PATENTS, ACCESS TO MEDICINES AND COVID-19

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What is a patent?

Patent is a contract between the inventor and the Government. Inventor agrees to disclose fully (operative) the invention to the public. In exchange, the Government grants for a "limited time" a "limited monopoly" on the invention to the inventor if certain patentability requirements are met.

What are the patentability requirements?

Patent protection is available for invention in all areas technology provided that it fulfills:

- **Novelty** – it must be new or novel, that is, it must show some new characteristic which is not known in the body of existing knowledge (called "prior art") in its technical field.
- **Inventive Step or Non-Obviousness –** it must be non-obvious or involve an inventive step, that is, it could not be deduced by a person with average knowledge in the technical field.
- **Industrial Applicability -** it must be useful or capable of industrial application.

Finally, the invention must be part of the so-called **"patentable subject matter"** under the applicable law. In many countries, scientific theories, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, or methods for medical treatment (as opposed to medical products) are not considered to be patentable subject.

PATENTS act as an incentive to innovation. It aims to achieve two goals; promote research & development (R&D) and encourage the disclosure of inventions, so that others can use and build upon research results.

The TRIPS Agreement

International co-operation and harmonization have been a major driver in the development of IP laws worldwide since 19th century.

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) introduced intellectual property rights into international trading system. It is administered by the World Trade Organization (WTO), provides international co-operation and harmonization.

- TRIPS applies to all intellectual property rights, provides minimum framework and standards and includes enforcement measures – a failure to comply with relevant obligation can lead to multilateral trade sanctions being imposed against the defaulting member state.

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- The main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection.

- The general dispute-resolution provisions and mechanisms established under WTO are available for resolution of disputes purely over IP protection and enforcement.

TRIPS and Access to Medicines

A classic example of the conflicting "North-South" perspectives that create such strong internal tensions within TRIPS is provided by the controversy that has raged for nearly 10 years now in relation to the "Access to Medicines" problem.

TRIPS provides patent protection available for inventions in all fields of technology including pharmaceuticals, for at least 20 years, for both products and processes.

It accelerated the introduction of higher IP standards into the countries that wouldn't ordinarily expected to adopt them. Patents skyrocketed the drug prices in developing countries.

Unjustified application of TRIPS rules led developing countries to demand that the WTO affirm the right to use the "flexibilities" built into the Agreement and negotiate important new flexibilities. The ministerial declaration of the Fourth Ministerial Conference in Doha, Qatar (2011), stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.

- Doha declaration on TRIPS and public health was designed to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines.
- It emphasised that the TRIPS Agreement does not and should not prevent member governments from acting to protect public health. It affirmed governments' right to use the TRIPS agreement's flexibilities in order to avoid any reticence the governments may feel.
- The separate declaration clarified some of the forms of flexibility available, in particular compulsory licensing and parallel importing.

Post-TRIPS period has been shaped by the Doha Declaration and the free trade agreements. TRIPS set certain minimum standards, but the industries wanted more. Thus, the term 'TRIPS-plus' emerged. The free trade (FTA) negotiations held 'behind closed doors' became main forum for patent policymaking for introducing obligations going beyond the TRIPS regime, eliminating TRIPS flexibilities and closing TRIPS loopholes.

Covid-19 and Access to Medicines

The issue of access to affordable medicines is one of great concern to developing countries whose health-care systems are often overwhelmed by HIV/AIDS and other infectious diseases. Covid-19 presents new challenges. There is no cure, treatment or vaccines for Covid-19.

As countries continue to search for medical breakthroughs to address the pandemic, there is a grave danger that research efforts will be stymied and access for many patients to COVID-19 treatments and vaccines will be delayed by limited manufacturing capacity, commercial secrecy and monopolies on key

medical technologies, as well as by hostility to global cooperation. However, many of these life-saving drugs, treatments and medical supplies are protected by patent rights.

One way for governments to deal with this issue is to activate the rights to forcibly license a patented invention when there is public health need, such as the COVID-19 pandemic. Under certain circumstances, prescribed by the law, compulsory licenses can be issued to allow others than the patent holder to produce and supply the product. Some countries have taken measures to address IP barriers.

Chile: The parliament of Chile adopted a resolution justifying the use of compulsory licensing to facilitate access to vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of people infected by the coronavirus virus in Chile.

Israel: Israel issued compulsory licenses related to lopinavir/ ritonavir (brand name Kaletra), which is an HIV medicine was tested, including in combination with other products, for effectiveness in the treatment of Covid-19. The license allows the importation of lopinavir/ritonavir from a generic company.

Following Israel's compulsory license on Kaletra, AbbVie further indicated that it will no longer be enforcing patents relating to lopinavir/ritonavir anywhere in the world.

Ecuador: The National Assembly in Ecuador approved a resolution asking the Minister of Health to issue compulsory licenses over patents related to coronavirus technologies.

Canada: Canada has amended its laws to make it easier to issue compulsory licenses.

Germany: Germany has passed new legislation raising the prospect of compulsory patent licensing.

France: France introduced a new article - L.3131-15 – to the country's public health code, allowing the Prime Minister to order the seizure of all goods and services necessary to: fight against sanitary disaster; to temporarily control the prices of products; and to take any measures necessary to make relevant medicines available to patients.

European Union: European Commissioner for Trade suggested the European Union use compulsory licensing to keep down the cost of coronavirus treatments and vaccines and ramp up production.

COVID-19: Principles for Global Access, Innovation and Cooperation

Open science, ramped-up manufacturing, fair pricing and sharing of technology, among other actions, are urgently needed to reduce loss of life during the coronavirus (COVID-19) pandemic.

300+ organizations have released a list of principles calling for action from governments, international agencies, manufacturers, donors and development partners. We called for transparency, affordability conditions and vaccine technology transfer – global sharing of vaccine-related knowledge and the licensing of patents and other proprietary rights to the public – so that a safe and effective vaccine can be produced by qualified manufacturers around the world and made accessible to all.

Health is a human right. Medical knowledge is a public good. No one should be left behind. We call on governments, agencies, manufacturers, donors and development partners to commit to:

- **Innovation for all:** Monopoly-based drug development is failing the world. Governments should support open science and research practices for COVID-19 related health needs that align innovation and timely access. Technology owners should commit patents, trade secrets, know-how, cell lines, copyright, software, data, and all other relevant intellectual property to the public domain. Access and affordability should be integral requirements of the entire research and development (R&D) and manufacturing process.
- **Access for all:** Medical tools urgently needed to diagnose, treat, mitigate and prevent COVID-19 should be accessible and available to all without delay, with necessary priority given to healthcare workers and vulnerable populations. Governments must ensure that diagnostics, treatments, devices, vaccines, and personal protective equipment are priced fairly and affordably to healthcare payers and are free to the public at the point of care in all countries. Corporations and other intellectual property holders must suspend enforcement of exclusivities.
- **Solidarity and global cooperation:** Governments, technology owners and researchers should urgently coordinate with the World Health Organization to organize platforms for the public sharing of R&D outcomes, data, know-how and intellectual property to accelerate innovation, quickly scale-up production and mitigate shortages and supply chain vulnerability. Medical tools must be manufactured for the public in robust supply to meet unprecedented global need and promptly distributed across borders.
- **Good governance and transparency:** Governments and international organizations should promote transparency and meaningful civil society participation in critical decision-making processes. Funders and technology developers should ensure that costs related to R&D and manufacturing as well as pricing, regulatory status and intellectual property claims all are published transparently.

Access to Covid-19 Tools (ACT) Accelerator – Global response to Covid-19

- In April 2020, the World Health Organization (WHO) and its partners announced a massive effort to scale up development and production of COVID-19 vaccines, treatments, and tests and ensure that they're equitably distributed, and countries and groups pledged $8 billion to make the plan—called the ACT Accelerator to accelerate development and availability of new COVID-19 tools.
- Accelerate equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics, and vaccines and ensure that in the fight against COVID-19, no one is left behind.

Three pillars