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Global Trade Rules and Access to Medicines

Sebastian Wolf

TRANSNATIONAL ECONOMIC LAW RESEARCH CENTER

Faculty of Law
Martin-Luther-University
Halle-Wittenberg
Universitätsplatz 5
06099 Halle (Saale)
Germany

Tel.: +49 345 / 55 23149
/ 55 23180
Fax: +49 345 / 55 27201

E-Mail: telc@jura.uni-halle.de
www.telc.uni-halle.de

TELC
Transnational Economic Law Research Center

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Significant advances have been made in health status in most countries all over the world in the last few decades. However, despite these general improvements there still remain major inequalities in health status within and between countries. Globalization has caused new conditions for health policies at an international level, but especially in developing countries. As the traditional distinction between national and international public health has been broken up by the process of globalization, sovereign states are forced to view health problems from a global perspective and depend on international cooperation in protecting the health of their citizens. The increase in international trade and travel has led to a greater and wider spread of emerging and re-emerging infectious diseases, while an increasing anti-microbiological resistance is causing even more difficulties in treating them effectively.

In this context, the supply of medicines is of particular importance in treating and preventing diseases. But despite the availability of many medicines in industrialized nations, one-third of the world's population still lacks access to the most basic essential drugs. As the supply of medicines is a key factor of a lasting and balanced development of nations, the trade in pharmaceutical products clearly shows the development tendencies in the course of the last years. The linkage between illness and growing poverty therefore represents a serious threat to international stability.

According to the World Health Organization (WHO), infectious diseases kill millions of people every year, with more than 90 per cent of these deaths occurring in the developing world. In addition to the AIDS/HIV pandemic, malaria and tuberculosis are the leading causes of death and morbidity in the developing world, regions that account almost four-fifths of the world's population. Although today's science and technology are sufficiently advanced to provide essential and innovative medicines for an effective disease treatment, very few new drugs are being developed. Drug companies neglect the production of drugs for infectious and parasitic diseases, because the affected countries often do not provide the needed profit potential to motivate research and development investment by the pharmaceutical industry.

However, drug discovery is not the major problem as access to essential and innovative medicines is affected by a number of factors including research and development programs, production, quality control and a public health infrastructure. The availability of medicines is not the only aspect, but it is an essential one.

Pharmaceutical drugs have become implicated in global politics like never before as they gain importance in international trade, intellectual property and health security. The international debate especially directed its attention towards the impact of global trade rules on public health and has raised concerns about the effects of intellectual property protection on prices and access to medication. With the conclusion of the Uruguay Round and the establishment of the World Trade Organization (WTO) in 1995 the Agree-

ment on Trade Related Aspects of Intellectual Property (hereafter, the TRIPS-Agreement) became the international standard for the protection of intellectual property. The TRIPS-Agreement sets minimum standards for patent protection to which all WTO-members must adhere and includes safeguards to overcome patent barriers whenever governments need. The deadline for implementation depends on the level of development. While most developing countries are given time until 2005, the deadline for implementation in some of the least developed countries has been prolonged until 2016. With the implementation of the TRIPS-Agreement in most of the world's countries in 2005, patent protection for pharmaceutical drugs will be extended for a minimum period of 20 years. The implementation of the TRIPS-Agreement scheduled for 2005 is expected to cause even more difficulties for developing countries in accessing affordable medicines or generic versions of patented pharmaceuticals.

The potential impact of TRIPS was brought sharply into focus in recent events. Seeking to reduce the costs of medicines, the government of South Africa threatened to ignore pharmaceutical patents by enacting national health laws favoring the manufacture and use of generic drugs. Additionally, parallel importing should be introduced, which would permit the importation of less expensive drugs from other countries. Pharmaceutical companies brought suit against the South African government to stop the implementation of the so-called Medicines and Related Substances Control Amendment Act on the basis that it would not be compliant with the TRIPS-Agreement. However, South Africa was not the only country that had come under pressure from industrialized countries and the multinational pharmaceutical industry for attempting to bring drug prices down.
In the context of national security concerns, government officials in Canada and the U.S. decided to stockpile a supply of Cipro, an antibiotic for treating anthrax, in preparation of a possible bio-terrorist attack. While Canada promptly ignored the German pharmaceutical company Bayer's patent by licensing generic manufactures to produce the drug, the U.S. won a significant price concession. Finally Bayer was forced to renegotiate the price and availability after the U.S. threatened to override the patent and allow generic production too.

Both cases, medicines in developing countries and anthrax treatments in industrialized nations, offer striking illustrations of how intellectual property rights and drugs prices came under fire for threatening public health and national security.

However, the claim that intellectual property rights are the only cause for the difficulties in accessing medicines is misleading in the search for solutions as a functioning patent system promotes the innovation and marketing of new drugs for the benefit of the public by providing incentives for research and development. Patents are not the only barrier to access to medicines, but they play a significant role by granting the patent holder a monopoly for a specific time. On the other hand it can not be denied that patent protection represents an obstacle to accessing medication as the patent holders freedom often results in drugs being unaffordable for most patients. Keeping a

balance between private and public interests in intellectual property systems will be particularly important for developing countries in protecting public health while getting their patent legislation compliant with the TRIPS-Agreement.

Designed to respond to the concerns of developing nations about the impact of the TRIPS-Agreement on access to medications, the 4th WTO Ministerial Conference, held in Doha in November 2001, adopted the "Declaration on TRIPS and Public Health". The Doha Declaration explicitly clarified for the first time the flexibilities of the TRIPS-Agreement in combating a public health crisis and affirmed the sovereign right of governments to take measures to override patents when necessary in order to protect public health. The declaration underlines the flexibilities inherent in the TRIPS-Agreement and refers to possibilities in case of a public health crisis by encouraging the use of a creative interpretation "in a manner supportive of public health".

The Doha Declaration is an important political and legal document by recognizing the specific concerns of poorer countries posed by the TRIPS-Agreement and giving primacy to public health over private intellectual property. This is an important step to ensure that patent protection is granted for the benefit of the broader public beyond commercial interests. However the general principle remains that TRIPS provisions can be used to forbid any unauthorized use of patented drugs.

Nevertheless the Doha Declaration did not completely remove the barriers created by the TRIPS-agreement and left several questions unanswered. A main problem resulted from the fact that under WTO rules a compulsory license could only be granted for the production and supply of the home market, not however for the export (Art. 31 TRIPS-Agreement). Therefore, WTO member states without sufficient production capacities could not import patented pharmaceutical products, if a patent protection existed in the export country.

In August 2003, the WTO General Council adopted the long delayed decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS-Agreement and Public Health. By accepting the proposal for compromise, the WTO-members terminated their prolonged negotiations which were to have concluded before December 2002.

The often cited breakthrough deal now enables countries to overcome the restrictions of Art. 31 TRIPS-Agreement by importing necessary medicines under a compulsory license from a third country. WTO-members are allowed to issue a compulsory license for exporting patented medicines to countries without sufficient manufacturing capacities. The use of the Art. 31 TRIPS route to implement paragraph 6 of the Doha Declaration is expected to facilitate the import of cheap drugs to poor countries under compulsory licenses.

What is problematic about this solution is, that countries in need will depend on the cooperation of other countries, in which manufacturing capacities for generic drugs exist. Additionally the system sets out burdensome procedural arrangements by es-

tablishing several notification obligations. The system is supplemented by special obligations for organization, packaging and labeling of pharmaceutical products, in order to prevent their detour into other markets. Nevertheless it has to be recognized positively that the solution is not limited to certain diseases, but also covers other health risks.

Besides it should be pointed out, that pharmaceutical products always took a privileged position regarding intellectual property protection. Especially under the provision of the TRIPS-Agreement pharmaceuticals are regulated by special rules. Therefore a historic turn in international patent protection as often termed, is out of question, at least on a long term basis. Recognizing that the WTO made a first concrete contribution for the better supply of medicines in developing countries, it has to be concluded that compulsory licensing only represents the attempt of a partial solution. The contribution of the WTO for a global and extensive solution of this problem limits itself to aspects relevant to trade and intellectual property protection. It remains to hope that the decision of the WTO, to facilitate the importation of cheap medicines in developing countries, is soon followed by other specific steps. Finding a more comprehensive solution will involve not only the WTO, but also the WHO, national governments and the pharmaceutical industry.

Sebastian Wolf is senior researcher at the Transnational Economic Law Research Center (Prof. Dr. Christian Tietje) at the Faculty of Law at the University Halle-Wittenberg.