

# Patents on drugs: the right policy for the wrong problem

*Pasqualina Curcio Curcio, PhD*

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Knowledge, according to economic theory, is a public good: it is non-exclusive, which means that the private sector, whose aim is to maximize profits, has no incentive to produce it since it can neither recover its investment costs nor make a profit.<sup>1</sup> Since private industry cannot recover the cost of producing new knowledge they have no motivation to invest in research and development (R&D).<sup>2</sup>

Knowledge is also a non-rival good; the fact that a pharmaceutical company (public or private) uses and consumes a particular knowledge in the manufacture of a particular medication does not prevent other companies from also making use of the same knowledge to produce an identical product.

The existence of public goods creates what economy theory calls “market failures.” These are situations in which the market alone cannot efficiently allocate resources. When producers cannot force consumers to pay for the consumption of a good they cannot recover their production costs, much less maximize their profits (in the case of private producers). The resulting incomplete markets are a failure from the economic point-of-view. To overcome market failures, an external agent is required to intervene. In the case of public goods, the state must create public policies that reduce or eliminate market failures by supplementing the market through a guaranteed supply of these goods.<sup>3</sup>

Intellectual property rights (IPR) have emerged as a public policy that responds to the disincentive

that private companies have to research and develop new skills; they grant inventors the right to prevent others from using their creations, thus securing their ability to obtain payment for the use of their inventions. IPR has been formalized in various international agreements.\* They are now consolidated and systematized in the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contained in the Marrakech Declaration of 15 April 1994.† IPR aimed at protecting innovation, invention, and technological creations are classified in TRIPS as patents.‡ They protect inventions for at least 20 years.<sup>4</sup>

Article 28 of TRIPS states:

*1. A patent shall confer on its owner the following exclusive rights:*

*(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;*

*(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: us-*

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\* See, for instance the Paris Convention (1883), the Berne Convention (1886), the Rome Convention (1961), and the Washington Treaty on Intellectual Property in Respect of Integrated Circuits (1989).

† This declaration included both the final act of the Uruguay Round of Multilateral Trade Negotiations as well as the founding of the World Trade Organization.

‡ The intellectual property rights established by TRIPS include the following: Copyright and related rights; trademarks and commercial names; industrial designs including maps, drawings and models; patents; designs of integrated circuits; commercial secrets; misuse of contractual licenses for anti-competitive purposes.

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**Pasqualina Curcio Curcio, PhD**

Universidad Simón Bolívar

Valle de Sartenejas

Edificio de Estudios Generales

Piso 1. Ofc. 35. Baruta. Edo. Miranda

Venezuela

Tel: +582129063742

Email: [pasqualinacurcio@gmail.com](mailto:pasqualinacurcio@gmail.com)

*ing, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.*

*2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.*<sup>4 (p. 332)</sup>

In economic terms, patents are a mechanism of exclusion. Nobody, except the inventor, can benefit from the invention unless by a negotiated license agreement. The inventor is not obliged to enter into such an agreement and can be the exclusive user of the invention. Exclusion allows the inventor to recover his/her investment in R&D during a period of at least 20 years. Once the need to respect patent rights restricts the use of knowledge, it ceases to be a public good and becomes a private one.

Our approach is similar to that of Kaul and Mendoza. They argue that the status of a good as public or private is not simply a function of the good's ownership or its natural characteristics. The broad concept of public goods is itself a social construction and the product of a political process. The authors classify the patenting of manufacturing processes as an example of a non-rival good that was made exclusive and thus subsumed into the private domain.<sup>5</sup>

### **Are drug patents the solution or are they the problem?**

Two key aspects are fundamental in analyzing the impact of drug patents. First, granting a patent confers exclusive rights to the use and marketing of both the production process and the goods resulting from it; this creates a legal monopoly, a form of market failure. Secondly, governments use patents to encourage R&D by private industry; however, this fosters only R&D designed to maximize private profits and hinders governments from developing a research agenda that responds to social needs. Public and private interests are not necessarily aligned, and the R&D priorities of the pharmaceutical industry are based on potential profitability rather than any public interest or social need. These two factors – market failure and the goals of private R&D – are of utmost importance when we examine the knowledge associated with the ability to prevent,

treat, or cure diseases, i.e., that knowledge closely related to people's health and lives.

### *Creating legal monopolies*

A patent provides an exclusive right to produce and market a good. When there is only one producer, a monopoly exists. The monopolist alone can satisfy the market demand. Unlike firms that must compete, the monopolist alone decides how much to produce, effectively determining the price.<sup>1</sup>

The monopolist can charge higher prices than a producer operating in a competitive market. In addition, the monopolist has less incentive to produce than someone working under normal market conditions. This restriction of output along with the increase in prices limits the availability of the product for those who need it, reducing economic efficiency.<sup>1</sup>

Pharmaceutical companies have such a monopoly for the production and marketing of drugs and this has resulted in limitations on the supply and access of medications. Those with low incomes or living in developing countries are particularly affected.

These monopolies are particularly problematic because they involve essential goods for which there are often no readily available substitutes. These particularities allow the monopolist to set a price far above the price in a competitive environment. The demand for pharmaceuticals is considered relatively inelastic,<sup>§</sup> which allows monopolies greater capacity to increase prices above those that would be charged in a competitive market.<sup>6</sup>

Under certain circumstances, the pharmaceutical industry, still using the monopoly powers conferred by the patent, will lower prices; this occurs when a product is priced differently depending on the consumer's ability to pay. Far from reducing profits, these price cuts actually serve to increase profits by

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<sup>§</sup> An inelastic good is one for which a given increase in price causes a smaller decrease in demand. In other words consumers will purchase the item no matter what the price is. Medical treatments which prevent, ameliorate, or cure diseases – and for which there is no substitute available – are absolutely vital and behave (economically) as inelastic goods.

compensating for economic inefficiencies associated with monopoly pricing.<sup>1</sup>

It has been argued that the disadvantages associated with these market inefficiencies are compensated for by the benefits that result from the creation of new knowledge and products by private industry. But the advantages of private R&D are questionable, particularly because the newly created knowledge will pass from the public into private domain, creating legal monopolies that benefit only a few. As Nicholson argues, “*Whether or not the benefits of such innovative behavior exceed the cost of creating monopolies is an open question.*”<sup>1</sup> (p. 299)

The problem of access posed by the TRIPS structure was acknowledged by member countries of the World Trade Organization on November 14, 2001 at the Doha Ministerial Conference. They recognized “*that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.*”<sup>7</sup> (p. 1) The ministers accepted the need for flexibility in the application of TRIPS to pharmaceutical products:

*We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.*

*In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.*<sup>7</sup> (p. 1)

#### *The R&D agenda*

The second concern of using of patents to incentivize the development and production of new drugs is the impact of the for-profit pharmaceutical industry on setting research priorities.

The pharmaceutical industry allocates R&D resources based on its private interests rather than those of the public. Private industry invests in re-

search on medicines that will ensure high levels of profit. The issue here is not that industry wants to maximize its profits. The problem is that the industry’s research priorities do not necessarily coincide with the pharmaceutical needs of the population, i.e., with priority health conditions. This situation seen clearly with the so-called “neglected diseases” for which there is little incentive for R&D investment by the private pharmaceutical industry. The Global Forum for Health Research has called this the 10/90 gap; only 10% of health research is devoted to those conditions which create 90% of the global disease burden.<sup>8</sup>

Doctors Without Borders (MSF) has documented the for-profit pharmaceutical industry’s lack of interest in the diseases of the poor. Between 1975 and 1999, only 15 new medicines were developed for those tropical diseases that accounted for 12% of the global disease burden; during the same period 179 new drugs were developed for cardiovascular diseases that accounted for 11% of the global disease burden. MSF argues that “purchasing power” is the main factor driving the research agendas and priorities of the pharmaceutical industry. This means the health needs of the poor are not taken into consideration.<sup>8</sup> Correa also points out that the pharmaceutical industry does not invest in fields in which potential profits are low, even when there is a possibility of obtaining a patent.<sup>9</sup> According to Doctors Without Borders, the primary interest of pharmaceutical R&D is in drugs that address diseases affecting people worldwide, such as cancer, cardiovascular diseases, mental illness, and neurological disorders. The industry has only a secondary (and subordinate) interest in the “neglected diseases” like malaria and tuberculosis, which primarily affect poor countries. In third place are those diseases classified as extremely neglected; these include sleeping sickness, Chagas disease, and leishmaniasis. Since these diseases only affect the poorest countries, they are entirely absent from the R&D agenda.<sup>8</sup> Finally, MSF identifies a group of pharmaceutical products addressing conditions that are not strictly medical; these include cellulite, baldness, diets, wrinkles, stress, and time zone adjustment problems. Such products account for approximately 50% of pharmaceutical

sales and are a highly lucrative market in rich countries.<sup>8</sup>

An additional problem with the R&D priorities of the private pharmaceutical industry stems from the way patents favor the improvement of existing drugs rather than the development of new ones. When pharmaceutical companies develop improved versions of existing drugs, patents can be extended an additional 20 years. In this way the monopoly can be extended practically indefinitely.

In October 2006, the US Congressional Budget Office conducted an investigation in response to concerns that the prices of new drugs had been increasing much faster than the rate of inflation. They found that despite increases in annual R&D expenditures, the pharmaceutical industry had become less innovative. Nonetheless, it had been able to charge high prices for new drugs that were only marginally different from existing ones. R&D costs for these new drugs were relatively lower because it is less expensive to conduct research on existing drugs.<sup>10</sup>

In 2007, the US pharmaceutical industry invested US \$44.5 billion in R&D; this represented 16.4% of industry total sales, which amounted US \$271.5 billion that year. The amount invested in R&D by the industry has increased annually since 1970. As a percentage of total sales, however, since 1985, R&D investment has remained between 15 and 17%.<sup>11</sup>

Our discussion so far has focused on role of profit in shaping the private pharmaceutical industry's R&D agenda and on the role of new drugs (whether or not they represent a real innovation or improvement) in a market with a high ability to pay. The result is a pharmaceutical industry that makes drugs for the diseases of developed, rich countries. However, it is worth noting that affordability is just one of several factors explaining industry behavior regarding R&D.

In this regard, Curcio has previously argued that *"it is not only countries' income levels and therefore their ability to pay that explains the behavior of the pharmaceutical industry."*<sup>12</sup> (p. 2364)

Other factors seem important. These include whether or not the drug treats an infectious disease, how it is transmitted, how disease transmission is controlled, the disease's lethality, and the type of product (vaccine, curative, palliative). These factors

have several implications for the future profitability of a pharmaceutical product. Palliative treatments (rather than vaccines or cures) will be favored for diseases that are 1) not airborne, 2) of low lethality, and 3) have no known cure. Preventative or curative interventions are favored for conditions that are airborne, hard to control, and highly lethal, such as influenza and pneumococcal disease.<sup>\*\*</sup>

The industry has no real incentive to invest in drugs that prevent or cure non-airborne diseases that are not highly lethal. In general, it would prefer to develop (or improve) palliative treatments that extend the life of the sick individual rather than finding cures or developing preventive vaccinations. Curing or preventing diseases represents an opportunity cost for the pharmaceutical industry; a prolonged palliative treatment ensures long-term profits. The development of a vaccine or a cure for HIV/AIDS would represent an opportunity cost for the pharmaceutical industry of as much as US \$276 billion of lost revenue from sales of anti-retrovirals to persons infected with HIV/AIDS.<sup>13</sup>

The patent structure magnifies the incentive to invest in palliation rather than cure. By offering pharmaceutical companies a monopoly position in the sale of anti-retrovirals, the opportunity cost of developing a cure is quite high. However, even if patents did not exist, the bias against cure or prevention would exist, albeit to a lesser extent. Even in conditions of perfect competition, palliative treatments will continue to be more profitable over the long run, although the absolute level of profit is less.

The incentive to develop or improve drugs for non-communicable and non-lethal diseases (sometimes referred to as "chronic diseases") is explored in a publication by PhRMA called *A Decade of Innovation*.<sup>14</sup> This report highlights pharmaceutical innovation in the preceding ten years, noting a focus on the following diseases: Parkinson's, rheumatoid arthritis, HIV/AIDS, Alzheimer's, schizophrenia, diabetes, hypertension, and cholesterol. These are all diseases or conditions that require lifelong treat-

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<sup>\*\*</sup> These considerations do not come into play in the case of vaccines for diseases which are highly lethal, highly contagious, and for which it is difficult to prevent transmission. They also do not apply to highly lethal conditions.<sup>12</sup>

ment and have no cure; in other words, patients remain sick and dependent on drugs.

Dr. Richard J. Roberts, 1993 Nobel Prize winner in Medicine, stated in an interview published in the newspaper *La Vanguardia* on July 27, 2007

*It is natural that the pharmaceutical industry is interested in research not into drugs that cure but rather into ones which make chronic diseases more chronic. Medications for chronic diseases are much more profitable than those that heal a disease once and for all.*

He went on to say:

*I am aware of researchers in private industry who might have discovered highly effective drugs that cure diseases.*

*Interviewer: And why did they stop their research?*

*Because the drug companies are often less interested in curing you than in getting your money. So, all of sudden, the research is re-focused onto the discovery of non-curative drugs that make the diseases chronic and make you feel better only as long as you take the drug.*<sup>15 (p. 1)</sup>

We have demonstrated the negative consequences that follow from the transfer of knowledge from the public into the private domain. It is worth asking whether or not current patent policy has solved the problem of incomplete markets with respect to pharmaceuticals. If it has not, we should be looking at where current policy has failed and developing alternative proposals designed to meet the knowledge needs of the entire society.

### **Drug patents: right policy, wrong problem**

The use of patents to foment development in drug manufacturing has not only failed to address the need for new pharmaceuticals, but it has also distorted the central purpose of patents. Amartya Sen, 1998 Nobel Laureate in Economics, noted:

*In addition to the momentous omissions that need to be rectified, there are also serious problems of commission that must be addressed for even elementary global ethics.*

*These include not only inefficient and inequitable trade restrictions that repress exports from poor countries, but also patent laws that inhibit the use of lifesaving drugs - for diseases like AIDS - and that give inadequate incentive for medical research aimed at developing nonrepeating medicines (such as vaccines).*<sup>16 (p. 15)</sup>

The defense of IP rights and the use of patents to promote research on new drugs have not been the correct solution to the public health issues. These policies solve the wrong problem; the public health problem is not the lack of incentives for the private pharmaceutical industry to invest in and develop research. The real issue is increasing our pharmaceutical knowledge both in its quantity and the type of knowledge required.

Patent policy suffers from what is known as a Type III public policy failure: it is the right policy applied to the wrong problem.<sup>17</sup> In theory it could be very good policy tool to encourage investment by the pharmaceutical industry; we have seen how it has vastly increased the amount of investment in R&D over the last ten years. But this is not the problem. Ironically, increased private R&D itself has become part of the problem. The correct public problem is that there is *not enough knowledge* of how to manufacture drugs that address *the health needs* of the world's population. Presenting the issue in this way highlights the two aspects of the problem: 1) the supply of knowledge and 2) the health needs of the population.

The fact that something is a public good does not mean that the only way for it to be produced in a market economy is to make it a private good; the solution, in the case of public goods, is that the state itself directly produces it. This is especially the case when the good in question is closely related to health and people's lives. It is therefore a social (meritorious) good. Privatizing it does not solve the problem; it worsens it.

Joseph Stiglitz, 2001 Nobel Laureate in Economics, argued:

*The argument in favour of the public provision of public goods is that it is more efficient. When the fact that a person consuming*

*a good has no marginal cost, the good should not be rationed. But if it is to be provided by a private company, it must charge for its use, and the price charged will deter consumers from consuming it. Thus, public goods are underutilized when provided by private companies.*<sup>3 (p. 138)</sup>

Stiglitz goes on to say:

*Goods whose marginal supply cost is zero must be supplied free of charge, regardless of whether its profitable or not...the argument for the public provision of some goods for which the user may be charged, then, is that the costs incurred by charging for their use – welfare losses resulting from reduced consumption – are greater than the costs incurred in raising revenue in other ways, such as through an income tax.*<sup>3 (p. 138)</sup>

Discussions within the WTO and WHO have focused primarily on ensuring that the world's poorest people have access to drugs. Working within the constraints planted by the Doha Ministerial framework, governments have tried to resolve the access problems created by legal monopolies by relaxing conditions on granting patents that relate to public health. These policies have been quite timid; governments tend to recommend rather than force the industry to reduce prices to those of perfect competition. It is pertinent to ask why measures have not been taken to regulate monopolies, to force them to produce at levels of perfect competition, to reduce prices and increase supply. Of course none of these actions ever even consider the possibility of eliminating patents in the health field.

### **Global actions and proposals**

At the 59th World Health Assembly held in 2006, member countries created an intergovernmental working group charged with developing a global strategy and action plan that would provide a medium-term framework to implement the recommendations of the Commission on Intellectual Property Rights. This group published a document outlining the progress made and set forth the elements of an action plan and global strategy, which stated:

*The focus of the strategy will be on diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available – either because no treatment exists or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable.*<sup>18 (p. 3)</sup>

The final document was submitted for review to the member countries and the action plan was approved at the 62nd World Health Assembly in 2009.

The action plan is based on eight elements:

- 1) Prioritizing research and development needs
- 2) Promoting research and development
- 3) Building and improving innovative capacity
- 4) Transfer of technology
- 5) Management of intellectual property
- 6) Improving delivery and access
- 7) Ensuring sustainable financing mechanisms
- 8) Establishing monitoring and reporting systems.<sup>18</sup>

We should acknowledge the efforts already undertaken by governments who take part in organizations such as the WHO in order to solve the problems of access to medicines and the lack of research into medicines for diseases that affect the poor. We need to note that none of these international organizations question intellectual property rights or the granting of patents.

Yet critics of IP and patents do exist. Among the most well known are Professor John Sulston (2002 Nobel Laureate in Physiology and Medicine) and Joseph Stiglitz (2001 Nobel Laureate in Economics). On July 5, 2008 at the “Who Owns Science?” conference, they stated that the intellectual property regime stifles science and innovation, arguing that

*Patent monopolies are believed to drive innovation but they actually impede the pace of science and innovation ... Another problem is that the social returns from innovation do not accord with the private returns associated with the patent system...*<sup>19 (p. 1)</sup>

Stiglitz offered a proposal to resolve the problems of patents in an article entitled “Prizes, Not Patents”:

*There is an alternative way of financing and incentivizing research that, at least in some instances, could do a far better job than patents, both in directing innovation and ensuring that the benefits of that knowledge are enjoyed as widely as possible: a medical prize fund that would reward those who discover cures and vaccines.*<sup>20 (p. 1)</sup>

He proposes a mechanism that does not replace patents but “*would be part of the portfolio of methods for encouraging and supporting research.*”<sup>20 (p. 1)</sup>

We do not believe that such a mechanism would necessarily solve the problem. On the one hand, the private pharmaceutical industry does not invest in cures or vaccines for some specific diseases, especially chronic diseases, because of the opportunity costs that would incur. As such, an award would not encourage the sector to invest unless it was high enough to cover the opportunity cost. Similarly, private industry does not invest in diseases that affect only the poor because they are unprofitable and it is a small market with low capacity to pay, which is an economic issue, not one of the incentive of a prize.

If the award is aimed at encouraging public institutions to invest in R&D in vaccines and cures, we face another problem. The public sector lacks resources in terms of qualified labor, facilities, and technology. The prize could be a good option, but it would not be enough.

Policies should aim to strengthen research capacity and drug manufacturing in developing countries. This is not simply a matter of resources. This requires the political will to put these items on the public agenda and define R&D in drug manufacturing as a priority in government budgets. There are examples of developing countries that have done this successfully: Brazil, India, Cuba, and China. These are countries with a history of educating and training researchers in the field of biotechnology. In some cases, the key factor was not the availability of resources but rather the political will to have institutions capable of carrying out R&D.

We have proposed the creation of a Global Fund for R&D in Drugs. The fund would not award prizes; it would finance R&D carried out by public institutions in developing countries. Resources would be allocated to priorities determined by the health needs of the population. The fund would be financed by governments, primarily those of developed countries, and non-profit organizations.

First, this proposal would solve the problem of the lack of resources in developing countries. Secondly, the research agenda-setting would be set by governments. A legitimate fund would have governance structure in which all governments had a voice and a vote. This would ensure that research focuses on public health needs and not on the special interests of the market.

Strengthening public R&D and making governments responsible for the production of public goods would solve the problem of incomplete markets. It would no longer be necessary to use patents to make public goods private in order to encourage private industry investment. In this situation, the state is the most efficient producer. By increasing competition in the production of knowledge, private R&D is stimulated. Finally, new knowledge would be available to all and not just to the inventor. The lack of a monopoly on knowledge would avoid access problems associated with high prices and limited production.

The countries mentioned previously – Brazil, India, China and Cuba – have taken this path. They have strengthened and supported public health research institutions that have achieved more and higher quality outcomes than similar institutions located in developed countries. These experiences show that our proposal is not impossible.<sup>††</sup>

It is important to remember that basic research – the very initial identification of compounds for new drugs – is often carried out by the public and aca-

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<sup>††</sup> Examples of innovation coming from developing countries include the following: vaccines for Hepatitis B (Institute Nuntan, Brazil), Hemophilus influenza (Heber Biotec, Cuba), typhoid fever (Bharat Biotech, India), and an oral recombinant vaccine for shigellosis dysentery (Institute Lanzhou, China) as well as diagnostic tests for Chagas disease (Bio-Manguinhos, FIOCRUZ, Brazil), Hepatitis C (China), HIV (Cuba) and HIV-1/HIV-2 (India).

demographic sectors. However, these sectors have lacked the resources both to develop their discoveries as well as to apply them practically, i.e., in the development and manufacturing of a new medicine.<sup>8</sup>

## Conclusions

Knowledge is defined as a public good by two of its attributes: it is non-rival and non-exclusive. Knowledge can be enjoyed by anyone who benefits from its consumption without having to make a direct payment. Because of this attribute, the private pharmaceutical industry has no economic incentive to invest in R&D and, because of this, we see the emergence of global agreements on intellectual property rights and the granting of patents.

In the case of health and specifically in R&D in new drugs, this policy has been neither efficient nor equitable. Patents have not solved the problem of the presence of incomplete knowledge markets. On the contrary, they have created new problems without having solved the main one. The patents have led to the following:

1. The creation of legal monopolies by which private pharmaceutical companies now enjoy the exclusive use and commercialization of knowledge.
2. Research agendas and priorities are defined by the private pharmaceutical industry with regard to their interests and not according to health needs.

Privatization is not the solution to the problem of incomplete knowledge markets. The solution must focus on the public provision of the good. Governments around the world, in both developed and developing countries, must invest directly in R&D in health, as this would ensure that the final product (a medicine that results from new knowledge) can be enjoyed freely by all those who need it. It would also ensure that the research agenda is focused on addressing public health issues and not the interests of the researcher.

Having the state be responsible for research would require investment in education, training, and infrastructure. This will not happen overnight. But the sooner we start the journey, the quicker we will see the results. As such, we propose the creation of a

Global Fund for R&D in Drugs, which would be financed mainly by wealthier governments and donors, and whose resources would be directed toward the strengthening of public research institutions in developing countries.

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