Selected Essays on IPR and Health

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I. Introduction

The following are some of my selected essays posted in the online magazine, www.thelobbyist.biz, on the subject on intellectual property rights (IPR) and health. I have taken interest on this subject because health care is among the favorite sectors that many governments around the world with trying-hard-socialist aspirations attempt to nationalize or heavily regulate, tax and control. A number of those governments in rich countries have succeeded in such nationalization.

I believe that public health will be served better if there is less government intervention and there is more competition among hospitals and clinics, health insurance and health maintenance organizations (HMOs), and innovator pharmaceutical companies and drug stores. Competition among plenty of players who are protected by well-defined private property rights, not higher taxation and bureaucratic regulations that discourage the entry of more players, is the best scheme to make health care and medicines become more affordable to the people.

My weekly column in that magazine is called ñBack to personal responsibilityò to highlight the need for individuals and parents to assume more responsibilities about their lives, their families and their communities, if they want their individual liberty to be respected. Consistent with this, I believe that health care is mainly a personal and parental responsibility, not the stateôs. For instance, people who abuse their body through heavy drinking, heavy smoking, getting into frequent fights, being drug addict, eating too much fatty food, or living sedentary life, have no right to demand free or heavily-subsidized hospitalization, physician visits and medicines. If they have that ñrightò, then the state will hound the healthy and hard-working people through high taxation, harass the pharmaceutical and health care companies through medicine price control, compulsory licensing of their patented products, etc.

Below are five of my articles posted in the magazine, from February to June 2008. These are mostly related to the ñcheaper medicines billò that became a law early this month.

II. Taxes and Hypertension: How to reduce medicine prices

06 February 2008

Sir Isaac Newtonôs 3rd Law of Motion states that for every action, there is an equal and opposite reaction. When government intervenes to reduce the price of something, it imposes taxes or fees/charges to finance whatever price subsidy and the salaries and perks of personnel who will do the price and income redistribution. Those taxes and fees raise the price of those things and services that government says it wants the price to go down. Sort of unintended consequence. And this affirms Newtonôs 3rd law of motion.

In the on-going discussions and debates about ñquality affordable medicinesò or ñcheaper medicinesò bill, to the point of developing or aiding hypertension to some actors or players or would-be interventionists, various factors suspected of contributing to the high price of medicines have been identified and diagnosed with more government intervention: amendment of the law on patent system, price regulation and control, parallel importation and disrespect patent rights, ñgenerics onlyò prescription by doctors. It is notable that government intervention itself ï those high and multiple taxes and fees on medicines and medical products, bureaucratic regulations, attempts at price control ï has never been identified as among the suspects. Why?

Blaming the multinational corporations, especially those in the petroleum, pharmaceutical, and transportation sectors is always a convenient excuse for policy makers, implementers, and their allied pressure groups. Thus, legislators and politicians can always impose various taxes (import tax, value added tax, documentary stamp tax, patent tax, and other regulatory steps and fees) on those commodities and services, then blame the producers themselves, especially if they are multinationals.

Aspiring cheaper price for anything ï cellphones, house, car, medicine, hospital stay, shoes, and so on ï is a perfectly rational behavior. The assumption is that people should get good quality and safe products. After all, fake, imitation, and dangerous products are sold cheap compared to their original counterparts so that they can easily be sold. Producers and sellers are happy, buyers are happy (except when some of them will develop adverse effects, if not die later, in the case of those taking counterfeit medicines).

One time-proven mechanism to reduce the price of something is to have as many producers and innovators of good quality products and let them compete with each other. And donôt impose high and too many taxes on the players so that they can compete more fairly. Some players will expand while others will fail. Thatôs the sad but necessary result when informed consumers make their decisions whom to patronize and whom to evade. Unfortunately, what the two versions of ñaffordable/cheaper medicinesò bills seek is to discourage entry of innovator companies and have more generics companies that do not engage in very expensive and time-consuming R&D and clinical trials. In addition, importers and distributors of locally-patented drugs other than the patentees are encouraged, under the ñparallel importationò scheme.

One question that can be asked under this scheme is this: supposing a patient develops bad allergies, if not died, after taking the imported medicines (maybe itôs a fake or mislabeled or mis-stored or mishandled that reduced or negated their effectiveness) from abroad by non-patentees, who will be accountable: (a) the physician who gave the prescription, or (b) the importer who brought the medicines, or (c) the drug manufacturer abroad, or (d) the local patentee who sells the same drugs domestically, or (e) the local drug store that stored and sold the medicine, or (f) the government which allowed and encouraged the entire scheme?

Unfortunately, the answer of who could be accountable could not be determined from both the Senate and House versions. What the two bills intend to achieve is to have cheap/affordable medicines at all cost. And at no cost to the government, i.e. government tax collections should never be reduced because there are billions of pesos of pork barrel projects to finance every year.

So why canôt we start with drastically reducing if not abolishing the taxes and other regulatory fees imposed on medicines? After that, letôs encourage the entry of more innovator companies into the country, or the importation of those medicines at zero import tax and zero trade barriers by their local patentees who should be the sole accountable entity to the patients, should they experience any adverse reactions later.

III. WHO's attempting health property rights confiscation?

26 March 2008

The perception that there is widespread "market failure" in public health care has prompted many government health ministers and bureaucrats, upon the prodding of health activists, some policy writers, and media people around the world to advocate more government intervention as "government solution to market failure." And the World Health Organization (WHO), through its InterGovernment Working Group on Public Health, Innovation and Intellectual Property (IGWG), will be one of the chief instruments of such bigger involvement by governments.

In late April this year, government health officials, health activists, and lobbyists for more government involvement in health care ï and more taxes and bureaucracies for such additional intervention ï from many countries will head to Geneva, Switzerland to attend the continuation of the second session of the IGWG.

Among the planned additional interventions that will be discussed by the attendees are for WHO member-governments to encourage: (1) entry of cheap drugs via parallel importation and/or copying without bio-equivalence testing; (2) local production through huge subsidies to chosen players; (3) issuance of compulsory licenses (CL); and (4) price controls.

The reason for the above respective measures are as follows: ***One***, there is the persistent pressure to deliver "cheap at all cost" drugs even without strict bio-equivalence testing that will ensure equivalent efficacy and safety of medicines. ***Two***, big multinational pharmaceutical companies do not prioritize in their R&D and production drugs for many poor country diseases. ***Three***, compulsory licensing is allowed even in WTO's trade-related aspect of intellectual property rights (TRIPS). And ***four***, price controls will allow more sick people to have access to otherwise expensive but effective drugs.

A longer discussion of these old and new government interventions and related issues are tackled by the new paper, "Increasing access to medicines: Civil society commentary on the IGWG draft Plan of Action". It is a report jointly sponsored by 24 independent think tanks and institutes from 21 countries, including Minimal Government Thinkers. (Editor's Note: If interested to see the document, send the author a private mail)

Due to space constraints, we will briefly discuss only the "copy" drugs and CL. The IGWG's draft Action Plan conflates "copy" drugs with generics drugs. The latter are required to pass "bio-equivalence" testing for a reference drug or product. If drugs do not go through this testing by a rigorous and scientifically-capable drug regulatory body, then these are just "copy" and very often, substandard drugs. Most counterfeit, unsafe ï and cheap ï drugs fall in this latter category and they can be dangerous if not fatal, to patients.

When a patient takes substandard or fake drugs, treatment failure happens. The patient either feels no improvement after taking the medicine, or develops resistance to genuine drugs while the disease may be mutating inside the body of the patient. So a hunt for "cheap at all cost" drugs can backfire.

On CL, assume there are 100 different medicines to cure AIDS patients. About 1/4 of them can cure an average patient in seven to ten years; another 1/4 can eradicate the disease in five to six years; another 1/4 can do the job in three to four years; and another 1/4 can control the disease in one to two years. But among the "top 25" medicines, about half are effective but have some adverse side-effects or cause

allergies to people who have other diseases (diabetes, hypertension, etc.) and the other half are plain effective.

Which of those medicines will be issued compulsory license (CL) by governments? The bottom 3/4, even if they are cheap, readily available, and can also fight the disease? Not a bit. It's those in the top 10 or 15 most effective medicines, which are also among the most expensive.

And this tells us one thing: the selective application of CL is driven by envy, by the simple desire for quick-fix solutions through more unproductive government intervention.

Huge investments by innovator companies do not matter. What matters is to spot who among those innovator companies have the most effective medicines, then disrespect their patent and intellectual property rights, and copy the effective medicines for use by a government corporation or crony generics manufacturing company which spent very small, if ever, in expensive R&D. And the State that issued the CL is now a "hero" while the innovator companies that invented the effective drugs and resisting the CL are now the "villains".

Instead of interfering with the market for medical treatments, governments should step aside. Scrapping taxes on medicines would be a good start. In the Philippines for instance, medicines are slapped with an import tax of five percent and a value-added tax of 12 percent.

Geneva next month will be crowded with many technocrats and bureaucrats who have little appreciation and respect for private property, and they won't hesitate to further incite national governments to extend their intervention and adapt confiscatory policies that disrespect the property rights of innovators and freedom to choose of patients.

Patent busting and price controls might bring cheaper drugs in the short term, but it threatens the well-being of poor patients and stifles medical innovation over the long haul. Governments can achieve "cheaper medicines" by simply getting out of the way and allowing more competition among innovator companies to reach out to the patients and their physicians.

IV. Free enterprise and health innovation

11 April 2008

I have always thought that product innovation ï new rice and vegetable varieties, new cellphones and laptops, new shoes and dresses, new burgers and pizza, new drugs and medicines, and so on ï is done by private firms and companies, not by governments.

When a company is the first to innovate on something that is very useful to its consumers, then that company is rewarded with big profits, and wide trademark recognition and support. That is why companies compete with each other in various forms of innovation ï whether in new products and processes at various price levels, or same/similar products and processes at a lower price or with better marketing package or better post-sale services, and so on.

Some documents by many governments and multilateral institutions, however, seem to suggest that itôs them who do the innovation and undertake costly R&D, or suggest that they can command and control the private companies that do the innovation, tell them what areas to innovate, how to do it, and at what prices the companies should sell their new products and processes.

One such document that I have encountered is the InterGovernment Working Group on intellectual property, innovation and health (IGWG under the World Health Organization or WHO) global strategy and draft plan of action. Itôs 26 pages long and unless you specifically look for it, you may not easily find it in the WHO website. This and related documents are very important if one wishes to see how the WHO and its member states represented by their respective health ministries or departments wish to ñmanageò intellectual property rights (IPR) and health innovation by private companies, especially pharmaceutical companies, to pursue certain public health objectives.

The IGWG global strategy and draft plan of action recognizes the important role of IPR on technological innovation but it also says that ñIPR do not and should not prevent Member States from taking measures to protect public health.ò And from this premise, along with many other premises, it identifies certain plans of action. Among them are the following:

One, health R&D of developed countries should reflect the health needs of developing countries. But governments of developed countries do not undertake R&D; itôs the health research and pharmaceutical companies based in developed countries that do it.

Two, promote and coordinate R&D for diseases in developing countries. This implies that the health ministries or departments of developed countries should coordinate the R&D work of innovator pharmaceutical and biotechnology research companies, and tell them to prioritize in their work the diseases in developing countries.

Three, build and improve innovative capacity of developing countries. Who will do this, the governments of poor countries, or the local health and pharmaceutical companies in poor countries, or both? If itôs the first, then this will require huge budgetary allocation for many years, which will require huge taxes and fees for many years, which can bleed productive enterprises including local health and pharmaceutical companies and disable them to improve their own innovative capacities.

Four, transfer of technology; from north to south. Technology transfer should be done voluntarily, where both the innovator and recipient bodies or enterprises will benefit. When the innovator company spent huge amount of time, effort and money ï invested by stockholders and/or borrowed from banks, both of which expect reasonable returns ï then it will not just transfer its technology and processes to other companies which did not help in its earlier efforts; or worse, they could be potential competitors. An innovator company will transfer technology only to its subsidiary or sister company which can give it reliable information on local conditions from which the mother or innovator company can consider in its on-going or future R&D work.

Five, manage IP to promote innovation and public health. This implies that governments should ñmanageò the IPR of innovator companies and if they cannot be managed, then governments can issue compulsory licensing (CL) to some of these companiesô effective and best-selling medicines. Or manufacture and export medicines without the permission of patent owner. The words ñallow CLò and ñexport medicines without the permission of patent ownerò are in fact contained in the said document.

These interventionist, if not invasive, ñplans of actionò by the WHO and its member-governments as drafted by the IGWG secretariat, are meant to socialize and collectivize the efforts and hard work by the innovator health companies. When you collectivize something, you normally disregard the rightful rewards of the innovators in the form of higher profit or wide trademark recognition by consumers. These are subordinated in the name of ñpublic healthò and ñcapsulizeò in the slogans, ñpatients over patentsò or ñpeople over profitò.

Okay, fine and cute slogans. But if the innovators will not be properly rewarded, why would they innovate in the first place? And if there will be no more innovators, who will produce more effective and safe medicines to fight evolving diseases in evolving environments and communities? Or at least mitigate the pain and impatience of the sick or dying patients, like curing a disease in just 1 or 2 days instead of 1 or 2 weeks or more that existing medicines are capable of doing?

The ñcheaper/affordable medicinesò bill now in the bicameral conference committee by the Senate and the House of Representatives is generally treading along these lines contained in the IGWG document. The Senate Committee Report that produced the current Senate version even proudly declared that ñfor developing countries, the fewer the patents, the betterò.

Fine, but if the few innovator pharmaceutical companies in the Philippines now will be threatened with weak patent and IPR laws for their innovations through ñgovernment useò which is more invasive than the CL scheme, and threat of price control of their effective and best-selling drugs by the DOH bureaucracy, are we not penalizing ourselves with even fewer innovator companies who can give us more effective and safe medicines for both existing and future diseases?

V. Parallel importation vs. Free trade

22 May 2008

People want cheaper food, cheaper oil, cheaper shoes, cheaper cell phones, cheaper medicines, and so on. This is a perfectly rationale human behavior. But there are certain irrational interventions often done by governments, which make commodities expensive, which results in expensive food, expensive oil, expensive medicines, and so on. Two of such ugly interventions are multiple taxes and trade protectionism.

Medicines in the Philippines are immediately slapped at least with 5 percent import tax and 12 percent value added tax (VAT). Companies that import, manufacture, distribute, and retail medicines are slapped with 35 percent corporate income tax each, 12 percent VAT on office rentals, plus a host of other taxes and fees. The reduction if not abolition of certain taxes that make medicines more expensive is surprisingly among the things that were never considered by the legislators who wanted cheaper medicines. The legislators with bleeding heart concern for the poor patients were too tax-hungry to spare medicines from high and multiple taxes and fees.

More than a month ago, I emailed Sen. Mar Roxas, the chief author of the Senate version. I admired his keen interest in reducing or abolishing the taxes on petroleum products for ñcheaper oilò, and asked why he canôt be equally keen in demanding for the reduction or abolition of taxes on drugs for ñcheaper medicinesò. I never got a reply from him.

The second ugly government intervention is trade protectionism. The 5 percent import tax is one proof of such protectionism. If we want cheaper medicines, we should have free trade ï zero tariff and non-tariff barriers ï and allow plenty of reliable pharmaceutical companies to come into the country. They will bring their medicines from Europe, US, Singapore, India, Pakistan, and other countries, and let them compete among themselves. But dismantling of trade protectionism in medicines was not considered in the medicines bill. What was put in the new ñCheaper and Quality Medicines Act of 2008ò was the institutionalization of parallel importation.

Parallel importation looks cute: the same medicines of the same dosage made by the same pharmaceutical company currently under patent in the Philippines are sold at only one-half, one-fourth, or even lower price, in India, Pakistan, China, or elsewhere. So, import those medicines even without the permission of the IP owner or patent holder and sell them here. Filipino patients get cheaper medicines, importers make money, the State collects taxes, and there is no IPR infringement done on local patent holders. Everybody happy, except the multinational pharmaceutical companies who are demonized to have made ñenormous profitò as a result of their monopoly of their medical invention and innovation.

Parallel importation is not equivalent to free trade. The former is allowing non-patent holders and ñcopycat-ersò to import medicines that are locally-patented without the

permission of the local patentees. Free trade is allowing plenty of medicine manufacturers, especially medicine innovators, who are patent holders to bring in their innovative and patented medicines and products, and they compete among each other here both in quality and price.

Under parallel importation, the State can practice double standards: it creates bureaucracies, and collects taxes and fees to domestic-based pharmaceutical companies that applied for patent and IPR, then turn its back and disrespect the same patent that it granted by allowing parallel imports, then further collect taxes and fees from importers and retailers.

On the other hand, free trade has only one goal: give consumers more choices. The State need not practice double standards to achieve this. If it wants to implement the patent system and protect IPR, then all importers should be patent holders. If there are not enough patent holders and local players, then allow more players from more countries to come in. And they will come in if there is enough profit to make, meaning operational costs ï like taxes, regulatory fees, and other compliance costs ï are low and simple to follow.

Competition, not bureaucratic regulation, is the best disciplinarian among producers and sellers. Customers can mark those who sell expensive products relative to their quality, those who sell bad quality products, especially unsafe and fatal products in the case of counterfeit medicines. Sellers and providers would naturally aspire to sell only good quality and safe products, even if some of those goods have to be sold at higher prices, and gain customer support and patronage.

The key is to encourage the entry of more innovators who will be directly accountable should the medicines they brought in would turn out to be ineffective and unsafe. Parallel importers may not be accountable when they ï intentionally or unintentionally ï bring in counterfeit drugs because they are not necessarily the ones who manufactured those medicines. Or if they mishandled or misstored the products which may adversely affect the effectiveness and safety of such drugs. Or if they mislabeled after re-packaging those medicines bought in bulk from abroad.

Medicine innovation should be encouraged to come in if we want newer, more effective medicines, to fight evolving diseases in our evolving communities and evolving environment. Innovative medicines are not cheap, with an average industry cost of around US$1 billion just to develop one good medicine. Copycat medicines are always cheap because the ñcopycat-ersò never spent a single centavo on medical research and development; they only have to spend on glitzy marketing strategies and sales people.

VI. Public health robbery through price control

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In both textbook economics course and everyday common sense, people would normally understand that one important reason why the price of a certain commodity is high is due to the scarcity, if not absence, of its supply relative to people's demand. For instance, the price of
tomatoes can fall down to Php5 (about US$0.09) per kilo, even Php2 a kilo, during the summer months of March-April in a number of provinces in the Philippines. During the rainy season, the same quality of tomatoes harvested and sold in the same municipality and province can go as high as Php40 to Php50 (about US$1) a kilo, or even higher. What explains the big jump in price for the same commodity sold in the same locality in a span of just three to four months? Were there "tomato cartels" suddenly formed during the rainy months? Were there massive pest attacks that affect tomatoes every year?

People understand the "seasonality" of certain commodities, and they understand the downward or upward swings in the prices of those commodities. So they do not ask for more government intervention like tomato price control, or new taxes to subsidize tomato farmers during summer months, or the establishment of another bureaucracy like a Tomato Development Authority.

Entrepreneurs, both new and incumbent, would flock to an industry or sub-industry that experiences fast demand growth, or projected to experience fast consumer demand in the near future. When suppliers in the market become plentiful, the price of the supplied commodity or
service can go down, the consumers benefit, and some producers will lose money. They will then try to innovate and produce a "hybrid" product or service that will hopefully attract a new set of consumers and buyers.

Government mentality though is often more myopic and conspiratorial than what consumers and producers would normally comprehend. Many people in government cannot appreciate the importance of just leaving the entrepreneurs or producers, and the consumers to interact with
each other. That is why governments tax both producers (income tax, business permit tax, franchise tax, etc.) and consumers (value-added tax, import tax, excise tax, etc.). Aside from taxation, governments also impose more sinister forms of regulation like price control.

By imposing price control, governments think the "evils" in society are the producers of innovative and revolutionary goods and services. That is why consumers rush to purchase that new product or service, resulting in higher-than-normal price hike. And governments think these innovative producers should be disallowed from making "extra high profit", even if these producers paid extra high costs, waited extra long years to develop their product, and endured extra high taxes and regulations.

In the recently-enacted "Cheaper Medicines Law" (Republic Act No. 9052) signed into law early this month, with the implementing rules and regulations (IRR) currently being drafted by concerned government agencies, price control is among the measures that the State ï through the President and upon the recommendation of the Secretary of Health ï can impose to make effective and safe, yet "expensive" medicines be made more accessible and affordable to the people. As mentioned above, the premise here is that the pharmaceutical companies that produce those medicines sought after by many patients are seen by the State not as innovators and revolutionary inventors of safe and effective medicines, but as "evil" cohorts that are only after big profit at the expense of poor patients.

But is it fair to impose price control after the State itself has imposed uncontrolled taxes and uncontrolled regulations, and devised a scheme (disrespect of patent and intellectual property right through parallel importation) that can pave the way for uncontrolled entry of unsafe and ineffective drugs, a.k.a. counterfeit medicines?

My bet is that people who understand and appreciate the role of profit to embolden entrepreneurs to take high risks, to face and incur huge losses in case they will not succeed in producing an innovative and successful product, will answer 'NO' to this question, while bureaucrats, politicians, and people driven by envy and hatred of profit and markets will answer 'YES'.

Even assuming, for the sake of argument, that the bureaucrats and the envious are correct in saying that the State has the right to impose uncontrolled taxes and uncontrolled regulations then control the price of medicines later, what if the price of raw materials and intermediate goods, not to mention the salaries of research scientists and pharmacologists, have increased to high levels. Is the State still justified in keeping a price cap to the final product, in this case, safe, and effective medicines?

The case of huge spikes in the price of raw materials and intermediate goods for making effective medicines has happened in India. The Indian government has that cute and magic formula to keep medicine prices low: price control through its Drug Price Control Order (DPCO) enacted in 1995. Unfortunately, the prices of raw materials and intermediate products have recently risen very steeply, by up to 100 to 200 percent, due to tight supply of such products from China. And yet the Indian government allows price hikes of active pharmaceutical ingredients (APIs) to only 10 percent. Those chemical inputs constitute up to 80 percent of the total cost of bulk drugs.

The immediate result of this situation is that many bulk drugs manufacturers will be forced to stop producing. This is according to the President of the Bulk Drugs Manufacturers Association (BDMA) of India, Narayan Reddy. So if patients need those bulk drugs and manufacturers will limit, if not stop, producing those drugs due to government price control, who will suffer, the patients or the demonized drug manufacturers? Unfortunately, both will suffer, but more so the patients. Despite this

situation, the Indian government is said to be dragging its foot in addressing this issue. Do we need the same thing to happen in the Philippines?

Finally, as I have noted in my recent paper, "Promoting innovation and public health through less government intervention" <www.minimalgovernment.net/media/mg_20080611/pdf>, price control will allow a corrupt President and/or Secretary of Health to use the measure for extortion. Like going to big pharmaceutical companies and telling them, "Hey, we're going to issue price controls to your best selling drugs, unless you pay usé " Not that I am saying that the current Health Secretary is corrupt, but a price control measure will encourage an 'extortionary' and corrupt behavior to top officials of the Health Department or Office of the President.

I have other arguments in my paper why price control is bad public policy. I just hope that the writers of the IRR of RA 9052 will consider them. Otherwise, the country will be courting future public health risks by putting the interests of the extortionists and interventionists ahead of the interest of the patients.