Securing IP and Access to Medicine: Is Oncology the Next HIV?

An IMS Consulting Group White Paper on compulsory licensing and other risks to intellectual property rights in oncology
### Table 1 Timeline of compulsory licenses, threats and IP losses since 2001

<table>
<thead>
<tr>
<th>Year</th>
<th>Market</th>
<th>TA</th>
<th>Products</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>Brazil</td>
<td>HIV/AIDS</td>
<td>Stocrin, Viracept, Crixavan</td>
<td>Discount</td>
</tr>
<tr>
<td>2001-2003</td>
<td>South Africa</td>
<td>HIV/AIDS</td>
<td>8 ARVs</td>
<td>VL/Discount/None</td>
</tr>
<tr>
<td>2002</td>
<td>Egypt</td>
<td>ED</td>
<td>Viagra</td>
<td>CL</td>
</tr>
<tr>
<td>2004</td>
<td>Malaysia</td>
<td>HIV/AIDS</td>
<td>Videx, Retrovir, Combivir</td>
<td>CL</td>
</tr>
<tr>
<td>2002-2003</td>
<td>Zimbabwe</td>
<td>HIV/AIDS</td>
<td>All ARVs</td>
<td>CL</td>
</tr>
<tr>
<td>2004</td>
<td>Mozambique</td>
<td>HIV/AIDS</td>
<td>Epivir, Viramune, Zerit</td>
<td>CL</td>
</tr>
<tr>
<td>2004</td>
<td>Zambia</td>
<td>HIV/AIDS</td>
<td>Epivir, Zerit, Viramune</td>
<td>CL</td>
</tr>
<tr>
<td>2005</td>
<td>Argentina</td>
<td>Pandemic Flu</td>
<td>Tamiflu</td>
<td>VL</td>
</tr>
<tr>
<td>2005</td>
<td>Brazil</td>
<td>HIV/AIDS</td>
<td>Kaletra, Viread</td>
<td>Discount</td>
</tr>
<tr>
<td>2005</td>
<td>Ghana</td>
<td>HIV/AIDS</td>
<td>All ARVs</td>
<td>CL</td>
</tr>
<tr>
<td>2004</td>
<td>Indonesia</td>
<td>HIV/AIDS</td>
<td>Epivir, Viread</td>
<td>CL</td>
</tr>
<tr>
<td>2005</td>
<td>Taiwan</td>
<td>Pandemic Flu</td>
<td>Tamiflu</td>
<td>CL</td>
</tr>
<tr>
<td>2005</td>
<td>China</td>
<td>Pandemic Flu</td>
<td>Tamiflu</td>
<td>VL</td>
</tr>
<tr>
<td>2005</td>
<td>Korea</td>
<td>Pandemic Flu</td>
<td>Tamiflu</td>
<td>CL</td>
</tr>
<tr>
<td>2006</td>
<td>India</td>
<td>Oncology</td>
<td>Glivec</td>
<td>Patent rejected</td>
</tr>
<tr>
<td>2006-2007</td>
<td>Thailand</td>
<td>HIV/AIDS</td>
<td>Stocrin, Kaletra</td>
<td>CL</td>
</tr>
<tr>
<td>2007</td>
<td>Brazil</td>
<td>HIV/AIDS</td>
<td>Stocrin</td>
<td>CL</td>
</tr>
<tr>
<td>2007</td>
<td>Thailand</td>
<td>CVD</td>
<td>Plavix</td>
<td>CL</td>
</tr>
<tr>
<td>2007</td>
<td>Canada/Rwanda</td>
<td>HIV/AIDS</td>
<td>Apo-TriAvir</td>
<td>CL</td>
</tr>
<tr>
<td>2007-2008</td>
<td>Thailand</td>
<td>Oncology</td>
<td>Glivec</td>
<td>Discount</td>
</tr>
<tr>
<td>2007-2008</td>
<td>Thailand</td>
<td>Oncology</td>
<td>Taxotere, Femara, Tarceva</td>
<td>CL</td>
</tr>
<tr>
<td>2010</td>
<td>Ecuador</td>
<td>HIV/AIDS</td>
<td>Kaletra</td>
<td>CL</td>
</tr>
<tr>
<td>2010</td>
<td>India</td>
<td>HIV/AIDS</td>
<td>Valcyte</td>
<td>Patent revocation</td>
</tr>
<tr>
<td>2012</td>
<td>India</td>
<td>Oncology</td>
<td>Nexavar</td>
<td>CL</td>
</tr>
<tr>
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<td>India</td>
<td>HCV/HBV</td>
<td>Pegasys</td>
<td>Patent revocation</td>
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<td>2012</td>
<td>India</td>
<td>Oncology</td>
<td>Sutent</td>
<td>Patent revocation</td>
</tr>
<tr>
<td>2012</td>
<td>India</td>
<td>Oncology</td>
<td>Tarceva</td>
<td>Ruling allows generic</td>
</tr>
<tr>
<td>2012</td>
<td>Ecuador</td>
<td>HIV/AIDS</td>
<td>Kivexa</td>
<td>CL</td>
</tr>
<tr>
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<td>Indonesia</td>
<td>HIV/HBV</td>
<td>7 ARVs</td>
<td>CL</td>
</tr>
<tr>
<td>2013</td>
<td>India</td>
<td>Oncology</td>
<td>Herceptin, Sprycel, Ixempra</td>
<td>CL initiated</td>
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Securing IP and Access to Medicine:
Is Oncology the Next HIV?

Developed countries were plagued by a growing epidemic with high mortality, as curative treatments had yet to be developed. Pharmaceutical manufacturers responded by investing in effective treatments, which helped to quell the epidemic. However, incidence and mortality in developing countries continued to rise, until the disease became one of their biggest killers. Most patients could not get the new treatments as they could not afford their cost. These countries were forced to find new ways to provide access to life-saving or life-prolonging therapies. Attempts by governments to cut prices were resisted by manufacturers, who had invested significantly in development. Manufacturers were concerned with maintaining the incentive for future innovation and protecting their prices in developed countries.

When developing countries could not reach agreement with manufacturers on prices, several resorted to compulsory licensing. Generic manufacturers were keen to take on these licenses as they could make a profit without investing in R&D. Civil society organizations such as Médecins Sans Frontières (MSF) and patient associations also welcomed the breaking of patents to provide broader access. Generic manufacturers and civil society organizations even collaborated to advocate for compulsory licenses.

Pharmaceutical manufacturers responded in two ways. First, they engaged with developed country governments to convince developing country governments to reverse compulsory licenses and protect their intellectual property. Second, they argued that healthcare financing, infrastructure and market imperfections, such as doctors and hospitals selling medicines to patients and not passing on manufacturer discounts, were more important barriers to access than price.

Neither of these responses was successful. Afraid of the public backlash from Non-Governmental Organizations (NGOs) and unwilling to be seen as supporting denial of access to life-saving or life-prolonging treatments, developed country governments offered only tepid support. Developing countries acknowledged the other barriers but did not agree that these needed to be fixed before addressing prices. They therefore issued compulsory licenses or used compulsory licensing as a threat to obtain lower prices.

Pharmaceutical companies were faced with the choice of either forgoing their intellectual property rights or collaborating with governments and third party organizations to provide broader access. Many companies decided to address the problem of access by following a set of strategies – differential pricing across countries, tiered pricing within countries, patient assistance programs, voluntary licensing to lower cost manufacturers, and partnerships with governments and international organizations – to tackle both the affordability issue and other barriers such as infrastructure, technology, awareness and education. This resulted in broader access and was
successful in bringing down incidence and prevalence in many developing countries, while reducing further infringements of intellectual property.

Most readers will recognize this as the story of HIV/AIDS. But drawing on the parallels between burden of disease, emotional impact and lack of access in developing markets, HIV/AIDS could potentially be replaced with cancer and the story would read comparably, except for the final piece: governments, manufacturers, and third party organizations have not yet found an access solution that protects intellectual property.

This paper looks at how compulsory licensing and other forms of patent denials are spreading beyond HIV/AIDS. It argues that while this has so far been limited to a handful of countries, there is a real possibility that patents will come under greater pressure, especially in oncology, which is becoming one of the leading causes of mortality in developing countries. The paper concludes with a discussion about possible solutions.

**Compulsory licensing and patent infringements are spreading beyond HIV/AIDS**

Subsequent to the Doha Declaration in 2001 (see Box 1), several countries used compulsory licensing, or the threat to use it, to increase access to HIV/AIDS drugs at more affordable prices. Brazil used the threat of compulsory licensing to obtain discounts for drugs such as Stocrin, Viracept, and Crixavan. This was followed by developing countries in Asia, Latin America, and Africa using compulsory licenses or threats to obtain cheaper access to anti-retroviral drugs (see Figure 1 and Table 1). Until the middle of the last decade, the use or threat of compulsory licensing was largely limited to HIV/AIDS. The only exceptions were temporary compulsory licenses for flu epidemics in China, Taiwan, Korea, and Argentina, and a one-off compulsory license for Viagra in Egypt.

Compulsory licensing started spreading to other therapy areas outside of HIV/AIDS and pandemic flu beginning in 2007, when Thailand authorized a

**Figure 1** The spread of compulsory licensing and IP infringement beyond HIV/AIDS

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Sources: See Table 1
compulsory license for Plavix, citing the importance of the therapy and the government’s inability to cover the cost of the branded drug. While this first non-HIV/AIDS or pandemic flu compulsory license was for a cardiovascular drug, recent compulsory licenses have mainly been in oncology. In 2007-2008, Thailand issued compulsory licenses for Tarceva, Femara, and Taxotere, stressing the high prevalence of lung and breast cancer in Thailand and the inaccessibility of adequate treatment. This has been followed by the granting of a compulsory license for Nexavar in India in 2012, and the initiation of a process for compulsory licensing Herceptin, Sprycel, and Ixempra in 2013. These decisions demonstrate how countries interpret the Doha Declaration in determining what constitutes a public health emergency. It is not just about ensuring adequate supply of treatment in a pandemic situation; lack of access due to affordability has also become a factor in determining when compulsory licenses can be issued.

Compulsory licenses are not the only form of post-TRIPS denial of intellectual property to grant access to innovative and expensive medicines. The patent office in India has also used a much stricter standard of innovation to either reject or revoke patents for several cancer drugs including Glivec, Sutent, and Tarceva. Compulsory licensing and other IP denial decisions have been challenged by manufacturers in the courts. However, these cases take several years to conclude as the decisions are appealed to the highest courts, during which time generics are available in the market.

There are two ways of interpreting these recent trends in compulsory licensing. On the one hand, as the instances of compulsory licensing and other forms of IP denial are still relatively rare, they do not pose a serious threat to the pharmaceutical industry. On this basis, the response of the industry should be mainly limited to contesting these decisions in the courts and lobbying the US and EU governments for stronger IP protection globally.

The alternative – and the view taken by this IMSCG paper – is that these decisions are harbingers of a more fundamental shift for the industry. This is especially the case in oncology, where the large disease burden, high emotional impact, typically high prices, and often limited therapeutic alternatives, put pressure on governments to facilitate access by denying IP rights.

To ensure the protection of its intellectual property, the industry’s response will need to be broad-based and multi-faceted, with new models of engaging and collaborating with governments and other stakeholders to deliver access to novel treatments in areas of high unmet need in commercially sustainable ways.

**Increasing demand for access to medicine puts pressure on patent protection**

Many developing countries have achieved or are moving towards universal health coverage. Countries
such as Brazil, China, Mexico, and Thailand have already achieved universal coverage through a mix of government and employer insurance schemes. Indonesia and South Africa are implementing universal coverage and India aims to achieve this by 2022. While this is being achieved by increasing the financial resources available for healthcare, funding is still stretched to limit coverage to basic or essential treatments in most cases. This means that public coverage reimburses mainly essential medicines, which are mostly generic.

These countries also have a growing middle class which is increasingly connected to the rest of the world through ubiquitous information technology and is consequently aware of new treatments that are available globally. This is creating a demand for such treatments in these markets. This middle class can afford some novel retail treatments such as oral anti-diabetics but patients typically find high-cost specialty treatments unaffordable, particularly in oncology. The middle class, often the most politically active class, then puts pressure on governments to obtain access to these drugs. While some developing countries aim to provide such treatments through universal coverage, they place a high cost burden on the healthcare system. In other countries, where these drugs are paid for out-of-pocket, there is often patient frustration at unaffordable prices. In both circumstances, the government faces the challenge of obtaining lower prices.

This pressure on price is expressed through local politicians, patient associations, and NGOs, as well as international organizations such as Médecins Sans Frontières. When prices remain unaffordable in areas of high unmet need, these stakeholders then resort to, or advocate for, patent denials or compulsory licensing to achieve affordable access through generics. As noted by Michelle Childs, Director of Policy and Advocacy at MSF’s Access Campaign, the decision for Nexavar in India “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.”

**Local profit from generic supply reinforces the pressure to infringe IP**

The pressure on IP from the demand side is complemented by pressure from the supply side. Generic companies see a profit opportunity from satisfying the unmet demand for high-cost treatments with low-cost generics. As the Nexavar case in India shows, generic companies are able to provide these treatments at a fraction of the originator’s price. This has led to generic companies seeking voluntary licenses to manufacture generic versions of new high-cost treatments, especially in India. In the absence of branded manufacturers voluntarily providing licenses, generic companies petition patent authorities to either challenge the validity of patents or to demand the issuance of compulsory licenses. For example, Natco Pharmaceuticals originally applied for a voluntary license to manufacture a generic version of Bayer’s Nexavar. After Bayer refused a voluntary license, Natco applied for a compulsory license in India.

In addition to formally seeking patent invalidation or compulsory licenses, generics companies also lobby for weaker IP protection. This is especially effective in countries with a strong domestic generics industry, as their case is not only supported by health stakeholders but also by industrial policy stakeholders. Often the generic companies and civil society organizations are part of the same side challenging the patents of originals. The Sankalp Rehabilitation Trust, a Mumbai-based civil society group, partnered with Wockhart Ltd, an Indian generics manufacturer, to successfully challenge Pegasys’ patent in India. It said: “The absence of a patent barrier will spur generic competition to bring down the price of this much-needed drug for those suffering from Hepatitis C.”

**A perfect storm is brewing in oncology**

The two complementary pressures from demand and supply of novel treatments are coming to a head in oncology. These pressures define two key criteria to assess the risk of a therapy area from being targeted for IP infringement (see Figure 2).
The first criterion is the need for access to medicine which depends on two factors:

- **Disease impact**: The impact of a disease can be seen in terms of how it affects patients, caregivers, and society. Diseases with high morbidity and mortality have a substantial effect on patients and caregivers and can therefore be said to have a higher need for access to effective medicines. If the disease affects a large number of people, then this need is even more pronounced. Further, diseases with high and relatively immediate mortality rates also have a huge emotional impact, thereby increasing the pressure for access to innovative medicines.

- **Lack of alternatives**: The need for access to medicine is also increased if there are no effective treatments in the therapeutic area. In such a situation, especially in diseases with a high prevalence and therefore a high burden of disease, the need for access to new medicine is high. Although some oncology agents may only extend life for a few months, the lack of alternatives and high burden of disease causes pressure for governments to increase access to therapies and for oncology agents to be made more affordable to patients.

The second criterion is the potential profitability from patent denial, which can be similarly distilled down to two factors:

- **Price**: The higher the price per patient of a product, the larger the profit incentive from arbitrage. The margin is likely to be higher in generics than in biologics, but it is likely to be large enough in both cases for generics companies with the required capabilities to seek patent denials.

- **Volume**: For similar price levels, disease areas with higher numbers of patients offer larger profit incentives. As a result, generics companies are likely to invest in advocacy for patent denial or compulsory licenses in diseases with higher incidence than in orphan ones. The pressure is therefore likely to be higher in oncology indications with higher incidence. However, given that several oncology agents are used across indications, the combined volume opportunity may also increase the pressure.
Orphan diseases, while potentially having a high disease severity and a lack of alternative therapies, have a relatively low impact on the total population in a given market and low volume. This reduces access to medicine pressure on the government, as well as the profit opportunity for generics manufacturers. As a result, rare diseases are at low risk for compulsory licensing or patent infringement.

Short-term epidemics such as flu outbreaks can lead to temporary compulsory licenses, as seen in 2005 with Tamiflu in Taiwan and Korea, and voluntary licensing of the product in Argentina and China. However, a lack of long-term volume potential limits the use of such products and therefore limits IP risk to temporary cases of pandemic outbreaks. In this case, compulsory licenses are invoked to ensure supply rather than lower prices.

Drugs for chronic conditions such as diabetes and cardiovascular disease may represent a more attractive area for generics suppliers. However, the wide range of generics available within these disease areas generally meets the demand and consequently the risk is likely to be limited in most cases. There could, however, be isolated circumstances in which drugs deemed of high clinical value compared with existing therapeutic alternatives are targeted. This was the case with Plavix in Thailand where a compulsory license was issued. As treatments in these diseases become more commoditized with increasing competition, the level of risk for patent denial and/or compulsory licenses is further reduced.

Oncology, particularly high prevalence tumor types and/or products demonstrating high incremental value, along with HIV/AIDS and potentially hepatitis C and B, can be considered high risk from both an access and profitability perspective. Although successes in early diagnosis and treatment have led to a reduction in mortality in developed markets, cancer is still an area of high unmet need. In 2008, 13% of deaths globally were caused by cancer. Additionally, assuming cancer rates remain stable, the estimated incidence of cancer globally is projected to rise from 12.7 million cases in 2008 to 21.4 million in 2030, highlighting the growing pressure faced by expanding and ageing populations.

Sources: WHO Globocan 2008 data; ranking based on classification groups defined within WHO Burden of Disease study 2011 NB. Maternal deaths exacerbated by HIV/AIDS not included in analysis

**Figure 3** Oncology one of the largest killers in emerging markets

![Estimated deaths by cause 2008](image)
Moreover, emerging markets are expected to suffer disproportionately. A total of 70% of all cancer deaths already occur in low- and middle-income countries, where populations are high and access to innovative treatments low. Cancer is ranked in the top four leading causes of death in 10 out of 11 key emerging countries; India is the only exception, where it is ranked sixth (see Figure 3). Additionally, the estimated percentage increase in cancer incidence by 2030, compared with 2008, will be greater in low- (82%) and lower-middle-income (72%) countries compared with upper-middle- (58%) and high-income countries (40%). By 2020, the cancer mortality rate in the developing world could be five times that found in developed countries, representing a major burden to healthcare systems and resulting in increasing demand for access to treatments.

Within oncology there are a large number of high-priced products with relatively few lower-priced competitors that provide comparable efficacy. The high cost of oncology agents makes them unaffordable to both cost-constrained governments and patients. This contrasts with areas such as cardiovascular disease or diabetes, where competition is generally high and prices are manageable. As governments in emerging markets increasingly finance pharmaceutical expenditure, particularly for hospital products, the pressure to fund oncology drugs – and the pressure on government budgets – will increase. As a result, oncology therapies could be at risk of IP denial as governments seek to expand access in the face of insufficient funding.

A further consideration is that the specialized capabilities required to manufacture biologic therapies, including oncologics, is likely to be beyond the reach of many generics manufacturers. Consequently, advocacy by generic manufacturers for patent infringement of biologic oncologics may be lower than for small molecule oncologics. However, this is likely to change as companies in countries like India, China, and Brazil develop biosimilar capabilities.

Country risk is driven by pressure and willingness to deny patent protection

The pressure for a country to use compulsory licensing is also a crucial measure to understand risk to IP in that country. Countries with fully functioning pricing and reimbursement systems, such as Taiwan and South Korea, are able to control prices of drugs to ensure access. They therefore tend not to rely on compulsory licensing, even though they are unlikely to drive prices as low as would be the case if they denied IP rights.

In countries with limited or inadequate pricing and reimbursement systems, compulsory licensing or IP denial is an easier tool to obtain access – especially in private market segments. The pressure for compulsory licensing is also higher in countries with a strong local generics industry, such as India, Brazil, and South Africa, where the supply side can lobby for IP infringement. Countries susceptible to strong societal pressures, for example from strong NGOs, may also present a higher risk to intellectual property rights.

A country’s willingness to deny IP can be judged on its historical record and by its susceptibility to international pressure from developed country governments (see Figure 4). This pressure can be applied during bilateral or multi-lateral negotiations, such as the negotiation of free trade treaties. Generally, smaller countries and countries more dependent economically or politically on developed countries are more susceptible to international pressure. South Africa and Brazil, for example, have been more prone to use IP denials in the past, though India and Thailand have invoked compulsory licenses in non-communicable diseases, which could indicate a higher IP risk to companies in the future. At the risk of generalization, they are also independent-minded countries with relatively limited susceptibility to international influence.

India, which only introduced patent protection for pharmaceuticals in 2005, has demonstrated its willingness to use compulsory licenses where it feels the patent system is restricting access. India’s lack of
decisions in courts, based largely on the interpretation of when compulsory licenses can be used. This response, while necessary, has limited impact for the following reasons:

- Court cases take several years to resolve, by which time the commercial impact of even a favorable resolution will be limited as the product may be nearing the end of its patent life. The damages awarded, if any, are likely to be too small to compensate for lost revenues. For example, Glivec's patent was initially denied in India in 2006. Novartis' appeal did not occur until late 2012, with results anticipated in Q1 2013.

- Manufacturers may not win the legal fight if the treatment is seen by courts as life-saving or life-prolonging, or delivering a high incremental benefit versus alternatives.

So far, industry's attempts to address the issue are inadequate

The pharmaceutical industry has responded in five ways to the issue of compulsory licensing and IP risk:

1. Legal challenge: Manufacturers have challenged compulsory licensing and other IP infringement
where cheaper alternatives do not exist, especially in the case of life-saving or life-prolonging treatments.

4. Stressing the importance of IP protection for future innovation: Companies argue that by issuing compulsory licenses or infringing on IP, countries are reducing incentives for investment in innovation and new treatments. While this argument is important, it has limited applicability because if affordability challenges prevent countries from enjoying the benefits of current or past innovation, it is unlikely that they will sufficiently value future innovation.

5 Communicating risk of investment flight: Manufacturers have also argued that weak IP protection and the issuance of compulsory licenses could lead to capital flight in the pharmaceutical industry. This argument has also not worked because:

- There is limited or no evidence of capital flight due to compulsory licensing.
- As emerging markets will provide an increasing share of sales in the future, the pharmaceutical industry will need to expand in these markets to ensure future growth.

A coordinated and collaborative approach including non-industry stakeholders is required to address the issue

To ensure the long term protection of IP in emerging markets, patients must gain access to innovative therapies. The pharmaceutical industry must therefore do its bit to increase access. However, it must also emphasize that it does not bear sole responsibility for providing access to medicine. Governments and other stakeholders need to do their part too.

As the case of HIV/AIDS shows, almost all manufacturers have developed strategies to increase access to their therapies in developing countries. Crucially, manufacturer initiatives have been supported by coordinated efforts from both governments (developing country governments and developed
country programs such as the US President’s Emergency Plan for AIDS Relief) and third-party organizations (such as UNAIDS and The Global Fund) to support access in this area, especially through increased financing and improvements in the treatment delivery infrastructure. A similar effort in oncology is likely to be required. To do this, each of the three sets of stakeholders must do their part (see Figure 5).

**Pharmaceutical companies**

Pharmaceutical companies can implement tiered or differential pricing strategies to improve access. Flexibility in a global pricing strategy can help to ensure adequate access to medicine in all markets. Some manufacturers have opted for a country-by-country approach, making price reductions where required or when requested by payers to secure reimbursement. For example, Roche has partnered with Emcure, an Indian manufacturer, to launch lower-priced versions of Herceptin and MabThera to proactively increase access to these therapies. However, the government still seems set on going down the path of compulsory licensing Herceptin. But if Roche’s efforts increase access substantially, then the government may find it more difficult to get a compulsory license approved and maintained legally. It would also find it harder to defend this decision internationally.

Others have set a broader corporate strategy to aggressively discount across developing countries in order to increase accessibility, drive volume sales, and reduce the risk of compulsory licensing. This strategy is perhaps most clearly demonstrated by GlaxoSmithKline, which caps the prices of its patented products at 25% of the UK and US prices in the least-developed countries and makes them more affordable in middle income countries such as Brazil and India, including oncology products like Tykerb.

Improving patient assistance schemes is another way to increase access by providing an overall discount on the net price for a course of treatment to low-income

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**Figure 5** A new collaborative approach could redefine the challenge

![Figure 5 Diagram](image)
segments of the population. Many manufacturers already operate some form of patient access program, though the number and extent is limited. One of the more extensive oncology programs is Novartis’ Glivec International Patient Assistance Program (GIPAP). The launch of GIPAP in Thailand prevented the issuance of a compulsory license. Mongkol Na Songkhla, the Minister of Health at the time, concluded: “Such a positive offer [did] not warrant the department to issue compulsory licensing for the drug,” and urged other manufacturers to follow Novartis’ lead.

Governments
The task of improving access is not the pharmaceutical industry’s alone. To complement supportive and philanthropic initiatives by manufacturers, governments must also push to improve financing mechanisms for oncology drugs. As specialty agents will remain out of reach for patients in low and middle income brackets even if significant price cuts are provided, financing support remains a pre-requisite for access for many patients.

Without governments providing some form of reimbursement or encouraging private insurance for high cost medicine access, lowering prices will not sufficiently facilitate access to those in need. Even governments with limited financial resources can explore new ways of financing catastrophic treatments through the creation of special funds, incentivizing or mandating individual health savings accounts, and focusing public healthcare financing on lower income population segments, while mandating private insurance for middle and upper income population segments. In addition, governments also need to address health infrastructure issues, which are especially challenging in a complex disease area like oncology.

Rellying on patent denial as a primary tool to provide access can be counterproductive in the long run to future patients who will need continued innovation in all countries. While governments have a legitimate concern for increasing access to innovative treatments, they need to do this in a balanced way, where they work with industry and other stakeholders to address issues of affordability in a collaborative way that ensures access while maintaining the incentives for continued innovation.

Third party organizations
Finally, third-party organizations such as private insurance, and national and international NGOs also have a pivotal role to play. Private insurance can increase the healthcare coverage in a country at least to the middle and upper middle income segments, especially if a developing country does not have the financial resources to provide universal healthcare coverage.

NGOs can help with providing financial assistance for both poorer countries and poorer segments of a country’s population, especially those who cannot afford premiums for private insurance. In addition to increasing funding for healthcare, third parties can also assist in areas including technology transfer initiatives – such as cold chain capabilities – improving health infrastructure, and increasing awareness.

Conclusion
Increasing IP risk means that rethinking existing approaches to pricing and access in emerging markets has now become an imperative. This is reinforced by the fact that these markets are also critical to the commercial future of the pharmaceutical industry. Some companies are realizing the dual imperatives of commercial growth and increased access to medicine and are already investigating new commercial and access models.

Given that the pharmaceutical industry needs to proactively adopt new models, a key focus of IMS Consulting Group is to assist companies in developing new growth-oriented, commercially sustainable strategies for increasing access to medicine in emerging markets.
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UK
Raja Shankar, Principal
rshankar@imscg.com
+44 203 075 4000

Katja Berg, Senior Principal
kberg@imscg.com
+44 203 075 4000

AUTHORS
Raja Shankar
Elizabeth Kinsey
Pete Thomas
Joel Hooper
Sheliza Tejani

EDITOR
Neil Turner, Senior Manager
nturner@imscg.com
+44 1223 273430