

# Managing the effect of TRIPS on availability of priority vaccines

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**Abstract** The stated purpose of intellectual property protection is to stimulate innovation. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires all Members of the World Trade Organization (WTO) to enact national laws conferring minimum standards of intellectual property protection by certain deadlines. Critics of the Agreement fear that such action is inconsistent with ensuring access to medicines in the developing world. A WHO convened meeting on intellectual property rights and vaccines in developing countries, on which this paper is based, found no evidence that TRIPS has stimulated innovation in developing market vaccine development (where markets are weak) or that protection of intellectual property rights has had a negative effect on access to vaccines. However, access to future vaccines in the developing world could be threatened by compliance with TRIPS. The management of such threats requires adherence of all countries to the Doha Declaration on TRIPS, and the protections guaranteed by the Agreement itself, vigilance on TRIPS-plus elements of free trade agreements, developing frameworks for licensing and technology transfer, and promoting innovative vaccine development in developing countries. The role of international organizations in defining best practices, dissemination of information, and monitoring TRIPS impact will be crucial to ensuring optimal access to priority new vaccines for the developing world.

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Voir page 364 le résumé en français. En la página 364 figura un resumen en español.

يمكن الاطلاع على الملخص بالعربية في صفحة 364.

## Introduction

The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) has extended the western concept of intellectual property (IP) to developing countries.<sup>1,2</sup> Members of the World Trade Organization (WTO) from developing countries have had to adopt a patent system with minimum standards that would allow product and process patents for pharmaceuticals and vaccines.<sup>2,3</sup> These changes have prompted claims that industrialized countries have, by imposing their standards on a global scale, not taken into account the public health needs of countries with a high burden of disease.

At the 2001 Doha Ministerial Conference,<sup>4</sup> a declaration was adopted to reaffirm the principle that TRIPS does not and should not prevent countries from taking measures to safeguard public health.<sup>4</sup> A waiver to article 31(f) of TRIPS was then adopted in light of the declaration to allow countries to produce pharmaceuticals and vaccines under compulsory licence, even for export purposes, under certain circumstances

and following certain conditions, so that countries with no manufacturing capacity could also benefit from this declaration. This waiver was adopted by the WTO General Council.<sup>5</sup> Subsequently, at the 2005 Hong Kong meeting, this decision was made a permanent amendment of the core WTO agreement.<sup>6</sup>

The Global Alliance for Vaccines and Immunization (GAVI) has created a new market in the developing world for vaccines that previously had been marketed only in the industrialized world (e.g. *Haemophilus influenzae* type b — Hib vaccine). In addition, GAVI efforts have resulted in some vaccines, such as meningitis A conjugate vaccine being developed specifically for developing countries. Although IP is only one of the many factors that can affect access to drugs and vaccines, developing countries (or international agencies acting on their behalf) will have to understand the specific implications of TRIPS compliance for each product.<sup>7</sup>

In this paper, we assess the current evidence for the effect of TRIPS implementation on access to vaccines in the developing world. We will consider im-

portant factors in stimulating research and development (R&D) for priority vaccines, and examine how the global implementation of an IP protection system might affect access — primarily represented by price and competitive production — to priority vaccines. We also analyse approaches to manage the effects of TRIPS on developing countries, and discuss the potential role of WHO and other international partners in ensuring both innovation in and access to vaccines for the developing world.

## Factors to stimulate vaccine innovation

### Markets

To encourage development of medicinal products, pharmaceutical companies need to be assured that they will see an appropriately large return on their R&D investment. By allowing the assertion of private intellectual property rights over practical ideas, the patent system should encourage individuals to invest in the creation and dissemination of knowledge,<sup>8</sup> and thus support innovation.

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Lanjouw & Cockburn<sup>9</sup> have looked at patent data, bibliometric data and data from National Institutes of Health (NIH) grants for empirical evidence on whether TRIPS has increased R&D for tropical diseases. Their research showed that there was no evidence for an effect, except perhaps in the case of malaria. Certainly, as Robert Shapiro<sup>10</sup> points out, the converse is true: “no private company will devote money to develop the ideas for new drugs or devices if others can appropriate the results.”<sup>10</sup> According to Webber & Kremer,<sup>11</sup> “undermining patent protection could discourage innovative activity on the part of industry.” Thus for products where there is likely to be a lucrative market, IP rights are needed to ensure adequate investment. However, such rights can not provide an incentive for the development of products where the market is weak — i.e. where financial rewards are likely to be low.

The difficulty in stimulating R&D in medicines for the developing world shows the effect of weak markets on development of new products. The Commission on Health Research for Development in 1990<sup>12</sup> showed that about 10% of funding for health research is allocated to 90% of the world’s health problems — the so-called 10/90 gap. Children in developing countries are not profiting from major breakthroughs in vaccine development seen in wealthier countries over the past few years. According to the Drugs for Neglected Diseases Working Group,<sup>13</sup> “... potential return on investment, not global health needs, determines how companies decide to allocate R&D funds. Fierce market competition means that, for diseases primarily affecting developing countries, neither promising drug leads nor research on new applications of existing drugs will be pursued.”

The lack of a market that could provide an adequate return on investment is thus a major factor affecting R&D, irrespective of the patent situation. “It is not possible to divorce effectiveness of the IP system in stimulating R&D from the viability of the underlying market in which it provides monopoly rights.”<sup>14</sup> Even in cases where the public sector has made efforts to guarantee a market, workers from the Meningitis Vaccine Project (MVP) note that opportunity costs meant that the return on investment from sales of the meningococcal

vaccine could be perceived by suppliers as insufficient.<sup>15</sup> It is thus unlikely that the implementation of the TRIPS Agreement will have an effect on the rate of innovation in products for which there is no strong financial incentive.

### Role of emerging suppliers

Clearly, the best source of R&D for interventions in diseases that affect developing countries is the countries where such diseases are endemic. Some research is now going on in countries such as Brazil, China, Cuba and India. Much of the work is under the auspices of major vaccine producers and is often in partnership with academic and research institutions. As these countries strengthen IP legislation to comply with TRIPS standards, national companies must begin to take steps to protect their R&D investments.

A report from June, 2004<sup>16</sup> discussed the effect of TRIPS on the pharmaceutical industry and vaccine production in China and India. The author notes the flourishing generic market in India, including the “biogeneric” market, but suggest that new IP laws will mean that Indian companies will be expected to invest in R&D, although this R&D may be focused on products for the wealthier segments of society. Scherer & Watal<sup>17</sup> found that as of 1999 only 16% of R&D expenditure in India was aimed at diseases concentrated in the developing world, and Kettler & Modi<sup>18</sup> cite the need for new incentives for Indian firms to invest in R&D for such diseases. However, a recent study of the vaccine market done for GAVI<sup>19</sup> showed that all of the five Indian vaccine manufacturers studied had projects in place for products of interest to the developing world.

In China, although regulations surrounding IP rights have been in place since 2002, a lack of infrastructure and enforcement means that protection of these rights is incomplete.<sup>16</sup> The export of innovative vaccines developed in China has been impeded by negative perceptions about the quality of Chinese vaccines.<sup>16</sup>

One area where developing countries can participate in vaccine development is in the area of clinical research. This idea was proposed by Raw<sup>7</sup> as a way to better use the skills of emerging suppliers in the area of vaccine R&D. As Grace<sup>16</sup> notes, clinical testing in developing countries also has cost and epidemiological advantages.

A promising recent development in stimulating research on vaccines for diseases that affect people in developing countries has been the emergence of disease-specific public–private partnerships.<sup>20</sup> Many of these partnerships (e.g. the Malaria Vaccine Initiative, International AIDS Vaccine Initiative (IAVI), and Aeras Global TB Vaccine Foundation) are investing in initiatives based in the countries where these diseases are prevalent. Efforts include basic research, vaccine development, joint production (i.e. products are produced partly in a industrialized country but filled and finished in a developing country) and clinical trials.

### Role of public-sector research legislation

In the United States, the Bayh-Dole Act allows public-sector employees to patent innovations in the public sector.<sup>21</sup> The Act gives fundees of the US NIH, among others, the right to patent products resulting from their research, and the NIH have issued guidelines to facilitate the availability of technology. Concerns have been expressed that the ability of researchers to patent discoveries will skew public research agendas to concentrate on areas associated with the greatest profit. NIH follows licensing policies that explicitly guarantee access for developing countries and limit exclusive or co-exclusive licences only to those situations where developing-country access is not relevant. The NIH has recently required development in markets outside Europe and North America to meet public health needs.<sup>7</sup>

The Bayh-Dole Act also provides for “march in” rights to force a patent holder to further license its inventions in certain circumstances.<sup>22</sup> Several countries in the Organisation for Economic Co-operation and Development (OECD) are interested in emulating Bayh-Dole.<sup>21</sup>

### IP rights and discouragement of R&D

Although there are few examples of how patents have helped to expand R&D in vaccines for the developing world, there are examples of IP discouraging such work. Heller & Eisenberg<sup>23</sup> used the term “tragedy of the anticommons” to describe the situation in which a scarce resource is underused because too many owners (in this case, patent holders) have rights over the resource. Thus, more

stringent IP rights could actually lead to fewer useful products, a situation that could be the case, for example, in the field of genomics.<sup>24</sup> Authors of a WHO report also cite specific examples of so-called patent thickets restricting development in the areas of immunostimulants and malaria vaccines.<sup>7</sup> In principle, market forces can help resolve those problems through such actions as cross-licensing or voluntary patent pooling. However, in practice, transaction costs, uncertainty over the scope and validity of patent claims, complex patent landscapes and diverging business interests can result in stalemate. Benkler<sup>25</sup> proposes solutions, including publicly-minded licensing, such as the PIPRA (Public Intellectual Property for Agriculture) model on co-operation for wide adoption of open licensing provisions.

## Impact of IP initiatives on access to vaccines

IP protection for vaccines operates through two main methods — patents, which limit copying an innovation for a set period, and manufacturing know-how held by the manufacturer for as long as they wish.

Because vaccines are almost impossible to define in precise chemical terms, companies have favoured process patents over product patents, which do not historically exist for vaccines, except perhaps when they consist of purified components. However, the patenting of processes may limit access to new technical developments in the future. The case of a patent for a combination vaccine that uses aluminum phosphate (a component of many combination vaccines) has been cited by several manufacturers in developing countries as an illustration of how patents could ultimately limit access to combination vaccines.<sup>7</sup> With the process for including aluminium phosphate in the vaccine now patented, producers will have to find another way to get the same effect. A 1999 report cited a lack of technical know-how as the predominant factor in the failure of low- and middle-income countries to manufacture newer vaccines.<sup>26</sup>

Today, although IP is a major factor in the product development cycle, it may not be an important barrier for vaccine manufacture. Of five new vaccines, acellular pertussis, hepatitis B recombinant, Hib conjugate, pneumococcal conjugates and rotavirus vaccines, only

### Box 1. Case study: the effect of intellectual property rights and competition on the price of recombinant hepatitis B vaccine

DNA recombinant hepatitis B vaccine is produced in yeast or mammalian cells with use of bioengineering technology. Research from the Centre for Management of IP in Health R&D (MIHR) indicates that there were three core patents for the production of recombinant DNA hepatitis B vaccine, held by the Pasteur Institute in Paris, Biogen in the Netherlands and the Regents of the University of California.<sup>7</sup> Biogen in particular obtained a broad patent covering all methods of making the vaccine antigens using recombinant technology.

Merck and SmithKline Beecham obtained licences to all three patents and put the recombinant vaccine on the market by the mid-1980s for US\$ 30–40 per dose. By 1993, despite the IP protection, competition from the plasma-derived vaccine caused the price to drop to about US\$ 1.25–2.00 per dose.<sup>14,27</sup> Biogen started infringement procedures against Medeva who, in 1992, had wanted to market a recombinant DNA vaccine, even though Medeva's product was made using a different production process. Following a counterclaim by Medeva, the House of Lords, in 1996, revoked the patent on the basis of the enablement provisions, which allow an attack on an overly broad claim: "the court stated that to grant a monopoly to the first person who has found a way of achieving an obviously desirable goal for every way of doing so would, stifle further research and healthy competition in the post grant phase."<sup>28,29</sup> Although the price of the recombinant vaccine had fallen significantly, access to the technology was still limited.

The entry of new manufacturers to the market led to even lower prices. By 1999, two manufacturers from the Republic of Korea had recombinant hepatitis B vaccines on the global market.

One had established its own in-house R&D programme to develop a recombinant hepatitis B vaccine from first principles; the other obtained patented technology from a European biotech company. Mahoney<sup>30</sup> also points out the importance of markets and the role of public sector intervention. The Government of the Republic of Korea created a market for the hepatitis B vaccine through a programme of universal immunization for infants. This provided incentives and attracted foreign companies with IP rights and knowledge to form joint ventures with Korean companies. Mahoney concludes that manufacturers in the Republic of Korea were not inhibited by existing IP laws because they managed to gain access to foreign knowledge.

Currently, recombinant hepatitis B vaccine can be obtained by international bulk procurement for less than US\$ 0.30 per dose.<sup>31</sup> There are at least ten manufacturers, five of which sell to UN agencies.

acellular pertussis and hepatitis B recombinant vaccines had exclusive licences that limited access to these products. Nevertheless, despite manufacturing methods used by major companies being in the public domain and an existing market, no manufacturer in a developing country produced the Hib vaccine until 10 years after its introduction in industrialized countries.

Box 1 shows the delayed access to recombinant hepatitis B vaccine, which was not seriously effected by its IP situation. A potential very important threat to access, however, could come from "TRIPS-plus" clauses included in bilateral and regional free-trade agreements. These agreements could include provisions that extend patent life beyond the 20-year TRIPS minimum, limit compulsory licensing in ways not required by TRIPS, and limit exceptions which facilitate prompt introduction of generics.<sup>32</sup> A TRIPS-plus provision specifically cited as an issue is a policy imposed by regulatory authorities to block export of material for clinical trials when licences are not in place.<sup>7</sup>

## Approaches to managing the effect of IP rights

The recent history of vaccine use in developing countries shows that uptake of innovative vaccines is often delayed, sometimes for decades. The case study in Box 1 shows that IP rights to protect technology do not have a direct effect on vaccine use; however, this is unlikely to be the case for future vaccines. Thus, constructive approaches must be sought to offset those instances where patents can limit access.

### Licensing and technology transfer agreements

Agreements to license vaccine technology for production of vaccines in disease-endemic countries can enable access to protected IP. Such agreements will be possible when there is a potential market identified for the product. However, not all countries can use the route of local production. In their 2003 paper, Kaplan et al.<sup>33</sup> conclude that universal local production does not make good economic sense, especially in light of the need for economies of scale.

A constructive example is the agreement between Sanofi Pasteur, a multinational company based in France, and Instituto Butantan, a Brazil-based vaccine manufacturer, for production of influenza vaccine.<sup>7</sup> The agreement was structured in a step-wise fashion, starting with filling and finishing and progressing to full-scale production with technology and know-how transfer. For the transferor, this is a way to ensure that the transfer will be successful. For the transferee, the agreement provides a faster way of getting the technology and allowing wider access to the product, even though the agreement imposes restrictions on sales territories. Important points to be considered in developing an agreement of this type include the size of the market available to the recipient company, the capacity of the recipient company relative to the product's profit margin, and the ability of the recipient company to manufacture and control the product.

The term "patent pool" can be applied to the aggregation of IP rights that are the subject of cross-licensing. These processes can function either through direct transfer or through an entity set up to administer the patent pool. The US Justice Department has set up guidelines for their use, which when carefully implemented can render patent pools beneficial and pro-competition.<sup>34</sup>

To date there are no examples of patent pools in the area of biotechnology. However, a pool of patents on parts of the severe acute respiratory syndrome (SARS) genome is being formed, which could facilitate the development of a SARS vaccine.<sup>35</sup> Patent pools have also been discussed in the context of malaria and pandemic influenza.

### Development of new technologies in the developing world

In Cuba, the Finlay Institute and the Center for Genetic Engineering and Biotechnology (CIGB), have been involved with development of, among others, vaccines for meningitis B and recombinant hepatitis B, respectively. Both products are now on the international market, and the hepatitis B technology is being transferred to India and the Islamic Republic of Iran.

The previously mentioned study for GAVI<sup>19</sup> found over 65 vaccine R&D projects of interest to the developing world among 18 manufacturers in seven countries. An account of three of these

#### Box 2. Case study: transfer of conjugate technology for a conjugate meningitis A vaccine for Africa

The agreement between the Meningitis Vaccine Project (MVP) and the Centre for Biologics Evaluation and Research (CBER) comprised three parts.

(1) *Cooperative Research and Development Agreement.* The objective of this agreement was to transfer technology for a high-yield group A meningococcal polysaccharide-tetanus toxoid conjugate vaccine.

(2) *Training for technology transfer.* Workers from Serum Institute of India Limited (SII) undertook 3 weeks of technology transfer training at the CBER laboratories in the USA. The course included verification of all standard operating procedures for process development and analytical methods, demonstration of techniques, replication of the CBER methods by SII scientists, production of six lots of the conjugate vaccine, and definition of analytical methods. Following the training, SII scientists successfully reproduced and scaled up the conjugation method at the SII laboratories in Pune, India. Training and technology transfer were covered by confidentiality and material transfer agreements.

(3) *License with NIH.* MVP successfully negotiated a license agreement for the CBER conjugation technology with the NIH covering two patents related to conjugate meningococcal vaccines. The licensed fields of use are "Conjugate meningococcal vaccines", with territory identified as low- and middle-income countries as defined by the World Bank.

projects, now in clinical trials, has been prepared by Kreeftenberg & Hamidi,<sup>36</sup> describing use of Hib conjugate vaccine production technology to develop combination vaccines.

MVP, a public-private partnership founded in 2001 with a US\$ 70 million grant from the Gates Foundation, has a mission to eliminate meningitis as a public health problem in sub-Saharan Africa through the development and introduction of meningitis conjugate vaccines.<sup>15</sup> MVP forged a partnership with Serum Institute of India Limited (SII) in Pune, India, for the industrial scale-up, testing and production of a serogroup A meningococcal conjugate vaccine, with tetanus toxoid as the conjugating protein. MVP are working with the Center for Biologics Evaluation and Research (CBER) in Rockville, USA, for the conjugation process, and with SynCo Bio Partners in Amsterdam, Netherlands, for the meningitis A polysaccharide. The case study in Box 2 shows how the technology was transferred from CBER to SII.

There can be no doubt that much more attention needs to be paid to stimulating R&D in the developing world; extension of IP rights has not been successful in achieving this aim.

### Role of international organizations

International organizations have a role in ensuring equitable access to new priority vaccines in a way that is consistent with TRIPS. Organizations might fulfil this role by:

1. developing guidelines and best practice standards and disseminating these widely. WHO has already developed several publications on TRIPS.<sup>1,3,7,32</sup> Best practices for technology licensing could be disseminated;
2. commissioning IP mapping and/or IP landscapes for products of particular interest, or publicizing such landscapes where available;
3. developing and disseminating case studies on different IP approaches;
4. monitoring the impact of TRIPS on innovation and access.

The World Health Assembly established a Commission on Intellectual Property Rights, Innovation, and Public Health in February 2004. One of the contributions of the Commission would be to advocate for proven useful approaches in this area. The report and action plan to be submitted by Commission to the WHO Executive Board in 2006 will be an important step towards this goal.<sup>37</sup>

### Conclusions

In this paper, we have identified ways in which TRIPS compliance might threaten access to needed vaccines in developing countries. Management of these threats requires attention at both regulatory and strategic levels.

At the regulatory level, all countries have the option to use provisions of the Doha Declaration on TRIPS, as well as the protections guaranteed by the TRIPS agreement itself to maintain access to new priority vaccines. Further, it will be necessary to maintain global vigilance on the additional conditionality

contained in any “TRIPS-plus” elements of free-trade agreements, which could limit the protection for vaccine access discussed here.

At the strategic level, licensing and technology transfer agreements may provide a framework for addressing both the TRIPS compliance requirements

and the timely high-priority vaccine access requirements of developing countries. Support for public-private partnerships could focus on the origination of novel technologies within developing countries.

Finally, WHO must play their part in safeguarding access to important vaccines and drugs in the developing world

through the execution of traditional standards-setting and best practice defining roles, development and dissemination of detailed case studies on the application of specific strategic approaches, and continuous monitoring. ■

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## Résumé

### Gestion de l'impact de l'accord TRIPS sur la disponibilité des vaccins prioritaires

L'objectif déclaré de la protection des droits de propriété intellectuelle est de stimuler l'innovation. «L'accord relatif aux aspects des droits de la propriété intellectuelle qui touchent au commerce» (TRIPS) impose à tous les États Membres de l'Organisation mondiale du commerce (OMC) de promulguer selon certaines échéances des lois définissant des normes minimales de protection de la propriété intellectuelle. Les opposants à cet accord craignent que ce type d'action soit en contradiction avec la garantie d'un accès aux médicaments pour le monde en développement. Une réunion convoquée par l'OMS sur les droits de propriété intellectuelle et les vaccins dans les pays en développement, dont s'inspire cet article, n'a trouvé aucune preuve que l'accord TRIPS ait stimulé l'innovation pour la mise au point de vaccins destinés aux marchés des pays en développement (marchés qui sont faibles) ou encore que la protection des droits

de propriété intellectuelle ait eu un impact négatif sur l'accès aux vaccins. Néanmoins, l'application de cet accord pourrait menacer l'accès du monde en développement aux vaccins du futur. La gestion de ces menaces suppose l'adhésion de tous les pays à la Déclaration de Doha sur l'accord TRIPS et l'application des protections prévues par cet accord, une vigilance à l'égard des volets dits «TRIPS-plus» des accords de libre échange, le développement de cadres pour la délivrance de licences et le transfert de technologie et la promotion de la mise au point de vaccins innovants dans les pays en développement. Le rôle des organisations internationales dans la définition de meilleures pratiques, la diffusion des informations et le suivi de l'impact de l'accord TRIPS sera essentiel pour garantir un accès optimal aux nouveaux vaccins prioritaires pour le monde en développement.

## Resumen

### Controlar el efecto de los ADPIC en la disponibilidad de vacunas prioritarias

La finalidad declarada de la protección de la propiedad intelectual es estimular la innovación. En virtud del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual Relacionados con el Comercio (ADPIC), todos los Estados Miembros de la Organización Mundial del Comercio (OMC) deben promulgar leyes nacionales que garanticen un nivel mínimo de protección de la propiedad intelectual en un determinado plazo. Quienes critican el acuerdo temen que esas medidas sean incompatibles con el objetivo de garantizar el acceso a los medicamentos en el mundo en desarrollo. En una reunión convocada por la OMS acerca de los derechos de propiedad intelectual y las vacunas en los países en desarrollo, en la que se basa este artículo, no se halló ningún indicio de que el Acuerdo sobre los ADPIC hubiera estimulado la innovación en el desarrollo de vacunas para el mercado de los países en desarrollo (un mercado débil), ni tampoco de que la protección

de los derechos de propiedad intelectual hubiera tenido efectos negativos en el acceso a vacunas. Sin embargo, el acceso a futuras vacunas en el mundo en desarrollo podría verse amenazado por el cumplimiento del Acuerdo sobre los ADPIC. Para hacer frente a esas amenazas, todos los países deberían observar lo estipulado en la Declaración de Doha relativa al Acuerdo sobre los ADPIC, así como los mecanismos de protección garantizados por ese acuerdo, vigilar los elementos ADPIC-plus de los acuerdos de libre comercio, desarrollar marcos para la concesión de licencias y la transferencia de tecnología, y promover el desarrollo de vacunas innovadoras en los países en desarrollo. El papel de las organizaciones internacionales en lo que atañe a la definición de las prácticas más adecuadas, la difusión de información y el seguimiento del impacto de los ADPIC será crucial para garantizar un acceso óptimo a nuevas vacunas prioritarias para el mundo en desarrollo.

## ملخص

### إدارة تأثير الاتفاقية المتعلقة بالجوانب التجارية لحقوق الملكية الفكرية (التريس) على توافر اللقاحات ذات الأولوية

ارتكزت هذه الورقة على ذلك الاجتماع الذي لم يجد بينات على أن الاتفاقية المتعلقة بالجوانب التجارية لحقوق الملكية الفكرية (التريس) قد عززت ابتكار اللقاحات في أسواق الدول النامية (حيث تكون الأسواق ضعيفة) وأن حماية حقوق الملكية الفكرية قد أدت إلى تأثيرات سلبية على إتاحة اللقاحات، ومع ذلك فإن إتاحة اللقاحات التي ستظهر في المستقبل للبلدان النامية قد تتهدد باتباع الاتفاقية المتعلقة بالجوانب التجارية لحقوق الملكية الفكرية (التريس). ويتطلب إدارة هذه التهديدات من البلدان جميعاً الالتزام

إن الغرض المعلن لحماية حقوق الملكية الفكرية هو تعزيز الابتكار. وتطلب الاتفاقية المتعلقة بالجوانب التجارية لحقوق الملكية الفكرية (التريس) من الدول الأعضاء في منظمة التجارة العالمية أن تسنّ قوانينها الوطنية لتطبيق المعايير الدنيا من حماية حقوق الملكية الفكرية ضمن فترة زمنية محددة. ويخشى الناقدون لهذه الاتفاقية ألا تتماشى هذه الإجراءات المتخذة مع ضمان إتاحة الأدوية للبلدان النامية. وقد عقدت منظمة الصحة العالمية اجتماعاً حول حقوق الملكية الفكرية واللقاحات في البلدان النامية، وقد

الدولية على التعريف بأفضل الممارسات، ونشر المعلومات ورصد تأثير الاتفاقية المتعلقة بالجوانب التجارية لحقوق الملكية الفكرية (التريس)، وسيكون هذا الدور بالغ الأهمية لضمان الإتاحة المثلى للقاحات الجديدة ذات الأولوية في البلدان النامية.

إعلان الدوحة حول الاتفاقية المتعلقة بالجوانب التجارية لحقوق الملكية الفكرية (التريس)، وما تتضمنه هذه الاتفاقية من سُبُل حماية، والتبقيظ إلى العناصر التي تتضمنها اتفاقية التريس الإضافية من اتفاقات حول التجارة الحرة، وإعداد أطر عمل للتخصيص (أو منح الإجازات) ونقل التكنولوجيا، وتشجيع ابتكار اللقاحات الجديدة في البلدان النامية. ويعتمد دور المنظمات

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