Compulsory licensing Patients vs Patents?

The recent grant of India's first compulsory license has once again brought the patients vs patents debate to the fore. ***Viveka Roychowdhury*** *presents reactions to this watershed judgement*

Mortgaging the future of healthcare in India

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March 12, 2012 will go down in the annals of the healthcare history of India as a day when India issued the first compulsory license for a pharmaceutical product — Nexavar. For a long time now, the research- based pharma industry has been saying that access and affordability do not necessarily go hand in hand.

Today, 65 per cent of the Indian population does not have access to modern healthcare facilities leave alone medicines. Low cost medicines and generics do not address the wide variety of issues such as lack of diagnosis, healthcare infrastructure and inadequate distribution that prevent the poor from getting treatment. Existence of trained healthcare staff and infrastructure, cultural acceptability of treatment, accessibility of healthcare facilities and quality of care all play a role in making medicines available.

Compulsory licensing certainly does not address the underlying issues of access to medicines and healthcare. Such licenses issued in the absence of a public health emergency will serve to dramatically discourage investment in new medicines for patients and halt medical progress for the millions worldwide suffering from diseases without adequate or without any effective treatments. They in fact serve to erode intellectual property rights that are at the heart of innovation and will actually serve to stifle innovation to the long-term detriment of the Indian patient.

In fact, patents in general have little to do with the healthcare challenges that India faces. All the drugs on the list of essential medicines in India are off patent and yet access is a challenge. Furthermore, according to the World Health Organization, even the drugs that are off patent on this list are affordable to only 20per cent of the population. Overall, less than 1per cent of all drugs available in India are patented.

Equating “public interest” and “lowest possible price” for a compulsory license entirely overlooks the fact that this not only endangers the business model of research-based pharmaceutical companies, but the very existence of pharmaceutical research in general. Granting patent holders a limited period of marketing exclusivity makes it possible for them not only to recover costs associated with the research and development of new medicines, it also enables them to finance the research and development of future treatments. It is the patent system, and not its absence, that best serves the needs of the public. Giving up on this system inevitably means sacrificing new treatment options. Patents are by definition limited in time, and the effective patent term is also greatly reduced by long approval processes.

By the very nature of their operations, research-based pharmaceutical companies are not in a position to compete with generics manufacturers, given that R&D expenses are the primary factor that account for the price of new therapies. The price of manufacturing a medicine for a generics manufacturer, which excludes the substantial costs of R&D and of clinical trials, will invariably be lower than for a pharmaceutical company which must bear all these expenses and the risks associated with them.

The long road to innovative research in the pharma industry is fraught with risk. Consider that only five out of 5,000 experimental

compounds in development will reach clinical trials, and only one of those five – at a cost according to one recent analysis ranging from $4 to 12 billion for each medicine approved depending on the company – will reach the marketplace. Thus each successful molecule that makes it as a drug needs to pay for the thousands of those molecules that fail.

In the case of Nexavar, Bayer had a patient assistance programme in place right since the product was launched in India. The access program significantly reduced the medicine's price for qualified patients to a level well below that needed to cover the expenses associated with the research and development of Nexavar, or any other innovative drug. It improved access for those with limited economic resources while also calling on those with the means to contribute towards the actual cost of developing Nexavar and future innovative drugs.

The research based pharma industry fully supports provisions of the law when used judiciously and hopes that India will look to the long term without mortgaging the future for the present. We need a more comprehensive healthcare strategy – one that will see more public-private partnerships – one that will see all stakeholders working together to achieve the common good of the patient. We need a strategy where access programmes help those with limited economic resources while those with the means to do so contribute towards the actual cost of innovative drugs.

CL meets a political objective rather than solving the actual problem

Is price the only barrier faced by patients in India?

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Price is not the only barrier faced by patients in India. Access to all medicines is a formidable issue - even to over the counter generic generic medicines. Medicines which are free and part of Government programmes too do reach those who need them the most. Further, poor patients do not have access to even the most basic healthcare. In order to improve public health requires a collective long-term commitment is required from the government, healthcare providers, and others comprising the healthcare system, as well as establishment of infrastructure at the local level.

Will the CL solve the access problem?

No. CLs cannot solve India's larger problems regarding access to medicines and healthcare. Patented medicines form barely two per cent of the pharmaceutical market. CL therefore meets a political objective rather than solving the actual problem. CLs erode the central incentive of the patent system, the exclusive right, for the development of new medicines. The use of CLs thereby impedes the development of, and access to, new medicines over the longer term.

Should CLs be reserved for infectious diseases affecting mass populations and not conditions affecting smaller subsets of patients? Or would this be deemed discrimination?

The fact that issuance of CLs are lawful in certain circumstances does not mean that they are appropriate policy measures to use in any or all instances. CLs should be issued in rarest of rare cases and reserved for instances of public health emergencies and other urgent situations as per the Doha Declaration of TRIPS and Public Health.

In the case of the Nexavar CL, the drug was of a life extending nature and Bayer sold to 15 per cent of the patients as Cipla was

selling an infringing product at 1/10 th of the price in any case. It was also an orphan drug in the US and therefore provided additional incentives. These facts were not taken on board.

Will this CL discourage MNCs from launching new medications in India?

Adequate IP protection and enforcement are critical to engendering a robust and vibrant innovative pharma industry. The findings in the recent CL decision particularly that with regard to working of a patent is not compliant with India's TRIPS commitment (as well as its broader WTO obligations). The decision will have ramifications beyond pharmaceuticals and send a wrong signal to the international community. The research-based pharma companies will have less incentive to develop new medicines for Indian patients, knowing that getting a return on their investment will be difficult, if not impossible.

CL should not be invoked in an arbitrary manner as it will undermine the innovative efforts of this industry and consequently investment in this sector

Association of Biotechnology Led Enterprises

Association of Biotechnology Led Enterprises – ABLE, believes that CLs should be used only when there is a national health crises or when lifesaving drugs are priced out of the reach of a common man, i.e., under some exceptional circumstances. The Sovereign Government of any country would be obliged to provide affordable health care for all its citizens. Most times a Government invokes this only if drug companies do not consider purchasing power parity and per capita income of a country when they do a pricing strategy. In this case Bayer has submitted before the Controller of Patents a cost of Rs 280,000 a month as against Rs 8,800 by NATCO. Most multinational and Indian pharma companies spend millions of dollars and many man hours to save patients from life threatening diseases and therefore the intent of all these companies broadly is to alleviate suffering of people. However, several times, overseas companies price their drug based on who they think can purchase and do not take into account the millions who could be deprived of a treatment due to affordability. Governments are likely to interfere under such circumstances like when a few countries have invoked this provision for making available lifesaving HIV drugs to its people. India should always keep in mind that a CL should not be invoked in an arbitrary manner as it will undermine the innovative efforts of this industry and consequently investment in this sector.

Sorafenib (Nexavar) in 2009, was not approved by NICE for NHS use (http://en.wikipedia.org/wiki/Sorafenib) in view of the fact that it increased survival in primary liver cancer by only six months . This is an orphan drug in the US and generally such drugs are developed with generous support of the government. While on pricing it is obvious that there is a case on the overall utility of this drug which prolongs life by half a year the question is why should India invoke CL in the case of Nexavar? This is a question that will come up for considerable debate as to whether it is really a true lifesaving classification. In future before such rulings are invoked it might be a good idea to debate on the cost of goods versus the cost of innovation. If we put in mechanisms to compensate the companies which do innovation then the severity of such rulings will be quite considerably mitigated. At a time when the Indian Government has declared this as the Decade of Innovation, ABLE is concerned that the momentum and global image of India’s focus on innovation is not adversely affected by the ruling.

Can there be a ‘free lunch’ when an average NCE requires 12 years and $1.2 billion?

It appears that Government of India (GoI) has reached this considered decision after substantial homework. This is the first assertion by GoI in this field and it looks like the 'first salvo has been fired'. Nexavar appears to be a test case.

The Indian generics industry will be jubilant, if there is more compulsory licensing in the pipeline.

On a legal footing, GoI is strong. Legal battles appear inevitable. Therefore the Supreme Court hearing on March 28 for Novartis will be carefully watched by all stakeholders.

The popular perception in India is anti-multinational pricing. For example, there is a 'Boycott Novartis Campaign' in Karnataka.

The international pharma world, especially. MNCs will have reservations along these lines:

- What is in the long-term interest of research for new drugs?
- With Reganomics, government support for new discoveries has gradually faded. Who should do the job?
- Can there be a 'free lunch' when an average new chemical entity (NCE) requires 12 years and $1.2 billion? Who compensates for the drugs that failed or were banned? Will compulsory licensing make drugs affordable?
- India held out the promise of protection of IPR in 2005; is it rolling back this promise?

As a CRO, I am apprehensive about whether a genuine sponsor will have the patience to award business to a genuine Indian CRO, given the uncertainties looming on the legal horizon, including retrospective effect to legislation.

Government's actions in the last few months sends a clear signal to an international investor that he is not welcome

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When, after years of dithering, India enacted the product patent law in 2005, the research based pharma industry heaved a sigh of relief hoping that innovation will replace imitation. Little did they know that its enforcement in India is going to be very challenging. The protection of IPR is one of the key strategic drivers for the sustainable growth of research based pharma industry. To prevent abuse of the patent system, international patent laws have several in built safe guards and one such provision is compulsory licensing. However, such provisions have to be exercised in extraordinary circumstances such a national emergency and therefore should be used with extreme caution and also sparingly.

India has also gone one step ahead of the developed world by introducing section 3 (d) which limits patent protection to new form of a known substance unless it can be shown that it differs significantly in properties regarding 'efficacy'. The law also does not recognise data protection. With such provisions, the Indian patent law seemingly managed to strike a balance between need for innovation and public health.

Last month, Emcure Laboratories became the third pharma company to use the provision of open patent pool created by Medicines Patent Pool (MPP), a Geneva based NGO. MPP brings together big pharma which has a large portfolio of patents and generic companies which can officially copy patented anti HIV drugs to supply affordable HIV drugs to poor countries while paying a modest royalty to the patent holder. This is a win-win situation. But the Indian patent office, instead of choosing such a balanced approach, went ahead and granted a patent to NATCO through the CL route to manufacture sorafenib, an anticancer drug which is an original research molecule

of Bayer having a valid patent in India.

Interestingly, the battle between CIPLA and Bayer is already on for CIPLA producing a generic version of sorafenib. While NATCO promises to sell the drug for Rs 8800 for a monthly dose, CIPLA is already selling the drug at a price 3.4 times higher, at Rs 33000 making a mockery of the 'affordability' factor for granting CLs. Such actions have hardly any impact on access to life saving medicines.

Recently, the Swiss drug major Roche which has one of the richest pharma patent portfolios, signed a deal with Emcure to manufacture blockbuster anticancer drugs Herceptin and Mabthera in India. This is an innovative move to produce and market patented yet affordable drugs in India and at the same time deter other generic companies to enter.

But to manufacture such high tech drugs in India to conform to ambiguous definition of 'working of patent' is not always possible. Such drugs are not high volume and their manufacture is highly specialised and complex and it makes sense to manufacture such drugs in a dedicated facility with a state of the art manufacturing technology and which is a best cost producer rather than spreading its manufacture all over the world.

Unfortunately, the Government does not see the larger picture. The Government's actions in last few months sends a clear signal to an international investor that he is not welcome. It started with reversing the policy of 100 per cent FDI in pharma through automatic route by creating 'greenfield' and 'brownfield' categories, increasing span of price control from 74 to 348 drugs in the draft pharmaceutical pricing policy, planning to appoint a separate committee to control pricing of patented drugs and zero succession planning for important positions like DCGI. The last straw of course is the Fimance Minister reversing the Supreme Court judgment in the Vodafone tax case; and that too retroactively from 1962 in the recent budget.

"I must be cruel only to be kind," confessed the Finance Minister while presenting his direct tax proposal in the Union Budget. In the pharma context, cruelty at times knows no bounds. Forget about foreign investment, with such actions, even domestic players will think twice before investing in India especially in the pharma sector.

There is no sweeping right or wrong simply because there are many factors that are to be considered

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CL is a sensitive issue - while the most important priority will always remain quality healthcare at affordable prices, a profit motive is integral to the growth of any Industry. It is important for the man on the street to be able to afford life-saving medicines, but it is also important that pharma companies, which invest time, money and human resources to create these drugs, see value in research and development. Their cost, production, distribution and marketing should be offset by the sales. A middle-ground between the government's healthcare objectives and the well-being of the pharma company, in question, has to be reached. When it comes to a delicate matter such as this, there is no sweeping right or wrong simply because there are many factors that are to be considered; the therapy segment in question; the most important factor being availability of the drug – whether its freely available or not; number of players manufacturing and marketing the drug; current pricing of the drug, the kind of costs in terms of drug development that have gone in, amongst others.

To sum it up, while the pharma industry at large does have some

concerns about what the impact of CL could be, the fact remains that quality healthcare for the masses is the most significant criterion as far as we go. Pharma companies could alternatively explore the option of supplying drugs to the Government at discounted prices.

In India, where the cost of drugs is amongst the lowest in the world, time should be invested in creating the requisite infrastructure and access to quality healthcare which are bigger problems as compared to just focussing on talking about cost of drugs & regulating prices. Pharma drugs and their prices are but a very small part of overall national healthcare expenditure.

Battle far from over, likely to be agitated right up to the Supreme Court in India as well as at the WTO

Excerpts from Nishith Desai Associates' IP LAB analysis, dated March 21, 2012

This order marks a watershed in the development of jurisprudence of compulsory licensing, not only in India, but also in the international legal framework. There has not been significant interpretation of Arts. 7,8, 30, 31 of the TRIPs agreement, nor how it interplays with Art 27 (1) of TRIPs and Art 5 of the Paris Convention.

A more pragmatic approach to CL on a case by case basis is the approach taken by countries such as Brazil. Instead of private generic companies obtaining CLs, the Brazilian government studies which diseases need intervention from the State and uses the CL only as a bargaining tool to get the innovator companies to come to the negotiating table.

This case offers a lot of takeaways for innovator companies, especially pharma companies. One, is the importance of Form 27. Due care and diligence needs to be undertaken while filing the Form 27 and not treat it as a mere mechanical exercise. The second takeaway relates to the working requirement. If Bayer had been able to show a readiness and willingness to manufacture the drug, they may have been able to get an adjournment under Section 86. Pharma companies should take care to be able to demonstrate intention and willingness to make the patented product available in India. Of course, if the patentee does not view India as a market for its product on the assumption that the market will not be able to 'afford' its drug, then grant of a CL in relation to such drug does not have an economic impact on the patentee, in fact, patentee may get certain royalty from India. Innovator companies need to rethink their strategy especially if they plan to only sell and not manufacture for initial period.

What remains to be seen in relation to the present matter, is whether oncologists will consider only the reduced prices of generic versions of the drug while prescribing it to advanced stage liver / renal cancer patients. While Natco will sell the drug at Rs 8,800, it still has the task of convincing doctors about the quality and efficacy of its product.

The IPAB or the Supreme Court will need to determine what 'reasonably affordable price' means and whether 'worked' in the territory of India excludes importation, thereby necessitating that every patent holder needs to locally manufacture patented products in India. This battle is far from over. The interpretation of 'working' of a patent to mean 'local working' (local manufacture within India) is highly contentious. It is likely that this issue will be agitated right up to the Supreme Court in India as well as at the WTO.

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The Judgement should not discourage MNCs but make them look at the market more realistically

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The provisions relating to CL have been a part of the Indian patent system since inception but it is only on July 29, 2011 that the first application has come to be filed.

An application for grant of CL can be filed by any person interested who has the ability to work the invention to the public advantage and the capacity to undertake the risk in providing capital and working the invention after three years of the existence of the patent. The filing of the application is historic for it shows the coming of age of the Indian pharma industry which now has the ability to work the invention and also undertake the risk in providing the capital to work the invention. The provisions with respect to the grant of a CL are not limited to pharma inventions but all inventions for which patents are granted in India.

The very objective of patent law is to encourage inventions and to contribute to the promotion of technological innovation and to the transfer and dissemination of technology and the provisions relating to the grant of Cl are in furtherance of these objectives of the Patents Act.

A three-year period is granted to the patentee from the grant of a patent to take adequate steps to (a) satisfy the reasonable requirements of the public with respect to the patented invention; (b) make the invention available to the public at a reasonably affordable price and (c) to work the invention in the territory of India either by themselves or by appointing licensees. In case the patentee despite due diligence is unable to fulfill these obligations within three years the law provides for an extension of time. The patentee must however strive to fulfill these obligations or be faced with an application for the grant of a CL from a person competent to work the invention commercially.

The grant of the CL does not absolve the patentee of its aforesaid obligations. If the situation is not remedied within a period of two years from the grant of the CL by the patentee and the patentee is found faulting on any of the three aforesaid grounds, any interested person can file for the revocation of the patent.

Pricing is but one of the factors which can lead to the grant of a Cl. Access to pharma medicines is not based on price alone. Lack of trained staff and infrastructure facilities can be a problem (hampering) accessibility of good medical treatment. The grant of a CL at least ensures that the medicine will be available to the section of the public which is able to avail the benefits of the medicines.

The Judgement, should not discourage MNC from coming into the Indian market but on the contrary make them look at the market more realistically and after obtaining the patent to put in place a proper pricing, supply and manufacturing policy to the mutual benefit of all concerned.

CL can solve the problem of accessibility and availability of latest drugs

Is price the only barrier faced by patients in India?

Price invariably is the key problem faced by patients in India, as the patented products tend to be priced exorbitantly

Will the CL solve the access problem?

Daara Patel
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CL can solve the problem of accessibility and availability of latest drugs, if the patent holder is averse to making the drug available in India at a 'reasonably affordable price'. The CL will ensure that the generic manufacturer who is granted the CL provides the life-saving drug at a 'reasonably affordable price' to the needy patients and at the same time takes care of the 'reasonable royalty' to the patent holder as determined by the Patent Controller. The Patent Act does not envisage the grant of CL unless the product is not reasonably affordable.

Should CL be reserved for infectious diseases affecting mass populations and not conditions affecting smaller subsets of patients? Or would this be deemed discrimination?

CL should be made available for all drugs that address life threatening and life extending diseases, whether it is for mass population or smaller groups of patients. The objective here is to ensure that the latest therapies are made available and accessible to the needy patients in India, at an affordable price.

Will this CL discourage MNCs from launching new medications in India?

CL should not discourage, but encourage MNCs to provide affordable drugs. CL is conditional as the applicant has to prove that the patent is not worked in India even after three years from the time of grant of patent. Hence the patent holder, by right has the opportunity to work the patent in India, i.e., manufacture and sell the drug at a reasonably affordable price and still enjoy monopoly rights.

The proposition that CL be reserved for a certain type of disease or a class of patients would legally not be maintainable

Is price the only barrier faced by patients in India? Will the CL solve the access problem?

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The law provides that once a patent is granted, the patentee has certain obligations and non-performance of those obligations leads to certain results. When a patent is granted the patentee is supposed to work the invention and make it available to the public so that the public is benefited. If for any reason it is found that the reasonable requirements of the public in respect of the patented product or process is not satisfied, or not worked in India, or not available at affordable price, then the Controller may grant CL. It could also be granted if there are circumstances of extreme urgency or national emergency or if it is a case for export of product to a country having insufficient or no manufacturing capacity.

The provisions of CL as in Indian law are based on the flexibilities available in TRIPS and those made explicit through the Doha Declaration. So far, CLs that have issued in Thailand and Brazil have been based on public use and were decrees passed by the Government. Natco's recent appeal for CL represents the first case wherein the provisions of 'reasonable requirements' etc as under section 84 of the Patents Act has been tested. Of course, it will be subject to appeal before the Intellectual property Appellate Board. The hearing before the board may take place after the parties have completed their pleadings.

Hence, CL is not based merely on price and is not awarded to the generic company on that basis. All the factors are considered and

evaluated.

Should CL be reserved for infectious diseases affecting mass populations and not conditions affecting smaller subsets of patients?

In India right to health is as important as any other right. And the Parliament cannot distinguish between cancer and infectious disease and treat one or the other better. And if the patient base is smaller, it does not diminish the right to health of those patients at all. Hence, the proposition that CL be reserved for a certain type of disease or a class of patients would legally not be maintainable. And even otherwise, it is not correct.

Will this CL discourage MNCs from launching new medications in India?

MNC invest in research anyways. And they do file patents/applications regardless of what happens to one MNC or the other. But yes, they may have an impression that it is quite tough to obtain a patent. However, I believe this is more temporary than anything else. Same was with Gliveec.

If the Indian Government declares T2DM as an epidemic, then the WTO and TRIPS Article 31(b) allows India to adopt CL for the production of these drugs

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Diabetes mellitus has assumed epidemic proportions in India, which will have the dubious distinction of becoming the world's capital of diabetes by 2025.

At present metformin plus oral DPP4 inhibitors (alogliptin, linagliptin, saxaglipitin, sitaglipitin, vildagliptin), and GLP-1 analogues (exenatide, liraglutide, taspoglutide, albiglutide, lixisenatide) are the most appropriate therapy for T2DM. The major constraint is the high cost and affordability of the newer drugs, which are patented and it will take 20 years before the patent expires, and the cost comes down to an affordable level for the poor patients.

WHO (Geneva) has written to the Indian Health Minister that after the WTO/ TRIPS (World Trade Organization / Trade Related Intellectual Property Rights), acceptance in 2004 India should ensure necessary steps to continue to cater to the needs of the poorest countries of the world. TRIPS article 7 recognises that the protection and enforcement of intellectual property right should be conducive to social and economic welfare.

TRIPS article 8 on principles, empowers member countries to adopt measures to protect public health and nutrition and to promote public interest in sectors of vital importance and to prevent the abuse of IPR by the right holders.

BK Keayla, Convener National Working Group on Patent Laws has criticised the patent (Amendments) ordinance 2004 for ignoring TRIPS flexibilities and freedoms and Doha Declaration and options available, to suit powerful MNCs.

Retired Supreme Court Judge Krishna Iyer in a letter to the Prime Minister has pointed out "the failure to ensure essential safeguards in the key areas of public health, which clearly demonstrate the power of influence and the reach of MNCs to the corridors of power."

If the Indian Government declares T2DM as an epidemic, then the World Trade Organization (WTO) and Trade-related Intellectual

Property Rights (TRIPS) Article 31(b) allows India to adopt compulsory licensing for the production of these drugs in India with a four per cent royalty on sale to the patent-holder.

Since the patent holder company will have a ready market of 30 crore patients (which is beyond their wildest imagination) a profit–sharing arrangement will benefit both the drug company as well as the patients- a win, win situation for all.

The Association of Physicians of India, Diabetic Association of India as well as the Geriatric Society of India should approach the Prime Minister with this proposal forthwith. As Mahatma Gandhi said, "There is enough on this earth for every one's needs but not for every one's greed."

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Groundbreaking move sets precedent for overcoming drug price barriers

Médecins Sans Frontières (MSF) Access Campaign

"We have been following this case closely because newer drugs to treat HIV are patented in India, and as a result are priced out of reach. But this decision marks a precedent that offers hope: it shows that new drugs under patent can also be produced by generic makers at a fraction of the price, while royalties are paid to the patent holder. This compensates patent holders while at the same time ensuring that competition can bring down prices. More generic companies should now come forward to apply for compulsory licences, including on HIV medicines, if they can't get appropriate voluntary licences"

Dr Tido von Schoen-Angerer, Director, Médecins Sans Frontières (MSF) Access Campaign.

"This decision serves as a warning that when drug companies are price gouging and limiting availability, there is a consequence: the Patent Office can and will end monopoly powers to ensure access to important medicines. If this precedent is applied to other drugs and expanded to include exports, it would have a direct impact on affordability of medicines used by MSF and give a real boost to accessing the drugs that are critically needed in countries where we work. Behind this action is the idea that the public has a right to access innovative health products and they should not be blocked from benefiting from new products by excessive prices. If more compulsory licences are granted in this vein, the answer to the question of how to ensure affordable access to new medicines could radically shift."