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DISCUSSION KICK-OFF

Innovations in Pharmaceutical Industry

How to Work Towards a Global Benefit for Consumers

DHIRAJ R. DURAISWAMI — 15 September, 2016

Intellectual Property Laws across the world is intended to provide incentives to creators, authors, innovators and [illegible] usually for a limited period. Those rights would reward their efforts, help recoup their investments and profit from their contributions to society. However, due to inconsistencies and loopholes in law coupled with the ineffectiveness or challenges in enforcement, society suffers from certain monopolistic, controversial and certain unfair trade practices; a few of

which are highlighted below to propose an effort to address the issues and work towards balanced solutions.

The dilemma facing patients – both in the developing and the developed world – can be linked more specifically to the patent law controversy emanating from the US and impacting societies. Many large pharmaceutical companies, including drug companies in the US, have been accused of denying generic drugs in the US and elsewhere to needy consumers, indulging in price gouging, appearing to disengage with the needs of the patients in third world countries and being overzealous in their efforts to protect their intellectual property rights by trying to extend the reach and validity of their patents globally. Incremental patenting to extend the validity of patents is a way adopted to keep some drugs away from becoming generic and more freely available.

Prices of life-saving drugs

Arbitrary and huge increase in the prices of life saving drugs – with the primary objective of short-term profit maximization – is one very controversial way consumers are denied what they should be entitled to. US Patent law in general provides creators of novel, non-obvious and useful products with a 20 year monopoly during which no one else can, except with the permission of the creator, produce and profit from such creations. WTO member states have to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as producing the chemical ingredients for a medicine), while allowing certain exceptions- according to Article 27.1 of the TRIPS Agreement. Article 33 of TRIPS also provides that Patent protection has to last at least 20 years from the date the

patent application was filed. On expiry of the protection the inventions become generic and go into public domain. New drugs, formulations and compounds are covered by utility patents and the period of protection starts from the date of First-to-File worldwide (earlier at the date of First-to-Invent in the US). Understandably, even if not agreeably, owners of such drug patents are driven to make the most return on investment in this first period.

Price Gouging – the Example of Daraprim

It is often claimed that pharmaceutical companies spend at least a billion dollars for any drug to make it through the long road from creation through testing, trials and to the consumers. Return on investment and the intent to maximize their profits within the protected time period is indeed the economic raison d'être. Recent news of Turing Pharmaceuticals increasing the price of Daraprim, used to treat toxoplasmosis, a life threatening condition affecting HIV patients, by 5000%, from $13.50 to $750 per pill has been controversial to say the least. Meanwhile, even when his company earlier agreed to cut prices by 50% for hospitals that handle about 80% of cases treated with Daraprim, it remains available in Europe for less than $1. Price gouging happens not just in developed countries like the US and surely with more impact would negatively affect developing and under-developed countries that do not have the means to make available such drugs for consumers in dire need.

Consequences for Developing Countries

We find a broad debates regarding price gouging and the claims about weak patent legislations and lax enforcement of patent rights in developing countries like India and China. At the same time, is the reality that many such life-saving drugs

are urgently needed in these countries and other least developed countries, but unaffordable given their cost. The non-affordability of such expensive patented drugs is worsened by the acute absence of paid or free medical insurance coverage. Stands such as the one taken by Bayer's CEO Marjin Dekkers in 2014, when he declared that the cancer drug Nexavar was made for rich westerners and not for poor Indians, suggest that corporate greed ultimately rules over consumer needs – a deplorable goal of pharmaceutical companies.

Possible Solutions

There are potentially two ways to counter unfair price gouging – by true competition, allowing the market determine true prices for the drugs, or by legislative price controls and more effective regulation that provides transparency and prevent unfair trade practices. Imprimis Pharmaceuticals' announcement to create a Daraprim alternative that is a compound using active generic ingredients would cost patients only $1 a pill. This competitive outcome, is a potent and quick way to counter and help treat the life threatening Toxoplasma infection that severely affects pregnant women and immune-compromised AIDS patients. However if the generic drug has to be acceptable for consumers, it needs to be FDA approved.

Another strategy to deal with this issue in emerging countries keen to provide life-saving drugs for their people, is the adoption of compulsory licensing invoked by the government to control costs and counter denial to those in need. Article 31 of the TRIPS agreement provides for the mechanism of compulsory licensing of pharmaceuticals and medicine, meaning that the patented product may be

produced without consent of the patent owner. The compulsory licenses may be obtained not only to supply in general the domestic market of countries that are among the least developed, but also under certain conditions for export to other countries that do not have production capacity. Normally, compulsory licenses can be granted by countries after their declaration to do so, subject to conditions listed under Article 31 of the TRIPS agreement. This includes the need for the person or company in the WTO member country to negotiate a voluntary license first with the patent holder on reasonable commercial terms. Only if such negotiations fail a compulsory license may be issued, after which the patent holder has to receive a payment of adequate remuneration. In the case of 'national emergencies', 'other circumstances of extreme urgency' or 'public commercial use', there is no need to try negotiating a voluntary license before seeking a compulsory license.

The market forces of demand and supply may indeed bode well when companies acknowledge the reality of the burgeoning middle income markets in countries like India, China and other developing countries, where competitive price policies would help reap returns while meeting the genuine and immediate needs of its consumers. With the growing reality of compulsory licensing that has been adopted by some WTO member states like India, it makes business sense for pharmaceutical companies to have an equitable approach to voluntarily licensing the drugs in question. Providing those consumers in need with prices lower that what they are charged for countries like the US, can still contribute to the return on investment given the larger volume of sales.

Looking at the initial investment in research and development, it is also argued that the claims of high expenditure for innovation are often grossly inflated. This if proven would undermine the argument of the threat to innovation posed to the industry. In that light, there is apparent need for transparent mechanisms to measure expenditure and ensure the reasonableness of the rewards sough in return for such innovation.

Conclusions

The dispute about accessibility of life-saving drugs, especially for consumers in developing countries, belongs to the most vehement and complex questions in today's world – touching upon issues of intellectual property, reasonable demands from society towards private companies, and global justice demands. There might be no easy reconciliation between companies' business interests and the claims of patients, but as has been shown in this contribution, international law offers some ways to mediate the two.

Most importantly, the lack of regulations to control price gouging and arbitrary extension of patents and ensure transparency of manufacturing processes, costing and market mechanisms need to be addressed. To strengthen the US Patent and Trademark Office (USPTO) and similar agencies worldwide, and to promote legislative action to tighten loopholes in the law can further balance between legitimate claims of innovators and interests of society. Individual governments also have a role to play in mediating this tension between Intellectual Property Law and Antitrust Law, each in their specific jurisdiction safeguarding that regulatory regimes are poised to protect the interests of the technology transferring licensors, while enabling the

maximum accrual of the benefits of innovation to the consumers world-wide.

Beside availability of legal channels, it is fair to expect that companies will abide by an ethos of their profession. One of the Bayer company's early presidents, George Merck, is quoted with the following: 'We try to never forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear. The better we remember it, the larger they have been.' In light of some of the discussion, the quote might sound ironic. It is hoped that it loses some of its irony.

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PEDRO A. VILLARREAL

22 September, 2016 at 18:31 (Edit) — Reply

Thank you, Dhiraj Duraiswami, for this compelling post on a hot-button issue, and for providing an International Law angle often overlooked.

I agree with the premises, insofar as it is a matter that requires tending to the currently existing legal loopholes in Intellectual Property law. The argument related to the profit-ratio of companies is a difficult one to make since, in my opinion, it could require both an accounting exercise as well as empirical evidence related to the pharmaceutical industry's active ingredient production, which is not always available. Nevertheless, I think the argument related to ongoing practices such as artificially extending patent rights (a.k.a. "evergreening") is sound as it is, insofar as there is hardly any convincing justification, economic or otherwise, on behalf of maintaining such regulatory artifices. This is where legal reforms can -and even, should- play a role in fixing the conundrum you describe with detail in the post.

That being said, I would like to briefly mention the promising -albeit still under dispute- case of price-

regulation done in Colombia for cancer drug Imatinib. After (failed) negotiations with Novartis, the patent-holder, the Ministry of Health of Colombia declared this drug to be of “public interest”. This will allow setting its price through the National Commission on Pricing on Drugs and Medical Devices and by using a different methodology, which will “simulate conditions of competition in the market” (quote from the Administrative resolution, available at https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/Resolucion-2475-de-2016.pdf) . Price setting will be effectuated without requiring the acquiesence of Novartis. If this initiave is successful, I believe it will show how current legal mechanisms, such as the one from TRIPs, can be used for circumventing monopolistic practices that restrain access to medicines in an unjustifiable manner. Of course, the issue is always how to determine when this is “justified” or not. In my opinion, there is no visible possibility of drafting a definitive legal criterion that overcomes the need for a case-by-case analysis.

Best regards

DHIRAJ DURAISWAMI

2 October, 2016 at 02:50 (Edit) — Reply

Thanks Pedro Villarreal, for your response which is pertinent and much appreciated.

The mention you made of the case of Novartis’ cancer drug Imatinib being subjected to price-regulation by the government is definitely a good case in point, which aims to bring the benefit of life saving drugs to its people and also balance the equitable rights of the drug company. Interestingly the long drawn case of this drug in Colombia (http://www.reuters.com/article/us-novartis-colombia-cancer-idUSKCN0YV2NT) indeed started with its sale

without patent protection since 2003 as Glivec or Gleevec till 2012 when its high prices sparked competition from generic producers at nearly 200 percent cheaper prices. The company only obtained a patent there with the intervention of a Columbian court order in 2012, followed by the debate of using the option of compulsory licensing (http://www.wsj.com/articles/colombia-threatens-to-override-novartiss-patent-on-gleevec-1463770091) which was opposed by groups and the governments of the US and Switzerland and hence the controversial decision by the Colombian government. This could very well set a precedent for other nations to adopt this mechanism on a selective basis to control arbitrary and rising costs of such key drugs.

Interesting, while other countries like Thailand, Brazil and India have adopted compulsory licensing to counter such high priced and crucial drugs, this very same drug Gleevec was the subject of seven-year battle when initially denied a patent in India for technical reasons by the Patent Office, and ended with the refusal being upheld by the Indian Supreme Court in 2013 (http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212). The patent law in India as amended in 2005 to comply with TRIPs also has given the ability to prevent “evergreening” that has been used from time to time. This evidences effective statutory action to close legal loopholes being exploited by large drug companies.

Also interesting is that, in the US Gleevec has lost its patent protection and even as generic drugs have been introduced in the market the price has only fallen modestly (http://www.npr.org/sections/health-shots/2016/02/01/465139901/generic-gleevec-imatinib-savings-will-be-modest). Even doctors including a developer of the drug had criticized the high prices and the questionable tactics adopted even after the recouping of costs. So additionally using a price regulatory mechanism within a statutory framework to receive and act upon complaints from and on behalf of patient

consumers could help to supplement other courses of action.

PEDRO A. VILLARREAL

4 October, 2016 at 15:58 (Edit) — Reply

Thank you very much for your very thorough reply. It is definitely illustrative to look at the particularly convoluted case of Gleevec, as it is a matter that transcends an individual country. The comparative perspective you provide is useful for tackling this issue.

I would only have one thing to add, followed by two questions:

One of the biggest factual challenges for compulsory licenses to work, is to actually find a company able and willing to undertake the production of a particular drug. This option may not always be available. We could think of the problem with Benznidazole, which is used to treat Chagas disease. The original patent-holder had ceded the rights to produce this medication, which from then onwards would be retaken by a public laboratory in Brazil (it should be stressed this was not compulsory licensing, but rather an agreement with the patent-holder). Afterwards, the governmental laboratory in charge of producing the active pharmaceutical ingredient fell short of the demand, blaming it on a back-and-forth disagreements with the Ministry of Health and another private drug producer. Some years later, this initiative was adopted by an Argentinian public-private partnership. However, the shortage of medication almost put the whole campaign against Chagas disease to a halt. In my opinion, these and other similar examples show how there are still economic and logistical challenges for

devising alternatives to intellectual property-based monopolies.
On another issue, you mention how the price of Gleevec in the United States has not been substantially reduced, even though there is already an “open market”. Would this mostly be due to high demand of the product? Or is there another possible explanation on why this is the case? In any case, I can see why you argue that price regulatory mechanisms would work for these situations.
Lastly, on the matter of recouping costs, would there be public records clearly showing when the initial investment has been considered to be fully covered? As this might be a yardstick for assessing when profits exceed the justification for maintaining the current length of patent protection regimes.

DHIRAJ DURAISWAMI

1 November, 2016 at 08:03 (Edit) — Reply

I apologize for the delay in responding and would start by responding to your questions first.
As to the persistence of high prices for drugs like Gleevec in the US, I would opine that it is a consequence of both the high demand for critical and lifesaving drugs combined with the aftereffects of the monopolistic impact that had caused the high prices in the first place. As can be seen from the same report quoted earlier there is only a single manufacturer (Sun Pharmaceuticals based out of India) making the generic version of the revolutionary cancer pill for the US market. Also the pill that was initially launched by Novartis in 2001 to greatly advance the treatment of myeloid leukemia specifically and improve cancer therapy overall, has since then be approved for use against all other types of leukemia and blood cancers, rare skin cancers and certain gastrointestinal tumors. The

launch of the generic imatinib drug hopefully by other companies would lead to a drop in prices, which for obvious reasons has not been drastic as yet while government approvals and regulatory challenges would also have to be overcome. Also to be kept in context is how the prices for one pill of the branded and protected Gleevec had risen from about $92.74 in 2010 to $179.93 in 2014 according to the Centers for Medicare and Medicaid Services who spent about $1 billion in 2014 on Gleevec. (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Drug Spending/Drug_Spending_Dashboard.html). This 'price inertia' would slowly but surely be overcome in time as more generic competitors appear on the scene.

As to the question of availability of public records to show if the costs of initial investment have been recouped, I guess there would not be any unless regulations are in force that arguably can require such transparency that would be in conflict with the industry's interests. There are various other factors in play such as role that industry plays in funding research, the promotion of alternate drugs, common pooling of costs and extending patent protection that would act as barriers to promote such transparency.

Finally, as in the case of Benznidazole it is obvious that the economic and logistical challenges that you rightly point out exist and would persistently scuttle efforts to fight disease and death. It is more interesting to note that this case specifically reveals how some of the same actors and corporate greed inspired motives are involved as was pointed out initially. (http://arstechnica.com/science/2016/02/in-comeback-bid-shkrelis-old-company-gets-ok-to-buy-life-saving-drug/).

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