## IP and Innovation in Developing Countries

## Overview

Intellectual property (IP) is critical to driving innovation and stimulating economic growth in countries throughout the world. While the extent to which a country benefits from IP depends on the country's relative strengths and characteristics, and factors including poverty, infrastructure, political stability, and respect for the rule of law, it is widely recognized that where countries have strong and effective IP protection regimes in place, there is a significant connection between increased incentives for local innovation, and the transfer of technologies that foster local innovation and economic growth.1 Strong IP systems foster an innovative culture, whereby local innovators can develop new products and technologies knowing that their inventions and creativity are secure. Moreover, strong IP protection afforded by effective patent systems, in particular, tends to provide incentives for increases in technology transfer, foreign direct investment (FDI), and local research and development (R&D) capacity. This is supported by a recent OECD study which found that "[s]tronger levels of patent protection are positively and significantly associated with the inflows of high-tech products, like pharmaceutical goods...," as well as evidence that government officials from a range of economies have sought to strengthen IP to enhance FDI and trade. 2

Strong IP systems can therefore play an essential role in fueling innovation and economic growth in developing countries. This is the case across a range of traditional IP fields, including patents, copyrights, and trademarks. For example, in Jordan, strong IP provisions including expanded data exclusivity (DE)<sup>3</sup> and expanded patent protection for pharmaceutical patents as part of the Jordan-United States Free Trade Agreement commitments have made Jordan's market more appealing for pharmaceutical research and development, as well as for sales and licensing agreements. This is supported by evidence that there have been 78 innovative product launches for new medicines.4 Further, in Egypt, the increase of feature-length films produced from 22 to 56 over a period of four years underscores the importance of copyright protection in protecting local creativity.<sup>5</sup> Moreover, in Ethiopia, the government has used trademark protection and licensing to capture a larger share of the value of its coffee, which could reportedly add \$50 million to Ethiopia's export income.<sup>6</sup> The link between IP and economic growth in developing countries has also been noted by economist Paul Romer, who stated that if

http://money.cnn.com/magazines/fortune/fortune\_archive/2007/03/05/8401343/index.htm

<sup>&</sup>lt;sup>1</sup> Park, W. and D.C. Lippoldt, "Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries," OECD Trade Policy Working Papers, No. 62, OECD Publishing, 2005.

<sup>&</sup>lt;sup>2</sup> Id at 5 and 8.

<sup>&</sup>lt;sup>3</sup> Data exclusivity is also referred to as regulatory data protection in some countries.

<sup>&</sup>lt;sup>4</sup> Ryan, M. Pharmaceutical Foreign Direct Investment, Technology Transfer, Health Competitiveness, and the Jordan-United States Free Trade Agreement, George Washington University Law School, Creative and Inpovative Economy Center (May 2007).

<sup>&</sup>lt;sup>5</sup> Moullier B. and Viswanathan B, "Giant with Feet of Clay: Creativity, IP Rights and Economic Challenges in the Egyptian Film Industry," George Washington University Law School, Creative and Innovative Economy Center (Oct. 2007).

<sup>&</sup>lt;sup>6</sup> Faris, S. "Starbucks vs. Ethiopia," Fortune at

a developing country "offers incentives for privately held ideas to be put to use within its border (for example, by protecting foreign patents, copyrights and licenses, and by permitting direct investment by foreign firms), its citizens can soon work in state-of-the art productive activities."

## IP and Medicines

Strong IP protection for biopharmaceutical-related innovation via an effective patent system and data exclusivity provides specific benefits to developing countries. While some contend that strong IP diminishes access to medicines, and weaker IP improves access, the reality is that strong IP is part of an overall policy framework, which is an essential pre-requisite to the development of a country's innovative capacity and overall economic growth.<sup>8</sup>

An effective patent system provides incentives for technology transfer and investment. Strong patent systems provide a secure environment where biopharmaceutical companies have incentives to transfer technology and invest in production and R&D facilities for new drugs in developing countries. This is because patent rights grant an owner an exclusive right to prevent others from making, using, or selling an invention for a limited period of time, and enhances the ability of biopharmaceutical companies to generate enough revenue to cover the extremely high costs of innovation. This is also supported by empirical data from a recent study which found that biopharmaceutical firms were more likely to invest in research into antimalaria treatments following improvements in IP protections in countries subject to malaria outbreaks.

Strong patent protection bolsters local R&D and fuels economic growth. As local biopharmaceutical-related innovation capacity expands, developing countries can focus on creating medicines and healthcare products to address diseases prevalent among local populations, including "orphan" diseases. The World Health Organization recently illustrated the impact of IP on increasing R&D and the expansion of local biopharmaceutical capacity in many developing countries, such as Brazil, Egypt, and India. In doing so, it noted that those countries, "now, after decades of investment in health research and manufacturing capacity, have the infrastructure to conduct their own R&D." Local companies may also benefit by being able to produce licensed local versions of drugs, which can help develop their own R&D capacities, as well.

Increased economic growth helps address infrastructure deficiencies and other barriers to access. The economic growth that results from local manufacturing capacity

<sup>&</sup>lt;sup>7</sup> Romer, P. "Economic Growth" in the Fortune Encyclopedia of Economics, David R. Henderson, ed., Warner Books, 1993.

<sup>8 &</sup>quot;Public Health: Innovation and Intellectual Property Rights," at 141, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, 2006.

<sup>&</sup>lt;sup>9</sup> Lanjouw, J. and Cockburn I, "Do Patents Matter?: Empirical Evidence after GATT," National Bureau of Economic Research Working Paper No. 7495, Jan. 2000.

<sup>&</sup>lt;sup>10</sup> "Public Health: Innovation and Intellectual Property Rights," at 143, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, 2006.

may have longer term effects, which as noted by the World Health Organization may include "developing drugs for diseases prevalent among local populations, which due to their lower cost base, can be developed at prices far lower than equivalent development in wealthy countries." Further, the economic gains that result from local innovative capacity may enable developing countries to increase spending on healthcare infrastructure, poverty reduction, clean water, sanitation, and distribution networks—all of which are fundamental access barriers in developing countries.

Protection of regulatory data also helps ensure that innovative biopharmaceutical products reach patients as soon as possible. Data exclusivity provides a fixed time period of exclusive use for an innovator's clinical studies and other data so that no unauthorized third party can rely on such data. This protection is an important incentive for the development and launch of innovative drugs since it takes approximately 10 to 15 years, 12 and on average more than \$1.3 billion to develop a drug. 13 As such, DE helps recognize the extensive effort and cost of creating the clinical studies required to ensure that drugs developed are safe and effective for patients, and provides biopharmaceutical manufacturers an opportunity to recover some of the costs associated with launching and introducing a new drug into a market, as well as the incentive to continue research and development. Data exclusivity may also have the effect of increasing access of generic drugs to developing countries, because following the exclusivity period, a generic company can seek marketing approval by relying on the cost-intensive clinical studies and other data that the research-based biopharmaceutical company generated. In the absence of a finite data exclusivity period, in some countries, protection of the data could be indefinite.

<sup>11</sup>"Public Health: Innovation and Intellectual Property Rights," at 8, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, 2006.

<sup>&</sup>lt;sup>12</sup> J. A. DiMasi, "New Drug Development in U.S. 1963–1999," Clinical Pharmacology & Therapeutics 69, no. 5 (2001): 286–296; M. Dickson and J. P. Gagnon, "Key Factors in the Rising Cost of New Drug Discovery and Development," Nature Reviews Drug Discovery 3 (May 2004): 417–429; and J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics 22 (2003): 151–185.

<sup>&</sup>lt;sup>13</sup>J. A. DiMasi and H.G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," Managerial and Decision Economics 28 (2007): 469–479.