Intellectual Property Rights Protection of Public Health Innovations

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ABSTRACT

To figure out the extent that public health innovations are protectable under intellectual property (IP) laws, innovations in public health are categorized into groups, each of which is analyzed for applicable legal regimes of intellectual property right (IPR) protection. With the exceptions of diagnostic, therapeutic and surgical methods for the treatment of humans or animals, public health innovations that involve physical objects, chemical/biochemical substances, or electronic and computer technologies are most likely to be protectable by patents as well as other IP laws. Certain body movement-oriented innovative activities and many computer-implemented public health innovations may be copyrightable. Other public health innovations may not be fully compatible with IPR protection systems due to incongruence in the subject matters. These include innovations that are basically economic or legal measures, innovations that involve social interactions, and innovations related to research questions, research ideas, research or survey methodology, as well as policy and policy advocacy. Understandably, some of these exclusions reflect the public policy against any hindrance to the spread of medical methods. Other innovations are not recognized or excluded from IPR protection probably because legal development has not caught up with advancement in public health. Policy studies should be designed and conducted with the initiation and assistance of public health policy bodies, to determine which group of public health innovation should be protected in order to derive positive aggregate social benefits. Protection, if any, could be implemented through expansion or re-interpretation of the scope of existing IP laws or by establishing a new form of exclusive rights.

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Introduction

In a typical university, a popular question that a technology management officer is often asked by Public Health faculty members is whether an innovation in public health can be protected under intellectual property laws. A short answer of "yes and no" would satisfy very few faculty members. At the legislative level, national policy makers have probably toiled with similar questions, starting with, perhaps, "Are our intellectual property laws adequate for protecting innovations in public health?" If the answer is "no," a more difficult question would follow: "Should there be any additional IPR protection to promote the creation and utilization of public health innovations in order to maximize the overall social benefit? In this article, I attempt to answer the first question in a quasi-systematical manner by breaking up IPR protection into different legal regimes and clustering public health innovations into a few broad groups. Then I will try to mesh up the innovation groups with the IPR protection regimes in order to get some feeling about the degree of harmony and incompatibility between the two.

Intellectual property rights (IPR) protection

Intellectual property (IP) refers to intangible "creations of the mind, such as inventions (i.e. new solutions to technical problems;[1] [and] literary and artistic works… ."[1]. An idea by itself is not considered an intellectual property while an idea that is "executed" in some way is. For example, an idea that is conceived and reduced to practice is called an invention, itself a type of IP, while an expression of idea can be a literary or artistic work, which is another type of IP.

The exclusive rights over an IP are called intellectual property rights (IPRs), which are legal rights to exclude others from competing in some way with the right holder in reaping the economic benefits of that particular type of IP. IPRs are granted according to national legislation for limited durations and often with certain restrictions or requirements in the hope that the limited monopoly resulting from such grants would stimulate creative and inventive activities, as well as provide incentives for private investment to bring these creations and inventions to market. Without protection, IPs can be exploited by anyone as public goods. Creators, inventors, and investors would have no incentive to create, invent, or invest. On the other hand, if the IP coverage is too broad or the degree of IPR protection is too stringent or the duration of protection is much longer than the economic life of the IP of interest, the strong incentives to invent, create, and invest would be shadowed by the excessive cost to the public consumers

in order to enjoy products or services containing such creations or inventions. Each society should try, in theory at least, to set its IPR protection systems to achieve the optimum point for the society, i.e. to balance between incentives to create and utilize IPs, i.e. the technical progress on one hand and the costs consumers have to bear plus the cost to society in order to establish and maintain components of the IPR systems, e.g. the patent office, the IP courts, etc. on the other hand.

Traditionally, IPs can be divided into two major groups: (1) Literary and artistic works, the rights of which are protected by copyright laws; and (2) Industrial properties, which practically include all other kinds of IPs that do not belong to the first group. IPRs of industrial properties are protected by other IP laws such as patent law, trademark law, trade secret law, plant variety protection law, etc.

Global minimum standard of IPR protection

Nowadays national IP laws of most countries are dictated to a large extent by a *de facto* global minimum standard of IPR protection. Since the conclusion of the Uruguay Round of the multilateral General Agreement on Tariff and Trade (GATT) and the signing of the Marrakesh Agreement Establishing the World Trade Organization (WTO) in 1994, WTO Members have been effectively bound by the Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (TRIPS)[2], which is published as Annex 1C to the Marrakesh Agreement (see Marrakesh Agreement Article XVI 5 and TRIPS Article 72.). Establishing the global minimum standard of intellectual property protection in all fields of application including public health, TRIPS touches upon different legal regimes of IPR protection including copyright, trademark, geographical indication, industrial design, patent, layout design (topography) of integrated circuits, and trade secret.

Subsequent to TRIPS, developments relevant to public health include the Doha Declaration and several bilateral Free Trade Agreements (FTAs). In 2001, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health, which, among other things, reaffirms the possibility of TRIPS Members (many of which were developing countries) to use the compulsory licensing mechanism in TRIPS to gain better access to essential medicines[3]. Developed countries then struck back with bilateral FTAs, which in several cases include provisions generally known as "TRIP plus,"[4] which severely limit the flexibility that a country would have under

TRIPS to ensure access to medicine.

Owing to the economic and social importance of pharmaceuticals access, when most people think about "intellectual property and public health," the first things that often come to mind would be access to medicines[5-7], the right to health[8], and compulsory licensing of pharmaceutical patents[9]. In our context, we will also look at other components of public health innovations besides innovative pharmaceuticals.

IPR protection regimes

Since IPRs are protected by various legal regimes, let us start by looking at each legal regime that may be relevant to protecting innovations in public health.

Copyright

Copyright protects original creations that are "expressions of ideas," such as books, research publications, paintings and photographic artwork, music, ballet choreography, etc. but not ideas themselves, procedures, methods of operation, or mathematical concepts, according to TRIPS Article 9 2. Copyright is basically a set of rights that exclude others from copying, modifying or distributing the copyrighted work of a copyright owner. As soon as a copyrightable work is created, it is automatically copyrighted without any need to file a copyright application or going through any copyright examination. Generally speaking, copyright protection lasts for 50 to 70 years from the death of the last joint creator. Domestic laws are allowed by TRIPS Article 13 to have limitations or exceptions to copyright, often called "fair uses" or "fair dealings" such as making limited copies for teaching or library archiving. Such limitations or exceptions, as also specified by TRIPS Article 13, must not conflict with a normal exploitation of the work and must not unreasonably prejudice the legitimate interests of the right holder. There are international treaties governing copyright, such as the Berne Convention for the Protection of Literary and Artistic Works. Copyright is applicable and relevant to public health research publications and reports, as well as choreography and music for exercise, etc.

It is interesting to note that, although not a traditional literary work, computer programs, whether in source code or object code, are required by TRIPS Article 10 1 to be copyrightable as literary work. Computer databases, "which by reason of the selection or arrangement of their contents constitute intellectual creations" are protected under the copyright regime according to TRIPS Article 10 2. For examples, health monitoring and health education software for computers and mobile phones are protectable by copyright laws.

Patent

Patent protects inventions, many of which are products and processes related to public health. It is interesting to note that in principle, patent protection is country-specific, i.e. a patent issued by a country does not provide protection in another country. Regional patent systems do exist in Europe, South America, the Middle East, Africa, and the former Soviet Union, though[10]. The ASEAN patent system, unfortunately, has been in the talking and planning stages for the past few decades.

Patent laws of TRIPS Members are required by TRIPS Article 27 1 to protect "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Domestic laws can, according to TRIPS Article 27 2, however, exclude certain inventions from patentability in order to protect public order or morality "including to protect human, animal or plant life or health or to avoid serious prejudice to the environment… ." More relevant to public health is the allowance by TRIPS Article 27 3(a) for members to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals," although there are still subtle differences between patent laws in different countries[11]. The United States, Australia and New Zealand are the only TRIPS members that do not exclude diagnostic, therapeutic and surgical methods from patentability[12]. According to TRIPS Article 27 3(b), members can also exclude from patentability "plants and animals other than micro-organisms …."

A patent application must disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." A patent law "may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date …" according to TRIPS Article 29 1.

Once a patent is issued for an invention, the term of protection is 20 years counted from the filing date. The exclusive rights granted are considered very strong, perhaps the strongest among any IPR protection regime. For example, in case of a product patent, the right owner can prevent others from at least "making, using, offering for sale, selling, or importing for these purposes that product" according to TRIPS Article 28 1(a). TRIPS Article 30, however, allows members to provide limited exceptions (such as a research exemption) to the exclusive rights conferred by a patent, "provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account

of the legitimate interests of third parties."

As a safeguard, TRIPS Article 31 allows members to include a few kinds of compulsory licensing provisions in their patent laws, but with a dozen conditions designed to limit the use of compulsory licensing to real and substantial need, and with remuneration to the patent holder.

In addition to the utility patent system, the traditional "petty patent" or "utility model" systems that exist in some countries are "toned down" versions of the utility patent system with the aim towards domestic inventions of little importance. The requirement for novelty or non obviousness (possession of an inventive step) or both are relaxed, but the period of protection is also substantially shortened from that of a regular utility patent. Petty patents or utility models are generally not suitable for protecting inventions that require significant investments to bring the protected technologies to market, such as those in the pharmaceutical industry, because the protection period may be too short for business to recoup the investment.

Finally, certain patents called "Standard Essential Patent" (SEP) happen to protect inventions that form part of a standard, e.g. standards in health data sharing. In this situation, the respective standard-setting organization often requires SEP right-holder to commit to license their patents on fair, reasonable and non-discriminatory (FRAND) terms[13].

Protection of industrial designs

Industrial design refers to the design of the outer appearance, as opposed to function, of a product. Members are required by TRIPS Article 25 1 to "provide for the protection of independently created industrial designs that are new or original." The owner of an industrial design can, for a duration of 10 years, "prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy … of the protected design … " according to TRIPS Article 26 1 and 3. Industrial design could be useful for protecting the outer appearance that helps to add esthetic value to a commercial product aimed at improving health.

Plant variety protection

Plant varieties are to be protected "either by patents or by an effective *sui generis* (stand-alone, unique or specialized) system (i.e. by a plant variety protection law) or by any combination thereof (e.g. in the case of the United States)" according to TRIPS Article 27 3(b). New varieties of plant (including genetically modified plants) as well as methods to produce these varieties can be protected in many countries. In addition

to new plant varieties, Thailand has enacted a legal system to protect existing or native plant varieties, many of which are endowed with medicinal properties.

Protection of integrated circuit layout design

In case a gadget, e.g. a medical device, incorporates a custom-designed original integrated circuit, TRIPS requires members to provide protection for the layout-design (topography) of such an integrated circuit according to various articles of the Treaty on Intellectual Property in Respect of Integrated Circuits (Washington Treaty of 1989). TRIPS Article 6(1) lists the exclusive rights conferred as reproducing, "… importing, selling or otherwise distributing for commercial purposes a protected layout-design (topography) or an integrated circuit in which a protected layout design (topography) is incorporated."

Trademark protection

Trademarks are usually seen on commercial products related to health, e.g. medications, medical devices, and even on hospital buildings. Trademarks are granted by the state as an incentive for trademark owners to establish and maintain the quality of their products. A WTO member needs to provide legal protection for trademarks according to TRIPS Article 15. TRIPS Article 16 1 states that the owner of a trademark has "the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion." A trademark registration must last at least 7 years and can be renewed indefinitely according to TRIPS Article 18. Compulsory licensing of trademarks are not permitted, according to TRIPS Article 21.

Protection of geographical indication

According to TRIPS Article 22 1, geographical indication (GI) is defined as "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin." Members are obligated by TRIPS Article 22 2(a) to "provide the legal means for interested parties to prevent … the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good." GI could be useful for protecting health-promoting

local or regional products.

Protection of Trade Secret

What ordinary people refer to as "trade secret" protection appears in the section on "undisclosed information" in TRIPS. To qualify as protectable undisclosed information, TRIPS Article 7 2 requires that the information must comply to all three criteria as follow: "(a) [being] secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question, (b) having commercial value because it is secret, and (c) having been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret." Members are required by TRIPS Article 7 1 to protect undisclosed information in the context of protection against unfair competition. In most countries, trade secret misappropriation by improper means, as well as disclosure or use of trade secrets are deemed to be illegal. Exceptions to "improper means" normally include discovery of the trade secret by independent invention and reverse engineering.

Protection of trade secrets is routinely utilized in and by all kinds of businesses including ventures related to public health, because the secret can be practically anything, e.g. invention, knowhow, commercial data such as raw material sources and customer lists. Even un-patentable knowledge or things may be qualified as trade secret if it satisfies all the requirements in TRIPS Article 7 2.

Another type of trade secret prescribed by TRIPS involves data that a pharmaceutical or agricultural chemical company submit to a respective government office in conjunction with an application for a regulatory approval. "Submitted undisclosed test or other data, the origination of which involves a considerable effort, [shall be protected] against unfair commercial use … [and] … disclosure [… except where necessary to protect the public]," according to TRIPS Article 39 3.

Innovation

Although "invention" has a relatively precise meaning as explained earlier, "innovation" can have several meanings. For some, innovation may only mean "doing something new that improves a product, process or service"[14]. Innovation may also include "social innovation", i.e. the "development of a new social paradigm with a sustainably global efficiency above the previous paradigm(s)"[15]. For most people, innovation seems to require ideas, execution, and value creation, e.g. "executing an idea which addresses a specific challenge and achieves

value ([e.g.] for both the company and customer)"[16]. Unlike the novelty requirement of patentable inventions, innovations are generally understood to be "unique" in the sense that "no one else is doing it (yet)"[17]. The "value" attribute of innovations can arise from such innovation being "better solutions"[18]. These solutions could be for felt needs or even for problems unrealized by consumers at the time, e.g. overnight mail and package delivery[19].

Thus, while an IP involves (creative or inventive) idea plus execution, our working definition of an innovation involves execution of an idea to yield a unique and valuable solution.

Public Health Innovations

Many public health innovations may be more closely linked to inventions than one might expect. Owing to the practical nature of the public health discipline, a public health invention, e.g. a new drug, a new and better mosquito trap or a new and more effective social empowerment technique, is usually tested in the field for practicality and efficacy. Once the invention is considered successful, it is automatically used by small groups of participants in the original testing, i.e. village people or practitioners, and will diffuse to other groups of people who can benefit from it. Thus public health inventions often become public health innovations.

Unlike "inventions," which are easy to find categorized by technology into "technical fields" on the International Patent Classifications (IPC) database[20] maintained by the World Intellectual Property Organization (WIPO) according to the Strasbourg Agreement Concerning the International Patent Classification (1971), "innovations" do not have a formal classification system. Our strategy here is to separate public health innovations into different groups and then to analyze whether each group of public health innovations can be protected under existing IPR protection regimes.

From the perspective of a non-health practitioner, I can think of several ways to categorize public health innovations. For example, I could group them into (1) Innovations related to healthy living and prophylaxis, (2) Innovations related to medical screening and diagnostics, and (3) Innovations related to therapeutics. Alternatively, public health innovations could also be divided into (1) innovation related to human and animal health and (2) innovations related to the environment. Another way of categorization is to divide public health innovations into (1) innovations related to public health research methodology and (2) innovations related to public health interventions.

For the purpose of comparing with IP protection regimes, let us categorize public health innovations into: (1) innovations that involve physical objects or chemical/biochemical substances, such as a rapid personalized drug preparation system, a new x-ray screening machine, or a medicine that cures Ebola hemorrhagic fever; (2) body movement-oriented innovative activities such as an innovative form of exercise, (3) innovations that are basically economic or legal measures such as a free smoke-alarm program for an anti-smoking campaign or a city-wide car-free ordinance for improving urban air quality; (4) innovations that involve one-to-one and group social interactions, such as a new and effective personal interview or new motivational group counseling; and (5) innovations related to research questions, ideas, research or survey methodology, policy as well as policy advocacy, and the like.

Innovations that involve physical objects or chemical/biochemical substances

Many of the "traditional" public health innovations, such as pharmaceuticals and medical devices fall into innovations that involve physical objects or chemical/biochemical substances. In most countries, these innovations may be protected by IP laws, especially the patent regime, as seen by the existence of "classes" in the International Patent Classifications (IPC). For example, products and process inventions related to dental hygiene are covered under IPC Class A61K. Contraceptive devices and processes are covered under IPC Class A61F. An innovation in painless blood sampling would be patentable under IPC Class A61M. Although patent laws in many countries exclude diagnostic methods from patent protection as allowed by TRIPS Article 27 3(a), diagnostic products (such as diagnostic kits for propensity to a certain type of cancer) may be patentable. Similarly, therapeutic methods are often excluded from patentability as allowed by TRIPS Article 27 3(a). Therapeutic products, i.e. pharmaceuticals and medical or surgical devices, may be patentable. For example, the specific therapeutic activity of chemical compounds or medical preparations are covered in IPC Class A61P; medical devices used for therapeutics are covered in IPC Class A61F; physical therapeutic apparatus are covered in IPC Class A61H; electrotherapy magnetotherapy, radiation therapy or ultrasound therapy are covered in IPC Class A61N; and therapeutics in dental medicine are covered by IPC Class A61K. Human cell reprogramming, a relatively innovative form of therapeutics, may be patentable under IPC Class C12N 15/00 or 15/0662.20

Application software related to innovations in this group may be protected as

literary work under the copyright system, while the algorithm underlying the software may be protectable by patents in many countries. With a few exceptions in developing countries, software algorithms (from software inside diagnostic ultrasound machines to diagnostic software operating on mobile phones) may be patentable. In developing countries that do not allow algorithm patents, however, such software could still be patented as an integral part of the diagnostic or therapeutic machine or device.

Second, the medical use of a known medicine, e.g. minoxidil, may be protectable by patent laws. Therapeutics for non-communicable as well as mental disorders may also be patentable. Innovations that contain inventions in emergency medicine or disaster mitigation may be patentable too.

The IPC classes mentioned above are all high-level groupings. Interested readers can dig deeper into subclasses in each technical field to find more specific products or methods. For example, within IPC Class A61F (medical devices used for therapeutics) there are many more subclasses which cover first-aid kits, bandages, dressing or absorbent pads, stents (a support placed temporarily inside a tubular structure of the body), fomentation (with many uses in traditional medicine), orthopedic devices, nursing devices, etc.

If the public health innovation involves traditional or alternative medicines, some countries, e.g. Thailand, have specialized laws, e.g. the Protection and Promotion of Traditional Thai Medical Knowledge Act of 1999, establishing exclusive rights to recipes or formulations of traditional medicine. In case of the Thai law, the exclusive rights are for manufacturing, distribution, use, research, improvement, and development of the registered formulation. Limitations to the exclusive rights include research according to government regulations and preparation of traditional medicine for individual patients according to prescriptions.

If the public health innovation involves a new plant or a new plant product, the plant itself, as an invention, may be patentable in some countries. The new plant variety can also be protected under the plant variety protection regime mentioned earlier.

If these innovations, e.g. an algorithm of a software application program, are implemented in an original custom-designed integrated circuit, the layout-design (topography) of that integrated circuit may enjoy protection under layout-design protection laws.

Any undisclosed information qualified as a trade secret, as already discussed, may be protected by trade secret protection laws.

If there is a trademark or a geographical indication associated with the commercialization

of the innovation, it may be protected under a respective legal regime.

Body movement-oriented innovative activities

For the group of public health innovations that involves action-oriented innovative activities such as an innovative form of physical exercise, some IP coverage may be applicable. Original choreography for a physical exercise, as well as the accompanied original music, may be copyrightable. Paraphernalia used in physical exercise, e.g. a new type of bouncing ball, may also be patentable.

Innovations that are basically economic or legal measures, involve social interactions, or relate to research questions, research ideas, research or survey methodology, policy as well as policy advocacy, and the like

For these groups of public health innovations, securing some type of IPR protection, especially a patent, could be problematic. In a developing country like Thailand where "process invention" is defined as production process, preservation process, improvement process, or adjustment process of products, including usage of a process, it would be difficult to fit the subject matters of these innovations into the legal definition slots. Even in a country like the United States, where patentable subject matters approach the requirement in TRIPS Article 27 1, a safer patenting strategy is to rely on computer implementation of such processes. In the extreme case, innovative ideas (including research ideas) without implementation or reduction to practice may not be patentable. Again in the United States, concepts relating to managing human behavior and certain methods of organizing human activity are deemed to be abstract ideas and thus not patentable[21]. This might cause problems with certain public health interventions.

Even a trade secret protection system may have difficulties dealing with these groups of public health innovations, starting with the qualification of having commercial value because they are secret. Some of these innovations are no longer secret once deployed. Others might not have commercial value since public policies in some countries might view these life-saving public health innovations as public goods.

The rest of IPR protection regimes, protection of industrial design, protection of integrated circuit layout design, plant variety protection, and protection of geographical indication, are only applicable to very small subsets of these innovations. For example, integrated circuit layout design protection laws would be applicable only to social

innovations that involve devices containing original integrated circuit layout designs.

Why some public health innovations are excluded from IPR protection

In the cases of abstract ideas and purely mental steps exclusion, the doctrines stem from the belief that patenting things (inventions or otherwise) that serve as basic tools or platforms for a number of offshooting branches of technology would tend to impede innovations.[22] There are also difficulties in enforcing a patent that is supposed to protect what happens only in the human brain. The situation might be avoided by making the ideas less abstract or link to tangible objects, which in many cases is easier said than done.

In the exclusion of diagnostic, therapeutic and surgical methods from patentability, a general explanation is "to ensure that patents would not impede and restrict doctors from fulfilling their duties towards patients …"[23]. In other words, the reason has to do with ethics and human rights[11] and reflects the general public policy against any hindrance to the spread of medical methods.

In other cases where an inventor may have difficulty patenting a public health innovation, the subject matter of the innovation might fall outside the legal definitions of patentable subject matters. Examples include innovative social interventions discussed earlier.

Recommendations

With respect to diagnostic, therapeutic and surgical methods for the treatment of humans or animals, each country should have freedom to shape its patent law as allowed by TRIPS Article 27 3(a) explained above.

With respect to compulsory licensing allowed by TRIPS Article 31, along with the Doha Declaration, many developing countries still count on them as their last resort for access to essential medicines. Any action that results in limiting the flexibility that a country would have under TRIPS to ensure access to medicine must be avoided.

With respect to innovations related to research and survey methodology, social intervention, policy, policy advocacy, and the like, their utilities might not fall within the industrial application requirement of the patent laws in many countries. It is difficult to view these as commercial activities. It is also difficult to convince others of their economic values to the right holders. On the other hand, one could argue that having some kind of exclusive rights over these innovations would allow the innovators, often doctors or public health researchers, to apply quality control to their methodologies and interventions, which will eventually benefit the

public. Such exclusive rights must not be too strong or the diffusion of such public health innovations may be severely limited. There should be an optimum degree of protection and promotion such that the public health researchers can implement quality control over their innovations while being encouraged to train others to help diffuse such innovations. Exactly what degree of protection and what kind of exclusive rights (re-interpreted IPR, expanded IPR, or even *sui generis* rights) are needed should be a policy research question for each country.

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References

1. World Intellectual Property Organization. WIPO Intellectual Property Handbook, 2nd ed. World Intellectual Property Organization Publication No. 489(E). 2004.
2. Agreement on Trade-related Aspects of Intellectual Property Rights. Available at https://www.wto.org/english/docs__e/legal__e/27-trips.pdf, accessed August 11, 2019.
3. The Doha Declaration on the TRIPS Agreement and Public Health. Available at https://www.who.int/medicines/areas/policy/doha__declaration/en/, accessed August 11, 2019.
4. Ho C. Access to medicine in the global economy: International agreeements on patents and related rights. Oxford Scholarship Online. May 2011. DOI: 10.1093/acprof:oso/9780195390124.001.0001, accessed August 11, 2019.
5. Correa CM. Public Health and Intellectual Property Rights. Global Soc Policy 2002; 2(3): 261-78.
6. Halabi SF. Multipolarity, intellectual property, and the internationalization of public health law. Mich J Int'l L 2014; 35(4): 715-72.
7. Musungu SF. Intellectual Property and Public Health: Will It Be Peace or War. J World Intell Prop 2004; 7(2): 249-52.
8. Intellectual Property, the Right to Health, and Human Rights. U. Ill. J L Tech & Pol'y 2006; 1: 63-116.
9. Li Y. Intellectual property and public health: Two sides of the same coin. Asian J WTO & Int'l Health L & Pol'y 2011; 6(2), 389-428.

10. Adams SR. Regional Patent Systems, Science & Technology Libraries 2001; 22(1-2): 89-99.
11. Asif E. Exclustion of diagnostic, therapeutic and surgical methods from patentability. J Intellec Prop Rights 2013; 18: 242-50.
12. Malhotra D, Lakshmikumaran M. Scope of Section 3(i): An analysis on diagnostic methods of treatment. IPR Articles. Available at https://www.lakshmisri.com/News-and-Publications/Publications/Articles/IPR/scope-of-section-3i-an-analysis-on-diagnostic-methods-of-treatment, accessed August 11, 2019.
13. World Intellectual Property Organization. Worldwide activities on licensing issues relating to standard essential patents. Available at https://www.wipo.int/wipo__magazine/en/2019/01/article__0003.html, accessed August 11, 2019.
14. World Intellectual Property Organization. Innovation and Intellectual Property. Available at https://www.wipo.int/ip-outreach/en/ipday/2017/innovation__and__intellectual__property.html, accessed July19, 2019.
15. Noailles P. European Forum for Innovation Policies. Available at https://www.ideatovalue.com/inno/nickskillicorn/2016/03/innovation-15-experts-share-innovation-definition/, accessed July 11, 2019.
16. Skillicorn N. What is innovation? 15 experts share their innovation definition. 2016. Available at https://www.ideatovalue.com/inno/nickskillicorn/2016/03/innovation-15-experts-share-innovation-definition/, accessed July 11, 2019.
17. Moskal D. Answer to: What is the basic difference between innovation and novelty? Quora. Available at https://www.quora.com/What-is-the-basic-difference-between-Innovation-and-novelty, accessed August 11, 2019.
18. Moya B. Novelty vs. Innovation. Available at https://borjamoya.com/2017/04/novelty-vs-innovation/, accessed July 11, 2019.
19. Our history. About Fedex. Available at https://about.van.fedex.com/our-story/history-timeline/history/, accessed August 11, 2019.
20. World Intellectual Property Organization. International Patent Classification (IPC). Available at https://www.wipo.int/classifications/ipc/en/, accessed August 11, 2019.
21. US Patent and Trademark Office. Manual of Patent Examining Procedure, January 2018 (9R-08.2017) Section 2106.04(a)(2) Available at https://mpep.uspto.gov/RDMS/MPEP/current#/current/d0e197004.html, accessed August 11, 2019.

22. Nossaman LLP. The Patentability Exclusion for "Abstract Ideas" is Even More Abstract Post-Alice. 2014; Available at https://www.jdsupra.com/legalnews/the-patentability-exclusion-for-abstrac-95036/, accessed August 11, 2019.

23. Kankanala KC. 'Diagnostic Method' patent model-patent incentives and socio-ethical concerns. J Intellect Prop Rights 2007; 12:104-10. Available at http://nopr.niscair.res.in/handle/123456789/229, accessed August 11, 2019.