



Intellectual Property and Access to Medicines in the Developing World

Advances in medicine and healthcare delivery over the past several decades have made significant strides in preventing illness, especially among infants and children, and in preventing premature disability and death due to infectious and chronic diseases, such as HIV/AIDS, cardiovascular disease, diabetes, cancer and other conditions.

Despite this legacy of success, much progress remains to be made along two equally important fronts: 1) to continue progress against illnesses for which we do not presently have adequate treatments or cures; and 2) to expand access to high quality healthcare among the millions that today do not have adequate access to such care. These two goals must be pursued in ways that solve the needs of patients today and those in the future, both in developed and developing nations.

As a global health care company, the role of Merck & Co., Inc., Kenilworth, NJ, USA is first and foremost to discover and develop innovative medicines and vaccines that treat unmet medical needs and prevent illness. For many decades, intellectual property protection has promoted an environment conducive to research and development in the pharmaceutical arena. We also recognize that we have a role to play in helping to ensure that our products are accessible and affordable to patients in need. We are committed to pursuing approaches - including partnerships with other key stakeholders - to foster access to high quality health care and critical medicines.

Fostering Innovation through Intellectual Property Rights

Intellectual property protection is essential to incentivize investments in research and development for the new medicines and vaccines that address unmet medical needs in both developed and developing countries. The development of innovative medicines and vaccines is a long, costly and very uncertain process. It is not sustainable for companies to invest the resources necessary to bring new innovations to market if competitors that do not bear the costs and uncertainty of research and development are free to introduce copies. Intellectual property is protected through a variety of legal instruments in most creative and inventive enterprises. Patents are the traditional way through which innovation in pharmaceuticals has been encouraged and rewarded. Pharmaceutical patents provide to the public a full

disclosure of a medicine in development in exchange for a limited exclusive right to prevent others from making and selling the medicine. Under international agreements, patents in the US and most other parts of the world run for 20 years from the time of filing. In contrast, copyrights and other forms of intellectual property protection applied in other enterprises typically allow their owners exclusive use of their property for much longer time periods.

In the pharmaceutical industry, patent applications must typically be filed many years before it is known whether the object of the patent will ultimately become a useful medicine. Most pharmaceutical candidates that are patented do not make it to the market place.

Those that are commercialized typically have a significantly reduced patent life due to the loss of term during the lengthy development and approval process.

Although some have advocated approaches other than patents or other forms of intellectual property protection to incentivize innovation and investment in medical R&D, none of these approaches has yet demonstrated the capacity to generate sufficient and sustained investment necessary to discover and develop new medicines. While our company is interested in new ideas and proposals, it would not be in the best interests of patients to advance unproven alternatives that would fail to incentivize and sustain the large investments necessary to develop and bring forth new medicines.

Addressing the Complex Barriers to Access

Due to the success of past innovations, most medicines on the market today are generics available from multiple suppliers, because patents have expired. These medicines are widely used to address health issues in both the developed and the developing world. Indeed, by 2020, 88 percent of medicines are predicted to be generic, non-original branded or over the counter (OTC) products, and in the US, the portion of prescriptions filled with generic medicines will rise from 88 to 91-92 percent (IMS Health, November 2015). The vast majority of medicines on the WHO's essential drugs list have generic versions available (Health Affairs 2004; 23 (3): 155-166; and D. Wayne Taylor, Pharmaceutical Access in Least Developed Countries: on-the-ground barriers and industry successes. 2010).

Despite the wide availability of generics, there remains a significant issue in terms of generic availability in many developing countries whereby access to the most basic medicines in much of the developing world remains inadequate due to a variety of factors including policy, regulatory, financial, and delivery barriers, such as inadequate health systems and the lack of viable financing mechanisms for health care. This is exemplified, for instance, by the low rates of access to HIV antiretrovirals and other essential medicines in India, long the home of the most developed generics market in the world, which since only 2005 has been granting patents for medicines.

As a result, many in India and other parts of the developing world unfortunately lack adequate nutrition, proper sanitation, access to clean water, and access to basic health care: hospitals, clinics, doctors, as well as medicines, whether for HIV, high blood pressure, or diabetes. Commonly cited data from the middle of the previous decade, indicate that one billion people in developing countries lived on less than \$1 a day, 2.6 billion lacked access to toilets and other sanitation facilities, and more than a quarter of the population in least-developed countries lacked access to potable drinking water (United Nations Millennium Project, 2006). About a third of the world's population lacked access to quality health care, including medicines (World Health Organization, 2004). While progress has been made since then, it is certain that substantial needs remain on all these fronts. For broad and meaningful access to be truly achieved, these fundamental barriers to effective health care delivery must be addressed.

Insufficient availability of generic medicines in many developing countries has led to the WHO's Global Action plan adopted in 2013 to achieve 80 percent availability of essential medicines, including generics, in both public and private facilities to treat non-communicable diseases.

Still, we recognize the role that generic medicines can play in meeting the needs of many people in the developing world, particularly in low income countries (LICs). While our company files for patents in commercially significant markets to provide the continued incentive to support innovation, given the inability of most portions of the population in the LICs to afford medicines and the very substantial resource constraints facing the governments, we have had a long standing general policy of not filing for patents for our products in low income countries and currently do not file in any LIC defined by The World Bank in its Country and Lending Groups classifications. Moreover, as evidenced by our recent announcement together with the Medicines Patent Pool of a licensing agreement for pediatric formulations of raltegravir (a key medicine approved for children less than 12 years of age living with HIV) covering 92 low- and low-middle-income countries, we are committed to expanding access to medicines globally, including through the availability of high quality generics in developing countries

Improving Access to Innovative Medicines

In addition to improving access to high quality generics, we believe that patients around the world should have access to innovative, patented medicines that often represent the most effective treatments for their health problems. Innovative companies, like ours, can also play a crucial role in ensuring that new therapies are well understood and properly used in developing world settings. For example, under our HIV Access Initiative, our Institutional Business Africa unit is working with governments, health care providers and other experts to understand barriers and challenges facing treatment- experienced HIV patients, to provide medical education on the appropriate use of our HIV medicines, and to identify

ways we can most effectively participate in helping the developing countries meet their medical needs in this and other important therapeutic areas.

For these reasons, our company has placed a high priority on bringing access considerations into all aspects of our business and partnering with other stakeholders to address the impediments to meaningful access to health care.

Incorporating Access Considerations into Our Business

We have adopted an Access to Health Statement of Guiding Principles (available at <http://www.merckresponsibility.com/>) that reflects our company-wide commitment to improving broad access to our medicines through all aspects of our work, including how we approach R&D, the registration, manufacturing, and commercialization of our products, and our community investment efforts. For example, with respect to commercialization, we endeavor to price our products through differential pricing frameworks, taking into consideration levels of economic development, channel of sale, and public health need. Not all developing countries are similarly situated. We should not expect patients living in poverty in low income countries to be able to afford prices that prevail in higher income countries.

By contrast, the situation in middle income countries (MICs) has been evolving rapidly in recent years. Many MICs have a higher level of economic development and a growing importance in the world economy. Many residents in MICs are becoming more affluent, as reflected in the growth of high and middle income populations in the large emerging markets.

From a global equity standpoint, these populations and their governments should support technological innovation by paying relatively higher prices than poorer segments in less economically developed countries. Recognizing that extremes in income distribution and inequality in access to health care still exists within middle income countries, we are interested in working with governments and other stakeholders to develop innovative strategies (such as differential pricing within countries) and appropriate systems for better reaching the most at-need segments.

In developed markets, such as the United States, we appreciate that there are parts of the population that often struggle to afford necessary medicines. We support and actively participate in a variety of Federal and State government programs designed to assist those in financial need in securing medicines, such as the U.S. Medicaid program, the many State AIDS Drug Assistance Programs, and the Medicare Part D program for elderly populations. Additionally, we have a long-standing patient assistance program that provides medicines for free to people who do not have prescription drug coverage and who, without our assistance, cannot afford our company's medicines.

Partnering to Improve Access

We believe that multiple stakeholders have a role and a responsibility to address the root causes of limited access in the developing world. Through programs with key partner governments and other stakeholders, we have made a sustained commitment to developing health capacity. For example, we have advanced a variety of programs to improve HIV treatment, including the African Comprehensive HIV/AIDS Partnerships in Botswana and the China-MSD HIV/AIDS partnership with the government of China to address HIV/AIDS through a comprehensive approach of prevention, patient care, treatment and support. Our efforts, however, go far beyond HIV/AIDS, and we have instituted programs to address neglected diseases, such as the MECTIZAN® (ivermectin) Donation Program which provides access to treatment for river blindness in Africa and Latin America and for the prevention of lymphatic filariasis in African countries where the two diseases co-exist. In addition, we have a wide array of efforts underway to expand access to vaccines and treatments for non-communicable diseases.

While programs such as these can help their target populations, broader efforts are necessary. Governments and other supporting organizations must prioritize spending to develop and improve medical care facilities, streamline regulatory procedures, enhance training for health care workers, improve physical infrastructure, expand reliable clean water supplies and develop self-sustaining financing mechanisms for health care delivery.

We are committed to playing a role in the future, as we have in the past, by partnering with others to support long term solutions to access needs.

Supporting International Agreements

The World Trade Organization's Trade Related Aspects of Intellectual Property Agreement (TRIPS) and subsequent amendments establish minimum standards which member states are to use in protecting intellectual property. Specific provisions that apply to the pharmaceutical industry cover issues such as patent protection, compulsory licensing, the protection of submitted regulatory data, etc. We support the TRIPS agreement, and are committed to playing an active role in the ongoing dialogue on trade issues through the WTO process.

We respect that international trade agreements provide a role for compulsory licenses in limited circumstances, such as meeting a health crisis or emergency in either a home country or for appropriate levels of export to countries that do not have the local capacity to manufacture licensed products. We believe that compulsory licenses should only be used in extraordinary and very limited circumstances in order to foster a global environment supportive of innovation.

However, when governments seek to expand the definition of "health crisis" and apply these provisions more broadly, the fabric of innovation is threatened. Outside the bounds of a true health emergency, the issuance of a compulsory license is a clear signal to the owner of the patent – and others reliant upon intellectual property rights – that the country will not respect intellectual property rights. In the growing Middle-Income countries in particular, maintaining strong intellectual property protection is an important condition for foreign direct investment, the promotion of economic growth, and nurturing the technological and commercial capabilities that are essential for the development of high value, knowledge-intensive industries – including the life sciences sector – that form the basis of progress. We continue to work vigorously, in the interests of meeting the health needs of current and future patients, to seek positive solutions to health care challenges facing developing countries and discourage compulsory licensing or other tools that threaten intellectual property rights, especially where they extend beyond the bounds of existing trade agreements.

Conclusion

Intellectual property protection has been a crucial incentive for scientific discovery that has brought forth vitally important medicines in use today. Serious unmet medical needs remain, however, and the best hope for addressing those lies in maintaining the engine of scientific discovery and effective intellectual property protection.

Across the globe, where patients do not have access to medicines, we are committed to doing our part to help, working with others to find ways to bring down the complex barriers to access. To achieve meaningful improvements, national governments and other stakeholders must work in concert to address the underlying factors impeding access, such as under-investment in health system capacity, poverty, and a lack of health care financing.