



Essays on IPR and Health, Part 7

Nonoy Oplas
July 14, 2011

Introduction

The last compilation of my “Essays on IPR and Health” discussion series was more than two years ago, Part 6, http://minimalgovernment.net/media/mg_20090619.pdf dated June 19, 2009. It was 16 pages long, check it too.

I am resuming this compilation as I have written several articles recently in my blog, <http://funwithgovernment.blogspot.com>, under the title “IPR and Medicines”. I just retained the “IPR and Health” title in order to provide continuity to previous compilations, Parts 1 to 6, written in 2008 and 2009.

A related paper is my recent compilation, “Should Intellectual Property Rights be Abolished?” <http://minimalgovernment.net/media/mg-20110530.pdf> dated May 30, 2011, 22 pages long.

Finally, apologies to some typographical or grammatical errors in the papers below. I tend to write what’s on my head, focus more on the content and arguments and overlook some errors in form. If I can afford someday to get an editor to go over these blog posts, such errors will surely be addressed.

Thanks and Enjoy!

IPR and Medicines, Part 3

March 4, 2011

More old articles of mine on the subject. The 2nd paper here was published in BusinessWorld.

OCTOBER 10, 2007

Innovators, intellectual property and human welfare

Today, news reports say that 2 European physicists, Albert Fert of France and Peter Grünberg of Germany, were awarded the 2007 Nobel Prize in Physics. These 2 men simply discovered that in "giant magnetoresistance, or GMR, very weak changes in magnetism generate larger changes in electrical resistance.. .." This way, they could shrink the size of electronic gadgets yet increase their memories and computing powers.

Innovators never tire in finding ways to improve human welfare. From inventing smaller yet more powerful laptops, cell phones and ipods, to inventing ever more fuel-efficient cars, airplanes and boats, to inventing more effective drugs and medicines that can reduce the pain and healing process of the sick and dying.

And what is the protection to innovators and inventors? Intellectualproperty rights (IPR), aka patents. So if we want more human welfare, let's pressure and challenge the innovators so they will produce more useful goods and services to humanity, let's increase the competition among them, not the regulations and taxation on them. More regulation (ie, less competition) and more taxation (ie, price distortion) are perfect combination to discourage innovation and to encourage copyingand mediocrity.

And yet we seem to be in an ironic age of more regulation, courtesy of international bureaucracies and influential left-leaning international NGOs. Witness for instance how the World Health Organization (WHO) is on a "missionary" path to weaken IPR of medicine innovators and reward the copy-catters around the world.

OCTOBER 24, 2007

Intellectual Property Rights

(published in BusinessWorld (www.bworld.com.ph) today, page 5, Opinion section.

Downloading pirated songs from the internet is cool. Dying from counterfeit medicine is not. But the pirates and the slack law enforcement that give you one also give you the other--and there are people who will tell you this is a good thing.

Many governments and humanitarian groups want you to believe that patents and intellectual property rights on medical innovations deprive the poor of important medicines and should be discarded in the name of public health.

But if one's innovation and invention that produces welfare to society, like producing medicines to cure malaria or cancer, using extracts from the leaves and fruits of the most common fruit tree in a particular country, is not respected, why would some guys innovate in the first place? It is protection of patents that brought those useful drugs into existence, along with millions of other products, wonderful and mundane alike: yielding to the slogan "patients over patents" would hurt poor patients the most by depriving them of new inventions.

Say you are an unknown band, performing in bars. You wrote a few good original compositions and your audiences like them. Suddenly your songs have been recorded and patented by someone else, on albums and CDs, with no mention of you and no royalties. How would you feel?

You are a researcher or academic. You presented a paper to a conference. A few months later, you see a paper published in some magazine or journal that contains most of your paper--your methodology, scientific model, data, results and conclusions. How would you feel?

You are an ordinary inventor. You invented a device that can reduce fuel consumption in diesels by 35% and you're selling it for a few bucks because you don't have a wide marketing network, or you don't have the capacity for mass production. Then, a few months later, your device is patented by someone who is selling it a handsome price, with no mention of you.. How would you feel?

The civil contracts of intellectual property, like deeds to physical property, underpin innovation, creativity and growth, as well as personal and political freedoms. Left-leaning health activists claim that breaking patents would hit multinationals and "Big Pharma" hardest--but these guys are innovators, they can find their way out like investing their money and people into something else, like new cosmetics and perfumes. It's the poor who will suffer most, from bad products, lack of new effective medicines, and economic stagnation.

And how do the consumers feel when they get these rip-offs? If you buy a pirated book or CD and it turns out to be of bad quality, you only lose your money. But if you buy pirated and bad quality medicine, you can lose your health--even your life.

This year Kenya found 20,000 counterfeit doses of anti-malarial Duo-cotecxin, one of many counterfeits in an uncontrolled market where some 35,000 people die of malaria each year. The fake, probably from China, does not just fail to cure the disease, it can increase drug resistance and make patients worse.

Governments around the world like to play the hero by promising to reduce prices, usually by price controls or patent infringement but never by cutting taxes on goods or service. My older brother, our eldest in the family, died of prostate cancer more than a year ago. His earlier hormonal chemo-therapy cost around P25,000 per session excluding the physician's fee. Of that amount, government VAT collection alone was P3,000 per session. After several sessions, he did not get well. He was later given chemo that cost P90,000 per treatment, of which government's VAT was nearly P11,000 per session. The import tax, corporate income tax, business permit and other related taxes not included yet.

If a government wants to bring down the price of medicines, rice, clothing, fertilizers, farm tractors, or any commodity essential to life and economic growth, the first thing would be to drastically cut, if not abolish, the import duties and direct taxes that hit the poor hardest.

So the next time your government blames foreign companies or international rules for high prices, find out what taxes and covert barriers it is hiding from you--and shout the truth out loud.

IPR and Medicines, Part 4

March 4, 2011

I posted my article on IPR which was published by BusinessWorld in October 24, 2007, to some of my discussion yahoogroups. Here is a long discourse.

OCTOBER 26, 2007

Comments to the IPR article

Four friends commented on my earlier article on IPR.

(1) From Ted:

Then why the hell are drugs from India only 20% of the price of the same drug pushed by the MNCs here in the philippines, at about the same efficacy? I agree that duties from imports and other taxes should be reduced, especially for medical products. But equally important, government should promote innovation and protect the patents of Filipinos who are creative innovators.

(2) From Alan:

You can't blame the absence or weak IPR on the presence of counterfeit products. When there is artificial pricing due to expensive medicines and DVD, it creates a demand for cheap products, fake or otherwise. If the drug manufacturers don't want fake medicines, they should not make their products very expensive. I would rather see government intervening to protect IPR and making quality drugs affordable to the general public, than government intervening to protect IPR alone.

(3) From Robby:

Intellectual property is the textbook example of a public good. Once something is invented, the knowhow that comes from the innovation is non-rival (my use of it does not diminish other people's ability to use the new information) and non-exclusionary (impossible to stop other people from using it)... If you want IPR or any form of private property protection, someone has to set up a regulatory institution and PAY for the costs of running that institution. So, if you cut all tariffs and taxes, how are you going to pay for all of these costs?

(4) From Randy:

Patent represents monopoly. Long patent means long monopoly. Hence, the patent should be cut short whenever possible. And discovery of new medicines results in enormous profits. The innovators of new medicines – those pharmaceutical companies – make enormous profits at the expense of public health. Hence, their profits should be regulated, if not cut.

Below are my reply to those comments:

(1) For Ted:

Drug prices in the Philippines are generally higher compared to their counterpart prices in India and Pakistan due to a few reasons. First, drugs are NOT taxed in India and Pakistan, whereas in the Philippines, we have import duties, value-added tax, other taxes. Second, there is more competition in India, with 8,000+ pharma companies, both local and multinationals. In the Philippines, there are probably less than 40. Third, economies of scale: India has 1.1 billion people or 12x that of the Philippines' 88 million. Pakistan's population is nearly 2x that of the Philippines.

"Price abuse" is definitely a possibility if the economy is not competitive and if there is no level playing field. If a country allows only a few, say a dozen, innovator companies to operate -- due to dozens upon dozens of regulations and restrictions -- and there are hundreds of copyers, then that country will be at the mercy of the few innovators. You are right that local innovators should be encouraged, but the state is not doing that. If the government can give a small entrepreneur who only wants to put up a small vulcanizing shop or small food shop, a dozen requirements (from barangay clearance to location permit to sanitation permit to fire dept permit all the way up to mayor's permit), how much more with a local company wanting to manufacture new drugs?

At the moment, many people and policy-makers hate the multinational innovators because "they make enormous profits", so they want to socialize their invention to the copyers. If the degree of socialization of invention will reach a certain high point, even local businessmen may not bother become innovators themselves, and multinational innovators may degenerate to become plain copyers themselves, stop innovating new medicines, and move instead to innovate new perfumes, new cosmetics, new shampoo, new bath soap, new skin whiteners, new fat burners, and so on. Pulling out from the country is one option, but they may not do that if they can make money innovating and selling new cosmetics products, but never new and more effective medicines.

So it depends on the incentives and disincentives you give. If there are lots of disincentives to become innovators, then people will just become copyers of innovations elsewhere, importers and traders of innovations elsewhere. What to do with specific diseases that afflict certain areas of the Philippines, new diseases that have morphed and evolved from previous diseases? Ahh, with no one innovating on these new diseases, people will scramble to import or copy somewhere else. Or just watch people get sick and die helplessly.

(2) To Alan:

"High prices" is mainly a result of supply not keeping up with demand. Many weak and sick people wanting new and more effective medicines, and too few innovator companies who produce and supply more effective medicines. So copyers (like generics manufacturers) and manufacturers of fake or counterfeit drugs surface, artificially expanding the supply of medicines, making some of them cheap and affordable.

But expanding the supply of counterfeit medicines, even if they are dirt cheap, is not our goal, right? It is expanding the supply of effective medicines, even if they are initially expensive. Something like instead of a medicine that can remove your viral infection (and the pain) in 1 or 2 week/s, why not go for a medicine that can do the same job in just 1 or 2 days? So one obvious solution is to expand the number of innovator companies, whether local or multinational, and let them compete with each other in giving us more effective medicines. It is competition, not over-regulation and high taxation (as done by many governments) that can bring down the price of anything.

(3) To Robby:

It is not correct to say that invention and IPR is a public good, non-rival, non-exclusive use. Invention is a private good. To illustrate: Some bright guys have the talent and initial resources to invent a device that can bring down fuel consumption of vehicles by xx percent. Then all the other guys around say that it is a "public good", they too should be entitled to use that invention at little or no cost for them because those inventions are non-rival, non-exclusive use anyway. What is the incentive/s for those bright guys to proceed with the invention? Who will pay for their time, effort, expenses, all those risks (remember, there is always a risk of failure for any invention)?

Or other bright guys have the brains, the network of financiers, access to laboratory facilities, etc., they can develop a rice variety that can pack up enough vitamins and boost immunity against malaria, against TB, against respiratory diseases. It can take them 20 to 30 years to develop and commercialize that rice variety. After all those years, all the other guys around will say that such rice variety is a "public good" because it involves public health, public nutrition, public safety, so that they should enjoy such rice variety at little or no cost for them. Why then would those bright guys proceed with such expensive and risky invention if they will not be compensated, even financially for their hard work?

I also did not propose to cut "all tariffs and taxes", so that nothing may be left to pay for all those government regulatory costs. I wrote,

"If a government wants to bring down the price of medicines, rice, clothing, fertilizers, farm tractors, or any commodity essential to life and economic growth, the first thing would be to drastically cut, if not abolish, the import duties and direct taxes that hit the poor hardest."

In this country, there are dozens upon dozens of different kinds of taxes. Income tax,

travel tax, excise tax, import tax, value added tax, amusement tax, documentary stamp tax, vehicle registration tax, real property tax, percentage tax, common carriers tax, franchise tax, etc.

Then there are dozens upon dozens of different kinds of government fees: driver's license fee, terminal fee, business permit fee, location clearance fee, sanitation permit fee, electrical permit fee, NBI clearance fee, police clearance fee, passport fee, quarrying fee, environmental clearance certificate fee, taxi meter calibration fee, jeepneys and buses new fare matrix fee, etc. etc.

Then there are dozens upon dozens of different government charges and penalties: expired driver's license charge, interest charges on delayed payment of real property tax, etc. etc.

In my paper, I never mentioned to cut or abolish ALL the above taxes and fees. I only proposed to drastically cut if not abolish the import tax and direct taxes on those things that government says it wants the price to go down.

(4) To Randy:

To say that "patent means monopoly" is only partly correct. An IPR or patent of an innovation for a specific number of years, is considered a "legal monopoly" for that invention, say for a device that can reduce a vehicle's fuel consumption, or a medicine that can reduce hypertension or cure leukemia. But this is not equivalent to an "economic monopoly" where one corporate entity, whether private or state-owned, monopolizes the production and marketing of all vehicle parts and devices, or all medicines.

A legal monopoly through IPR and patent for a particular medicine cannot be considered a full monopoly to cure a particular disease. Consider this hypothetical case:

To reduce hypertension, these pharmaceutical companies have discovered and patented medicines, subsequently marketed them, with different raw materials: Pharma A uses extracts from mango fruits. Pharma B uses extracts from mangosteen fruits. Pharma C uses extracts from pineapples. Pharma D uses extracts from bananas. Pharma E uses extracts from corn. Pharma F uses extracts from a particular rice variety. Pharma G uses extracts from a particular wheat variety. Pharma H uses extracts from apples.... Pharma AB uses extracts from basil leaves. Pharma AC uses extracts from maple tree leaves... Pharma ZA uses extracts from dog urine. Pharma ZB uses extracts from cow liver...

Where now is the medicine monopoly here? None. Can all of them to be taken as collective monopolists? No. This is against the formal definition of a monopoly being the "single, lone producer".

Innovators who discover new products (cell phones, cars, tvs, medicines, etc.) do not automatically make enormous profits. Toyota launches several car models every year around the world. Toyota does not automatically makes money from each model, some do not "click" with buyers, but Toyota still makes billions of dollars of profit because its other models are selling briskly. The same for pharma companies,

their biggest drugs do earn “enormous profits” but others do not. Meeting strict regulations by governments also involves “enormous costs”: per industry estimate, of the 10,000 new chemical entities that are granted patent approval (by government food and drugs regulatory boards) and enter phase 1 clinical trials, only 1 emerges as a likely candidate to reach the market. And only 3 in 10 of those are actually profitable.

If the economy is competitive and the playing field is fair and level, people who enter high-cost, high-risk research and innovation, should be rewarded with high returns if they come up with novel and successful products and services. The same way that people who risk nothing and do nothing should also be rewarded nothing. But medicines, they say, is different compared to say, inventions in new car manufacturing and accessories, or inventions in more powerful cell phones and televisions, or inventions in skin whitening and hair shining, because medicines involve public health. Hence, investors and innovators in the former can be left to reap enormous profits but investors and innovators in medicines that can cure previously incurable diseases by many people should be regulated. This is double talk, if not double standard and regulation based on envy.

IPR and Medicines, Part 5

March 14, 2011

There is a discussion in one of my facebook groups, on intellectual property rights (IPR) in the pharmaceuticals sector. One argument goes like this:

When a person invents a useful “1st-gadget” people will want to buy it and the inventor will Profit. Inevitably someone else will make a cheaper or an improved “gadget mark 2”. Now Everyone will want to buy the “mark 2” version and the person who invented the “1st-gadget will lose a portion of his expected profits unless he makes a more attractive gadget. Of course, there is nothing to stop “1st-gadget” inventor from improving on “gadget mark 2” and start selling “gadget mark 3”. In this way the world progresses and life gets better and easier for us all.

Progress depends on what happens after the “1st-gadget” is invented. The “1st-gadget” inventor is not obliged to share this invention to “improve the world”. No one can force him/her to share the idea. He could rightfully keep it to himself. However, if he reveals this knowledge to the world, then others may act upon that knowledge. Will people be willing to share knowledge if others are able to make a bigger profit from an Invention than they made? That depends on the motives of the inventor....

The “1st-gadget” inventor might wish to call on the government to use the law to prevent anyone else from copying or improving on his “1st-gadget”. He then has a patent on “1st-gadget” and nobody else may sell it or make improvements to it without paying him. One problem is that it is impossible to invent something without using ideas of others who Came before. Every inventor is building on ideas that came from an idea, sight, book, or invention that touched him. If this is so, how can

the "1st gadget" inventor are permitted to restrict other people's freedom to use his invention for further inventions? What about intellectual rights – the right to own the use of ideas? Do the rules for inventing "1st-gadget" apply to "1st-song", "1st-fi lm" and "1st-computer program"? Haven't these originated from other people's ideas and inventions of music, musical instruments, photography, computers, and programs? Would there be more harmony and less Aggression, more co-operative spirit and fewer disputes, without patents?

A number of good ideas and points above. But there are a number of faulty logic as well. Let me enumerate them.

1. An IPR like patent is granted on each specific invention. There are 1,000 composers of 1,000 different rock songs, so there are 1,000 copyright holders here. No one can claim that another band's rock song is also their invention, and no one has a monopoly on the rock songs category; instead, there are 1,000 "mini-monopolies" here.

2. People want a cheap but comfortable sedan, so Toyota invented Vios, Hyundai invented Getz, Honda invented City, and many other car manufacturers (Ford, Isuzu, Daewoo, Mazda, GM, Cherry, Tata, etc.) have their own invention of a cheap but comfortable car. There is no monopoly of a "people's car." Rather, there are dozens of mini-monopolies on the cheap and comfortable car category. Then there are dozens of mini-monopolies too, on the 2.0 to 2.5 engine displacement car category, on the SUV category, and so on. There is no industry monopoly.

3. People want a drug against prostate cancer (or breast cancer and all other cancer types). Pharma A invented a drug using molecules from tropical herbs, Pharma B invented a drug using molecules from temperate herbs, Pharma C invented a drug using molecules from sea shells, Pharma D invented a drug using molecules from big fishes like barracuda, sharks and blue marlin, Pharma E invented a drug using molecules from wild animals, and so on. No one has a monopoly on anti-prostate cancer drug. Rather, there are dozens of mini-monopolies and patents on anti-prostate cancer drugs.

4. Private property is private property, it can never be national or collective property, unless the inventor will voluntarily share his invention (a drug molecule, a song, a poem, a business software, etc.) to others. Or if he thinks that the cost of enforcement is much larger than the benefit of going through it. If we say that all IPR should be confiscated, that's coercion. Let inventors decide whether they want their invention to be shared to all or be protected by IPR laws (patent, trademark, copyright, etc.).

5. Not all lawyers and players in the pharma sector are pro-IPR. Those working in innovator pharma companies (the multinationals) are generally pro-IPR. Those who work in generic pharma are, to some extent, anti-IPR, citing TRIPS flexibilities. Then there are also other NGOs, media and academics who argue on "patients over patents", "people over profit", "health is a right" arguments. The Cheaper Medicines Law (RA 9502) is generally an anti-IPR law for institutionalizing IPR confiscation via compulsory licensing, parallel importation, government use, and so on, with riders like drug price control provisions.

IPR and Medicines, Part 6

March 15, 2011

This is the continuation of my debate with some friends who are also advocates of free market and individual liberty, but do not believe in intellectual property rights (IPR). Here are among their arguments.

1. Ideas are non-scarce goods. Nothing is lost by me using another person's idea. Copying is not theft.

2. IP is pointless. IP does the opposite of motivating Innovators, it scares them. For the protected, since his idea is protected, he has monopoly over it and isn't motivated to innovate more since there's no more competition.

3. The other potential innovator, even though he knows the innovation better to the point that he can upgrade it 100000x better than the original, he can not. Why? Because it is government enforced IP.

4. It is taken for granted that a patent is necessary to be profitable, that competitors should be restricted so as to allow innovators to recoup their expenditures. That's misrepresenting capitalism. If high costs were a hindrance to innovation, no railroads or shopping malls or anything could have been made at all; the opposite is true in fact.

5. If IP didn't exist, there would still be a competition of ideas, but no group is restricted from applying ideas to their products and seeing if customers patronize them. The IP process, while seemingly protecting innovations by rewarding patent holders, actually aborts many innovations that would have otherwise sped up developments in the particular field, because of restrictions in market application, if not in lab testing itself.

6. During the time a drug/invention is reverse engineered, the 'original' creator has a temporary monopoly on its sale. IPR stops the means of innovation by outlawing derivative works. The market process is about competition between old and new ideas. The entrepreneurs must copy the old ideas first before they can improve upon them.

7. IP actually concentrates resources among fewer pharma players rather than allows smaller competitors to come in. Big pharma's lobbying makes them buddies with politicians; they have greater pull in getting and renewing patents.

I think the answers to a number of the arguments above I have already articulated in [Part 5](#) yesterday. Let me restate them again and will expand the argument further.

1. Limitless raw materials to invent a new drug molecule

An IPR like patent is granted on each specific invention.

People want a drug against prostate cancer or any other type of cancer. Pharma A invented a drug using a molecule extracted from tropical herbs; Pharma B invented a drug using a molecule from temperate herbs; Pharma C invented a drug using a molecule from sea shells; Pharma D invented a drug using a molecule from big fishes like barracuda and sharks; Pharma E invented a drug using a molecule from deer or monitor lizards... Pharma X invented a drug using a molecule from mangos and avocado; Pharma Y invented a drug using a molecule from rambutan and mangosteen....

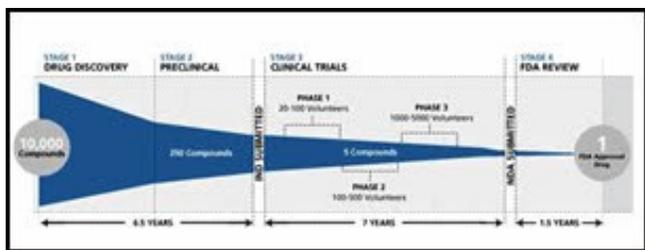
Assume further that each newly-invented drug molecule is able to treat patients with prostate cancer but at various degrees of success. Pharma A's, B's and C's drugs do not really kill the disease but they somehow prolong a patient's life by 1 to 5 years and their prices are different. Pharma D's and E's drugs are effective but they cannot be used for prostate cancer patients with hypertension as they can trigger some adverse effects. Pharma F's and G's drugs are also effective but cannot be used for cancer patients with diabetes, and so on.

In this case, no one has an industry monopoly on anti-prostate cancer treatment. Anyone and everyone who desires to neutralize if not kill prostate cancer can do so, as there is limitless raw materials and processes available as human imagination is limitless.

So it is possible to have 30 or more "mini-monopoly" drugs representing the 30 or more patented drug molecules to control if not kill prostate cancer cells.

2. Patent life

Such mini-monopolies in the form of patent on each molecule are not permanent. The international practice is 20 years patent life starting from the discovery of a molecule. It is not clear to me too why they randomly chose 20 years. Why not 12 or 35 or any other number of years.



The IPR of 20 years patent includes complying with all the strict and costly regulations by the drug regulatory agencies (currently governments like the US FDA, but it can be a private agency someday). Those multiple clinical trials on animals, then different groups of people with different health conditions, eat up around 10 to 10 years of the original 20 years patent life.

And that leaves the patent holder -- assuming their drug molecule becomes

successful in hurdling all the regulatory requirements by governments to ensure substance efficacy while ensuring safety of patients -- with only about 8 to 10 years of commercial, patent monopoly period. And from what I read, not all patented and highly-advertised drugs are successful and profitable.

When the patent of a successful drug molecule expires, then copying by all other interested generic manufacturers is possible and allowed by law. It becomes a free for all to manufacture and create their own product brands. This is what happened to paracetamol molecule. Innovator drug then was Tylenol. Upon its expiration, every Tom-Dick-Harry pharma, Filipino or Indian or Pakistani or Chinese or American, etc. produced their own brand of paracetamol. Currently, the most popular brand in the Philippines is "Biogesic" produced by one local pharma.

3. Launch delay or non-launch of patented drugs in anti-IPR countries

It is possible to disrespect all inventions with IPR protection. Copyrighted songs and softwares, pirate them. Patented drugs, copy them. But patients who buy the copycats that turn out to be counterfeit or substandard drugs will have a hard time suing or running after their manufacturers.

The existing Cheaper Medicines Law or RA 9502 contains many provisions that allow such tweaking of IPR, like compulsory licensing (CL), parallel importation, early working on a patented drug, government use of a patented drug, drug price control, and mandatory production of generics equivalent by the patent holder.

Here is one possibility, a reality for other countries already. Some of the more revolutionary, more disease-killer but patented drugs, are available in Hong Kong, Singapore, S. Korea, Japan, US, etc. but not in the Philippines. Why? There are no CL, no price control and similar measures awaiting those expensively-researched drugs there. In the Philippines, all the threats to introduce a revolutionary but patented drugs are present. So Filipino patients who are desperate to get such new drugs will have to buy those from abroad, and this will make treatment even more expensive. And this defeats the purpose of having "cheaper medicines" as envisioned by the law.

An alternative to non-launch of a new but patented drug is launch delay. After all regulatory requirements (with US FDA, etc.) are hurdled, out of the remaining 8 to 10 years of patent life, innovator companies can bring into the country such drug when there are only about 2 years before the patent will expire.

IPR and Medicines, Part 7

March 15, 2011

I will discuss two related topics on the role of government in IPR. See my earlier discussion on why fellow free marketers and advocates of individual liberty do not believe in IPR in [Part 6](#).

Should IPR be granted by governments only?

Currently, governments through their Food and Drugs Administration (FDA) and Intellectual Property Office (IPO) or similar agencies, are the ones that produce the various regulatory and health requirements then grants (or denies) the IPR application by the innovator pharma or biotech companies. There is no private entity yet like those private credit rating agencies that does the job. Government would think that public health is too important to be left to the market players and thus, unlucky for us, it seems improbable that government will abandon this function.

Let us assume just for discussion purposes, that one government in the rich world will allow a private body, say a federation of pharma + biotech companies + universities, with DOH/MOH participation, to grant or deny an IPR application for drug molecules.

Most likely it will be a less bureaucratic set up than existing government FDAs' approval process. Thus, the entire regulatory procedures before a drug can be finally marketed to the public will be shorter, less than the current 10 to 12 years. It is not the regulatory procedures that will put fear in the hearts of the innovator pharma companies should they produce an ineffective or effective but unsafe drug. It is the fear of being sued left and right and from many countries that will put fear and internal discipline for the pharma companies.

Between a government and a private agency that will grant or deny the IPR application, I would choose the latter, for the reason I cited above. But nonetheless, I am indifferent for now of who should give or grant the IPR, government or private. The point is that there should be a mechanism to assure those who invested huge amount of time and money to give us effective and safe medicines, to recoup their investments. Those drugs and vaccines will save or prolong our own lives and the lives of our loved ones anyway.

Please note that we are not talking about simply copying others' ideas here. We are talking about innovation and first time invention, about originality and creativity. Some can start from scratch, some can start from other researchers' studies, some can start from their previously failed experiment on other diseases. Their ultimate goal is to produce something that is new, something that is revolutionary and was never invented by anybody else.

Legislation and cronyism

I think that most if not all legislations after the State has expanded, are favoring certain vested and crony interests, mostly local. I discussed for instance that the Renewable Energy (RE) law is cronyism in favor of the wind, solar and other

renewable plants. See here, [Energy rationing and climate alarmism, part 2](#).

The current Cheaper Medicines Law also has the signature of favoring local pharma which have the capacity at large-scale manufacturing of drugs that can be issued a CL or can use the “early working” provision. It appears to me that the CL benefactor is saying, “The high cost of your innovator drug’s R&D is yours and yours alone; the losses of your non-successful or non-profitable drug molecule are yours and yours alone. But your successful and profitable drug invention is also MY invention too.”

Government can give in a silver platter, certain favored local companies this kind of privilege. Luckily, CL has never been issued so far. I think the main reason is not that government regulators and politicians suddenly have a change of heart and decided not to issue CL. Rather, there are no more blockbuster drugs with long patent life remaining in the market. Most if not all have their patents expiring in 2 years or less. The cost of litigation is high compared to just waiting for those patents to expire naturally.

I have argued before and I will repeat it here – government’s multiple taxes on drugs (import tax 3 to 5 percent; VAT 12 percent; local taxes, etc.) that contribute to expensive medicines were never touched or withdrawn by RA 9502. Government taxes, over-regulations and local cronyism conspired to discourage the entry of more innovator companies.

The good thing is that competition in the generics drugs is intensifying among more and more players. Major players producing different drugs from the same drug molecule only compete in branding and brand loyalty by customers.

IPR and Medicines, Part 8

March 31, 2011

In a discussion with fellow free market bloggers here in Manila, I argued that a patent (or any other type of intellectual property right (IPR)) applies only to one molecule or product and that it is possible to have hundreds of patents, say, to cure a particular disease like blindness. See my longer argument here, [IPR and medicines, part 6](#).

One commented that it's like saying, "You're free to produce tires, just not rubber tires. You can use wood, or leather..."

This is wrong logic. There are hundreds, if not thousands of molecules and molecular compounds, that can be invented from rubber. That is why there are dozens of different tires from Michelin alone, from Goodyear, from Bridgestone, Continental, Dunlop, Firestone, Kumho, Pirelli, Toyo, Yokohama, etc. Each tire manufacturer would have a phalanx of different tires suited for different types of roads: ordinary roads, race track, rugged terrain, snow, mud, sand and desert, and so on. Not one of those many tire manufacturers make tires from wood or leather.

There is also one concern that two or more inventors can work independently on something, but only one of them will be rewarded with a patent on a first come, first served basis.

Although this might be theoretically possible, I do not know if this ever happened. Let me expand on the search for new drugs to kill different diseases, say prostate cancer. Photo credit here and the next picture from [Mens Hormonal Health](#).

I often cite prostate cancer for the simple reason that it's the disease that killed my elder brother about 4 years ago, also my mother's cousin just 2 years ago. And just this afternoon, I talked to a friend here in Manila, said she's working 7 days non-stop to earn more to help her father who has prostate cancer, stage 4.

I checked the web and searched if there are new drugs that can potentially control if not kill prostate cancer cells someday. I was delighted to know that in the US alone, there are [101 different molecules](#) - patented, granted IPR -- that are potential drug candidates. Drug molecules with weird names like *abiraterone acetate*, *azacitidine*, *befetinib*, *cixutumumab*, *docetaxel liposomal*, *enzastaurin*, *intetumumab*, *ixabepilone*, *lenalidomide*, *nimotuzumab*,... my tongue is tied just trying to pronounce those weird names. There are also acronym-numbers like *MLN 8237*, *ISIS EIF4ERx*, *GDC 0449*,...

If I write blog articles like this, I did not hire molecular biologists or biochemists or zoologists or botanists or other natural scientists. I also did not construct a laboratory and will not require dozens of animals, then people, sick and non-sick, for different types of clinical trials. Thus, if other people will confiscate my blog articles and say that they are the ones who really wrote such papers, then no problem with me if they can steal and claim authorship of 1, 2, or a dozen article from this blog. There was little cost on my part to write each blog article.

But can the same comparison apply to the inventors and developers of those weird-sounding drug molecules? And those inventors are not even sure if after hurdling 10

years of continued research on each molecule, it will become successful and hurdle the 2nd to the last and the last clinal trials. Meanwhile the clock is ticking. Their 20 years patent on the molecule has only 10 or 8 or 6 years to go and they have not marketed and sold the drug yet.

Let each IP owner or holder decide whether they want their IP invention (a song, a poem, a blog article, a book, etc.) be shared for all, zero IPR, or be made exclusive for them, even for a few months or years. A call to "abolish all IPR" is coercion by itself, when free marketers are supposed to be fighting coercion in the first place.

As to whether it should be the government or some private entity that should grant an IPR, I have discussed it earlier in [IPR and medicines, part 7](#).

2 Comments:

Paul said...

Hi Nonoy,

Re: simultaneous discovery, I urge you to download this e-book
<http://levine.sscnet.ucla.edu/papers/imbookfinalall.pdf>
and turn to page 231, for a whole section on it. I think you'll find it very interesting.

On the rubber tires thing, which was my argument, you do make a good point that there are many molecules that can be used. But the point was that the principles that make a certain component useful to treat, say, cancer, could not be so readily applied elsewhere because of the limitations on the use of the component. Ultimately, however, the question of IP has to do with whether ideas could be considered property at all. :)

Nonoy Oplas said...

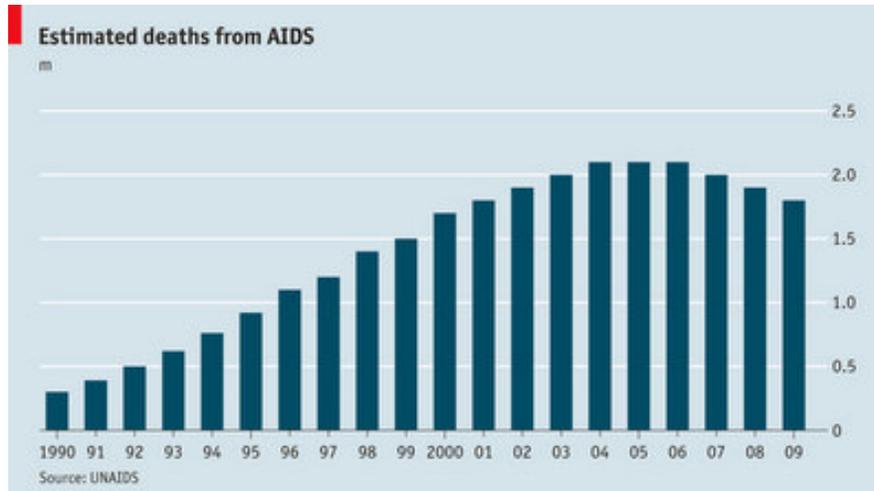
Thanks Paul. On simultaneous discovery, I mentioned above 101 different drug molecules that are simultaneously on development stage now to treat prostate cancer alone. Who was disenfranchised or prevented from developing their own drug molecule? There are 101 drug molecules there, each one is different from the other. It is possible to have 1,000 drug molecules simultaneously being developed, not one is marketed yet, to treat say breast cancer alone worldwide. No one is prevented from developing another molecule bec they are exactly different from the 999 other molecules.

Ideas are properties. But as I wrote in the concluding paragraph, it is up to the idea owner, or the property owner, if he/she wants his ideas to be shared for free to all, then no problem. But if he wants his ideas to be protected, then no external coercion should be imposed on him to say, "You are not entitled to ownership of your own idea." Isn't that dictatorship? In addition, ideas are not exactly the same as a molecule. The former is non-tangible, the latter is tangible. A drug molecule against hypertension is different from a drug molecule against stroke and is different from a beer molecule of Heineken which is different from a beer molecule of San Mig light.

IPR and Medicines, Part 9

June 8, 2011

There's a good graph from **The Economist** in its [Daily Chart](#) section last June 3, 2011 issue. It's about the declining trend in deaths due to AIDS.



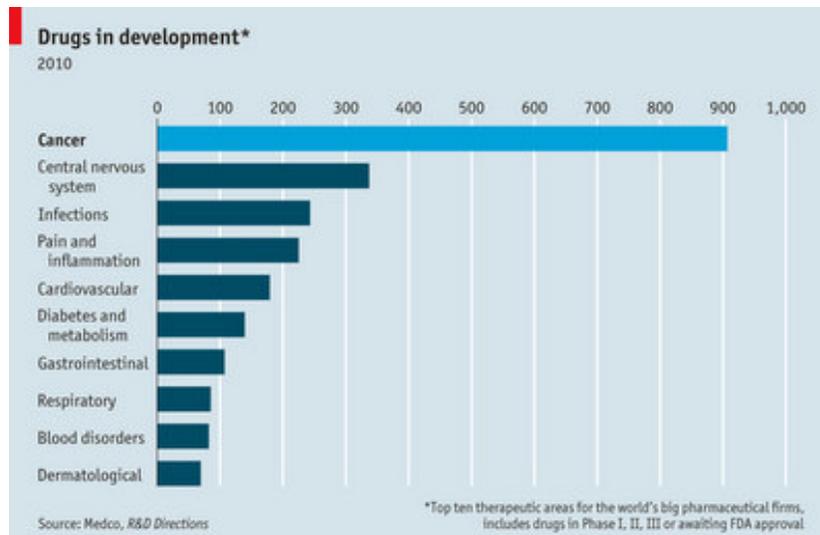
The Economist wrote, "... A decade ago, half of the people in several southern African countries were expected to die of AIDS. Now the death rate is dropping. In 2005 the disease killed 2.1m people. In 2009, the most recent year for which data are available, the number was 1.8m. Some 5m lives have already been saved by drug treatment. In 33 of the worst-affected countries the rate of new infections is down by 25% or more from its peak. Even more hopeful is a recent study which suggests that the drugs used to treat AIDS may also stop its transmission (see article). If that proves true, the drugs could achieve much of what a vaccine would."

Now, there are three issues and possibilities here. *One* is that the anti-HIV drugs and vaccines were indeed successful, even partially, in keeping the AIDS virus at bay, which allows the patients to improve their immune system. But the drugs and vaccines are not yet totally successful in killing the disease.

Two, previous estimates of actual deaths and future deaths due to AIDS were bloated and exaggerated. Thus, when a "recount" was made at the later years, the mistake of exaggeration was discovered. I remember it was the WHO and/or another UN office focused on AIDS, that made really scary scenarios about the AIDS epidemic in the future. Meaning they wanted more money if the world did not want their scenarios to happen.

And *three*, it could be a combination of the two above. The end result is that there are less people actually dying of AIDS, and the alarmism about AIDS has also gone down.

Last May 27, 2011, there was another good chart also from **The Economist**. It's about Drugs in development, or drugs not yet marketed, are patented, and are still in the research laboratories.



Caption in the chart said, "...in 2010 America spent \$125 billion on cancer treatment. By 2020 that number may rise to \$207 billion, according to the National Institutes of Health. Drug companies are scurrying to become leaders in cancer research. This month Roche submitted an application to the Food and Drug Administration (FDA) for a new melanoma drug, vemurafenib. Pfizer boasted that the FDA had granted "priority review" for a drug, crizotinib, that treats some types of lung cancer. Other firms are hawking progress ahead of an important conference in June. There is a risky, two-part strategy. First, create drugs that work. Second, charge a fortune for them."

Those 900+ different new drugs against cancer, still in various R&D stages, are proof that the claims by the anti-IPR people that "IPR like patent kills innovation and competition as whoever invents a new product like a new drug, automatically shuts off the door to other researchers and inventors to produce another product, another drug."

The opposite happens. Someone invents a new drug against breast cancer, more powerful than existing and old drugs against the same disease, he patents it. Another corporation or group of researchers invent a new drug, from different raw materials, forming a different molecule, to treat or control breast cancer. Several hundred companies or research institutes compete with each other in producing a more powerful drug or vaccine against a particular disease, and all of them have their discoveries and inventions patented. No one is excluded or disenfranchised from pursuing their own research and innovation work. Rather, everyone is encouraged to pursue such as there is a system of laws that recognize and protect them as the original inventors.

Here in the Philippines, there are very few patented drugs in the market. It is noticeable for instance, that the biggest pharma here, a local one, [Unilab](#), is less noisy now in running after the patented drugs of Pfizer and other multinationals. Patent of Norvasc is expiring this year I think; that of Lipitor (anti-cholesterol; UL's brand is Avamax) is also expiring next year or the next, I think. These will make the provisions of the Cheaper Medicines Law (RA 9502) on compulsory licensing (CL), special CL, and parallel importation of patented drugs, become moot and academic. There simply are very

few, and possibly, NO MORE, patented drugs here in the Philippines soon.

It is possible that the policy of some multinational pharma of delayed launching, or non-launching, of patented drugs to countries with laws authorizing price control, CL and related IPR-busting policies, has come to us. Some of the newest, more disease-killer, more expensive, patented drugs, are available in Singapore, Hong Kong, Taiwan, S. Korea, Japan, US, etc. but not available in the Philippines, other countries. I am not sure about this as I do not have data yet.

If this is happening now, then desperate patients in the Philippines, rich or non-rich, may have to travel abroad to get these more powerful drugs and boost their chance of survival from certain diseases. But that will make treatment even more expensive.

A basic law, the "Law of unintended consequences", almost always produce undesirable, non-anticipated negative result, whenever governments come in to intervene supposedly to protect the public.

IPR and Medicines, Part 10

JULY 13, 2011

There was an interesting but controversial article yesterday in the Washington Post written by a physician, Dr. Ranit Mishori, [Some doctors insist on brand-name drugs even when cheaper generics are available](#).

Dr. Mishori quoted the *American Journal of Medicine* article where "researcher doctors noted that out of a sample of 5.6 million prescriptions written for more than 2 million patients, nearly 5 percent "were designated as dispense as written by physicians and patients."

So Dr. Mishori in effect is questioning the nearly 5 percent of physicians (in the US) why they do not allow drug switching anytime anywhere for all patient cases. Not a big number then. But let us pursue her points. She wrote further,

So why do some doctors prescribe a brand-name drug when a generic is available? Researchers report that many doctors still don't trust generics. In one recent survey, published in the Annals of Pharmacotherapy, nearly 50 percent of the doctors participating acknowledged holding some negative perceptions about the quality of generic medications.

It is also habit. Brand names are the names doctors most easily remember. Drug samples left in physicians' offices — seemingly a free gift for doctors to dispense and patients to receive — make them more memorable. Often, sales representatives will treat a physician and his staff to lunch, and leave behind an array of pens, coffee mugs and USB memory sticks branded with the name of their drugs....

On the first paragraph, I think Dr. Mishori did not mention some considerations by physicians, pharmacists and pharmacologists before they would recommend drug switching to any generics equivalent -- bioequivalence, pharmaequivalence, cGMP, etc. The same drug, patented or generic, branded or non-branded, by the same manufacturer given to two patients with the same disease may produce different results. This is because although they have the same disease, the two patients have different biological and physical conditions (one is older than the other, or one has diabetes or hypertension while the other has none, and so on).

On the second paragraph, both innovator and generic manufacturers are doing those things -- giving free drug samples, mugs/pens/USB/bags with the name of the drug or manufacturer. In the Philippines for instance, the biggest advertiser of drugs are not any of the multinational innovator companies. It is Unilab, the biggest pharma company here, it is a local and generic manufacturer firm. One can see Unilab's products on tv, newspapers, billboards, pens, and so on; hear it on radio, etc.

A short rebuttal to the WaPo article was made by Ms. Kate Connors in her blog post, [Setting the Record Straight: Patients Need Innovation, Not Just Generics](#). She wrote,

I reiterate that we do not discount the importance of generic drugs to patients and to the healthcare system as a whole. However, let's not forget that without innovative brand medicines, there would be no generics.

Our CEO John Castellani has a great line: "We love generics. They're our grandchildren. We created every single one of them."

Today's groundbreaking medicines will likely someday find their way to patients as generic options, as well.

But at the end of the day, if we rely solely on generics, innovation will stagnate. The future of medical progress lies not just in generic drugs, but in brand-name medicines.

I agree with her observations there. Both innovator and generic drugs are important, they have their uses to patients and their physicians. Where drug switching is allowed by our physicians, then let us go for generics, they are cheaper and safe at the same time.

But some patients are more impatient than others, they want to get well soon; not next month or next week, but the next 2 or 3 days. They want more powerful, more disease killer drugs, even if these are more expensive than those currently available. And that is the role of continuing drug innovation.

Well, at least Dr. Mishori did not advocate in her article the abolition of patent and IPR system in drugs, unlike what the socialists and some libertarian anarchists would suggest.