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An Ethical and Economic Outlook into Patenting Pharmaceuticals and Safety

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ABSTRACT

Product patents for pharmaceuticals and life-saving devices are often questioned on whether such patents are ethically wrong due to the fact that they prevent certain classes of persons from gaining access to the drug/device due to a multiplicity of factors such as increased prices, geographical restrictions etc. Product (material) patents were introduced in Japan as late as 1976. The first half of the article analyzes data from Japan just prior to as well as after 1976 to determine how such legislation changed the dynamic of the Japanese domestic pharmaceutical system; evolving from a system that rewarded processes rather than the product. There is evidence to suggest that Japanese pharmaceutical companies stopped striving to find unpatented processes to make drugs and transformed into innovating new types of drugs aimed at curing different ailments. There is also strong evidence to show the growth of pharmaceutical companies as well as the increasing quality and concentration of pharmaceutical innovation. Japan's pharmaceutical regulator, the Ministry of Health, Labor and Welfare, mandated that prices were to be controlled by the Ministry itself. This prevented an abuse of the patenting process by large pharmaceutical companies. Comparing such a stance to different first-world nations, we see countries such as the United States wherein pharmaceutical companies have free reign over medicine-pricing citing "free market" policies. From our analysis of the evolution of Japanese pharmaceutical companies, there is evidence to support the implementation of a "public utilities method" wherein governments allow private entities to have monopolies over certain commodities but regulatory bodies also establish regulatory pricing to prevent indiscriminate hiking that go against public policy.

In the afternoon of 4th April 1958, a relative of Volvo CEO, Gunnar Engelau, died in a car crash[1]. This incident, relatively unknown, has led to one of the most used safety mechanisms in the history of the world – the three-point seatbelt, a standard in all cars from 1970. After the death of his relative, Gunnar Engelau hired Nils Bohlin to be the company's first chief safety engineer who invented and patented the belt system; a system that has saved almost a million lives till date[2]. But what's really interesting to note is the fact that though Nils Bohlin patented such a remarkable innovation, Volvo made the three-point belt system available to all car manufacturers for free[3]. The story of the three-point belt system is a feel-good story of how one man saved almost a million people over a span of 60 years but it leads to the question of whether this was actually the best possible outcome of the situation that occurred. If history dictated that the three-point belt system was not available freely to all car manufacturers, what would have happened then? The answer to this lies within two alternate and mutually exclusive paths. Car manufacturers could have defaulted to their own original two-point systems (which was relatively unsafe)[4] or profits could have been spent on research and development into better safety mechanisms as compared to the original two-point systems. We know for a fact that the latter would have been more likely - companies would have had to invest into better forms of safety mechanisms due to the multiple automobile safety regulations that were being implemented. This could have led to even better mechanisms than that patented by Nils Bohlin. The fact that car manufacturers were given such an effective safety mechanism on a plate might be the reason that prevented them from ever innovating newer and better methods of combating a fairly complex problem.

Throughout history, governments have introduced a system of patenting for two main reasons. The first being to stimulate research and find solutions to problems that vexed the nation. The second being to promote the broader good of the country[5]. This has been epitomized in the pharmaceutical and drug industries wherein the patenting process is a highly competitive field – even going as far as crashing company stock prices through failed drug trial testing[6]. This paper postulates that patenting of pharmaceuticals and safety mechanisms are a necessary evil to promote innovation and production in such industries.

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[1] Jacobs D. (2014), *Why You're Less Likely to Die in a Car Accident These Days*, INJURY LAW BLOG, (Apr. 10, 2014), https://www.nwinjurylawcenter.com/why-youre-less-likely-to-die-in-a-car-accident-these-days
[2] National Highway Traffic Safety Administration, *Seat Belts Save Lives* (2012)
[3] History Editors, *Three-point seatbelt inventor Nils Bohlin born,* HISTORY, Jan. 27, 2010
[4] Crandall J. et al., *A Comparison of Two and Three Point Belt Restrain Systems* (University of Virginia 1994)
[5] Denoncourt J., *Intellectual property, finance and corporate governance* (London Routledge 2008)
[6] Pastor R., *GTx stock crushed after Phase 2 trial failure; Baird downgrades company shares,* (Proactive Investor 2018)

In certain countries like Japan, pharmaceuticals could not be patented until as recently as 1976 when new legislation implemented methods to patent newly invented medicines[7]. Prior to 1976, Japan allowed for patents for processes rather than products. Hence, Japanese pharmaceutical companies strove to find unpatented processes to make drugs rather than innovating new drugs[8]. This was a rational economic consequence of rewarding imitation rather than innovation. Companies had no reason to innovate new drugs since there was more money in patenting new processes. In its strive to make profits, Japanese pharmaceutical companies focused on launching new versions of pre-existing drugs rather than new drugs[9]. In 1976, with the introduction of new legislation allowing for product (material) patenting, Japanese economists forecasted that certain substitutes would be made unavailable to certain markets and hence, result in increased prices of products that were protected through Japan's patenting legislation[10]. To counter this, Japanese legislation, for ethical and liability reasons, mandated that prescription drug prices were to be set by the Ministry of Health, Labor and Welfare. This was to be done for the reason of insurance reimbursement and to prevent the market from determining the price[11]. The availability of products was not adversely affected by stronger patents and any variation within the statistics could be attributed to variance rather than the implementation of the new legislation[12]. Prices of over-the-counter products surprisingly fell and there was a steady increase in the number of drug products after the introduction. For the first time in Japanese history, pharmaceutical companies in the nation were making headlines around the world for their new innovations. This can be directly attributable to the fact that products could now be patented. These facts lead us to the conclusion that the quality of Japanese pharmaceutical patents shifted from imitation to invention.

Japan's exemplary standard of innovation is a landmark in the implementation of proper patenting legislation along with maintaining moral ethics. Compared to countries like the United Stated of America wherein pharmaceutical companies have free reign over medicine-pricing citing "free market" policies, Japan has shown the world that equity does not have to be mutually exclusive to profit-maximization. The American health care and pharmaceutical industries are

[7] Maurer R., *Japan's drug patent laws aided modernisation,* Financial Times, Dec. 2, 2013
[8] *Id.*
[9] *Id.*
[10] Aoki R. and Saiki T., *Implications of Product Patents – Lessons from Japan,* Apr. 2005
[11] Takemoto Y. and Kajimoto T., *Japan health minister to consider U.S. drug firms' views in pricing overhaul,* Reuters, Sept. 22, 2017
[12] *Id.*

arguably one of the worst among first-world countries[13]. Due to its free market policies, companies have often forced the poorest of the poor to spend life-savings on drugs they cannot afford – often making death their best alternative[14]. Just take the example of Martin "the most hated man in America" Shkreli. Shkreli is the chief executive of Turing Pharmaceuticals, the company that acquired the rights to Daraprim – the drug which helped combat against HIV/AIDS. Prior to acquiring the drug, a single dose would cost USD 13.50. Upon acquiring the rights to Daraprim, Shkreli hiked prices to USD 750 per dose – a whopping 5,000% increase for a life-saving drug. Turing Pharmaceuticals took the defence that insurance companies would have to pay for the cost of the drug and hence, end-consumers would not be affected. This was blatantly false as was noted in a BBC investigation dated August 4, 2017[15]. Such unethical practices must not be condoned by State governments nor should pharmaceutical companies be given a free market to rule over if such actions could cause wide spread loss of life.

A better approach is to implement a "public utilities method" which is used by many States when there is a natural monopoly in production such as for water or power[16]. In this case, the governments allow private entities to have a monopoly over a certain commodity but also establish regulatory pricing to prevent indiscriminate hiking against public policy. In Japan, pharmaceuticals follow a very similar approach. Retail prices of drugs are set by the Ministry of Health, Labor and Welfare[17] based upon a formula that accounts for the size of the market and the age of the drug[18] (please refer to Annexure 1, (a) for Japan's Drug Price Index). Economists often call price-regulation a bane to development but in the case of Japan, the number of approved drugs increased after introduction of patent protections and price regulation[19] (please refer to Annexure 1, (b) for data on Japan's approved pharmaceuticals). During this period, imports rose and so did domestic production of pharmaceuticals regulation[20].

Critics of patenting pharmaceutical products cite ethical and moral reasons to prevent protection of newly approved drugs. These usually run along the lines of "if pharmaceuticals are patented, then companies will have a monopoly over them and increase prices to a level that individuals can no longer afford them". In the US, such critics are silenced with the reasoning that free

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[13] Khazan O., *The 3 Reasons the U.S. Health-Care System Is the Worst,* The Atlantic, June 22, 2018
[14] Arak M. and Tschinkel S., *Why the 'free market' for drugs doesn't work and what we can do about it,* The Conversation (Oct. 1, 2018), http://theconversation.com/why-the-free-market-for-drugs-doesnt-work-and-what-we-can-do-about-it-70007].
[15] Thomas Z. and Swift T., *Who is Martin Shkreli - 'the most hated man in America'?*, BBC, Aug. 4, 2017
[16] Arak et al., *supra* note 14
[17] Takemoto et al., *supra* note 11
[18] Aoki et al., *supra* note 10
[19] Japan Pharmaceutical Manufacturers Association, *JPMA Data Book* (1978)
[20] *Id.*

market policies, which allow for the high prices of drugs, and strong patent laws allow the pharmaceutical industry to invest large sums of money into R&D. According to the industry it costs around USD 2.6 billion to introduce a new drug into the market[21] and hence, these firms claim that they need to be allowed to set their own pricing thereby, allowing for future R&D. This reasoning stated by US pharmaceutical companies does indeed stand on the backdrop of factual data but not entirely. "Free market" policies in the US have not adhered to any form of moral and/or ethical standards. In Japan, R&D expenditure in the pharmaceutical industry was under 200 million Japanese yen in the year 1967 (prior to the new legislation) – about 3% of total sales[22]. After the new legislation, in 1980 R&D expenditure had grown to 190 billion yen – about 5.5% of total sales[23]. By 2000, this figure had grown to 746.2 billion – around 8.6% of sales[24] (please refer to Annexure 1, (c) for growth trends of Japanese pharmaceutical R&D expenditure). These increases in R&D investment occurred despite of pricing regulations in Japan. Hence, free market policies are not a defense to US pharmaceutical companies since the data clearly shows that price regulation along with strong patent laws have allowed for growth in R&D.

India, as well, has taken this outlier but ethical standard of moral patenting standards. In 2013, the Indian Supreme Court decided the case of *Novartis AG v. Union of India*[25]. Though most of the *Novartis* judgement deals with novelty and the presence of a concrete inventive step, the apex Court of India must be commended due to its refusal to cave into this supposedly global paradigm of monopolistic pricing through strict patenting procedures. The apex Court's refusal to protect foreign investment through patent monopolies, though grounded in statute, also appears to emerge from a national interest perspective[26]. The Court took into account both public interest and private interest in a country that houses a significant number of those living below the poverty line as well as housing some of the leading pharmaceutical companies of the world. India accounted for 30% of the production-volume of pharmaceuticals consumed world-wide in 2017[27]. India did this through a system of allowing generic companies to enter the market on day one after paying a form of royalty or compensation to the drug patent-holder[28]. This encouraged competition and allowed for prices to remain stable and controlled by the forces of

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[21] DiMasi J., Grabowski H. and Hansen R., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, J Health Econ, Feb. 12, 2016, at 20-33.
[22] Japan Pharmaceutical Manufacturers Association, *supra* note 19
[23] Japan Pharmaceutical Manufacturers Association, *supra* note 19

[24] Japan Pharmaceutical Manufacturers Association, *supra* note 19
[25] *Novartis AG v. Union of India,* (2013) 6 SCC 1 (India)
[26] *Id.* at 79
[27] India Brand Equity Foundation, *Indian Pharmaceutical Industry,* Rohtak, 2018
[28] Basheer S, *Patent with a purpose,* The Indian Express, Apr. 3, 2013

demand and supply. Furthermore, the efficacy of this system has been seen in India wherein drug prices have always been relatively low[29] while at the same time allowing for patent-holders to receive compensation for their R&D. Along with this, India also implemented price controls for over 300 drugs in 2013[30]. This system is similar to the Japanese system we saw earlier, but instead of a blanket price-control over all pharmaceuticals, India only implemented regulatory pricing on 300 essential and life-saving drugs. Though there is currently no freely available, unbiased data to infer any conclusions on whether *specific* price regulation on only essential drugs has affected innovation, we see from past examples that this might not be the best idea since firms often divert their efforts into substitute markets to respond to price caps and regulations (please refer to annexure 2 for examples unrelated to patenting)[31]. This is a simple economic consequence of indirectly incentivizing the production of non-regulated goods. Luckily for the Indian pharmaceutical industry, price caps of the 300 essential drugs were not detrimental enough to cause firms to shift to other industries. Further, the companies making these pharmaceuticals were large enough so as to make such price-regulation not affect end-of-the-line profit margins.

CONCLUSION

This paper has heavily relied on Japanese data to reach the following conclusions. This is because, Japan is the only country that has changed its law from a system wherein pharmaceuticals predominantly could not be patented to a system in which specific drugs were granted patents. Hence, we can clearly see the economic effects of such a change in real time without having to make vague assumptions and/or inferences.

The investment that goes into the R&D of new drugs cannot be made unless investors are assured some form of return. Basic economic principles teach us that an investment with 0% return would be an irrational investment. We also see that strong patent laws in the field of pharmaceuticals have evolved seemingly dormant industries into full-fledged and thriving industries. Without the new legislation implemented in Japan in 1976, the pharmaceutical industry within the country would not have grown. Hence, the question of moral ethics becomes a vague one since without a patenting system, the question does not arise due to the fact that there is almost no innovation of new drugs. Higher pricing due to patents is a necessary evil

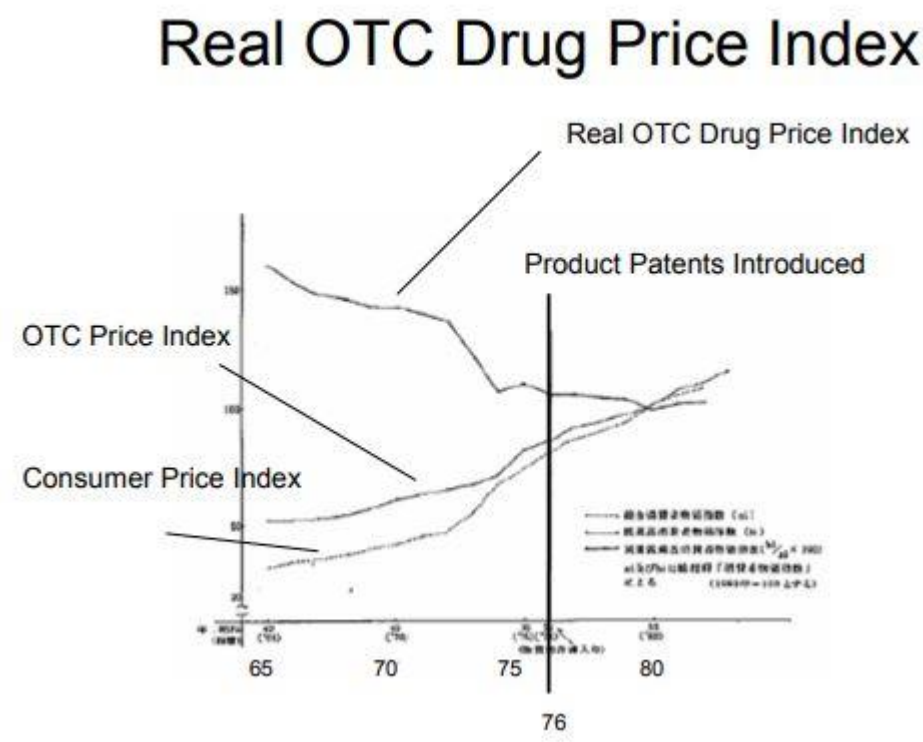
[29] Roy V., Gupta U. and Kumar Aggarwal A., *Cost of medicines & their affordability in private pharmacies in Delhi (India),* Indian J Med Res, Nov. 2012
[30] Drugs (Prices Control) Order, 2013, Gazette of India, pt. II sec. 3 sub-sec 3 (May 15, 2013)
[31] The Economist Group Limited, *Socialism in Venezuela - Feeding frenzy,* The Economist, Mar 12, 2009

since otherwise no industry would strive to innovate solutions to problems unless they benefited from these solutions. To counteract these consequences with regard to higher pricing, Japan's system of regulated pricing of pharmaceutical products seems to be the best system so far according to the data supplied by the JPMA Data Book[32]. From the data we see that blanket price-regulations will do far better than India's system of price caps over specific goods. This is due to the fact that regulations only over *specific* goods causes firms to be incentivized into moving away from price capped goods and producing those goods that are not regulated. This does not occur in the case of blanket price-regulations since all goods would be regulated.

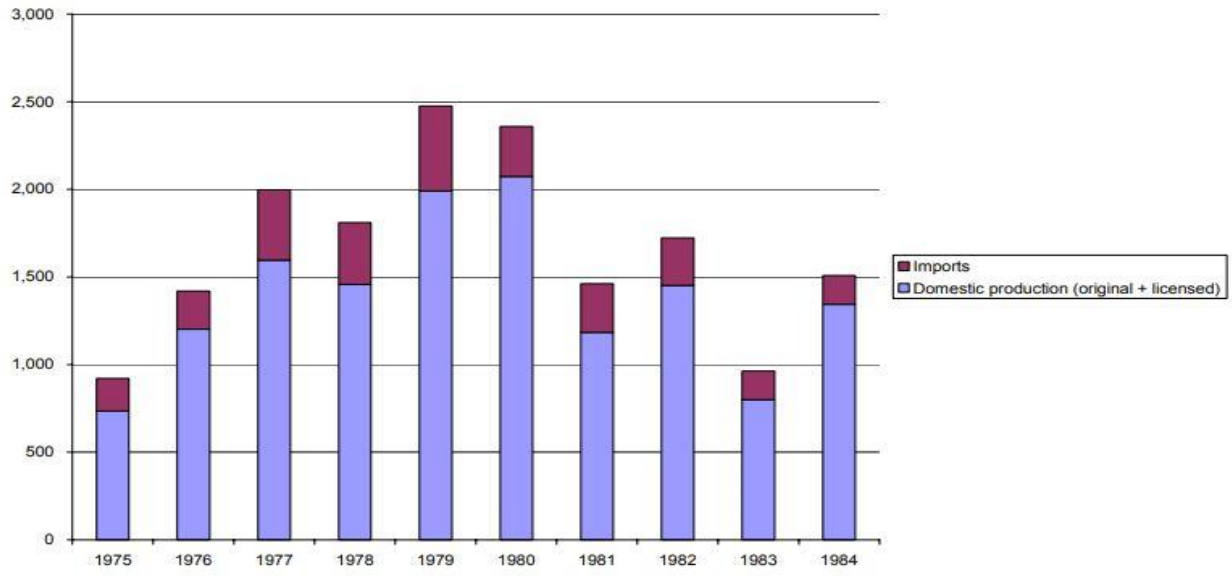
Strong patent regimes are a must for any country to evolve and develop, not only their pharmaceutical companies, but all other industries where innovation is a requirement. Though strong patent regimes have caused negative effects in terms of pricing, this can be countered by the ethical legislative practices discussed in this paper.

[32] Japan Pharmaceutical Manufacturers Association, *supra* note 19

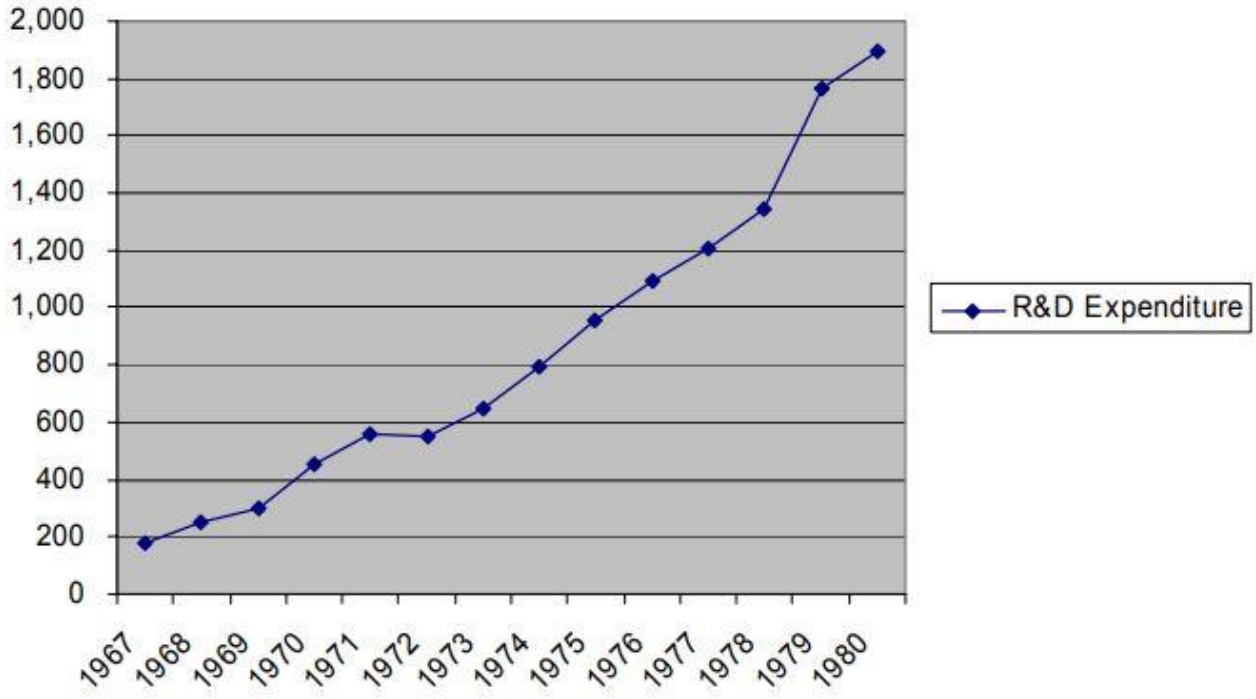
ANNEXURE 1



(a) Japan's Over-the-Counter (OTC) Drug Price Index (1965-1985)



(b) Growth of Japan's Approved Pharmaceutical Industry (1975-1984)



(c) Japanese Pharmaceutical R&D Expenditure Growth (1967-1980)

All graphs obtained from Japan Pharmaceutical Manufacturers Association, *JPMA Data Book* (1978).

ANNEXURE 2

Under Hugo Chavez's rule from 2002 to 2013, multiple price controls were placed on essential food commodities produced within Venezuala. This led firms to switch from price-controlled commodities such as white rice to non-price-controlled commodities such as flavoured rice[33]. A similar switch was seen from price-controlled milk to non-price-controlled cheese[34]. The government claimed that there was no shortage but rice producers, on the other hand, said output had dropped due to the lack of incentive to invest in production houses or farms[35]. Due to Venezuela's strict socialist paradigm, the government took control over two production houses, one that manufactured pasta and the other a tune-packer. Other staple food production house that were not taken over by the government began to be frequently inspected and directed to concentrate on producing price-controlled commodities[36]. Hence, price regulations over a

[33] The Economist, *supra* note 31
[34] The Economist, *supra* note 31
[35] The Economist, *supra* note 31
[36] The Economist, *supra* note 31

certain sector of goods, in this case being essential commodities, incentivizes firms into producing goods that are unregulated. Hence, they often move away from producing essential goods and into producing other goods. In this way, the production of essential commodities falls even further cementing a loss of revenue that is very hard to recover from.