.

Other innovator companies, pharma companies B, C, D, E, etc. now afraid to develop a new medicine to potential diseases like goat flu, horse flu, carabao flu, dog flu, cat flu, etc. Because once you become successful in developing an effective medicine against those potential diseases, your invention will be confiscated through issuance of a CL. And some copycat pharma companies U, V, W, X, AA, etc. are unhappy too, there is no more new and innovator drugs to copy.

Societies will have to grapple with those contradictions, both present and future. Here's the news story.

Indian group to sell copy of Tamiflu

By Andrew Jack in London

Published: May 14 2009 03:00

An Indian pharmaceutical company is gearing up to sell a cheap version of Tamiflu , the leading patented antiviral flu drug, to emerging economies in a move that will pit intellectual property rights against affordable access to drugs.

Cipla, based in Mumbai, said yesterday it had agreed to sell significant quantities of its Antiflu preparation to Mexico, the country at the centre of the outbreak. The move came only hours after the World Health Organisation said the drug was as effective as Tamiflu.

Yusuf Hamied , the head of Cipla, confirmed that Mexico had already agreed in principle to purchase stocks of Antiflu, and talks were under way with a number of other governments in Latin America, the Middle East and Africa.

The launch risks provoking a clash with Gilead and Roche, the companies that developed and distribute Tamiflu, the drug known generically as oseltamivir, which Antiflu replicates.

Cipla recently won a case within India against Gilead, which holds the patents on Tamiflu, paving the way for the manufacture of its version. If Mexico now issues a compulsory licence to waive the patent on the drug, existing international trade rules would allow purchases of Antiflu, although intense lobbying by drug companies has severely limited such practices until now.

Amar Lulla, Cipla's managing director, stressed he would sell stocks of Antiflu to Mexico and other countries only on condition that they indemnified the company against any legal action over patents.

He said his company would offer Antiflu for sale at about $10 (£6.60) per course of treatment. Roche sells Tamiflu for government pandemic stockpiles at €15 (£13.50) for richer countries and €12 for poorer ones....

(5) Counterfeit drugs and substandard health services

May 27, 2009
http://www.thelobbyist.biz/lobbyist.biz/perspectives/columns/back_to_personal_responsibility/718.html

Early this week, the International Policy Network, a think tank based in London, released its new report, "Keeping it Real: Combating the spread of fake drugs in poor countries". The 28 pages long paper is also co-sponsored by 18 international think tanks from 18 countries, including Minimal Government Thinkers.
The new Report has some figures that can be shocking to patients. Among these are the following. One, fake tuberculosis and malaria drugs alone are estimated to kill 700,000 people a year. That's more than 1,900 deaths per day and equivalent to four fully laden jumbo jets crashing every day. Two, the WHO estimates that counterfeit drugs constitute up to 25 per cent of the total medicine supply in less developed countries (LDCs). Three, 68 percent of artesunate (anti-malaria) drugs in Laos, Myanmar Cambodia and Vietnam contain insufficient active ingredients, rendering them less effective, if not totally useless, in curing the sick. Four, about 75 percent of imported counterfeit drugs come from India, according to one European Commission estimate; and China is also a significant producer of counterfeit drugs.

These figures are significant because the new "Cheaper Medicines Law" (RA 9502) has a provision legalizing "parallel importation" of locally-patented medicines, and the premise of this provision is that cheaper medicines to be imported will come from India, home to some 22,000 small drug producers, many of whom are informal.

Since the foreign manufacturers (Indian, Chinese, others) are different from the wholesalers, importers and local retailers, i.e., they are not one and the same company but several different companies, tracing of who will be accountable if the imported drugs are counterfeit or substandard that can result to adverse effects to the patients, will be difficult.

One of the dangers of taking fake drugs is failure to provide effective treatment. The Report says "as fake drugs usually contain insufficient bioavailable active ingredient, a patient who believes he is addressing his disease is in fact going untreated. The disease thus progresses, often leading to death, especially in children and the elderly."

Meanwhile, I attended this morning a round table discussion on "Quality issues in delivery of health care services: A Policy perspective" at the AIM Conference Center. The event was sponsored by the Health Policy Network (HPN) project of the Center for Legislative Development (http://hpn.cld.org) and was attended by mostly NGO leaders. A 30-page long paper entitled "Equity Issues in Access to Quality Health Care: A Policy Perspective" by the event organizer was also distributed to the participants.

Access for all to quality health care. This is a vision dreamed by almost all people in the world and is thus perfectly rationale. But resources are limited, the supply of well-trained doctors and other health professionals, the supply of good quality hospitals and clinics with sufficient laboratories and diagnostic instruments, the supply of safe and effective medicines and vaccines, are limited. While the demands for such health services and medicines are unlimited.

This is where the initial problem of access to quality health care arise. Add the fact that some people are too irresponsible to take good care of their own body and that of their own family, like those who drink and smoke heavily, take illegal drugs and fatty foods excessively, live in dirty places and do not observe personal hygiene, get into frequent fights, have sedentary and promiscuous lifestyle, etc.

Then add the fact that many governments think that medicines and health care are just like any other commodities like beer, hamburger and movies that must be slapped with multiple taxes and fees. That government corporations engaged in health insurance are accountable to the President and top politicians, and not to private citizens who were coerced to contribute to the health insurance funds.

One concept that was emphasized by the HPN is that for health care to be accessible, first it must be made available and second, it must be affordable. That is, available + affordable = accessible. While this may be correct in many cases, it does not mean that this will lead to "quality" health care which is the ultimate goal of all those public policies that people are talking about.

Take the case of those medicine warehouses managed and owned by some local government units (LGUs). During the MeTA forum last January in Manila, a World Bank-Philippines staff showed – complete with pictures – some of those medicine warehouses by big cities and provinces, where rats, garbage, useful and expired medicines are mixed in one room, often with no stable temperature control, some do not even have a thermometer to monitor room temperature.

Here, those medicines are available. They are more than affordable, they are distributed free. The poor patients in those LGUs therefore, have "access" to medicines. But do they get "quality" medicines that can cure them from their illness and diseases? Probably Yes, but probably No, and some may have contracted new diseases and complications if they happened to take substandard, expired or garbage-contaminated drugs.

It is not enough that there should be "more government budget for health care" as demanded by many sectors in society. Money can buy us subsidized or free medicines, safe and counterfeit alike, and money can also give us lazy and irresponsible government personnel who dispense expired and contaminated drugs.

More than bigger government taxation, regulation and intervention in health care, what is needed more is individual and parental responsibility for preventive health care, plus a competitive business environment where private health care providers and medicine producers can compete with each other in providing the safest and most reliable drugs and health care services to the people with varying health needs and varying financial resources.