

# Benchmarking progress in tackling the challenges of intellectual property, and access to medicines in developing countries

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**Abstract** The impact of intellectual property protection in the pharmaceutical sector on developing countries has been a central issue in the fierce debate during the past 10 years in a number of international fora, particularly the World Trade Organization (WTO) and WHO. The debate centres on whether the intellectual property system is: (1) providing sufficient incentives for research and development into medicines for diseases that disproportionately affect developing countries; and (2) restricting access to existing medicines for these countries. The Doha Declaration was adopted at WTO in 2001 and the Commission on Intellectual Property, Innovation and Public Health was established at WHO in 2004, but their respective contributions to tackling intellectual property-related challenges are disputed. Objective parameters are needed to measure whether a particular series of actions, events, decisions or processes contribute to progress in this area. This article proposes six possible benchmarks for intellectual property-related challenges with regard to the development of medicines and ensuring access to medicines in developing countries.

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يمكن الاطلاع على الملخص بالعربية في صفحة 370.

## Introduction

In January 2004 the Commission on Intellectual Property, Innovation and Public Health (CIPIH)<sup>1</sup> was established at WHO pursuant to the World Health Assembly (WHA) Resolution on Intellectual Property, Innovation and Public Health (Resolution WHA56.27) which requested WHO's Director-General to establish the terms of reference for a time-limited body to: "Collect data and proposals from different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries."<sup>2</sup>

Resolution WHA56.27, signaled the emerging global consensus on the relationship between intellectual property rights and public health in accordance with, and partly building on the World Trade Organization's (WTO) Doha Declaration<sup>3</sup> (Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health).

Resolution WHA56.27, however, acted beyond the confines of the intel-

lectual property system focussing attention on eliminating the 10/90 gap, i.e. developed countries that account for nearly 90% of the global pharmaceutical sales represent only 10% of the 14 million or more deaths that occur globally every year due to infectious diseases, while developing countries which represent 90% of the 14 million deaths account for only 10% of the global pharmaceutical sales.<sup>4</sup> Thus the current system for innovation has failed to ensure that research and development (R&D) priorities reflect health needs in developing countries. Although non-communicable diseases now contribute to a large proportion of deaths in developing countries, the current challenge is primarily related to access to existing medicines as opposed to lack of relevant R&D. Also, since infectious diseases, unlike noncommunicable diseases, predominantly affect only developing countries the focus on infectious diseases and the 10/90 gap is justifiable.

In this regard, the work of the CIPIH represents considerable progress in tackling the intellectual property-related challenges to R&D, as well as accessibility of essential medicines, particularly those relevant for treating and

managing diseases that disproportionately affect the populations of developing countries. The required action to address the interplay between intellectual property rights, innovation and public health was outlined fairly clearly in Resolution WHA56.27. The WHA in response to the 10/90 gap sought action at two levels. First, the WHA "Urged Member States to seek to establish conditions conducive to R&D that spur development of new medicines for diseases that affect developing countries"; and second, for the CIPIH (a time-limited body) to analyse intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products for diseases affecting developing countries.

There are two central issues with regard to diseases affecting developing countries. All countries need to take action to establish conducive conditions for R&D and rethink intellectual property rights and innovation approaches in the context of funding and incentives.

The work of the CIPIH, which is now completed, was mainly directed at the second issue though it also addressed important aspects of the first

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issue. However, the usefulness of the work of the CIPIH can only be assessed by follow-up. If there is no agreement about the value of the CIPIH findings and other similar reports in a situation where we have no objective criteria for thinking about value, then follow-up action will be very difficult, if not impossible.

There are two primary challenges regarding follow-up: (1) what is required to implement the findings of the CIPIH as well as continue research on these issues? and (2) how to measure progress and the impact of various actions, decisions, and proposed mechanisms of the CIPIH's findings?

The first point is considered in another paper in this issue (see Winters, D, pp 414-416). I will enlarge upon the second point here.

The objective of this article is to propose possible benchmarks that can be used to track progress in tackling the intellectual property-related challenges and ensuring access to medicines in developing countries. Such benchmarking will help determine the impact of various decisions, actions and processes (from WTO, WHO, the World Intellectual Property Organization (WIPO) or elsewhere). It will also assess whether the actions and decisions taken and the mechanisms put in place are facilitating the movement from the 10/90 situation to a 20/80 situation and so on or vice versa.

Intellectual property is just one factor affecting R&D and access to medicines in developing countries. Consequently, benchmarking the progress in overcoming other challenges to R&D and access, such as health education, health systems, rational drug use, government taxation and tariffs policies, are also required for a complete assessment. This, however, is beyond the scope of this article.

## Why is there a need to benchmark progress?

The relationship between intellectual property, patents in particular, and innovation in the pharmaceutical sector has been a central issue in the debate on intellectual property and public policy objectives. This explains why at the adoption of the TRIPS Agreement, in countries such as Argentina, Brazil and India did not grant patents for pharmaceutical products. The contentious

issue during the negotiations of the TRIPS Agreement was the mandatory requirement to grant patents to products and processes in all fields of technology (primarily pharmaceutical patenting).<sup>5,6</sup> There were two main concerns. Firstly, intellectual property rights were not necessarily the best mechanism to stimulate innovation, especially for medicines related to diseases that predominately affect developing countries. Secondly, that even where medicines were available, the monopolies granted by patents were making them unaffordable and inaccessible to developing countries.

The debates and discussions in various international fora including WHO, WTO and WIPO on intellectual property and public health resulted into a number of high profile events, actions, and processes. These included the adoption of the Doha Declaration,<sup>3</sup> as well as the 30 August 2003 Decision<sup>7</sup> and the subsequent amendment to the TRIPS Agreement on 6 December 2005,<sup>8</sup> implementing paragraph 6 of the Doha Declaration; the report of the UK Commission on Intellectual Property Rights;<sup>9</sup> the various WHA resolutions.<sup>10</sup> The formation of the CIPIH was one of the latest developments in this ongoing debate.

During this debate, people have been unable to reach agreement on whether various decisions, events, actions, and processes have contributed to, or stifled, progress. While developing countries, health professionals and activists were hailing the Doha Declaration for placing the needs of patients before profits, the pharmaceutical industry was predicting the end of innovation.

Similarly, with the amendment to the TRIPS Agreement made on 6 December 2005, health professionals and activists were concerned about how feasible it was to use compulsory licensing as a public health tool. Yet the WTO Secretariat, the pharmaceutical industry, and some developed countries, hailed the amendment as the final resolution of the problem.<sup>11-13</sup> Thus the parameters and benchmarks used by the WTO Secretariat and the pharmaceutical industry versus those used by the health professionals and activists are clearly different.

Establishing a framework for assessing progress towards eliminating intellectual property-related barriers is not an easy task. There are bound to be

disagreements not only on what to measure but also the methods for measurement. However, the potential complexity and/or potential disagreements should not hold up this imperative task. The overall benchmarks as well as the specific indicators used should help determine the impact of the measures proposed or adopted in various international fora such as the WHO and the WTO. These benchmarks should also be applicable to any alternatives to the intellectual property system.

## How can progress be benchmarked?

Indicators can be built, and progress measured, against the following six benchmarks.

### 1. The extent to which innovation and R&D priorities are based on health needs

The 2006 gap can be measured using the methods that helped determine the 10/90 gap. Of the 1400 new products developed by the pharmaceutical industry and public laboratories between 1975 and 1999, only 13 were for tropical diseases and three were for tuberculosis.<sup>4</sup> It is possible to measure the various causes of death and the resources spent on innovation and R&D for solutions, as well as the therapeutic advance that each new patented medicine represents over existing therapies.<sup>14</sup>

Evidence beyond the 1975-99 figures should be used to determine the progress made towards matching innovation and R&D priorities with health needs. These measures would also inform us about the progress that can be achieved, and over time, that which is achieved as a result of implementing the CIPIH recommendations. In this regard, more thought should be given to the Medical R&D treaty,<sup>15</sup> which proposes ways of determining priority medical research and measuring minimum support for such research.<sup>16</sup>

### 2. The extent to which sustainable investments in R&D are made in areas that are of the greatest priority

This benchmark is closely related to earlier benchmarks. To determine whether intellectual property-related barriers to the development of medicines for diseases affecting developing countries

are being eliminated, data on disease burden, health needs, and priorities as discussed above should be used to measure whether sustainable R&D investments are being made in areas of greatest need. It is important to establish whether the intellectual property system or other proposed mechanism(s) are able to drive R&D investments into areas of greatest need on a consistent basis. There are challenges regarding how priorities would be set and by whom, which need to be addressed.

Such an assessment will help evaluate the possible contribution of the proposed medical R&D treaty, in comparison to the intellectual property rights system, public–private partnerships (PPPs), and other mechanisms. This sustainability benchmark could also be used to develop indicators on the effectiveness of response to public health needs.

### 3. The extent to which access is ensured to quality medicines at affordable prices

The first two benchmarks serve to measure innovation and R&D outputs versus health needs and priorities based on disease burden, R&D expenditures, and other related data. This third benchmark will reveal whether those outputs are reaching the relevant people and those most in need. Assuming that the intention is to remove the 10/90 gap at the output level, there is a need to measure whether this is happening at the actual access (consumption) level.

The work done on accessibility of antiretroviral medicines for human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) treatment in the context of initiatives such as “3 by 5” is an example of explicitly quantifying access. Affordability measurements based on income, government spending on the purchase of medicines, and out-of-pocket expenditures can be used to test the performance of innovation and R&D systems in providing access to medicines for people in developing countries.

### 4. The extent of consistency with human rights obligations, particularly the obligations relating to the right to health

Decisions, actions and processes regarding intellectual property, innovation and public health should also be measured against their overall contribution to

the protection, fulfillment, and realization of the right to health. This can be done by testing various measures against the core obligations under the right to health. Article 12.2 (c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) requires steps to be taken to prevent, treat and control epidemic, endemic, occupational and other diseases. Ratifying states are obligated to ensure the provision of equal and timely access to basic preventive, rehabilitative health services and appropriate treatment for prevalent diseases, illnesses, injuries and disabilities as well as the provision of essential drugs.<sup>17</sup> The right to health therefore entails both R&D and access obligations for the state.

The state has the obligation to implement laws and policies in the least harmful way to consumers of health-care products and services. For patents it means that the monopoly pricing needs to be counterbalanced by appropriate competition mechanisms. For example, it can be argued that the application of the TRIPS standards tempered by competition principles and rules would constitute a less restrictive means of protecting inventions and providing incentives for pharmaceutical R&D than applying the TRIPS standards without competition considerations.<sup>18</sup>

### 5. The extent of a long-term view on the nature, costs, and distribution of medical knowledge

This is a critical benchmark for determining progress. The measurements and indicators used should be able to determine how the system can support responses to unknown epidemics, progressively reduce the aggregate cost of medicines, and improve general access to medical technology and knowledge.

The performance of the current intellectual property rights-based incentive system has not been beneficial, as experience with HIV/AIDS, SARS, and more recently avian flu, has shown. Every time there is a major health crisis increasing amounts of energy and resources are expended for control.

General contributions to the advancement of science, including appropriate technology transfer, are also important. Indicators should measure such contributions, as in improving accessibility of copyrighted research

results, whether publicly or privately funded. The proposed Medical R&D treaty contains ideas regarding obligations to providing incentives for open access research, which could be a good starting point.<sup>15</sup>

### 6. Extent of fair sharing of innovation costs between and within countries

Monopoly pricing under the patent system inevitably raises important questions of equity and justice, such as “What should different countries, individuals or communities be obliged to contribute towards the global costs of innovation and R&D — for all diseases generally and for diseases that affect developing countries?”

To address the question of fair share and burden, the TRIPS Agreement, similar to other WTO agreements, uses the special and differential (S&D) treatment mechanism. However, within WTO the S&D approach is failing to deliver the desired results.<sup>19</sup> S&D treatment provisions in the form of transition periods for the implementation of TRIPS obligations have failed to address serious concerns that the obligations assumed by developing countries under the Agreement are overly broad and burdensome and bear no relationship to their levels of development. The S&D approach has also failed to address concerns that the distinction underlying S&D is arbitrary and does not provide a justifiable basis for differentiation in international rules on patents. The application of the same rules to all countries and industries, despite factual differences in the area of patents as in other areas, fails to respond to fundamental precepts of justice.

To address these concerns, there is need to build a system that ensures that WTO and other related international patent rules reflect the differences between and within countries. Only such a system can ensure that each country is doing its fair share to contribute to the global burden of paying for innovation and R&D while ensuring that those costs are fairly allocated among different players within countries.

There already exist various indicators for measuring investment in innovation and R&D, which can be refined or adapted for this purpose.<sup>20</sup> There is also significant evidence to demonstrate that indicators that base the rate of innovation and R&D on patent applications or grants are faulty and would not

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be useful here.<sup>21</sup> However, the Medical R&D Treaty, which proposes a system of credits for assigning values to various contributions, provides a framework for indicators for this benchmark.<sup>15</sup>

## Conclusion

While significant progress has been made towards tackling the intellectual property-related barriers to development and accessibility of medicines for diseases that disproportionately affect developing countries, the actual amount of this progress remains contested. It

is critical that objective parameters by which to measure progress be made in all countries to establish, within their borders, conducive conditions for R&D on diseases affecting developing countries. Likewise, progress needs to be measured on mechanisms established globally to address the 10/90 gap.

The benchmarks proposed in this article could be used to develop a framework for assessing progress. While sufficient data and indicators are available for the benchmarks discussed, these need to be refined and applied. The task of establishing such a framework is an

interdisciplinary process requiring the efforts and contributions of everyone. The focal point for coordinated action, however, could be the WHO-centered CIPIH follow-up programme that Winters suggests. Once the benchmarks are established, WHO could produce an annual report on the state of R&D and access for diseases that disproportionately affect developing countries. Such accounting would assess if the 10/90 gap, as well as the gaps related to noncommunicable diseases, are being reduced. ■

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## Résumé

### Amélioration des critères permettant d'évaluer les solutions aux difficultés pour préserver à la fois les droits de propriété intellectuelle et l'accès aux médicaments pour les pays en développement

Les conséquences pour les pays en développement de la protection des droits de propriété intellectuelle dans le secteur pharmaceutique ont été l'une des principales questions vigoureusement débattues au cours des 10 dernières années dans les forums internationaux, notamment l'Organisation mondiale du commerce (OMC) et l'OMS. Le débat se concentre sur les questions suivantes : (1) le système de protection de la propriété intellectuelle est-il suffisamment incitatif à l'égard de la R & D portant sur des médicaments permettant de traiter des maladies qui touchent de manière disproportionnée les pays en développement; et (2) restreint-il l'accès de ces pays aux médicaments existants ? La Déclaration de Doha a été adoptée dans le cadre de l'OMC en

2001 et la Commission sur les Droits de propriété intellectuelle, l'Innovation et la Santé publique a été mise en place sous les auspices de l'OMS en 2004, mais leurs contributions respectives à la résolution des difficultés liées aux droits de propriété intellectuelle sont controversées. Des paramètres objectifs sont nécessaires pour évaluer si un ensemble donné d'actions, d'événements, de décisions ou de processus apporte des améliorations dans ce domaine. L'article propose six critères pour évaluer les solutions aux difficultés qu'entraîne l'application des droits de propriété intellectuelle à l'égard du développement des médicaments et de l'accès des pays en développement à ces produits.

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## Resumen

### Criterios para determinar los progresos de la respuesta a los retos que plantea la propiedad intelectual en relación con el acceso a los medicamentos en los países en desarrollo

El impacto de la protección de la propiedad intelectual en el sector farmacéutico sobre los países en desarrollo ha constituido un tema de capital importancia en el arduo debate mantenido durante los últimos diez años en varios foros internacionales, particularmente en la Organización Mundial del Comercio (OMC) y en la OMS. El debate se centra en determinar si el sistema de propiedad intelectual está: (1) ofreciendo incentivos suficientes para la investigación y el desarrollo de medicamentos contra enfermedades que afectan desproporcionadamente a los países en desarrollo; y (2) restringiendo el acceso a los medicamentos existentes para esos países. En 2001 se adoptó en la OMC la Declaración

de Doha, y en 2004 se estableció en la OMS la Comisión de Derechos de Propiedad Intelectual, Innovación y Salud Pública, pero la contribución de esos dos instrumentos a la resolución de los problemas relacionados con la propiedad intelectual es objeto de debate. Se requieren parámetros objetivos para determinar si una serie particular de medidas, eventos, decisiones o procesos favorecen los avances en ese terreno. Este artículo propone seis posibles criterios para determinar si se está respondiendo a los retos que plantea la propiedad intelectual en lo que se refiere al desarrollo de medicamentos y a la necesidad de garantizar el acceso a los medicamentos en los países en desarrollo.

## ملخص

### التقدم المحرز في مؤشرات مواجهة التحديات في حقوق الملكية الفكرية وإتاحة الأدوية في البلدان النامية

عُقد عام 2001، وأنشئت لجنة الملكية الفكرية والابتكار والصحة العمومية ضمن منظمة الصحة العالمية عام 2004، إلا أن الاستجابة الخاصة بمواجهة التحديات في حقوق الملكية الفكرية لاتزال موضوع جدل. وتمس الحاجة لمتنابنات موضوعية لقياس فيما إذا كانت سلاسل الأعمال والأنشطة والأحداث والقرارات والإجراءات تساهم في إحراز التقدم في هذا المجال. ويقترح هذا المقال ستة مؤشرات للتحديات المتعلقة بحقوق الملكية الفكرية، تتعلق بابتكار الأدوية وضمان إتاحتها للبلدان النامية.

لقد كان تأثير حماية حقوق الملكية الفكرية في القطاع الصيدلاني على البلدان النامية من القضايا الرئيسية التي دار فيها نقاش حاد خلال العقد المنصرم في العديد من المحافل الدولية، ولاسيما منظمة التجارة الدولية، ومنظمة الصحة العالمية. وقد تركز الجدل حول نظام حقوق الملكية وفيما إذا كان: (1) يقدم حوافز كافية للبحوث والابتكار في الأدوية الخاصة بأمراض تصيب البلدان النامية أكثر من غيرها من البلدان. (2) حصر إتاحة الأدوية للبلدان النامية. وقد تم اعتماد إعلان الدوحة في مؤتمر منظمة التجارة العالمية الذي

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