

Policy brief



Diagnostics & **intellectual property**

Intellectual property in healthcare

In healthcare, intellectual property (IP) rights are commonly applied through patents. Products that are new and inventive, including novel diagnostics, therapeutics, and vaccines, can qualify for a patent. Patents give companies exclusive rights that prevent third parties from using, making, selling, or offering to sell the patented invention for a fixed period (generally 20 years), unless granted an authorized license by the patent holder or – under certain internationally recognized conditions – by an authorized government agency. Patents have been used for more than 500 years to provide an economic incentive to invest in the long process of innovation and developing new products. The effectiveness of the patent system in supporting innovation and the role of the patent system in enabling or hindering global equity in access to new technologies are now widely discussed.

In certain territories, patents can act as barriers to equitable global access to healthcare products, by limiting their availability and by driving prices that are unaffordable in lower-income countries. Generic competition, which can bring down prices, and local manufacturing, which promotes equity, are both prohibited during the protected period, unless a license is granted by the patent holder or a compulsory license is issued by an authorized government agency.

Patents and diagnostics

The pharmaceutical and vaccine industries both make regular use of patents to protect their innovative products. The situation for diagnostics is less straightforward; in many cases, patents are less consequential for diagnostics than for other health products.¹

The reasons relate to the unique nature of diagnostic products. *In vitro* diagnostics such as blood tests have four components: biomarkers, capture reagents, detection reagents, and sensing technology. **Biomarkers** are generally considered a “product of nature” and are therefore not eligible for patent protection and/or deemed to be novel inventions. **Capture reagents** come in many forms, and some may be novel and patentable, such as monoclonal antibodies. Many **detection reagents** are already generic and commoditized products, and the most widely used detection reagents are not novel and cannot be patented. **Sensing technologies** may qualify as patentable IP and are often where novelty arises in the diagnostics industry.



COMPONENTS OF DIAGNOSTICS

Biomarker

A biological molecule or gene encoding a molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease

Detection reagent

Substances or solutions that react with other components to generate a detectable signal from the assay process

Capture reagent

A chemical or biological molecular used to bind to a biomarker of interest, often as a means to link to a detection reagent and sensing technology

Sensing technology

The platform used to detect the biomarker, including methods to amplify faint biological signals. Sensing technologies can differ depending on the type of biomarker (e.g. lateral flow for antigens or antibodies, polymerase chain reaction (PCR) for DNA or RNA), or the type of signal (e.g. fluorescence imaging)

Other intellectual property rights in diagnostics

The timeline for a diagnostic innovation, especially a sensing technology, to mature from a novel, patented idea to a commercial diagnostic product is long and can approach 20 years. As a result, the patent holders for many novel diagnostic technologies have a short window for protecting their IP commercially. Many important sensing technologies used today, like PCR, were invented decades ago and key patents have already expired. For some diagnostic platforms, commercializing a diagnostic product means bundling multiple patents into one platform; for others, workarounds may exist that enable competitors to evade patented IP. Finally, and critically, many diagnostic products result from solving engineering problems in ways that require technical know-how rather than scientific discovery.

As a result, a single blocking patent in the diagnostics industry is unusual, and many diagnostics developers in the diagnostics industry do not build their business models around protecting global patents, but around their technical know-how. There are exceptions: some reagents, and some emerging sensing technologies – such as point-of-care multiplex molecular platforms – may be susceptible to patent-related access barriers in the coming years. As a generalization, however, individual patents are rarely a primary barrier limiting global access to diagnostics products, unlike the importance of single patents as critical barriers for equal global access to therapeutics and vaccines.

Patents are not the only or even the most important form of protected IP in much of the global diagnostics industry. The second form of IP core to diagnostics is ‘know-how.’ Know-how refers to confidential information associated with a technology; it includes trade secrets, which is a legally defined term. Know-how is a proprietary form of ‘private IP’ to distinguish it from patents, which are public IP filed with a government patent office.

In diagnostics, companies maintain proprietary know-how that ranges from engineering skill to chemistry recipes (i.e. the precise mix of chemicals to add to a sample to generate the strongest biomarker signal) to proprietary manufacturing equipment and manufacturing processes. Closely held trade secrets within the diagnostics industry are often the most significant trade-related IP barriers to global access to diagnostic products.

In particular, proprietary manufacturing know-how and proprietary manufacturing equipment are essential to produce the high-quality, low-cost tests that are important for global health. Technical know-how in diagnostics manufacturing is currently based in a small subset of G20 countries, and the concentration of know-how and technology in only a few G20 countries is a major driver of global diagnostics inequity.

Diagnostics and the TRIPS agreement

The Agreement on Trade Related Aspects of IP Rights (TRIPS) is an international agreement between all members of the World Trade Organization (WTO) signed in 1994.² The TRIPS agreement establishes minimum standards for the regulation of IP, including both patents and know-how.

The TRIPS agreement includes flexibilities to allow member countries to take necessary action to protect public health, including the right to circumvent patents through compulsory licenses in order to improve access to medicines, and to exclude method of diagnosis from patent protection. This was reaffirmed in the Doha Declaration, adopted by WTO in 2001.

For instance, in response to the COVID-19 pandemic, certain patent-related TRIPS Articles were waived specifically for COVID-19 vaccines, with the aim of improving access to COVID-19 vaccines for least-developed WTO member states.⁴ Other COVID-19 therapeutic and vaccine patents were licensed voluntarily by the patent holders to select 'generic' suppliers or to the Medicines Patent Pool, to enable production in select middle-income countries.

The key COVID-19 diagnostic tests were based on PCR and lateral flow; consequently, patent-related barriers

to diagnostics access during COVID-19 were minimal. Neither compulsory nor voluntary licenses on diagnostic technologies would have been likely to stimulate innovation or enable local manufacturing of COVID-19 tests in middle-income countries. Nonetheless, patent-related waivers under the TRIPS Articles may one day be applicable to essential diagnostics or future pandemics, such as emerging sensing technologies.

The more relevant TRIPS Articles relate to know-how, and TRIPS provisions on trade secrets (Article 7, Section 39) and technology transfer (Article 66, Section 66.2), which is how barriers in equitable diagnostics access due to trade secrets can be addressed. At present, these provisions offer limited tools to address key barriers. Article 66, Section 66.2 of the TRIPS agreement states that developed countries should incentivize voluntary technology transfer to least developed country members,² a position reaffirmed in the Doha Declaration.³ Given the importance of manufacturing technology and know-how to diagnostics, application of the principles in Section 39 and Section 66.2, particularly increased incentives for robust technology transfer, would likely have a significant impact on global diagnostics access, both during pandemics and for essential diagnostics.



References

1. For a recent series of analyses on the relationship between diagnostics' patents and global health access see: Médecins Sans Frontières, 2017. Diagnostics, Market Monopoly and Intellectual Property: Notes to Global Health Agencies and Civil Society Organizations; An Analysis of the Patent Landscape Related to Diagnostic Devices and Their Consumable Parts: GeneXpert, AlereQ, and OraSure; and Preliminary Literature Review on Patents and Diagnostics. Available at: <https://msfaccess.org/research-references-diagnostics-intellectual-property-and-market-monopoly-landscape> [Accessed October 2022].
2. World Trade Organization. Overview: the TRIPS Agreement. https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm [Accessed September 2022]
3. World Trade Organization. Declaration on the TRIPS agreement and public health. https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [Accessed September 2022]
4. World Trade Organization. Ministerial Decision on the TRIPS Agreement Adopted on 17 June 2022. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:WT/MIN22/30.pdf> [Accessed September 2022]

ABOUT THIS POLICY BRIEF

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis across the world. We connect patients, communities, health care providers, governments, global health agencies, decision makers, product developers, and the diagnostics industry to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and to save US\$1 billion in healthcare costs to patients and health systems.

From time to time, FIND publishes technical briefs and policy briefs on issues relevant to the diagnostics equity agenda. All briefs, including this one, are prepared by FIND staff and reflect FIND's view at the time of publication. Further information on this and other technical briefs and policy briefs can be found on our website at www.finddx.org. We also welcome feedback on this and other briefs at info@finddx.org.