TRIPS and the developing countries - What should be done and why it should be done?

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The tale of two settlements

It was a rainy day in December of 1994 when Ya'ad – small Jewish settlement in Eastern Galilee situated on the peak of Ya'ad mountain - has voted to do the unthinkable and build a fence surrounding the settlement. It was the middle of the second Intifada, buses were exploding weekly and suicide bombings happened daily, the whole country of Israel was bleeding and terrified and Ya'ad – a brainchild of young Jewish Technion graduates who wanted to spend their life according to Robespierre's "Liberté, equality, fraternité" – was concerned mostly with petty crime. Ya'ad was established in 1974 on lands previously owned by Arab village of Shaab, which situated at the bottom of the Ya'ad mountain and was an example for co-existence between the 2 very animated branches of Abraham's descendants. Ya'ad boasted architectural bureau, software engineering company, electronic scales manufacturer and some other High-Tech businesses. Shaab's business was primarily agriculture and crime.

In 1994 the coexistence came to an end – not due to bombings, the fear and the reign of terror that aimed at taking Israel over, but since nothing in Ya'ad could be left outside. Bicycles were stolen 2 weeks after purchase on average. Laundry hanged outside was … blown away. Jewish clothes were seen on Arab teenagers. Petty crime, it was believed that this is a necessary evil and someday the Shaab economy would pick up and the co-existanse would further strive – but it never happened. In 1994, tired of trying, Ya'ad voted to build a fence surrounding the settlement. The next day, the only access road was blocked by angry Arab mob, stones were thrown at Jewish cars and petty crime incidents tripled overnight. Shaab was furious. The reason? "Jews took away our source of livelihood" – as claimed in regional council and police mediated discussions that took place in the "peace tent" between the councils of Ya'ad and Shaab. The conflict was resolved to satisfaction of both parties – the fence decision was scrapped and every Jewish families regained their right of passage and restored their believe in co-existence.

This story has it all – property rights, international relations, different standards (as exemplified by different views on what is acceptable treatment of other people's bicycles) dispute settlement

mechanism (“peace tent” is centuries-old mediation tool traditional in the Middle East). Moreover, it addresses such issues as Most Favorable Nation Treatment – as Jews definitely would’ve face a harsher treatment by local police, should they steal bicycles from Arabs.

Add the word “intellectual” to property, change bicycles to life-saving drugs use have the WTO instead the regional council drafting a case summary and guidelines – and have the TRIPs agreement.

Introduction of TRIPS

"The World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 1994 seeks to implement a uniform set of intellectual property protection across member nations to provide greater stability in international economic relations. Critics argue that the TRIPS agreement provides unnecessarily strong protection of intellectual property rights which serves to prevent the ill in developing nations from having access to affordable essential medications."[1]

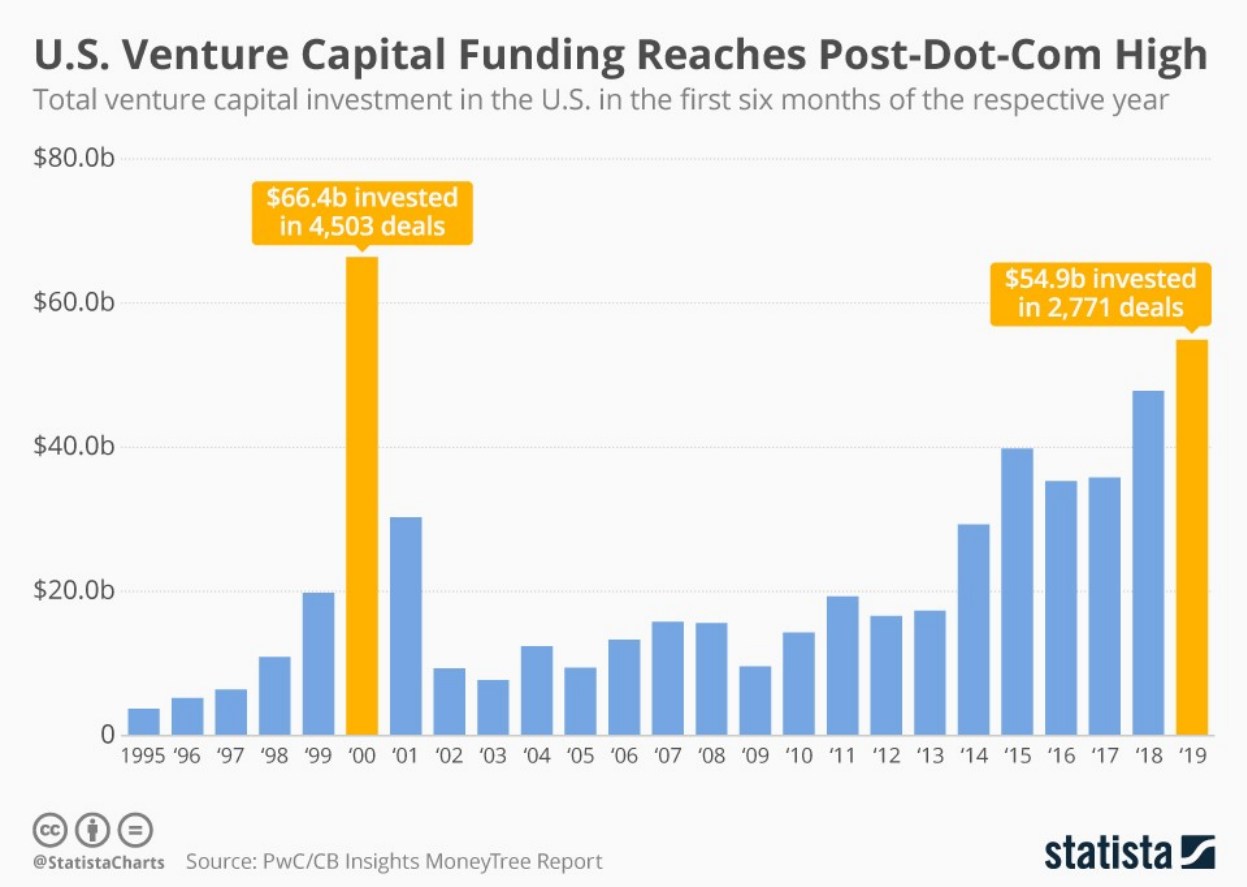
This paragraph describes a 2-sided conflict where side X has essential medication that side Y wants. Side X has (intellectual) property rights over these essential medications. Side Y needs the medication regardless of property rights. TRIPS agreement should regulate these rights, while – according to some critics – effectively blocking access to medication by enforcing (intellectual) property rights.

[1] Subhan J. Scrutinized: the TRIPS agreement and public health. *Mcgill J Med*. 2006;9(2):152–159. Retrieved from here on Feb 23, 2020.

Distribution of rights

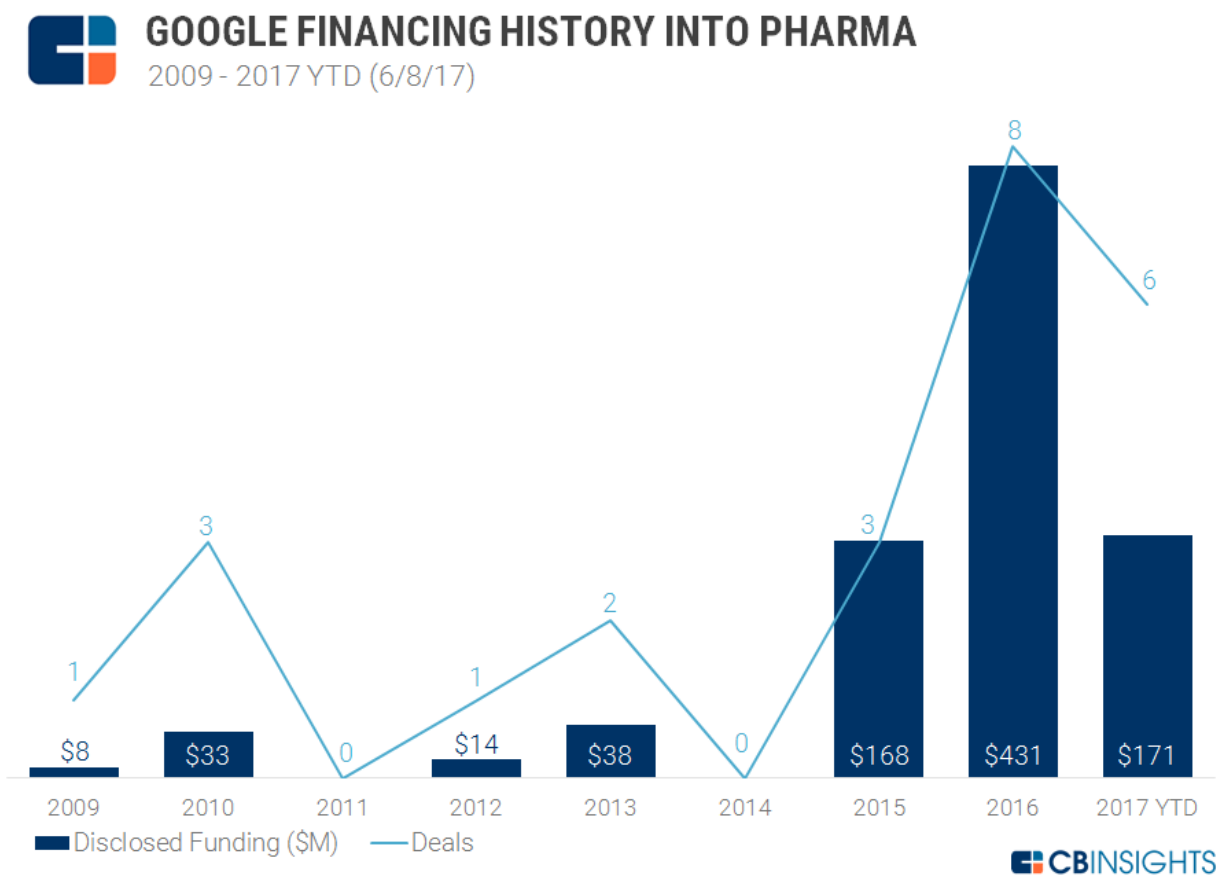
TRIPS handles such IP instruments as patents, Trademarks, Copyrights and others. For better focus, patents mostly will be addressed in this essay.

Patents, as oppose to Trademarks and Copyrights, are acquired rights. A patent is an exclusive right granted by government to an inventor in exchange for enabling disclosure of the invention. As such, an IP right – patent - requires an invention to come into existence. Given the scientific progress of recent decades, inventions are very complicated and expensive business. According to Statista, total VC investment in first 6 months of 2019 reached $54.9B USD in US alone [2]:



[2] https://www.statista.com/chart/11443/venture-capital-activity-in-the-us/ retrieved on Feb 24, 2020

Of these dollars, Google – company well known for its diversified product portfolio - provides an example of investing into pharma, focusing on gene therapy, anti-bacterials and neurobehavioral disorders:

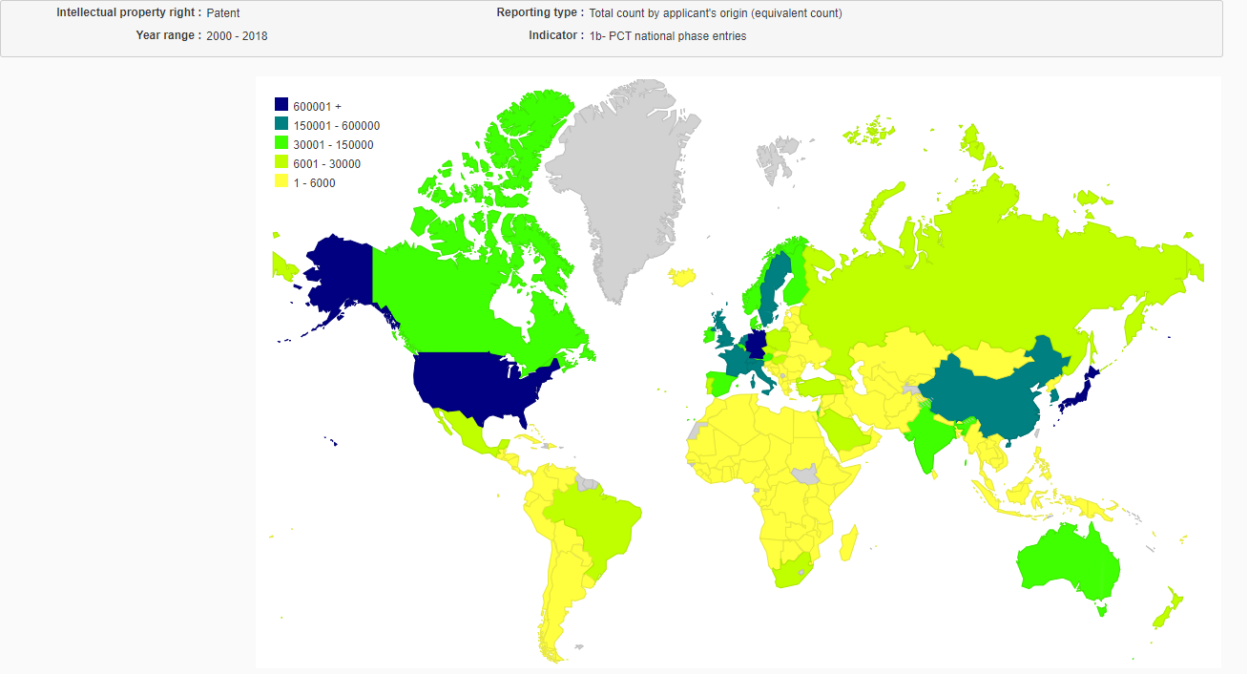


[3]

The above provides interesting insight into the size of US VC (Start-up) economy – the prominent creator of new patents - and size of investment being made into pharma companies. For comparison, US GDP per capita is $67,063, while Investopedia claims that a "Developed Country" GDP per capita threshold is $12,000[4]. The gap is self evident. Of 191 countries, only 79 are above that threshold[5]. It means not only that people are richer in the 79 countries, but also the salaries are higher, education

[3] https://www.cbinsights.com/research/google-pharma-startup-investments/ retrieved on Feb 24, 2020
[4] https://www.investopedia.com/updates/top-developing-countries/ retrieved on Feb 24, 2020
[5] http://worldpopulationreview.com/countries/countries-by-gdp/ retrieved on Feb 24, 2020

levels are higher and R&D is more thriving in these countries, resulting in more patents, as shown in below chart indicating amount of PCT applications sorted by applicant's origin between 2000 and 2018:



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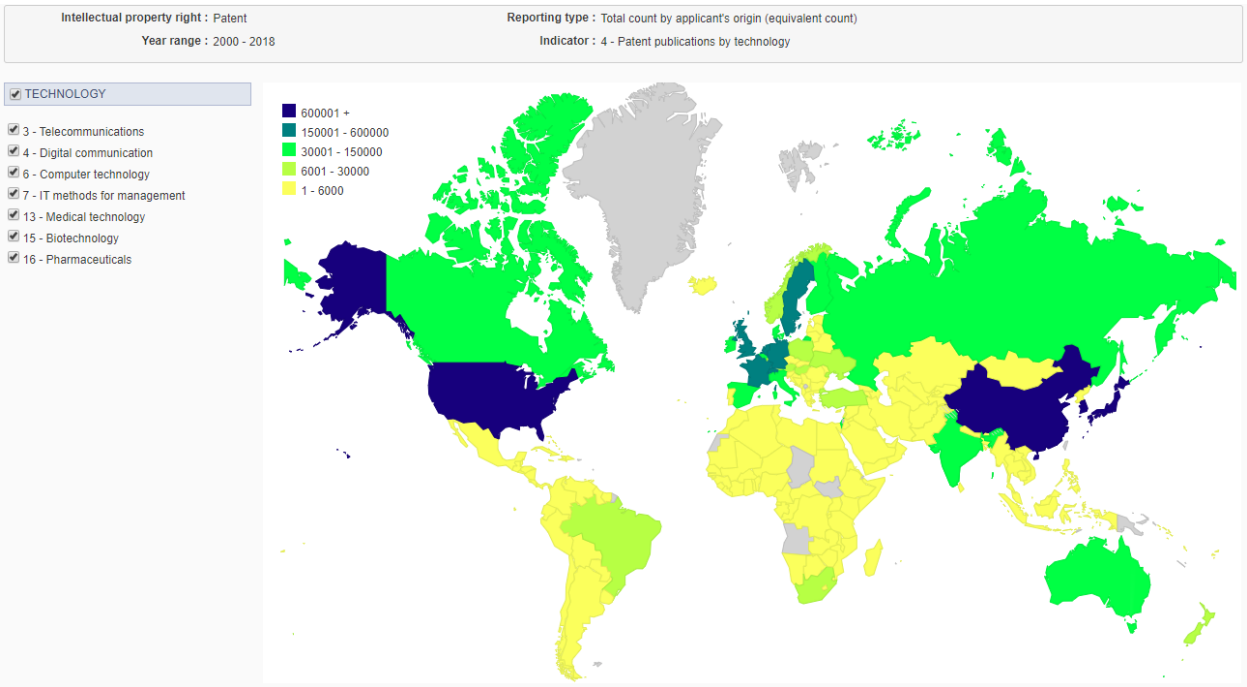
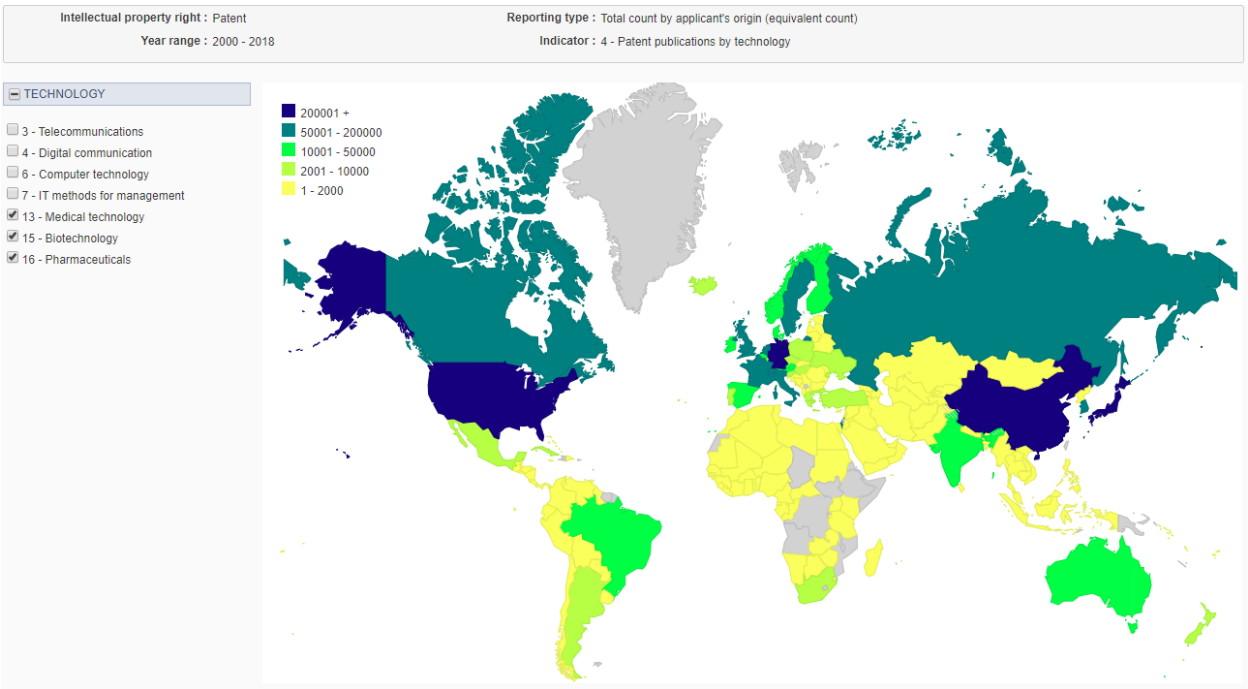
As shown, there is a link between education levels, higher salaries, investment in R&D – and amount of patents. As pharma is one of the most profitable investment target industries, the amount of patents filed within Hi-tech and Pharma industries by countries of origin correlate to overall filings:

[6] https://www3.wipo.int/ipstats/ipsMapchart retrieved on Feb 24, 2020



However, once IT and related technologies were removed from the blend, the picture differs:



Russia and Canada gained significant relative weight as global players, while some African countries are not filing at all.

It is clearly seen by patent filings where R&D activity takes place. It would be only logical to assume that R&D benefits domestic market and if no R&D is locally present, IP right will have to be imported. As creation of these rights involved significant monetary investment – DiMasi[7] cites $2.6B in pre-approval R&D costs. Naturally, these costs are expected to be collected in worldwide sales. Deeper look into the process of R&D provides an interesting picture: out of all the compounds that started R&D between 1995 and 2007, only 7.1% were approved, 80.3% were discontinued at some phase and 12.6% were still active in some phase[8]. Again, less than 10% of initial batch make it to the market phase.

Once the patent expires – 20 years after priority filing date – generic drug manufacturers will step in. As TUFT's study shows, there is at least 11 years gap between the synthesis (and priority patent filing) date – and FDA approval. This gap is growing, with some estimate now it to be 15 to 17 years from synthesis to approval. It means that the IP right effectively exists for 9 years or less only – providing an at most 9-year window to recover the initial investment. While there are lots of critique to the cost figure[9], no one argues the timeline.

[7] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016;47:20–33. Retrieved here on Feb 24, 2020

[8] https://www.academia.edu/34807407/Cost_of_Developing_a_New_Drug_Tufts_Center_for_the_Study_of_Drug_Development retrieved on Feb 24, 2020

[9] https://www.citizen.org/news/pharmaceutical-research-costs-the-myth-of-the-2-6-billion-pill/

Translating the metaphors:

Some countries have pharma industries. Those countries invest heavily in R&D through tax credits and state-sponsored research grants. Those countries also create IPR regimes to protect their investment in R&D and push for enforcement of the IPR on international scene.

There are also other countries. These countries population live below $12,000 GDP per capita threshold, they are poverty infested and lack the means to purchase expensive medicine. People in these countries are dying at age unthinkable for their developed neighbours and from diseases that elsewhere are considered long gone. Naturally, these countries cannot allow to buy expensive medicines. Yet, they want them. What is left to them to upkeep their livelihood (Remember Shaab and the road blockade?)

TRIPS

TRIPS is considered by some one of the most important developments in international IP protection. For first time in history, legal enforcement of rights became a crucial component of international IPR regime. Not only it addressed the shortcomings of Paris and Berne conventions in terms of detailed rules on the enforcement of rights, it also provided an effective dispute settlement mechanism between states. Moreover, as 3rd world countries were catching up with technology – smartphone penetration rate was 45% median in emerging economies vs 76% in advanced[10], for example – new opportunities for infringement of IPRs arose and had to be addressed.

Naturally, different stakeholders had different interests. While the developed countries pushed for stronger IPR regime, the developing countries were concerned strong IP regime would present barrier for trade and access to technology. Every IPR presented a battleground – geographic indicia was disputed (is Parma ham should be made in Parma, Italy or in Canada?), patent rights and standards were discussed (notorious South African patents are very different in nature from US patents, which are being heavily prosecuted), copyrights are perceived differently in every country – while people are willing to pay for their music in Europe, Russian artists only want to be heard as much as they can for greater publicity and trademarks, as used by Hollywood in the US, cannot be used the same way in Bangladesh.

But the most striking example is pharmaceutical patents. Providing an actual barrier to usage, pharma patents are blocking an access to essential medicines. Throughout history, compulsory licenses were used to address public health emergencies – as the case of Brazil between 2001 and 2005 in its fight against AIDS[11]. Moreover, the threat of compulsory license provides highly effective bargaining chip – as the Brazil has reduced the price of ABBOTT's drugs by 30%. One should bear in mind, though, that Brazil is not one of the under-developed countries, its GDP being 9th in the world (Canada is

[10] https://www.statista.com/statistics/539395/smartphone-penetration-worldwide-by-country/ retrieved on Feb 25, 2020

[11] Day M. Threat to break patents saves Brazil $1bn in cost of HIV treatment. BMJ. 2007 Nov 24;335(7629):1065. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2094169/ retrieved on Feb 25, 2020

10th)[12].Yet, the provisions of National Treatment and MFN provide for effective tool for Brazilian economy to save some 1B USD in drug costs, without affecting patent holder rights in other jurisdictions (national exhaustion).

Additionally, TRIPS help to address such issues as antitrust and parallel imports. Through Article 31 and 40, anti-competitive and antitrust measures are taken, allowing, for example, parallel imports of Indian generic drugs into US.

The Doha round reaffirmed the route later taken by Brazil. The TRIPS agreement should be interpreted in light of its objective and purpose, each member has the right to grant compulsory licenses and the freedom to determine grounds for such licenses, as well as what constitutes a national emergency, and each member is free to set up its regime on exhaustion without challenge.

[12] http://worldpopulationreview.com/countries/countries-by-gdp/ retrieved on Feb 25, 2020

Real Life Considerations

As TRIPS deals with Trade-related IPR, perhaps the best sources of information and analysis are economic metrics and economist. Literally, there are two conflicting views of TRIPS – just as there are two conflicting layers of the Ya'ad – Shaab conflict – economic and humanitarian. The economic view is best summarized by John M. Curtis (2012)[13]:

"A direct link between trade and intellectual property rights appears to be even weaker when examined on empirical rather than on theoretical grounds. Yet some support may exist for an indirect link through the impact of patents in a few clearly identifiable sectors, copyright in several sectors and, to a lesser extent, trademarks. For example, an empirical tie can be established between strengthened patent protection and innovation in the pharmaceutical and chemical sectors. The empirical link between trade and intellectual property, particularly with regard to patents, is also evident in the newer fields of nanotechnology and genetic engineering, and in the "older" non-electrical machinery, transportation, office equipment and metals sectors.

In these and other sectors, however, factors such as conventional trade and investment policies, the tax system, production incentives (subsidies), and competition laws and practices — which can all be shown to influence the rate of knowledge creation and its adaptation to product design and production technologies — appear to be more important than intellectual property rights in stimulating innovation and commercialization; thus, the quality and, perhaps, even the volume and value of goods and services traded.".

As Thailand case shows[14], Pharma companies are less than happy when forced into compulsory license and prevent access to medicines not subject to compulsory licenses – "Abbott initially responded by withholding a number of new medications from the Thai market including the heat stable

[13] https://www.cigionline.org/sites/default/files/no.3.pdf retrieved on Feb 25, 2020

[14] Kerry, Vanessa Bradford, and Kelley Lee. "TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?." *Globalization and health* vol. 3 3. 24 May. 2007, doi:10.1186/1744-8603-3-3, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1892549/ retrieved on Feb 25, 2020

form of Kaletra®. The company has since offered the medicine to Thailand and 39 other countries for US$1000 per patient per year, although it continues to withhold other medications."[15]

While the conflict between pharma companies and less developed countries is burning across the East-West line, there is another line of tension along the North-South line in plant breeding rights and patented genetically-modificated plants – as described by Debra Strasuss:

"Many experts have noted the inequities of the current system of intellectual property protection as applied to developing countries in the area of biotechnology.

Imposing a Western view of intellectual property that fails to protect traditional knowledge creates a one-way flow of genetic resources from the South (i.e., developing countries abundant in germplasm) to the North (i.e., industrialized nations advanced in biotechnology).113 The genetically modified organisms and plants are then patented and removed from the public domain, while their use back in the developing country from which they originated, without permission and payment, is labeled "biopiracy.""[16]

While providing an interesting point of view, it is highly doubtful, as a patent is granted for the "inventive step" – novel and non-obvious invention, not the underlying genetic material. For example, refer to claim 1 of US5188642A2[17]:

1. A method for selectively controlling weeds in a field containing a crop of planted crop seeds or plants which method comprises the steps of:

a) planting said crop seeds or plants which are glyphosate resistant as a result of a chimeric gene being inserted into said crop seed or plant, said chimeric gene having

i) a promoter sequence which functions in plant cells,

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[15] *ID*

[16] Strauss, Debra M., The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology (December 14, 2009). Stanford Journal of International Law, Vol. 45, No. 2, pp. 287-320, 2009. Available at SSRN: https://ssrn.com/abstract=1523514 retrieved on Feb 25, 2020

[17] https://patents.google.com/patent/US5188642A retrieved on Feb 25, 2020

ii) a coding sequence which causes the production of RNA, encoding a chloroplast transit peptide/5-enolpyruvylshikimate-3-phosphate synthase fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be imported into a chloroplast of a plant cell, and

iii) a 3' non-translated region which encodes a polyadenylation signal which functions in plant cells to cause the addition of polyadenylate nucleotides to the 3' end of the RNA,

where the promoter is heterologous with respect to the coding sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate resistance of a plant cell transformed with said gene; and

a) applying to said crop and weeds in said field a sufficient amount of glyphosate to control said weeds without significantly affecting said crop

Naturally, in order to be infringed all of the elements of the claim have to be present in the infringing device (seed), therefore it is clearly seen that “natural” non-modified seed will lack at least a “chimeric gene being inserted into…”.

Why this patent was chosen to exemplify the tensions between IPRs and farmers? This patent was subject to SCC decision in flagship case of MONSANTO CANADA INC vs. SCHMEISER[18], which exemplified the tensions between farmers and IP right holders and was decided – in Canada, where the farmer had the means to go all the way up to the Supreme Court – against the farmer. Yet, Strauss[19] refers to the situation in following words:

“Small and peasant farmers are ill-suited to genetically modified crops, which are “the antithesis of sustainable and self-reliant food production.” The aggressive promoting of intellectual property rights

[18] Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34 retrieved on Feb 25, 2020

[19] Strauss, Debra M., The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology (December 14, 2009). Stanford Journal of International Law, Vol. 45, No. 2, pp. 287-320, 2009. Available at SSRN: https://ssrn.com/abstract=1523514 retrieved on Feb 25, 2020

by biotechnology companies and their governments challenges traditional seed saving and sharing. Under the intellectual property system being forced upon them, farmers become dependent on seed companies and need to change their farming practices, cultivating “cash crops” to sell for export to afford to buy more seed; the shift and limitation in crops, together with the elimination of farmers unable to pay licensing fees or defend lawsuits, further jeopardizes food production in these countries.”

Real life examples – such as Schmeiser’s – proved Strauss point of view wrong. Once access to GMO seeds is obtained, farmer prefers utilizing the GMO seed to non-GMO – and for good reason, as the GMO canola translates to higher yields and higher profits for the farmer. Would Monsanto’s patent be infringed should’ve Schmeiser continue to use non-GMO seeds? No, as it could’ve been easily shown, as non-GMO seeds lack the “chimeric gene”.

However, the case exemplifies a possible problem described as “cumulative development” – once a technology is obtained under compulsive licence, it can be further developed by the licensee without adequate compensation of the licensor. New agreements, such as ACTA[20], had to be negotiated to support TRIPS that failed to fully address this problem.

So, once again Ya’ad-Shaab conflict exemplifies itself – Ya’ad has something (genetically modified seeds), the farmer wants that something, but is not willing to pay the price demanded by Ya’ad (Monsanto). Arguably, any solution to the situation other than payment in any form – will comprise theft, as shown by SCC verdict.

[20] https://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/ip-pi/acta-text-acrc.aspx?lang=eng retrieved on Feb 25, 2020

Conclusion

TRIPS and 3rd World States. Strong IPR and developing economies. North and South, East and West, rich and poor. The conflict ever present has exemplified itself once more by standardization of IPRs. The conflict itself is best understood by paradigm shift – measuring not strength of IP, but distribution of IP origins – while some countries create IP, others buy it. Investment in education, creating start-up economies, providing research facilities and attractive investment climate will facilitate economic growth and strong IPRs can only support this goal. In 1992 Crook[21] declared: "The hallmark of economic policy in most of the Third World since the fifties has been the rejection of orthodox free-market economics. The countries that failed most spectacularly (India, nearly all of sub-Saharan Africa, much of Latin America, the Soviet Union and its satellites) were the ones that rejected the orthodoxy most fervently….. There is no lack of entrepreneurship in the Third World. To release this huge potential, governments first need to do much less. Above all, they must stop trying to micromanage the process of industrialization, whether through trade policy, industrial licensing, or direct control of state-owned enterprises. But they also need to do more. They must strive to keep public borrowing and inflation in check, while investing adequately in physical and nonphysical infrastructure.". In 2020, this maxim remains true. Mgbeoji[22] provides an argument for African success through presence of highly trained IPR professionals, which will support the growing entrepreneurial activity by ease of access to highly trained IPR professionals.

Summarizing, this essay aimed at showcasing the strong connection between IPR origins, economic activity and IPR strength. While strong IPR benefit developed countries the most, developing countries, once development of economy through entrepreneurial activity will start to accelerate, will benefit from strong IPRs – and TRIPS, as a standardization tool providing equalization, dispute

[21] Crook, Clive., Third World Economic Development (1992), The Concise Encyclopedia of Economics, available at https://www.econlib.org/library/Enc1/ThirdWorldEconomicDevelopment.html# retrieved on Feb 25, 2020

[22] Mgbeoji, Ikechi, "The Comprador Complex: Africa's IPRs Elites, Neo-Colonialism and the Enduring Control of African IPR Agenda by External Interests" (2014). *Articles & Book Chapters.* Paper 2174.

regulation and mediation framework serves greatly, while providing for emergency needs of countries fighting life-threating emergencies.

And Ya'ad-Shaab? In 2019, as Shaab's population was provided with better education and employment opportunities during the 2000's and its income level rose, amount of petty crime incidents was reduced by 3 times. People with means respect property rights – and it is up to us, IPR professionals, to ensure the means belong to the people.