IP, TRADE AND ACCESS TO MEDICINES PHM 2019
(Brook K Baker & Yousuf Vawda)*
GLOSSARY OF TERMS

Advocacy campaign: An advocacy campaign is a collective effort by individuals or groups to change a policy or practice that they find harmful or ineffective.

August 30 Decision and Art. 31bis: This was the temporary waiver adopted by the WTO on August 30 of 2003, that permitted a manufacturer to supply set quantities of a medicine to a "non-producing country" (a country with insufficient or inefficient capacity to manufacture domestically) even if those quantities would otherwise violate the 'predominantly for domestic use' rule of Article 31(b). The Decision established a procedurally complex system of notifications and product modifications and other protections against product diversion. Art. 31bis is a subsequent proposal to actually amend the TRIPS Agreement to include the exact content of the August 30 Decision. This amendment requires and is still awaiting approval from a required number of WTO members.

Blockbuster drugs: Certain drugs have very high global sales, typically more than $1 billion per year, and thus they are considered blockbusters. Pharmaceutical company profits are highly contingent on blockbuster drugs because not all medicines actually make money once the costs of R&D are included.

Commercially reasonable period of time: refers to the requirement in the TRIPS Agreement that mandates that the patent holder and the prospective license or license-granting government to negotiate for the period of time that would ordinarily permit private parties to reach an agreement. However, the TRIPS Agreement also seems to allow governments to set time periods on the length of negotiations, especially since patent holders historically have dragged out the negotiations for so long that the patent lapsed before the issuance of the license.

Commercially reasonable terms: refers to the requirement in Article 31 of the TRIPS Agreement that mandates that a prospective compulsory licensee or a government seeking to authorize a compulsory license negotiate with the patent holder for a voluntary license on terms that would ordinarily be reached in private commercial negotiations between equal bargaining partners. The U.S. sometimes seems to assert that price reduction alone could be a commercially reasonable result, but this assertion is not supported by the text of Article 31.

Competition: Competition occurs when two or more companies are competing to sell an equivalent product or service to the same consumers. When there is only a handful of competitors, the market may be considered an oligopolistic market where the "competitors" collude directly or indirectly to sell at a higher than competitive price (price fixing). In the pharmaceutical context, the market seems to become truly competitive (at least in rich country market, when there are eight or more competitors.

Competition-based licenses: As stated, TRIPS permits the granting of compulsory licenses when a patent holder violates a countries competition policy (either general or IP specific). Special rules apply to competition-based licenses: there is no requirement of prior negotiations, the compensation can be less, and unlimited quantities can be exported.

Compulsory licenses: Compulsory licenses are authorizations granted by governments allowing others to produce a patented product or to utilize a patented process without the voluntary assent of the patent holder. Compulsory licensing is authorized by Art. 31 of the TRIPS Agreement, but must also be authorized by national legislation. Compulsory licenses can be authorized on multiple grounds, but TRIPS (and national legislation) requires that certain procedures by followed. Compulsory licenses can be granted to one or several licensees or may even be "open" to all qualified manufacturers. They can be granted to a local manufacturer to allow domestic production and/or to a foreign manufacturer to allow importation. (A second compulsory license might be required to permit exportation.) Compulsory licenses ordinarily require that the patent holder be paid adequate remuneration – a reasonable royalty – for the allowed use.

Data exclusivity: Data exclusivity is a form of data protection that prevents a drug regulatory authority from relying on data previously supplied by a prior drug registrant, or the fact of prior registration in the same country or elsewhere, in order ascertain the safety and efficacy of a therapeutically equivalent pharmaceutical product.

Data protection: Data protection is a term used in Article 39 of the TRIPS Agreement that requires countries to avoid disclosure of otherwise confidential (undisclosed) information that the registration applicant has to supply to the drug regulatory authority. In addition to prohibiting disclosure except where necessary to protect the public, data protection also requires governments to prevent unfair commercial use of the data. Data protection under TRIPS only applies with respect to new chemical entities and only when the origination of the data involves considerable effort, usually understood to mean considerable expense.

Disclosure: As part of the patent "exchange", patent holders are obligated to disclose sufficient information about the patented product or process so that another person, reasonably skilled in the arts, could utilize that information and reproduce the invention. Disclosure allows follow-on innovation during the life of the patent and imitation at the end of the patent. Some patent holders "game" the disclosure system by providing confusing or incomplete information, and pharmaceutical patent disclosure is often insufficient because a final pharmaceutical product may be based on many subsidiary patents, but they are all filed separately and none of them include either the proprietary name or the international generic name.

Doha Declaration: The Doha Declaration on the TRIPS Agreement and Public Health was passed in November of 2001 after a special request by the Africa Group that the WTO clarify the rights of countries to prioritize public health and to ensure the right of access to medicines for all as long as TRIPS requirements and procedures were followed. The Doha Declaration also clarified and reaffirmed some of the flexibilities that countries had, to facilitate access to more affordable medicines including parallel importation and compulsory licenses. It also directed Member Countries to create an exception to the "predominantly for domestic use rule" that prevented effective utilization of compulsory licenses by countries that lacked sufficient and efficient capacity to manufacture a medicine domestically.

Domestic/regional production: Domestic production refers to manufacturing and selling drugs only within one country. Regional production is manufacturing and selling to a number of countries in a region, e.g., Latin America or SADC.

donation programs: Drug companies sometimes donate medicines in emergency situations, for particular diseases (river blindness) that are curable but where people can't afford the medicine, and even to poor customers in richer countries who could not otherwise afford their medicines. Drug companies enter into donation programs for multiple reasons including as part of the corporate responsibility initiatives, for favorable publicity, as a result of access campaigns, or even to reduce public opposition to their patent and monopoly rights. More tactically, some drugs companies may donate medicines in order to deter or punish generic entry.

Drug regulatory authorities: Drug regulatory authorities (DRAs) are the national government entities that are given the power to assess whether or not a pharmaceutical or other medical product may be marketed for human (or animal) use. DRAs with ample capacity authorize clinical trials and thereafter assess the safety and efficacy of the product, its stability, and its built-in quality, called Good Manufacturing Practices, are sometimes referred to as *stringent DRAs.* DRAs with less capacity do not undertake comprehensive assessments and sometimes rely only on certification that the product has been approved for use elsewhere or on previously published studies.

Early working (Bolar): An early working, or Bolar, provision is designed to allow a generic producer seeking to register a follow-on equivalent of a previously approved/registered medicine to begin product development and development of the required registration dossier even before the patent has expired. It also permits the generic company to file the registration application before the patent term expires, but final approval will only be granted on the date of patent expiration.

Economies of scale: Often it is cheaper to produce a product – like medicines – when you are making larger quantities. Because you are purchasing large volumes of active pharmaceutical and other ingredients, you will probably get a cheaper price (esp. if those manufacturers are not monopolists and are producing at efficient economies of scale). Likewise, you can have larger and longer product run, which in the drug manufacturing process means you have less down time and fewer machinery cleanings. Sometimes, there are diseconomies of scale such that you are trying to produce so much that you become less efficient. This is rarely an issue in drug manufacturing.

Essential facility: An essential facility is a competition theory which requires the owner of a facility or asset to allow others to use that facility or asset if such use is the only practical way to engage in an economically beneficial capacity. So, for example, if one railroad owns the only bridge over a river, but the railroad tracks are otherwise open to other railroads, then the bridge owner may be required to allow others to use its "essential facilities" bridge. The same concept can apply in the context of medicines, either with respect to generics or even more so with respect to fixed dose combination products.

Essential medicines: In order to promote rational use of medicines, the World Health Organization established a list of medicines it deemed essential to adequate health care and urged member countries to adopt their own national essential drug lists that they would provide within the public health system. Although the composition of the essential drug list was initially premised on safety, efficacy, and cost, the WHO has more recently reduced excessive reliance on affordability and instead emphasized therapeutic effect.

Ethics of clinical trials: Clinical trials using human subject must be undertaken to investigate a scientific question of medical significance and promising patient benefit (for example, the safety and efficacy of a medicine). They must be undertaken without undue inducements to the participants (human subjects), and must be conducted so as to safeguard, to the maximum extent reasonably possible, the safety, well-being, autonomy, and health of the human subjects. Conduct of a clinical trial ordinarily requires approval by an ethical review panel or system. Participation in clinical trials ordinarily requires informed consent by each and every participant. Participants are entitled to an appropriate (perhaps even the best) standard of care during the clinical trials and thereafter for adverse effects resulting from the trial. The trial should be expected to benefit both the human subjects in the trial and the greater population of the country where the trial is conducted.

Evergreening: Evergreening is a negative term used to describe the process by which patent-holding pharmaceutical companies make minor changes in a pharmaceutical product or process in order to get a new patent that extends the period of monopoly protections and thus higher prices. Examples, of evergreening include adding a simple coating to a tablet to decrease stomach irritation, or patenting a slight variation in the chemical entity, or combining two previous known products.

Exclusions from patentability: The TRIPS Agreement allows countries to exclude certain subject matter from patent protections.

Exclusive marketing rights: The TRIPS Agreement (Article 70) requires that Member Countries grant five years of exclusive rights to make and sell a patented medicine to the patent applicant once the patent for that product has been placed in the country's patent mailbox, but only if the medicine has been registered for use in the countries and only if the medicine has been granted a patent and granted marketing approval in another country.

Failure to work: refers to the failure of a patent holder to produce and market the patented product or to use the patented process commercially even after the patent is granted. Failure to work has historically been a ground for compulsory licenses because governments don't want to give a patent holder the right to exclude others when the patent is not being "worked" by the patent holder. In most systems and under TRIPS, the patent holder is given three years within which to work the patent, and a compulsory license for failure to work cannot be granted until the passage of the three year period. The patent holder is also permitted to explain or justify the failure to work, and the failure is forgiven if the grounds are reasonable, especially if they are out of the control of the patent holder, e.g., R&D on a medicine is ongoing or the failure of the drug regulatory authority to allow marketing of the medicine.

Forum shifting: Forum shifting in the context of intellectual property rights refers to the practice of IPR holders and governments that pursue higher intellectual property protections to change the forum or institution(s) within which they pursue higher intellectual property protections. For example, IPR holders and its supporter shifted forums from WIPO (the World Intellectual Property Organization) to the GATT, which became the WTO, and then to bilateral and regional free trade agreements.

Free trade agreements: Often considered a misnomer because the agreement are unfair to developing countries and often contain market protections for good and services manufactured in richer and more powerful trading partners, the term free trade agreements refers to comprehensive agreements between two or more countries (bilateral or plurilateral)

that typically lower barriers to trade including tariffs. Increasingly free trade agreements include many other terms including investment clauses, clauses affecting trade in services, and government procurement clauses. Paradoxically, free trade agreements also typically include intellectual property provisions even though these are terms that guarantee protections for IP monopolies rather than promote more and freer competition between countries.

Government use: Also called crown use, government use is a grant by the government to itself or to other entities or contractees acting on behalf of the government to make use of a patented product or process without the assent of the patent holder. Although government – non-commercial public – use does not require prior negotiations with the patent holder, the TRIPS Agreement does require notice and payment of adequate compensation.

Human rights: Human rights are the rights held by individuals regardless of who they are and where they live. They include civil and political rights like freedom of speech, freedom of religion, freedom of association, the right to vote, freedom from discrimination and persecution, freedom from torture or slavery, etc., but they also include social, economic, and cultural rights including the right to health, the right to food and shelter, the right to earn a living, and the right to benefit from scientific progress. Although human rights may not be eliminated or denied, they may be subject to the principle of gradual realization in accordance with the resources of the country, and there are occasions where rights of individuals and groups may conflict and where accommodation will be necessary.

Incremental innovation: The term incremental innovation applies broadly to the fact that innovation does not ordinarily proceed by great leaps forward but instead consists of relatively small steps that add to and rely on the body of prior innovations. Distinguishing between "evergreening" and "incremental innovation" and determining what if any incremental innovations are entitled to patents involves careful consideration of patent criteria and of other relevant public policies including the right of access to essential medicines.

Industrial applicability: Industrial applicability requires that the innovation has a concrete practical use – that it is more than a mere idea. A weaker form of industrial applicability only requires that the innovation have utility.

Industrial policy: Industrial policy refers to the national policy whereby a country seeks to encourage its own industrialization and domestic manufacturing/industrial capacity. Thus, for example, South Africa, pursuing industrial policy, may have preferred to try to encourage voluntary licenses with drug companies for Aspen Pharmacare rather than to pursue compulsory licenses.

Intellectual property Rights or Rules (IPRs): Intellectual property rights or rules is a relatively recent concept that encompasses a variety of legal protections for innovative and reputation-based assets including patent rights, copyright, trademarks, trade secrets, and more recently data protections and protections for new forms of information transmission.

Inventive step: In addition to having novelty or newness, a patent must show inventiveness – a step beyond mere routine discovery. One meaning of inventive step is that the innovation must be non-obvious to a person skilled in the relevant art or practice or that it must be more than the mere adding together of previously known products or processes.

Investor rights: Rights granted via trade agreements or otherwise that grant foreign investors the same rights as domestic investors to invest in a country, as well as protection of those investments against expropriation, excessive regulation, or even beneficial public policies that may diminish the value of the investment. Many investor rights clauses give the investor the right to bring a lawsuit directly against the offending government, either in domestic courts or in special trade courts.

IPR rachet: This is a term first used by Peter Drahos to describe the process by which once a higher intellectual property protection was gained in one forum or agreement or another, that higher protection became the floor from which even greater protections were sought thereafter. Therefore, IPR protections always increase and never decrease and often those new consolidations are retrofitted to apply even to older agreements.

Justiciability: This is a concept that refers to the issue of whether a particular claim or dispute is subject to court adjudication or whether it is a political question more appropriately addressed either by the legislative or executive branch of government. Some commentators question whether social, economic, and cultural rights are justiciable or not.

Local working requirement: Refers to the requirement that the patented product be produced or that the patented process be utilized via domestic manufacture. Historically, since it was permissible to discriminate against imports, it was concurrently permissible to require "local working" of a patent and the failure to work locally was a ground for compulsory licensing. Since the TRIPS Agreement prohibits discrimination against imports, some argue that it does not permit a local working rule, such as that enacted in Brazilian law (the subject of a 2001 WTO complaint by the U.S. against Brazil). Others argue that since the TRIPS Agreement also encourages the transfer of technology, that some forms of a local working requirement may be TRIPS-compliant.

Mailbox provisions: Although the TRIPS Agreement gave developing countries transition periods that would delay the date of TRIPS-compliance, the Agreement also required that those same countries begin to collect patents for innovations arising after 2004 and to place them in a so-called mailbox. When the country became TRIPS-compliant, it would be required to process the mailbox patent applications according to the new patent standards. If granted, the mailbox patent would be for twenty-years from the date that it was first placed in the mailbox.

Marginal cost of production: What it costs to simply make the product and recoup the cost of capital investment with only a modest rate of profit.

Marketing studies: Critics of pharmaceutical companies sometimes claim that certain clinical trials are undertaken not to assess the essential safety or efficacy of the medicine but in fact to be able to make certain marketing claims, often in comparison with a competitor's product, e.g., "proven to give longer-lasting relief", when the same relief could be obtained with the competitor's product merely by taking another dose. These kinds of studies add greatly to the alleged costs of R&D.

Market segmentation: Market segmentation refers to the practice whereby drug companies create barriers or separation between different kinds or sectors of markets so that they can sell at differential prices in the differing sectors. For example, drug companies oppose parallel

importation because that allows them to segment the market between rich countries, middle-income countries, and poor countries so that they can sell at profit-maximizing prices in each country. In addition to trying to create country-based market segmentation, drug companies also trying to segment submarket or sector, for example the private sector from the public and NGO sector. Again this permits them to sell at higher prices to the rich and middle income people who tend to utilize the private sector and still make lower priced sales to the public sector for broader distribution to poor people.

Me-too drugs: These drugs are drugs that are produced by a competitor that are sufficiently distinct from the originator's drug so that it does not violate the patent, but that are therapeutically indistinct from the originator product. Me-too drugs are drugs designed to wrest market share from another successive drug where the market is already established.

Monopoly pricing: When a company does not face any competition for a product, for example when it can exclude generic competitors because it has a patent and there are not other therapeutic substitutes for the product, then the monopolist can charge whatever the market will bear. In these circumstances it will earn super-competitive profits (far more than it would have earned in a competitive market) and it can chose its selling price so as to maximize profits because there is no one that can undersell it (perhaps by selling to more people at a lower price.)

Multilateral institutions: Multilateral institutions are institutions or organizations like the United Nations and its affiliated bodies (the World Health Organization, UNICEF, UNAIDS, UNDP, World Bank, International Monetary Fund, WIPO, International Labor Organization, etc.) that are governed by multiple governments rather than just a few. Certain regional entities could also be considered multilateral, e.g., SADC, the African Union, and the European Union, but these are usually referred to as regional institutions or bodies.

New chemical entities: The term new chemical entities is ordinarily understood to refer to a therapeutic chemical entity (an active pharmaceutical ingredient) that has never previously been used for a medicinal use. Minor variations in the form of the chemical entity (salts forms, esters, polymorphs, metabolites, combinations etc.) are ordinarily not considered to be new chemical entities. Some countries interpret this term more leniently.

New uses: Frequently when a medicine is researched and developed it is investigated for clinical efficacy against one disease or condition only. However, subsequent studies may find that the medicine is also safe and efficacious for treating a new disease or condition. In these circumstances, the medicine is said to have a new indication or a new use, and some patent systems will allow a new patent on such new use. The U.S. has recently been trying to require its trading partners to adopt such terms in its bilateral and regional trade agreements.

Non-assignable: In the context of compulsory licenses, the requirement that the licenses be non-assignable means that the compulsory licensee cannot not "assign" or transfer the entire license to another party, though the licensee is permitted to use sub-licenses. Sub-licenses permit a government or distributors who have received a license to sub-license manufacturing and even distribution to others.

Non-discrimination against a field of technology: The TRIPS Agreement prohibits discrimination in the granting or enforcement of intellectual property rights against a certain field of technology. Although countries can differentiate with respect to fields of technology,

they cannot bar or overly burden patents in a particular field of technology like pharmaceutical products and processes.

Non-exclusivity: This is a requirement for compulsory and government use licenses that prohibits the extinguishment of the patent holder's right, via the license alone, to continue to make and market the patented product or process and/or to voluntary license the use of the patent to others.

Non-producing countries: This term refers to countries that lack any or sufficient means for efficient manufacturing of a particular pharmaceutical product. Many developing countries lack such manufacturing capacity.

Non-retroactivity: The TRIPS Agreement was not made "retroactive," meaning that if a country had not previously granted a patent for a pre-TRIPS invention it would not be obligated to do so merely by the passage of TRIPS.

Novelty: Novelty is a requirement for patentability of a product or process that requires that the invention be new, meaning that it has not been previously described (usually in writing) or widely used. Under the Paris Convention, an innovator has one year from the date of first disclosure of a patent claim in one country to file it elsewhere.

Open licenses: As stated, a government may issue a compulsory license on "open" terms, meaning that any entity meeting the stated terms and conditions of the license, e.g., being able to produce medicines of good quality and at an affordable price, will be granted a license.

Parallel importation: Parallel importation is based on the principle of "international exhaustion" of intellectual property rights. What this means is that when a patent or copyright holder first sells a patent protected product, the patent holder has "exhausted" its rights to place further patent-related limitations on the resale of the product to others either domestically or internationally. (Patent holders sometimes place contractual limitations on the right of resale.) Parallel importation permits drug distributors in one country to comparison shop for a cheaper version of the same patented product that is sold more cheaply abroad than it is domestically. An open question concerning parallel importation is whether the first sale must have been "assented to" by the patent holder or whether parallel importation also allows purchase and importation of a medicine produced elsewhere pursuant to a compulsory license.

Patents: Patents are private rights granted to individuals or other entities that create novel, inventive, and useful *products* or novel and inventive *processes* for making useful products. Patent rights are negative rights granted by governments within a national territory that allow that person to seek judicial enforcement to exclude or prevent others from making, selling, distributing, or importing a patented product without the permission of the patent holder or from using a patented process without the permission of the patent holder.

Patent enforcement: Since patents are private rights, most enforcement procedures historically have been via private judicial remedies, i.e. lawsuits. Patent holders are increasingly trying to get governmental authorities to help in the enforcement of patent rights by border control measures and seizures, by criminal prosecutions, and by linking regulatory approval (drug registration) to patent status.

Patent pools: A patent pool is a portfolio of assets consisting of the entire set of patents (and, if desired, know-how, data dossiers and other intellectual assets) held by various actors (companies, universities, government institutions) related to a particular technology that are made available on a non-exclusive basis to a group of manufacturers and distributors of medications. The pool is operated through the auspices of a licensing agency which holds licences to the patents (and other intellectual assets) for sub-license to manufacturers and distributors. The licensing agency collects royalties and distributes them to the patent (and other intellectual asset) holders. The licensing agency can manage a variety of pools (e.g., one for ARVs, another for anti-malarial drugs, and so on).

Patent-registration linkage: Patent registration linkage refers to a concept originating in U.S. law that requires the drug regulatory authority to refuse to allow the registration of a follow-on generic equivalent if the first registrant has listed any patents concerning the product thereby claiming the right to exclude others. Linkage ordinarily requires at least notice to the patent holder, who has an absolute right to object and thereafter to seek a stay or delay in the registration of the follow-on while the validity of the patent is being challenged. Old law in the U.S. allowed successive stays, but more recent law only allows one 30-month stay.

Patent term: The patent term is the length of time that the patent is in affect after it is first filed. The minimum term under the TRIPS Agreement is 20 years. Many countries have provisions to extend or lengthen patent terms to compensate for regulatory delays in granting the patent.

Patent term extension: Some governments are willing to extend the term of a pharmaceutical patent beyond its original 20 year minimum term in order to compensate patent holders for regulatory delays in issuing the patent, regulatory delays in registering the product for sale, and/or to reward the patent holder for certain public benefits, like conducting pediatric trials. U.S. trade agreements have historically required trading partners to extend patents to compensate for regulatory delays.

Petty patents: Historically some patent regimes allowed patents of shorter duration for minor improvements or relatively small degrees of incremental innovation that would not otherwise meet the standards of novelty, inventive step, or industrial applicability. Also *utility models.*

Pipeline provisions: When it became TRIPS compliant, Brazil acceded to the request of the U.S. and placed all pharmaceutical patents that had previously been filed anywhere in the world, but had not yet been approved and sold anywhere, into a "pipeline" patent application system that would assure patenting of those products or processes regardless of whether they satisfied Brazil's standard of patentability or not. Virtually all of the pipeline patents would be considered non-novel because they had been disclosed more than one year before filing in Brazil. This is a form of "retroactive" patentability that was not required by the TRIPS Agreement.

Pre- and post-grant opposition: After a patent has been filed but before it is granted, some countries permit pre-grant opposition whereby interested parties, most especially competitors, can challenge the granting of the patent, usually by presenting evidence that the patent does not meet patenting standards, for example that there is prior art indicating that the patent is not novel or that it does not demonstrate an inventive step. Some countries also have a stage

for opposing the patent, even after it has been granted, via post-grant administrative procedures that allow proof that the patent was improvidently granted. These opposition procedures are to be distinguished from patent invalidation procedures, which are ordinary court procedures that take longer and are more expensive and where the patent can only be overturned on limited grounds, often requiring an elevated standard of proof.

Predominantly for domestic use: This is a requirement under the TRIPS Agreement that the products produced or imported pursuant to a compulsory license be consumed and used predominantly inside the country. The leading interpretation of this phrase is that it requires that at least 51% of the product be consumed domestically, meaning that only 49% could be exported to other countries. A more liberal interpretation of the term is that the compulsory license must have been issued primarily for the benefit of local consumption rather than for the purpose of exportation, for example where economies of scale and lower cost production are achieved by manufacturing much more than you could consume locally.

Pre-regulatory approval: Even before a drug regulatory authority has issued final marketing approval (registration) of a medicine, many countries have special procedures allowing for the importation and/or use of the medicine, especially if it is a therapeutically important medicine. The proponent of the use of the medicine is often required to submit preliminary evidence of the safety, efficacy, and quality of the product, e.g., via WHO prequalification or qualification by a stringent drug regulatory authority, and may furthermore have to list the identity of the patients who will be taking the medicine.

Private use and prior use: Since patents are primarily granted in order to encourage commercialization of inventions by protecting such commercialization from immediate competition, patent acts frequently exempt so-called private (and sometimes humanitarian) use from patent infringement claims. Likewise, in some instances and without public disclosure, one inventor may have been making a product or using a process that was subsequently invented by another person/entity that thereafter went through the formalities of seeking a patent. The prior user, in some countries, is protected from patent infringement claims if it can prove prior use.

Public health: Public health is that branch of health that deals with efforts to protect the health and well-being of populations not just individuals. It includes population-based preventative activities and policies rather than individual clinical care or cures. Examples of public health measures include clean water, sewage/waste disposal, and tobacco control.

Public non-commercial use: The term of art used in the TRIPS Agreement to describe a government use license – a license granted by the government to itself or to its contractees to practise a patent for public purposes in a non-commercial rather than commercial way. Public non-commercial use is understood to permit the government to procure and supply medicines to the public through publicly supported social insurance systems or in public sector health services. The term non-commercial does not mean that the licensee may not make a profit in the sale of the patented product.

Refusals to license: The refusal to license a technology to another upon request so as to increase competition or to allow the other entity to utilize the patent as a component to another patented (or unpatented) product can constitute grounds for issuing a compulsory license. Although a patent theoretically gives a patent holder (the patentee) the right to exclude others, competition law can restrict abuses of such powers.

Research and development (R&D): In the context of medicines, R&D refers the process of screening chemical entities and biotechnology products to find medicines that are safe and efficacious. In also involves the process of devising efficient manufacturing process that ensure the built-in quality of the product. The process of R&D for medicines is time consuming and expensive, though estimates of both the time R&D takes and the costs of R&D are highly disputed, and they vary between types of medicines.

Revocation: Revocation is an act by the government (usually the Patent Office) reversing or revoking the earlier granting of a patent, usually on the grounds that there was fraud in the prosecution of the patent application or that the patent, on reexamination, fails to meet mandatory patent standards.

Royalties: The TRIPS Agreement requires that the patent holder be paid "adequate remuneration under the circumstances" – in commercial lingo, a royalty – for the involuntary use of the patent. Some countries, like the U.S., require a higher royalty rate based on the principle of reasonable and entire compensation. A royalty is usually based on the wholesale sale price of the product. Royalties for pharmaceutical patents are usually in the 2-10% range.

Special 301 Priority Watch List: This is a special list used by the USTR to report on the degree to which other countries support U.S.-style intellectual property rights and otherwise allow fair access of U.S. produced goods and services. Industry groups, including the pharmaceutical industry, routinely submit detailed reports with exaggerated claims about the degree to which other countries deny them intellectual property protections. There are three levels in the list, which in decreasing level of severity are: Priority Country, Priority Watch List, and Watch List. Countries on the Priority Country List are most likely to suffer pressure and even trade sanctions from the U.S. Priority Watch List countries will face pressure but will be given ample opportunity to respond before sanctions are imposed. Watch List countries will receive encouragement to do better.

Strategic licensing: Drug companies sometimes enter into voluntary licensing agreements with other companies for purely commercial reasons – the other company can make the product more cheaply or the other company has a related technology or the other company has a better distribution and marketing system either globally or in a particular region/country. However, drug companies sometimes enter into licensing agreements purely for strategic purposes in order to deter broader generic competition. For example, several drug companies have granted limited licenses to South Africa generic companies, like Aspen Pharmacare, with the probable intention of deterring broader competition from Indian generic producers like Cipla.

Strategic litigation: Strategic litigation is court action that is designed as part of a larger more comprehensive campaign to achieve a greater outcome. Sometimes it is appropriate to establish particular claims to lay the groundwork for future claims. Oftentimes, strategic litigation takes place not only as part of a judicial campaign but as part of a broader social movement that attempts to affect certain policies or practices, like access to medicine or protecting the rights of people living with HIV.

Sunset rules: rules in certain data exclusivity provisions that if the data owner does not file in a country within a certain period of time from the date of first registration elsewhere, i.e., one

year, then the country will no longer grant data exclusivity. This is another kind of "use it or lose it" rule designed to encourage drug companies to promptly register medicines.

Territoriality: Patents are granted within the territory or boundaries of particular countries. There are no international patents, though there are mechanisms for cooperating in the filing of patent applications and in some preliminary investigations of the merits of the patent.

Transition period: The TRIPS Agreement had differing time periods for countries to become compliant with its provisions. Developed countries had one year; middle-income developing countries had until Jan. 1, 2000; least developed countries originally had until 2006, although the transition period has been extended in general until 2013 and with respect to pharmaceutical patents until 2016. A select group of countries that had not previously granted patents for medicines, like Brazil and India, were given until Jan. 1, 2005 to become TRIPS-compliant.

Undisclosed data: The data protection provisions of the TRIPS Agreement only protect "undisclosed" data, data that has been treated as confidential, i.e., as a trade secret, by the data owner and that has not been previously disclosed by publication or otherwise.

Unfair commercial use: This term is used in Article 39 of the TRIPS Agreement and is generally understood to mean that the data must be protected from unfair or unscrupulous practices like commercial espionage. The terms is not ordinarily understood, except by the U.S., certain European counties, and Japan, to refer to the use of registration data or the fact of prior registration by a drug regulatory authority to assess the therapeutic efficacy and safety of a follow-on product without the need to repeat clinical trials.

USTR: The USTR is the Office of the United States Trade Representative, the executive agency empowered to conduct trade negotiations and to otherwise pursue U.S. trade objectives.

World Trade Organization (WTO): The WTO is an organization established at the end of the Uruguay Round of GATT negotiations to regulate the international trading system and to adjudicate country-to-country disputes involving alleged violations of WTO rules and agreements, and to allow the enforcement of sanctions for alleged violations.

WTO TRIPS Agreement: In 1994, at the conclusion of the Uruguay Round of negotiations on the General Agreement on Tariffs and Trade, Member Countries adopted the Agreement on Trade Related Aspects of Intellectual Property Rights, or TRIPS. The TRIPS Agreement established new global standards for protection of patents, copyright, trademarks, and selected other forms of intellectual property, certain exceptions to and flexibilities concerning those rights, and transition periods within which countries must become compliant with the new standards.

*** (Abridged version of Glossary Compiled by Brook K Baker & Yousuf Vawda for UKZN Intellectual Property & Access to Medicines Short Course).**