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Intellectual Property Rights and Health

The ASEAN Context

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Executive Summary

Studies have shown that better health outcomes are achieved with increased trade openness and human development, particularly in lower-income countries. To facilitate international trade and catalyse economic growth, countries should promote robust intellectual property rights (IPR). A strong and effective IPR system will support, protect and stimulate innovation. It will also encourage transfers of technology and increase the availability of products in new markets.

The link between IPR protection and drug affordability is controversial. The price of medicine is strongly influenced by the considerable amounts of money invested by pharmaceutical companies into the development of new treatments, the majority of which fail. Generics have an important role to play in adjusting price mechanisms but are sometimes an unreliable substitute. A number of developing countries have argued that IPR can hamper their ability to intervene in public health matters and decrease accessibility, but this paper suggest that steps can be taken to mitigate these concerns.

This paper argues that countries must be able to exercise their right to cater to the public health needs of their population. Efforts must be put in place to stimulate competition and prevent monopolistic behaviour. Governments across ASEAN should work together to introduce policies that will support innovative practices while addressing public health matters, particularly efforts to maintain accessibility. This paper offers policy recommendations to encourage this practice.

Introduction

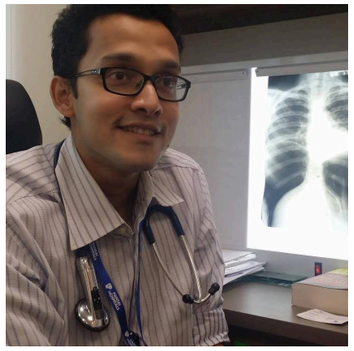
The 10 countries of the Association of Southeast Asian Nations (ASEAN) have a combined population of approximately 620 million with a total GDP of USD2.6 trillion (Embassy of Philippines KL, n.d.). An abundance of natural resources, a developing service sector, close regional ties and a well-educated workforce provide an opportunity to consolidate the regional economy while increasing competitiveness on a global scale.

The ASEAN Economic Community (AEC) Blueprint 2025 was adopted by ASEAN leaders in November 2015. This called for a highly integrated and cohesive economy with enhanced connectivity and sectoral co-operation in areas such as healthcare. However, the topics of trade and health are not without controversy. Some argue that globalisation and an overall decrease in barriers to market access might lead to a drop in drug accessibility. Others point out that trade provides for access to drugs and health technology in the first place.

Policies that lift individuals out of poverty are arguably the most important public health tool. The positive correlation between poverty and disease burden is a well-known fact (World Health Organisation, n.d.). A recent study (Stevens et al, 2013) showed that better health outcomes are reached with increased trade openness and human development, a relationship that is more pronounced in lower-income countries. It has also been postulated that economic growth and freer trade lead to better living conditions (Froning, 2000), allowing authorities to spend more on public health measures such as sanitation and universal vaccination.

Developing countries in ASEAN stand to benefit the most from removing barriers to free trade. There are many components to achieving this, including the presence of robust intellectual property rights (IPR). A strong and effective patent system will support, protect and stimulate innovation (OECD, 2004). It will also encourage transfer of technology and increase the availability of products in new markets. Such incentives ensure that pharmaceutical companies continue to invest in new markets, both in terms of products and human capital.

This paper utilises examples from across the globe to highlight the importance of IPR and its implications for healthcare in ASEAN countries. Part 1 provides an overview of the intellectual property landscape in the region, Part 2 looks at the accessibility and price of medicines and Part 3 identifies areas where IPR can be combined with other mechanisms to promote and address various healthcare issues. Each part provides policy recommendations that ASEAN countries can implement as an economic and trade bloc in order to strike a balance between a strong IPR system and maintaining access to affordable healthcare for its people.



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Part I: Integration and Harmonisation of IPR in ASEAN

This section looks at the existing intellectual property rights that are common to all ASEAN member-states. It covers Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is part of the World Trade Organisation (WTO) rules and TRIP-Plus provisions which were negotiated outside of the WTO, as well as drug patenting systems and ever-greening. These issues are briefly introduced and assessed before providing some recommendations on how ASEAN can streamline and strengthen the IP regime for pharmaceuticals for its member countries.

TRIPS: What it is about and the controversies surrounding it

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement came into effect on 1 January, 1995. This set global minimum standards for the protection of intellectual property. An example of these standards is the 20 years of patent protection that is required for pharmaceuticals (WTO, n.d.). The agreement obliges all member states to offer adequate protection of confidential information submitted as a prerequisite for gaining market approval for a new drug (Owoeye, 2015).

The TRIPS has been controversial - its proponents argued for even greater IPR to protect investment and drive innovation. Developing countries however, were concerned that it hampered their ability to intervene in public health matters, limited drug adoption by generic pharmaceutical companies[1] and hindered the development of local pharmaceutical industries (Novak, 2003).

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This led to negotiations which resulted in the Doha Declaration on TRIPS Agreement and Public Health provided for flexibility of signatories to ‘adopt measures necessary to protect public health and nutrition’[2] (Correa, 2002). Essentially, the Declaration was an attempt to balance anxiety regarding public health issues with concerns by the pharmaceutical industry regarding the lack of IPR. For example, countries are allowed to use compulsory licensing in circumstances where there is a need to address an urgent gap in healthcare provision. In this situation, a government allows a third party to produce the patented product or process without the consent of the patent owner (WTO Glossary, 2016).

[1] Generic pharmaceutical producers are typically viewed as a makers of cheaper and more accessible drugs.
[2] The Doha Declaration includes the following paragraph 5(c):
‘Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.’

TRIPS-plus: what we need to know about it

The term ‘TRIPS-plus’ refers to intellectual property legislations that go beyond the scope of TRIPS. These are defined by the WTO as “standards at a higher level than the agreement requires”.

Examples of TRIPS-plus provisions

- Extending the term of a patent beyond the 20 years minimum.
- Introducing provisions that limit the use of compulsory licences.

These tend to be part of bilateral or regional free trade agreements (FTAs) outside the framework of the WTO.

The TRIPS-plus have been controversial with literature both welcoming and condemning the impact of such inclusions in FTAs. Despite concerns regarding increased inaccessibility, there is evidence that FTAs and trade openness lead to positive health outcomes (including decreased mortality from non-communicable diseases and reduced infant mortality) (Stevens et al, 2015). It is fair to say that TRIPS-plus provisions need to be analysed independently and in context, as what is suitable for one country or region may not be for another at a particular time.

Countries in ASEAN should utilise the flexibility provided by the Doha Declaration to address public health concerns. However, this should be done on a background of strict IPR protection. Countries must be careful to ensure that the process in which provisions such as compulsory licensing are issued is transparent. The purpose for deviating from TRIPS should also be rooted firmly in public health needs as opposed to political considerations e.g. supporting the development of a particular local company.

The ability of and need for a country to adhere to TRIPS-plus provisions are unique and likely depends on the country’s stage of economic development. **ASEAN should be careful when negotiating these terms lest the terms be disadvantageous for some of its members.**

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Drug patents: the financial motives

The pharmaceutical industry is the only industry in which patents are limited to 20 years from the date of filing. The clock starts ticking at the moment of discovery in the country of origin. During this period, it can take up to 12 years from the discovery of the relevant molecule to the running of a Phase III trial, where the drug is given to a large group of people for the second time to evaluate its effectiveness, monitor any side-effects and compare it to other commonly used treatments (U.S. National Library of Medicine, 2016). This is followed by a number of years[3] the company has to wait to obtain the green light for registration in a foreign country. Hence, the 20-year protection is not very long when one takes into account the delays inherent within the system.

Moreover, most pharmaceutical research ideas do not lead to the creation of a successful product (DiMasi, 2014). Innovator companies have to invest significant amounts of financial and human resources to identify and subsequently sell drugs that are needed and wanted by patients. It is undeniable that a financial motive does exist, and strict considerations are taken into account when a decision is made to pursue the development of a particular drug.

Patents are granted by the patent and trademark office anywhere along the development lifeline of a drug and can encompass a wide range of claims. In the United States, the term 'exclusivity' refers to exclusive marketing rights granted by the Food and Drug Administration upon approval of a drug (U.S. FDA, 2014). This statutory provision may run concurrently with a patent and was created to promote a balance between new drug innovation and generic drug competition.

> *Hence, the 20-year protection is not that long when one takes into account the delays inherent within the system.*

The process of harmonising healthcare in ASEAN should include measures to increase the efficiency of local registration. It could be argued that a single point of entry that allows for regional registration would be more efficient and time-saving. By decreasing the bureaucracy associated with releasing a drug to the market, the argument made by pharmaceuticals to extend patent time will be less applicable.

[3] The number of years would be determined by the efficiency (or inefficiency) of a given country's registration process.

Ever-greening: Spurring or preventing innovation in pharmaceuticals?

It is important to note that a patent-processing system that rewards too easily and/or is too bureaucratic runs the risk of limiting its effect. Patents are supposed to spread knowledge and spur innovation, but are sometimes used to lock in incumbents' advantages and therefore reduce competition (The Economist, 2015).

> *Patents are supposed to spread knowledge and spur innovation, but are used instead to lock in incumbents' advantages and therefore reduce competition.*

'Ever-greening' is the term used to describe an industrial practice of modifying existing drugs with the aim of extending or renewing patents (and thus, monopoly) (Collier, 2013). It has been argued that ever-greening is anathema to the principles of driving innovation as incremental innovations[4] do not necessarily lead to therapeutic breakthroughs and may have more to do with increasing a company's revenues and less about driving research (Redberg, 2012).

In 2005, India introduced amendments to its Patent Act that served to strengthen IPR (as per TRIPS requirements) and prevent ever-greening. The Act defined the term 'new invention' and explicitly mentioned that patents would not be granted on the following grounds:

- the mere discovery of a known substance, which does not result in the enhancement of the known efficacy of that substance;
- the mere discovery of any new property or new use for a known substance; and
- the mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant.

This resulted in one of the more famous cases involving a country denying a patent for a new drug to a company on the basis that it was not unique enough when compared to the previous version (Novartis AG v. Union of India & Others, 2013). The unprecedented decision was naturally met with resistance by the said pharmaceutical company that took the Indian government to court, but was welcomed by opponents of ever-greening.

[4] Incremental innovation can include expanding existing therapeutic classes by improving complex molecular structures, reformulating medicines to improve patient administration, or exploring new uses for existing medicines (Incremental Innovation: Adapting to Patient Needs, International Federation of Pharmaceutical Manufacturers & Associations, 2013)

More neutral observers noted that the decision discourages the least useful instances of ever-greening while still preserving an incentive for innovation (New York Times, 2013). A scholarly review (Banerjee, 2013) of the Court's decision has also concluded that it was done within the context of TRIPS and should be adopted by countries who wish to limit the effects of ever-greening.

ASEAN should note that it is important that its member countries hold on to the philosophy that patents are essential to spur the right kind of innovation and should not be used as a tool to stifle competition. Delays in a country's process of allowing a drug into the market should be met with efforts to reduce regulatory review periods and not by extending patent duration. The latter only serves to further discredit the role of IPR while neglecting the need to introduce a more efficient system within governments.

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Additionally, legislation should include clear definitions of products and the degree of modifications that need to be present in order to grant patent extension. Too rigid a system will stifle innovation, but the opposite can be just as harmful to patients, as a system that is too lax will be taken advantage of.

Intellectual Property Courts: Improving confidence in the region's IP regime

The presence of a court that deals specifically with patent litigation will accelerate the resolution of disputes and decrease associated costs. This will encourage companies to operate in new markets as it will give them the confidence that a robust IPR protection system provides. Additionally, this measure will deter counterfeiters as they can be dragged to court for violations.

Although courts tend to be national, **ASEAN should work towards developing a court that will cater for disputes within the 10 countries.** This will likely reduce bureaucracy and ease market access whilst ensuring that disputes are transparently dealt with.

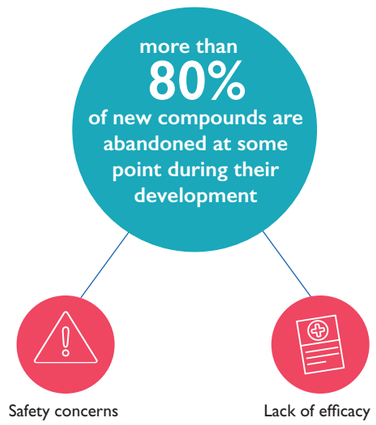
Part II: Inclusivity in Healthcare

The cost of drugs is always a point of contention between consumers, governments and pharmaceutical companies. This section looks at the reasons why costs of drugs are so high and if generics are a better option for consumers. It then discusses what actions ASEAN as a regional bloc can take in order to mitigate increasing costs of drugs while continuing to respect the IPR regime recommendations made in Part I.

Why are drugs expensive?

The actual cost of developing a drug varies. In 2014, the Tufts Center for the Study of Drug Development published a paper that estimated the cost of developing a new drug at USD2.6 billion (Tufts Center for the Study of Drug Development, 2016). This was a huge increase compared to the USD 802 million that the centre mooted as the developmental cost in 2003.

On the other hand, a study by the Federal Trade Commission identified considerable variation in costs depending on the maker and type of drug (Adams et. al, 2006). Their paper found that the average cost of drug development for one large manufacturer was USD521 million, while it was USD2.1 billion for another.



However, most stakeholders agree that a major factor that drives up manufacturing costs is that most drug development research ends in failure. According to the Tufts Center's study, more than 80% of new compounds are abandoned at some point during their development. Abandonment tends to occur as a result of safety concerns and/or lack of efficacy. Companies try to make up for these losses when they are able to sell a product that has been approved by regulatory agencies.

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Additionally, the price of a drug is not solely determined by its manufacturing costs. In the US, "companies take advantage of a mix of laws that force insurers to include all expensive drugs in their policies" (Peter, 2015), irrespective of costs or the degree of added advantage. This creates a disincentive for companies to offer their products at a reasonable cost and also encourages the development of medicines that may have a similar level of therapeutic effect to those already in the market (Alpern et. al, 2014).

The situation in Europe is dissimilar, where there are committees that decide on the efficacy and affordability of a drug. For example, The United Kingdom's National Institute for Health and Care Excellence (NICE) was created with the mandate to ensure that drugs approved for national use meet a high level of standard at a cost-effective price (NICE Website, 2016).

A report by McKinsey (2008) estimated that the costs for prescription drugs in Europe were 50% lower than in the US, but without any significant differences in availability.

It is important to note that a purchasing system which allows for greater competitiveness among pharmaceutical companies has led to a cap in the costs to healthcare providers while ensuring that patients are able to access drugs with proven therapeutic benefits.

A similar system is in place in Australia – the Pharmaceutical Benefits Scheme (PBS) - which allows for fixed out-of-pocket expenses for patients to purchase drugs covered under the scheme, with a financial safety net for the very sick or those with chronic illnesses. It involves very strict controls and allows the government to negotiate with drug companies, which has led to Australia having one of the lowest costs of medicines in the developed world (Sweeny, 2005).

The additional costs of regulation

The costs of medicines are not solely the product of patent protection. There are a variety of factors that determine the costs of and accessibility of drugs.

EXAMPLE

Claims have been made that the costs of medications were to rise over 40% in Australia as a result of the government charging an 'administrative and handling fee' for chemists (Dunlevy, 2015).

Australian chemists also maintain a monopoly in selling prescription drugs and there are restrictive rules that ban the opening of new pharmacies within 1.5 kilometres of an existing pharmacy (Dunlevy, 2015); both of which limit competition and protect incumbents.

In some countries, the price of drugs differs depending on prices negotiated by individual hospitals and/or ministries. Profiteering leads to a wide variation in pricing, with consumers lacking the necessary information to ascertain if the price paid for medication is appropriate.

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With this in mind, **ASEAN should identify local legislation that confers unfair and monopolistic advantages to incumbent industries across all levels of drug supply chains.** Patents are a factor in the costs of drugs, but significant savings can be made by ensuring appropriate governance when dealing with issues such as government procurement and non-tariff barriers.

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Understanding how generic medicines work

It is important to understand that a generic drug is not the exact same branded drug under a different label. When a patent expires, the components of a drug are made available to a generic company, but the exact mechanism of making the drug is not. A form of reverse engineering takes place, which may lead to a product that is not as potent (or more potent) as the original drug.

Under FDA rules, generics must contain the same active ingredient as the original but additional ingredients (excipients) need not be the same and can be of differing quality. The differences may appear to be subtle, but may have profound effects if the bioavailability is affected (this refers to the degree or rate of which a drug is absorbed into the blood circulation system).

In 2012, the FDA recalled a generic version of buproprion, a drug used in psychiatry, after hundreds of individuals complained of excess side-effects and/or drug inefficiency (Marris, 2012). It was discovered that the generic drug's active ingredient dissolved four times more quickly in the first two hours and on average, the product achieved a 75% concentration within the blood - although in some cases it was as low as 40% (Eban, 2013).

The degree of drug efficacy and side-effects is arguably more important in diseases like cancer. Chemotherapy is fraught with challenges; one of which is to explain to patients the likelihood of side-effects and the cost-benefit ratio of undergoing what is undoubtedly a harrowing experience. The information given to patients are derived from data using proprietary products, which is not automatically applicable to generic products.

A study looking into 31 commercially available generic docetaxel (a type of chemotherapy) purchased in 14 countries discovered that 90% of the generic formulations contained insufficient active ingredient, high levels of impurities or both (Vial et al, 2008). The implications are worrying. Cancer outcomes may be affected, side effects may be higher and ultimately, the cost to the patient and the healthcare system is higher both financially and medically.

Are generics always a better option?

The argument for decreasing a patent period is to allow the introduction of drugs manufactured by generic companies. These usually lead to a drop in pricing, but it is essential that governments ensure that the generic drugs are provided by reputable manufacturers. Generic drug manufacturers are driven by the same profit incentives in a free market.

Some generic companies, such as India's Cipla, have taken substantive steps to prove that their products have the same bioavailability as innovator companies. For generic companies such as these, trademarks and IPR are also essential as it is a marker of quality for their products. There are strong incentives to maintain their reputation and it is telling that more reputable generic companies tend to be supportive of government measures to protect their products.

"For generic companies, trademarks and IPR are also essential as it is a marker of quality for their products."

In countries without adequate IPR, pharmaceutical companies have had to take extra precaution to prevent the spread of fake medicines.

EXAMPLE

VS International, a leading exporter of ciprofloxacin (a type of antibiotic), had to introduce a range of anti-counterfeit measures to curb the rise of fake versions of their antibiotic (Bate, 2012).

Where possible, **ASEAN should encourage generic companies to provide studies showing that their products are within a predetermined narrow margin of error from a proprietary product's bioavailability**.

Furthermore, **ASEAN governments should form a regional-wide committee that transparently assesses the therapeutic benefits of a given medicinal product prior to granting it patent protection or marketing approval**. The committee should consist of representatives from across ASEAN, and should act as a gatekeeper for drug evaluation. To avoid unnecessary bureaucracy and delays in accessing medication, the committee's decision should be applicable to all member countries without the need for repetition at a local level.

Part III: Beyond IPR

The rising cost of bringing medicines to the market has not been matched by the production of new, innovative products. Governments, doctors and patients have become cynical knowing that many big pharmaceutical companies spend more on marketing than on research and development. It is therefore essential to look at how IPR can be combined with other policy tools to enhance innovation in research and development.

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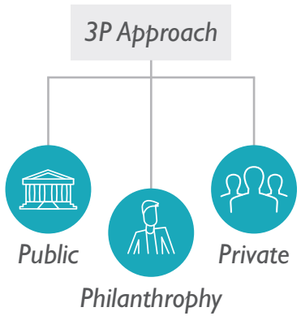
The lesson of most countries seem to indicate that a robust system for IPR protection is essential, but that countries must also be able to exercise their right to cater to the public health needs of their population. Efforts must also be put in place to stimulate competition and prevent monopolistic behaviour.

Affordable medicines: A cooperative approach

IPR protection can be combined with other mechanisms to promote and address unmet healthcare needs. For example, the Global Access programme by the Bill and Melinda Gates Foundation requires grantees and partners to commit to making products widely available at an affordable price to benefit the people the it is trying to help (Bill and Melinda Gates Foundation, n.d.). The Foundation acknowledges the critical role of IPR in encouraging innovation but its philanthropic policy target allows for research to be conducted in areas that governments and the private sector are unable or unwilling to participate in.

Governments may also choose to participate in Advance Market Commitments (AMC) or Advanced Purchase Commitments, where certain guarantees are given to push companies to address healthcare issues that do not have an attractive market. This, too, can be done using a 3P (public, private, philanthropy) approach.

One example of AMC was the scheme to provide subsidised pneumococcal vaccines in developing countries. The World Bank supported the governments of Italy, the United Kingdom, Canada, Russia and Norway as well as the Bill & Melinda Gates Foundation by putting forward USD1.5 billion to help cut the cost of a vaccine from USD70 down to USD3.50 to be used in 60 poor countries (The World Bank, 2013).



Affordable medicines: A cooperative approach *(continued)*

It is not inconceivable for **ASEAN countries to pull their resources together in order to link up with a philanthropic foundation and the pharmaceutical industry with the aim of providing similar types of interventions for populations most at risk.** For example, vaccines are instrumental in not only saving lives, but in preventing the escalation of healthcare costs to both the individual and country (Johns Hopkins Bloomberg School of Public Health, n.d.). A firm commitment from stakeholders, including the provision for IPR, improves access to those most in need.

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The Medicines Patent Pool (MPP) is another novel manner in building partnerships between various stakeholders. Fully funded by UNITAID, the pool consists of a consortium of companies that agree to cross-license patents relating to particular drugs and technology (UNITAID, n.d.). Importantly, these are done transparently in order to facilitate research and faster bilateral negotiations between the innovator and generic pharmaceutical companies.

In general, **ASEAN countries should also look beyond IPR as a sole mechanism to encourage research into diseases that may not appear to be profitable to the private sector**. A 3P (public, private, philanthropy) approach will allow the identification of diseases that are of regional public interest (e.g. dengue) to be married with research capabilities of pharmaceuticals and non-governmental organisations.

Conclusion

Increased trade openness stimulates competition, improves economies of scale and reduces long-term healthcare costs.

One of the lessons learnt from experiences across the globe is that a robust IPR system is a key underlying factor in ensuring that trade not only flows smoothly, but allows for innovation and investment within the healthcare sector while ensuring that patients receive safe, guaranteed and efficacious products.

ASEAN countries should adopt policies that would support the transfer of drugs and technology for the benefit of their citizens. These policies should stimulate competition within the region and prevent the entrenchment of monopolies that could further increase the cost of healthcare to society.

References

Adams C. P. & Brantner V.V. (2006) "Estimating The Cost Of New Drug Development: Is It Really $802 Million?" *Health Affairs,* 25, (2), 420-28.

Alpern J.D., M.D., William M. Stauffer., & Aaron S. K. (2014). High-Cost Generic Drugs — Implications for Patients and Policymakers. *New England Journal of Medicine*. Retrieved from http://www.nejm.org/doi/full/10.1056/NEJMp1408376.

ASEAN. (2016). *ASEAN Economic Community - Asean | One Vision One Identity One Community*. Retrieved from http://www.asean.org/communities/asean-economic-community>

Australian Government Department of Health. (2016). *Pharmaceutical Benefits Scheme (PBS)*. Retrieved from http://www.pbs.gov.au/pbs/home>

Banerjee, R. (2013). The Success of, and Response to, India's Law against Patent Layering. H*arvard International Law Journal 54.* Retrieved from http://www.harvardilj.org/wp-content/uploads/2013/06/Banerjee-to-Publish.pdf>

Bate, R. (2012) . Washington, D.C: AEI Press

Bill & Melinda Gates Foundation. (2016) *Global Access.* Retrieved from http://www.gatesfoundation.org/Global-Access

Collier, R. (2013). Drug Patents: The Ever-greening Problem. *Canadian Medical Association Journal*, *185(9).*

Correa, C. M. (2002). *Implications of the Doha Declaration on the Trips Agreement and Public Health - Health Economics and Drugs Series № 012*. World Health Organization. Retrieved fromhttp://apps.who.int/medicinedocs/en/d/Js2301e/>

DiMasi. J. A., Henry G. G., & Ronald W. H.. (2014). *Cost of Developing a New Drug*. Tufts Center for the Study of Drug Development, Retrieved from http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf>

Dunlevy. S. (2015). T*he price of hundreds cheap medicines will rise by 40 per cent under new pharmacy deal.* NewsComAu. Retrieved from http://www.news.com.au/lifestyle/health/health-problems/the-price-of-hundreds-cheap-medicines-will-rise-by-40-per-cent-under-new-pharmacy-deal/news-story/f41fd407ca6c30937d441d1a230c0710>

Eban, K, *Are Generics Really the Same as Branded Drugs?* (2013). Fortune. Retrieved from http://fortune.com/2013/01/10/are-generics-really-the-same-as-branded-drugs/>

Embassy of Philippines KL. (2016) *ASEAN Economic Community At A Glance "10 Things You Didn't Know About ASEAN"*. Retrieved from http://www.philembassykl.org.my/main/images/pdf/asean_doc.pdf>

Froning D. H. (2005). *The Benefits of Free Trade: A Guide For Policymakers*. The Heritage Foundation. Retrieved from http://www.heritage.org/research/reports/2000/08/the-benefits-of-free-trade-a-guide-for-policymakers#_ftn33>

Johns Hopkins Bloomberg School of Public Health. (2016). *Pneumococcal Disease: Prevention & Treatment.* Retrieved from http://www.jhsph.edu/research/centers-and-institutes/ivac/resources/solutions-pneumococcal-disease-prevention-treatment.html>

References *(continued)*

Marris, D. (2012). A Drug Recall That Should Frighten Us All About The FDA. *Forbes*, Retrieved from http://www.forbes.com/sites/davidmaris/2012/10/10/fda-recall-points-to-serious-problems-at-the-fda/>

National Institute for Health and Care Excellence. (2016) Standards and Indicators. *Quality Standards*. Retrieved from http://www.nice.org.uk/standards-and-indicators>

New York Times. (2013). *India's Novartis Decision*. Retrieved from http://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html>

Novartis AG v. Union of India & Others. (2013). Civil Appeal Nos. 2706–2716 OF 2013 (Arising out of SLP(C) Nos. 20539–20549 OF 2009). Available from http://supremecourtofindia.nic.in/outtoday/patent.pdf>

Novak, K. (2013) The WTO's Balancing Act. *Journal of Clinical Investigation*. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC228482/>

Organisation for Economic Co-Operation and Development.(2004). *Patents and Innovation: Trends and Policy Challenges – OECD.* Retrieved from http://www.oecd.org/science/sci-tech/24508541.pdf>
Owoeye, O. A. (2014) Data Exclusivity and Public Health under the TRIPS Agreement. Journal of Law, 23 (2), Information and Science 106

Redberg Rita F. (2012). Evidence of Pharmaceutical Innovation and Therapeutic Enthusiasm. *Arch Intern Med Archives of Internal Medicine*, 172 (9), , 683. http://www.ncbi.nlm.nih.gov/pubmed/22493408 Accessed February 05, 2016.

Stevens P. J. U., & G. Wills. (2013) Healthy Trade: The Relationship Between Open Trade and Health. *Foreign Trade Review, 48 (1),* 125-35. http://ftr.sagepub.com/content/48/1/125.short?rss=1&ssource=mfc Accessed February 05, 2016.

Stevens, P. & Venkatamaran S. (2005) *Are Free Trade Agreements Bad for Health? - Geneva Network*. Geneva Network. Retrieved from http://geneva-network.com/wp-content/uploads/2015/08/FTAs-and-health.pdf>

Sweeny, K. (2005). *Medicine Prices in Australia: An International Comparison*. Working Paper No. 29 Pharmaceutical Industry Project Working Paper Series, September 2005. Centre for Strategic Economic Studies. (2016) Victoria University of Technology. Retrieved from http://vuir.vu.edu.au/15949/1/(15949).pdf>

The Economist. (2015). *Time to Fix Patents*. Retrieved from http://www.economist.com/news/leaders/21660522-ideas-fuel-economy-todays-patent-systems-are-rotten-way-rewarding-them-time-fix>

The World Bank, Development Finance. (2016). *Advance Market Commitment*. Retrieved from http://web.worldbank.org/WBSITE/EXTERNAL/EXTABOUTUS/ORGANIZATION/CFPEXT/0,,contentMDK:22468028~pagePK:64060249~piPK:64060294~theSitePK:299948,00.html>

Tufts Center for the Study of Drug Development. (2016) *How the Tufts Center for the Study of Drug Development Pegged the Cost of a New Drug at $2.6 Billion*. Retrieved from http://csdd.tufts.edu/>

UNITAID. (2016). *UNITAID Statement on the Medicines Patent Pool's First Licensing Agreement with a Pharmaceutical Company*. Retrieved from http://www.unitaid.eu/en/resources/news/349-unitaid-statement-on-the-patent-pools-first-licensing-agreement-with-a-pharma-company>

References *(continued)*

United States Department of Agriculture. (2009) *Access to Affordable and Nutritious Food: Measuring and Understanding Food Deserts and Their Consequences*. Retrieved from http://ers.usda.gov/media/242675/ap036_1_.pdf>

U.S. Food and Drug Administration. (2016) *Code of Federal Regulations - Title 21 - Food and Drugs*. Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm>

U.S. Food and Drug Administration. (2016). *Frequently Asked Questions on Patents and Exclusivity*. Retrieved from: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm>

U.S. National Library of Medicine. (2016) *FAQ ClinicalTrials.gov* - Clinical Trial Phases, Retrieved from http://www.nlm.nih.gov/services/ctphases.html>

Vial J., Cohen, M., Sassiat, P., & Thiébaut, D. (2008) Pharmaceutical Quality of Docetaxel Generics versus Originator Drug Product: A Comparative Analysis. 2008 *Current Medical Research and Opinion,* 24 (7), 2019-033

World Health Organisation. (2016) *Poverty and Health.* Retrieved from http://www.who.int/hdp/poverty/en/>

World Trade Organisation. (2016). *Glossary Term: Compulsory Licensing*. Retrieved from https://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm>

World Trade Organisation. (2016). *Overview: the TRIPS Agreement*. Retrieved from http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm>

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