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FEATURED Q&A

Should Drug Makers Refrain From Filing Some Patents?



GlaxoSmithKline has expressed hopes that its decision will allow independent companies to make versions of its pharmaceuticals for use in poorer countries. // File Photo: GlaxoSmith-Kline.

Q GlaxoSmithKline announced in March that it will not file patents in some of the world's poorest countries in order to make it easier for manufacturers in those locations to copy its pharmaceuticals. What factors drove the company to shift its position on patents and intellectual property protection? Should other drug companies follow suit? What will be the effect of GSK's decision on public health in developing countries including in Latin America? How will the decision affect the company's business?

A Andrew I. Rudman, managing director at ManattJones Global Strategies: "GlaxoSmithKline's announcement that it will no longer file patents in some of the world's poorest countries underscores its commitment to improving access to its life-saving medicines in the poorest countries of the world. The decision not to file for patents will eliminate one aspect of the access to medicines challenge. However, in Latin America, access to innovative medicines is far more likely to be hampered by slow regulatory review timelines and/or delays in gaining inclusion on national drug formularies. Even if not protected by a patent, innovative products will still be subject to a regulatory review regarding their safety and efficacy. While some countries are moving toward regulatory harmonization schemes to accelerate this process—such as the seven countries that accept Mexican regulatory approvals—regulatory reviews, even of products already approved in the United States, Europe or Canada, are often extremely slow. The absence of a patent filing will not remove these impediments to improved patient access. Once a product receives regulatory approval, it must be includ-

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TODAY'S NEWS

POLITICAL

Brazil Senate Forms Impeachment Committee

Brazil's Senate formed a committee to weigh whether to proceed with the impeachment of President Dilma Rousseff. If the full Senate votes to impeach Rousseff, she would have to temporarily step down during a trial.

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BUSINESS

Codelco Scaling Back Plans for Rajo Inca Mine

The world's largest copper producer is planning to scale back its plans for the project in an effort to extend the mine's life amid a fall in prices for the metal.

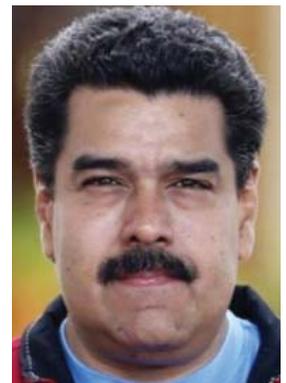
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POLITICAL

Venezuela's High Court Blocks Effort to Shorten Maduro's Term

Justices ruled that a proposed constitutional amendment to shorten the presidential term could not apply retroactively.

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Maduro // File Photo: Venezuelan Government.

POLITICAL NEWS

Brazil's Senate Forms Impeachment Committee

Brazil's Senate on Monday selected members of a committee to determine whether to impeach President Dilma Rousseff, Bloomberg News reported. The committee's formation is the Senate's first major step in the process, which may result in Rousseff being removed from office. The committee, which includes representation from several political parties, is made of up 21 members and is scheduled



Rousseff // File Photo: Brazilian Government.

to select its president and rapporteur when it holds its first meeting today. Committee members have 10 days to hear arguments in Rousseff's defense and recommend to the full Senate whether to proceed with an impeachment trial. A simple majority vote by the Senate is needed in order to put Rousseff on trial in the chamber, during which she would have to step down temporarily as president. Surveys released by local media show that there is enough support in the Senate to proceed with a trial. Once Rousseff temporarily steps down from the presidency, she will have a more difficult time convincing legislators to side with her, Rafael Cortez of Tendencias Consultoria, a São Paulo-based consulting firm, told Bloomberg News. "Once she's forced to step aside—even temporarily—she loses her bargaining power," he said. "Parties will cozy up to the transition government in her absence." At lawmakers' current pace, Rousseff could be removed from office as early as May 12. Rousseff has vowed to fight to remain in office and has said she might

appeal the process to the Supreme Court. Rousseff's government is officially accused of improperly manipulating the country's budget ahead of her re-election in 2014. She denies wrongdoing. Rousseff's critics have also argued that the president has mismanaged the economy, and her popularity has also been hit by anger surrounding the massive corruption scandal at state-run oil company Petrobras, in which she has not been charged.

Venezuelan Justices Reject Bid to Cut Short Maduro's Term

Venezuela's Supreme Court has rejected a proposal by the opposition-controlled National Assembly to cut short President Nicolás Maduro's term through a constitutional amendment, BBC News reported. The justices ruled that while the proposed amendment to shorten the presidential term to four from six years is constitutional, it could not be applied retroactively to Maduro's current term. The opposition has considered several ways to oust Maduro. Venezuelan law allows presidents to be recalled halfway through their terms through a referendum, and Maduro's term is half over as of today. If a recall referendum is held this year and Maduro loses it, a new presidential

“**The recall referendum has to be this year. If it's not this year, there's no point.**”

— Henrique Capriles

election would be called for. However, if Maduro leaves office during the last two years of his term, then Vice President Aristóbulo Istúriz would take power. "The recall referendum has to be this year. If it's not this year, there's no point," said opposition leader Henrique Capriles. Maduro's popularity has fallen amid several economic problems, including a deep recession, triple-digit inflation and shortages of basic goods.

NEWS BRIEFS

Mexico Has Hindered Probe of Missing Students: Human Rights Panel

Members of an independent panel created by the Inter-American Commission on Human Rights to investigate the disappearance of 43 Mexican college students in 2014 say the government has hindered them from completing their assignment, CNN reported today. "The Inter-American Commission deeply regrets the Mexican government's decision of not supporting, of not extending our mandate in spite of the fact that our objectives remain unfinished," said James Cavallaro, the commission's president. Panel members accused the government of undermining the probe by preventing them from re-interviewing suspects, not giving them access to key information and ignoring investigative angles that experts had suggested.

Colombia's Santos Names New Cabinet Members

Colombian President Juan Manuel Santos on Monday named seven new cabinet members whom he said would help guide the country toward peace as the government seeks to conclude its peace talks with the FARC rebels, EFE reported. Among the new ministers are Jorge Londoño as justice minister and Clara López as labor minister. Cabinet members including Finance Minister Mauricio Cárdenas and Foreign Minister María Ángela Holguín are remaining in their posts.

Chile's Codelco to Scale Back Rajo Inca Plans

The world's top copper producer Codelco will scale back its plans for its Rajo Inca project, intended to extend the mine life of its Salvador deposit, and will make an investment decision within two years, CEO Nelson Pizarro, said Monday, Reuters reported. Codelco is cutting spending by \$6 billion over the next five years as a reaction to the drop in copper prices.

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ed in the national formulary of the public health system (the list of drugs purchased by the state for use in the public health care system), on which most of the population depends. This process is often bureaucratic, non-transparent, and unpredictable. Unless national health systems improve their procedures for regulatory approval and access, GSK's decision, likely to be emulated by other pharmaceutical companies, will have a far more limited impact than desired. National governments need to make a comparable commitment to improving and accelerating patient access if GSK's decision is to have tangible benefits for patients."

A **Nuria Homedes, associate professor at the School of Public Health at the University of Texas:** "In view of the conflict between intellectual property (IP) protection and access to medicines, United Nations Secretary-General Ban Ki-moon convened a High-Level Panel on Access to Medicines 'to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technology.' The panel received 170 proposals. Two were from GlaxoSmithKline (GSK) denying the conflict, asserting that IP protection is indispensable to innovation, and proposing business models that expand access while leaving IP intact, such as the public-private partnerships and tier pricing. The announcement on March 31 prior to the Panel's meeting is consistent with the company's IP position, by Andrew Witty, GSK's CEO and member of the High Level Panel on Access to Medicines. It might be aimed at maintaining the status quo while distracting attention from other proposals that seek to increase innovation and access by revising the current IP system, such as delinking the research and development efforts from pricing. GSK's promise not to file patents in low-income countries is of little or

no consequence, because the World Trade Organization committee on IP rights will not enforce IP protections in these countries until 2033. The lower middle-income countries eligible to benefit from GSK's licenses for generic production in exchange for a small royalty based on sales have limited or no capacity to produce generics. The only Latin American countries included in the latter category are Bolivia, El Salvador, Guatemala, Honduras and Nicaragua (just over 6 percent of Latin America's population). The rest of Latin America, G-20 member countries, all upper-middle-income and high-income countries will be unaffected. Thus, the impact on the company's bottom line will be negligible."

A **Peter Maybarduk, director of the Access to Medicines group at Public Citizen:** "Pharmaceutical companies often make more money selling at high prices to the few rather than affordable prices to all. Most countries ration access to the medicines that people need. The problem is worse in countries with fewer resources or higher income inequality. Many people needlessly suffer or die. GSK's announcement moves the company cautiously toward a less-extreme business model, one that does not rely purely on monopolies everywhere and on rationing access. The policy will limit patent barriers in low- and lower middle-income countries, allowing some additional competition. Generic competition has consistently proven to be the most effective means of reducing medicine prices. GSK's new policy makes a modest but symbolically important contribution. Perhaps most significant is GSK's commitment to licensing its future cancer treatments to the Medicines Patent Pool. Many companies routinely charge \$100,000 per person for new cancer drugs. Making cancer treatment affordable in Latin America will depend in part on ending monopolies and applying some of the same access policies that countries have used for HIV/AIDS. GSK and other companies consider

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ECONOMIC NEWS

Argentina May Allow Pension Manager to Sell Some Assets

Argentine President Mauricio Macri's government is considering submitting a bill to Congress that would allow state pension manager Anses to sell as much as 70.6 billion pesos (\$5 billion) worth of shares in publicly traded companies, according to a source familiar with the plans, Bloomberg News reported Monday. The Macri administration may submit the proposal before July or issue a decree to modify the

State agencies are barred from selling shares without lawmakers' approval.

pension fund's rules, though a final decision has not been made. A law passed in October prohibits state agencies from selling shares without lawmakers' approval. The fund owns a more than 20 percent stake in companies including Banco Macro, Banco de Galicia y Buenos Aires and Grupo Clarín. Anses' investment fund, Fondo de Garantía de Sustentabilidad, had 612.2 billion pesos worth of assets at the end of October, mostly in Argentine government bonds. The proposal is one of many steps Macri has taken to repeal the policies of his predecessors in an effort to promote foreign investment and jump start the economy. Since Macri's inauguration in December, the government has removed most export tariffs, reduced subsidies on utilities and resolved a 15-year dispute with bondholders. The government will likely use the proceeds from the divestment to pay pensioners who have outstanding court cases tied to the lack of increases in pensions in the years following the Argentine economy's default in 2001.

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much of Latin America too rich to include in their licensing arrangements. Near-term benefits for the region may be slim, although Central America and Bolivia could benefit where new sources of supply overcome other challenges to disrupt a monopoly status quo. Industry patent licensing initiatives may be seen in part as efforts to stay ahead of public outrage about medicine prices and thereby maintain control. For people, however, it is better if governments develop independent policies which end monopolies, ensure access to medicines and use more efficient economic tools to contribute to medically important research and development. We all invest in health care, and the health of people we care about depends on our governments standing up."

A **Diana Muller, of counsel, and Michael Nesheiwat, associate, at Gottlieb, Rackman & Reisman, P.C.:** "In this day and age, it isn't often that the world's major pharmaceutical companies score some positive press when it comes to making drugs affordable for the world's poorest people. That is why it was especially surprising when GlaxoSmithKline (GSK) announced that it would no longer seek pharmaceutical patents in the world's least-developed countries, presumably to allow generic manufacturers in these countries to produce these drugs at a lower cost for their citizens. However, it is unlikely that this change will have any real effect on drug prices and public health around the world. For one, the 'least-developed countries' mentioned in this press release do not include the major players in the generic drug market, including India, China, Russia and Brazil. In addition, the countries that are actually covered under this announcement were already exempt from recognizing pharmaceutical patents until at least 2033 due to a recent World Trade Organization decision. Therefore, if GSK were to file pharmaceutical

patent applications in these countries now, it is likely that the resulting patents would expire, or would be soon to expire, before they would become enforceable, making their return on investment practically non-ex-

“ It is unlikely that this change will have any real effect on drug prices and public health around the world”

— Diana Muller & Michael Nesheiwat

istent. The emerging markets that interest multinational pharmaceutical companies the most are lower-middle-income countries, which includes much of Latin America. Through loopholes available under the TRIPS agreement, many of these countries have been able to circumvent pharmaceutical patent protection through laws limiting the patentability of certain innovations or forcing low-cost compulsory licenses on patent owners. Even though GSK also announced a more generous licensing policy for generic manufacturers in these countries, the announcement is not likely to have much of a practical effect in light of the current legal and regulatory frameworks in these countries. In short, while the GSK announcement may have inspired hope for those wishing to increase access to medicine around the world, it is unlikely that its new policy will have much of an effect on global medicine availability, or on GlaxoSmithKline's financial bottom line, whether or not other multinational drug companies also follow suit."

The Advisor welcomes comments on its Q&A section. Readers can write editor Gene Kuleta at gkuleta@thedialogue.org.

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