Essays on IPR and Health, Part 4

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Introduction

This will be the fourth compilation of my short essays on intellectual property right (IPR) and health, focusing on medicine innovation and counterfeit medicines. These short papers are posted in the online magazine, www.thelobbyist.biz or in my blog, http://funwithgovernment.blogspot.com. Five papers are included here. The continuing scare on swine flu, the absence of an existing vaccine to fight it, and the reality of forever evolving and mutating diseases, provide the background for these short papers.

(1) Swine flu and medicine innovation

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http://www.thelobbyist.biz/column_detail.php?id_article=1121&id_category=25

San Francisco – The swine flu scare here and in several states in the US has mellowed. Partly because the initial scare was several million times larger than the actual casualty in America, only one toddler in Texas.

But there is one pattern that persists in public health policy whenever a disease outbreak or pandemic emerges. This is the call by certain sectors of society, sometimes including the Health Ministry or Department, for the mass production of an existing patented medicine or vaccine through compulsory licensing (CL) or similar schemes.

In the case of the current swine flu, certain sectors proposed the issuance of CL for Tamiflu by Roche, and Relenza by GSK. While the reason calling for the confiscation of intellectual property rights (IPR) via patent abrogation of those medicines may be understandable, the reason for invention of new and innovative medicines for existing and soon to exist diseases should also be taken into consideration.

Before it was foot and mouth disease (FMD) for cows ("cow flu"?), then SARS, then avian or bird flu. Now it is swine flu. And tomorrow what, horse flu, carabao (water buffalo) flu, goat flu, duck flu, sheep flu, salmon flu, tilapia flu, etc.?

If any or all of those hypothetical (or past) diseases will emerge or re-emerge, where will the new vaccines and medicines to come from? From the World Health Organization (WHO)? From the Ministry or Department of Health? From international health NGOs?

The pharmaceutical companies, the big and multinationals especially, that the public often attack and demonize, unfortunately are the ones that research and develop new and innovative medicines to combat new and evolving diseases. The bird flu virus that we know today will be different from the bird flu virus that we will see tomorrow. And perhaps a swine flu virus has already shown in the past, but the swine flu virus that we see today is different from its "cousin" that emerged many years ago.

All things change and evolve. Some evolve after one year, others evolve after one million years. The disease virus that we see today will evolve into a new strand of virus tomorrow. There are two important implications for this. One, medicines should evolve to deal with those evolving diseases. And two, incentives for inventors and developers of those innovative and evolving medicines should be kept, not abrogated or abolished.

The competitive system of rewards and punishment will push various players and companies to undertake their own system of invention and innovation. To develop a new vaccine for current and future strands of swine flu for instance, pharmaceutical company A will use extracts from mangos as main ingredients; company B will use extracts from onions as main ingredients; company C will use chicken liver as main ingredients, up to company Z.

If all of them will succeed in developing a new medicine for swine flu, then not a single pharmaceutical company will have a "monopoly" in medicine treatment. Drug A by company A can cure a patient in one week or less but the price is high. Drug B by company B can cure a patient in two weeks but the price is a bit lower. Drug C by company C can cure a patient in two months but the price is even lower. Drug D by company D can cure a patient in six months but the price is much lower, up to drug Z by company Z.

Thus, the IPR and patent monopoly given to company A applies only to drug A. The patent monopoly given to company B applies only to drug B. The patent monopoly given to company Z applies only to drug Z.

The argument "patented = expensive" medicine is not exactly true. If company A spent $1.5 billion to produce drug A alone (in the example above, is the most effective drug), then company A deserves higher price for its very high cost of research and development (R&D) and marketing. If company B spent $1 billion to produce drug B alone, then company B also deserves a high price for its second most effective medicine. If company C spent $0.7 billion for its drug C alone, then it deserves medium price, and so on.

Cheaper and affordable medicine is relative. Drug A, the most effective of all, may be very "expensive" but if it can cure a dying patient fast, then that drug is "cheap" compared to the life of the patient whose life has just been saved. The poorest patient can opt for drug Z by company Z, the cheapest among patented drugs to cure swine flu, though treatment period can be long but nonetheless, there is chance of being cured.

Compare that in a situation where only 1 or 3 pharmaceutical companies – versus 27 firms (companies A to Z) in the above situation – will dare research and innovate for each emerging and potential disease because of fear that their successful invention, the IPR of their new and effective medicine, will just be confiscated by the government anytime. Is this a good situation?

Affordable medicines will come next after the innovative medicines have been invented, manufactured, and sold in drug stores. Ultimately, the most expensive but the most effective medicine that can cure a patient, or millions of patients, may not be "expensive" after all, if we want to save people's lives. The "villain" pharmaceutical companies that we like to demonize for the convenience of finding the easiest scapegoat, may unfortunately be the "hero" that can save the life of people dear to us, if not our own lives itself.

And the "hero" that we look up to, the governments and sectors that demonize the drug innovators, may unfortunately be the "villain" that make medicines more expensive by over-taxation, if not discourage medicine innovation by heavy regulation and IPR confiscation.

(2) BFAD Strengthening Bill

May 5, 2009

A proposed law strengthening the Bureau of Food and Drugs (BFAD) under the Department of Health (DOH) is now in the bicameral committee of the Philippine Senate and the House of Representatives. It's called the Food and Drugs Administration (FDA) bill.

I did not know that less than a year after the enactment of "Cheaper medicines law" or RA 9502 where a chapter for BFAD strengthening was included, another law will soon be enacted on BFAD alone.

A friend informed me that this BFAD bill has been there for several years. But since the IPR and patent aspect of pharmaceutical products was the "hot" issue then, it was pursued and the BFAD strengthening was included as a "rider" chapter in the law. Not bad because it is now a law with implementing rules and regulations (IRR).

My main observation of the proposed new law is that the important "ingredients" to strengthen BFAD are already in RA 9502 -- retention of income, continue receiving annual appropriations for at least 5 years, freedom to review and hike fees and charges. If money is the problem for BFAD, then the current law already provides it with enough flexibilities. So, I am wondering why pursue this new, separate bill and nearing enactment into a law.

If one goal is to further strengthen post-marketing, post-sale monitoring of pharmaceutical products, then that "order" is already in RA 9502 and its IRR. Besides, BFAD only has to worry or keep watch of those cheap and parallel imported medicines from lesser-known pharmaceutical companies. The bigger pharma companies have strict pharmaco-vigilance corporate practices imposed upon them by (a) their own shareholders and stockowners, and (b) industry associations, both national and international, where they belong.

My daughter's pediatrician for instance, told us once that she sticks to the products of one or two pharma companies because of a single criteria: medicine quality and strict pharmaco-vigilance. Just a single incident of negative effect to patients, if confirmed, immediately results in product recall, recall the medicines and other health products before the public and media will report any negative side effect to patients. So all the products they sell are only of good quality medicines, no counterfeit, no substandard, no mis-stored or mis-handled products.

She added that there are plenty of medical representatives from other pharma companies, usually from India, approaching her to endorse their product. She asks them if they have BFAD clearance, any pharmaco-vigilance procedures, these guys cannot produce any. They simply want to sell cheap and affordable medicines, with possibly questionable quality, that can possibly worsen the situation of patients.

I also notice in the bicam bill, that the proposed FDA is creating new offices or divisions within it. And perhaps expanding existing ones. If BFAD wants to expand itself into a huge bureaucracy, I think there is nothing in the current law that prevents it from doing it. They got plenty of money, with continuing appropriation from Congress + retention of income, it is possible for BFAD to perpetuate its own bureaucracy. All they have to do is to justify and explain their move to the Congressional Oversight Committee every year. If Congress will not object to the expansion of the BFAD bureaucracy, then they can continue the expansion. No need to create a new law for that.

It seems a lousy bill. BFAD could have waited for a few years and work with the current provisions given by RA 9502 on BFAD strengthening.

However, since that bill will soon become a law as it is now in the bicameral committee, the provisions on drug assessment for locally manufactured and parallel imported drugs should be strong. Patients can easily be hoodwinked into buying any cheap medicine, without knowing that they are taking fake or sub-standard medicines that will not help them get cured, or will even allow the virus in their body to mutate as they stay longer, resulting in even prolonged treatment period, if not produce another diseases in the body.

With the current proliferation of counterfeit medicines, sub-standard medicines, which I feel will be amplified under the parallel importation scheme, then BFAD should indeed be strengthened. I find the parallel importation scheme lousy. The drug manufacturer abroad, the wholesaler, importer, retailer at home, are different entities. When a drug is defective, say can cause negative side effects and bad allergies to the patient, or it lacked its effectivity due to wrong handling, wrong storage, wrong temperature control, etc, who will be accountable? The foreign manufacturer, or the importer, or the drug store, or the local patent holder (but did not sell those drugs), or the physician, or BFAD, or DOH, or the legislators?

But that provision is already in the law, RA 9502, it's now implemented. BFAD or the proposed FDA should therefore monitor those parallel imported drugs, especially from India where the WHO itself says is the origin of about half (or 70%?) of all counterfeit medicines in the world.

(3) Parallel importation and BFAD

May 6, 2009

The Congressional Oversight Committee on RA 9502 (cheaper medicines law) held a public hearing yesterday to monitor the implementation of the law. Sen. Mar Roxas was reported to nearly blow his top when some BFAD and DOH officials could not answer him why some medicines are still "expensive".

Among the issues tackled was why parallel imported medicines (from India, Pakistan, etc.) take 6 months to reach the Philippines. Even the state-owned Philippine International Trading Corp. (PITC), in charge of parallel importation, admitted they do not have the capacity for such a big task, they need "third party importation" (private importers) which takes 6 months for the drugs to be delivered here.

My guess why it takes parallel imported medicines half-year to reach the country is that BFAD is putting some strict monitoring of those imported drugs. Remember that those cheap drugs are mostly manufactured in India -- where WHO says is the origin of about half of all counterfeit medicines in the world.

If some patients here will die, or at least develop new diseases and allergies because of those parallel imported medicines that are counterfeit or sub-standard, no one is exactly accountable. Not the importers, not the foreign manufacturers, not the foreign wholesalers, not the local retailers, not the physicians, not the legislators, not DOH or BFAD. That is why I noted earlier that parallel importation scheme is lousy and can be dangerous to patients.

To prevent this possibility, I think BFAD is trying to be strict in giving permits to those parallel imported drugs. Because if one patient will die and it is heavily publicized, BFAD will be put in a hot seat situation, will be subjected to endless congressional investigations.

Unlike if the manufacturer, importer and distributor is one and the same company, say GSK or Roche or Pfizer or Novartis or whatever multinational pharma, if one patient will die as a result of using their medicine, and it is proven that their medicine was defective, they are clearly accountable, they'll go to prison. BFAD will be out of the blame game there.

If my conjecture is correct or valid, then BFAD should say so and those legislators should listen.

One compromise there is that whoever is the importer of those parallel imported drugs, will have the SOLE responsibility and accountability, should something bad happens to the patients who took the drugs they brought in. BFAD will be safe. If it's the PITC that brought in any defective drugs, then they will be accountable.

I have heard of a few local cases where some patients tried to "save" on medicine prices, they bought those cheap medicines from India or Pakistan because the products by multinational pharma was expensive. After several treatment, the patient vomitted and developed new diseases. Could be counterfeit or sub-standard drugs. They ended up paying more in the hospital as their diseases have worsened or increased.

During the MeTA national forum last January, a WB-Philippines staff showed -- complete with pictures -- how some local government units (LGUs) that they inspected were dispensing expired, nearly expired, mis-stored and mis-handled medicines to the public. The medicine warehouses of those LGUs, cockroach, rats and garbage mixed in the same warehouse! Some warehouse personnel cannot tell how many drugs are on stock, and from those stocks, how many are expired, how many are still useful, etc.

Some medicines need storage of below 30 Celsius (or at lower temperature) all the time. But some warehouses don't even have thermometers, don't have air-con. For some warehouses with thermometers and air-con, when weekend or holiday comes, they turn off the air-con, room temperature can shoot up to 34 or 35 C, which can render those medicines ineffective immediately. But the LGUs were still dispensing those drugs. That is why during the open forum, I spoke up and said that it was

possible that those LGUs and their health personnel may have killed some patients by dispensing expired or ineffective medicines.

Is this situation still under BFAD's nose? I guess not, should be under the DOH and LGUs' noses and responsibility.

(4) Drug price control and LP populism

May 5, 2009

I read a news report today, where Sen. Mar Roxas was "exasperated" why the drug price control provision in the "cheaper medicines law" (RA 9502) is still not implemented by the DOH.
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http://businessmirror.com.ph/home/top-news/9871-where-are-cheap-drugs-.html
Tuesday, 05 May 2009 22:33

Where are cheap drugs?

…"It seems the government is in cahoots with the big drug companies, that's why they are not much interested in having the law implemented," said Sen. Mar Roxas II at a public hearing at the Senate....

Roxas complained the Health department has yet to set the maximum retail prices for medicines as mandated in the law. "Nine months have passed since the law was enacted but the DOH has not done it. They are too slow; so we are looking for a solution to the bureaucratic obstacle."...

Price control is a favorite advocacy by socialist-leaning politicians, political parties, NGOs and other organizations.
Food prices are high, impose price control.
Housing rental is high, impose rent control.
Gasoline prices are high, impose price control.
Medicine prices are high, another price control.

Individual pricing by individuals, firms and enterprises are wrong, that is why their prices have to be socialized, through government-imposed maximum pricing.

But there are uncontrolled taxes in medicines (import tax + import doc stamp tax + import processing fee + local govt tax + value added tax, etc. on medicines is about 20 % of retail price); uncontrolled income taxes for companies manufacturing, wholesaling, retailing medicines; uncontrolled health regulations by BFAD and DOH; uncontrolled wages and benefits as mandated by the DOLE; uncontrolled prices of active pharmaceutical ingredients (APIs, mostly imported), uncontrolled cost of R&D and marketing (about $0.8 to $1.0 billion per successful medicine), uncontrolled risks

of possible IPR confiscation through compulsory licensing (CL), etc. etc. And the final product, the price of medicine, will be controlled by the government?

Uncontrolled taxes and costs in production and marketing but controlled price of the final product. That is a perfect formula for socialized pricing, for medicine socialism.

I thought that the Liberal Party (LP) is for liberal politics and economics, where individual liberty in most cases is more paramount than collective liberty?

I believe that Sen. Mar made a serious mistake in agreeing to having a price control provision in the law where he put his personal and political stake at a high level. Since that provision is among the "last resort" provisions, then it should not be used nor implored since there is no "national health emergency" existing. But there he is, castigating the DOH for not implementing drug price control.

Is Sen. Mar and the LP moving leftwards and trying-hard socialist just to put the Senator up in the Presidentiable surveys?

(6) Emerging diseases vs non-existing medicines and vaccines

May 8, 2009

The continuing scare against influenza A(H1N1), previously called “swine flu”, is partly triggered by the absence of any existing vaccine that can control or kill the disease in the patient’s body. According to the World Health Organization (WHO), there is no effective vaccine yet already available against the said virus, and making the new influenza vaccine can take five to six months. See http://www.who.int/csr/disease/swineflu/frequently_asked_questions/vaccine_preparedness/en/index.html

There is continuing improvement in medical science detection and identification of new, emerging or re-emerging diseases. But the capacity of drugs and vaccine manufacturers to quickly respond to sudden disease pandemic is limited. Partly because of the huge costs of R&D in simply anticipating new medicines for emerging diseases.

It is important to reiterate, therefore, to provide all the necessary incentives to people and companies whose business and profession, is developing new medicines for the people with varying diseases and health needs. If huge profit for a blockbuster medicine that can cure a new killer disease is the incentive, then give it to them. And since all companies, be they restaurants or a barber shop or a pharmaceutical company, are driven by profits, then the competition among medicine inventor companies will later drive down prices while ensuring more choices for patients.

The market system of reward and punishment, of profitability and bankruptcy, will ultimately be in the interest of patients and the sick.