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INTELLECTUAL PROPERTY RIGHTS, PHARMACEUTICALS AND FOREIGN DIRECT INVESTMENT

Douglas Lippoldt

GEM
SCIENCES PO

197 boulevard St Germain 75007 Paris
Tel: 331-4549-7256. Fax: 331-4549-7257
http://gem.sciences-po.fr

Executive Summary

In response to the challenges and opportunities of globalisation, the pharmaceutical sector has evolved to become one of the most dynamic and rapidly internationalising sectors in the world. One key dimension of globalisation for the sector has been the development of enhanced rules under the multilateral trading system, enabling pharmaceutical firms to better capitalise on their intellectual property. These rules have expanded the range of economic opportunities for firms in the sector, opening markets and providing improved protection for intellectual property. Many firms appear to have reacted positively to the changes in the economic environment by adjusting their investment strategies to take advantage of the integrating global economy.

Given the critical role that technological innovation plays in the sector, and the role that intellectual property rights (IPRs) play in the ability of the pharmaceutical sector to capitalise on that innovation, it is not surprising to find a positive relationship between IPRs and foreign direct investment in the sector. The strength of IPR protection appears to be one important factor – among others – influencing pharmaceutical sector trade and investment decisions. As IPR standards in some developing countries begin to approximate those in OECD countries, one could reasonably anticipate further geographic diversification in pharmaceutical sector investment, including with respect to research and development.

DOUGLAS LIPPOLDT is a Senior Trade Policy Analyst with the Organisation for Economic Co-operation and Development in Paris and is affiliated with Groupe d'Economie Mondiale at Sciences Po (GEM). The views expressed are those of the author and do not necessarily reflect those of the OECD, OECD Member Countries or GEM. The author thanks Valérie Paris, Sébastien Miroudot and Christina Sampogna for suggestions in relation to his research concerning the issues addressed in this policy brief and Mounira Nakaa for her assistance in accessing certain FDI data. All errors and omissions remain the author's responsibility.

Introduction

In response to the challenges and opportunities of globalisation, the pharmaceutical sector has evolved to become one of the most dynamic and rapidly internationalising sectors in the world.[1] One key dimension of globalisation for the sector has been the development of enhanced rules under the multilateral trading system, enabling pharmaceutical firms to better capitalise on their intellectual property. These rules have expanded the range of economic opportunities for firms in the sector, opening markets and providing improved protection for intellectual property. Many firms appear to have reacted positively to the changes in the economic environment by adjusting their investment strategies to take advantage of the integrating global economy.

Recent intellectual property developments

Particular impetus to the strengthening of intellectual property rights (IPRs) arose from the advent of the World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which entered into force in 1995 [Park and Lippoldt (2005)]. The TRIPS Agreement covers the main types of intellectual property[2], establishing more effective -- and geographically inclusive -- international minimum standards of protection for IPRs than had existed previously. The Agreement specifies WTO member obligations to enforce IPRs; through the WTO's framework for trade policy review, dialogue and dispute settlement it also provides pathways for redress among WTO members in cases of non-compliance by governments. Additional strengthening of IPRs in recent years has also come about as a consequence of initiatives under the framework of the World Intellectual Property Organisation (WIPO), various regional trade and investment accords and unilateral actions.

Supporters of IPRs have promoted this strengthening, in part by underscoring the incentives that IPRs offer for innovation and its subsequent "real-world" application. IPRs help to ensure that innovators are able to capitalise on their innovations. This is because IPRs provide the owners of intellectual property with legal means to prevent others from abusing the corresponding rights of the owner. Under the various systems governing IPRs, the rights of the owner are balanced against certain obligations (e.g., the public disclosure of certain information related to patents), limits on the extent of protection (e.g., in terms of duration of patents or copyrights, granting of research exemptions, or public health waivers) and some other constraints (e.g., with respect to anti-competitive practises in contractual licenses).[3] Seen from an economic perspective, the incentives for innovators need to provide for an appropriate degree protection without conferring excessive market power.[4]

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1 E.g., in the OECD area from 1994 to 2003 the pharmaceutical sector had the highest growth rate of any sector with respect to manufacturing trade (13.5% annual growth versus an average of 5.8% for manufacturing as a whole) [OECD (2005)]. Manufacturing trade refers to exports plus imports. On average among the 15 OECD countries for which data are available, exports increased as a share of pharmaceutical production from 18% in 1992 to 33% in 2001 and, during the same period, imports increased as a share of domestic pharmaceutical demand from 17% to 32%.

2 These include copyright and related rights, trademarks, geographical indications (of origin), industrial designs, patents, layout-designs (topographies) of integrated circuits, and protection of undisclosed information (trade secrets).

3 WTO (2006) provides a useful summary of some of these issues in relation to the TRIPS Agreement and pharmaceutical patents.

4 Overly-stringent protection could, in theory, risk to confer excess market power (e.g., from patents that are too broad), thereby diminishing competition and encouraging some rights holders to continue exploiting existing innovations while postponing new innovation efforts.

Potential relationship of IPRs to investment

The preamble to the TRIPS Agreement recognises the developmental and technological objectives of national systems for the protection of intellectual property. One way that this can operate is by encouraging foreign holders of intellectual property to trade and invest. A country that enhances its IPR regime may attract additional knowledge-intensive product imports otherwise unavailable on the domestic market or it may attract inflows of foreign direct investment; in either case, international technology transfer is likely to flow as a consequence. Likewise, improved protection of IPRs in foreign markets may provide a given country's investors and traders with improved opportunities to enter the foreign markets with reduced risk of putting their intellectual property at risk.

The pharmaceutical sector is a particularly high technology sector as evidenced by its rate of investment in research and development (R&D). As shown in Table 1, pharmaceutical sector R&D expenditures in relation to production and value added are more than three times as high as for manufacturing as a whole. Moreover, the absolute volume of R&D expenditure in the sector has risen significantly in recent years (Chart 1 highlights this for selected OECD markets). Given the scale of this investment, it is clear that the industry has a lot at stake with respect to the intellectual property generated through the R&D. That is, the ability of innovators in the sector to ensure a return on their R&D investment depends in part on their ability to defend and capitalise on the resulting intellectual property.

Table 1. Technology intensity of the pharmaceutical sector, selected OECD countries, 1999

Sector	R&D in relation to production (%)	R&D in relation to value added in sector (%)
Pharmaceuticals (ISIC 2423)	10.5	22.3
Chemicals excluding pharmaceuticals (ISIC 24, excl. 2423)	2.9	2.2
Total manufacturing (ISIC 15 – 37)	2.6	7.2

Source: OECD (2005), *Science, Technology and Industry Scoreboard 2005*, Paris.

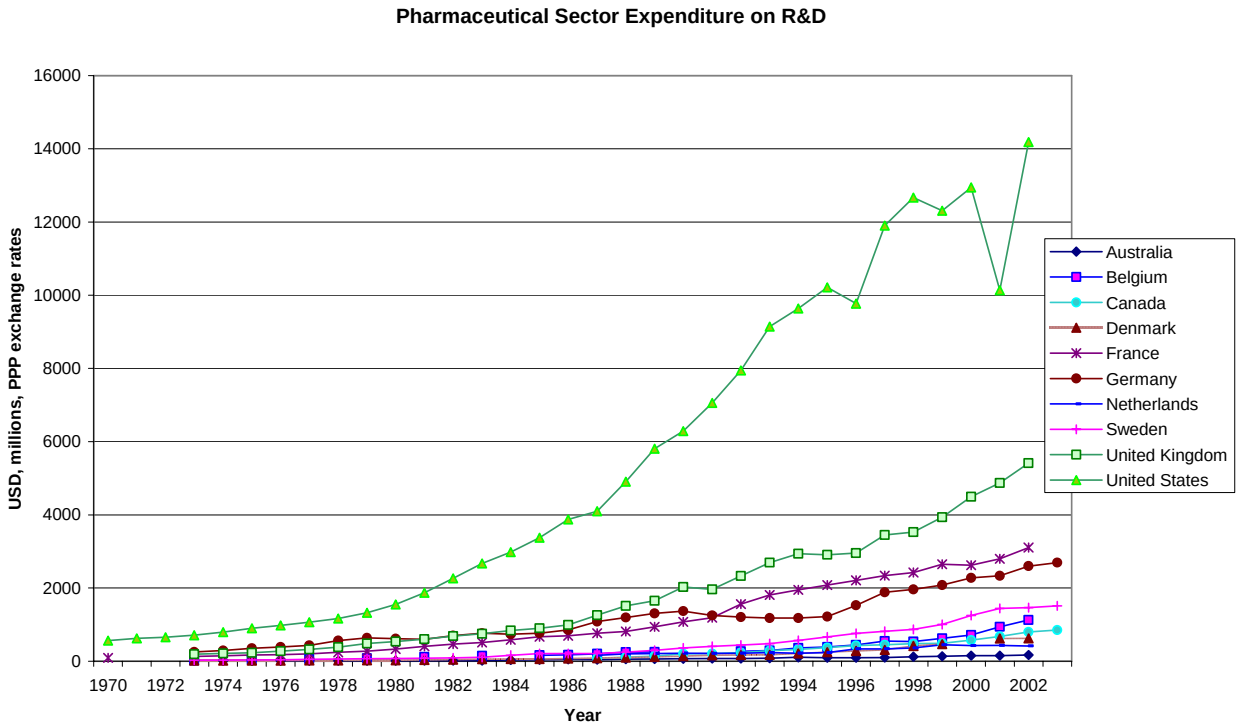
Notes: Technology intensity refers to aggregate R&D intensities calculated after converting countries' R&D expenditures, value added and production using GDP PPPs. The table is based on data for 12 OECD countries: Canada, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Spain, Sweden, United Kingdom and United States. ISIC codes refer to ISIC Rev. 3.

Foreign direct investment and the pharmaceutical sector

Foreign direct investment (FDI) refers to cross-border investments made with the objective of establishing a lasting interest in an entity that is resident in a market other than the investor's home market.[5] The investment may consist of equity capital, reinvested earnings and other capital contributions. Flows of FDI have exhibited impressive growth in recent years, particularly since 1990 but with significant year-to-year variation. OECD countries attract the bulk of the inflows (Chart 2), but China has grown in importance and has been a top destination in recent years (e.g., accounting for about 10% of global net inflows in 2002).

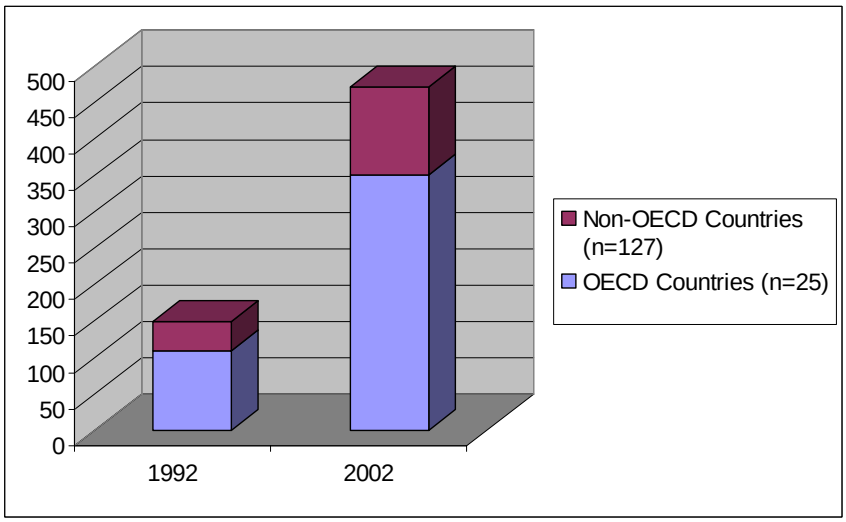
[5] For statistical purposes, a "lasting interest" is defined as investments to obtain a share of 10% or more of the voting power in the foreign enterprise. For a more detailed definition of direct investment and related terms, see [OECD (2006b), Box 1.1, p. 20].

Chart 1. Pharmaceutical sector expenditure on R&D, selected OECD countries



Source: OECD Health Division, *OECD Research and Development Expenditure in Industry* database.
Note: The data refer to ISIC (Rev. 3) 2423 encompassing manufacture of pharmaceutical, medicinal chemicals and botanical products. They cover research and development activities undertaken by the corporate sector in order to develop new compounds to correct somatic or physic dysfunction or to improve individual's state of health, irrespective of the source of funding.

Chart 2. Net inflows of FDI, USD millions (BoP)



Source: World Bank, *World Development Indicators*, on-line edition.
Note: Figures for OECD do not include Belgium, Luxembourg, Korea, the Czech Republic or the Slovak Republic.

Table 2 presents FDI inflows and outflows with respect to the pharmaceutical sector in several OECD economies. The size and variability of the flows (including reversals) is quite striking. These recent data provide an indication of a continuation of the restructuring in the sector that was quite pronounced in the 1990s. FDI flows related to merger and acquisition activity account for a large share of the total flows in the sector. In some years, merger and acquisition activity has been the main element in the flows. All of the top 15 pharmaceutical companies were involved in merger and acquisition transactions during the 1990s, in part because merger and acquisition strategies have become an increasingly important for lowering the high cost of R&D and achieving economies of scale [OECD (2006a)].

Table 2. Direct investment in the pharmaceutical, medicinal chemical and botanical products sector (USD, millions)

	2002	2003	2004
A. Inflows			
Belgium	110.2	527.5	385.1
Czech Republic	n.a.	-105.3	159.4
Finland	n.a.	-124.2	-86.9
France	2,459.7	910.5	-515.5
Hungary	n.a.	21.3	-32.4
Mexico	n.a.	n.a.	327.3
United States	-4,132.0	7,917.0	1,566.0
B. Outflows			
Belgium	-16.0	371.6	4,813.0
Czech Republic	n.a.	3	1.9
France	-752.9	1,503.6	1,003.8
Hungary	n.a.	3.5	20.6
United States	4,411.0	4,403.0	5,969.0

Source: OECD (2006), *International Direct Investment Statistics*.

Notes: Inflows can turn negative because of net repatriation of investment by foreign owners; outflows can turn negative because of a net repatriation of investment by domestic owners. "n.a." = not available.

Moreover, the cost of drug development is high and rising. For example, one estimate put the average total cost for development of a new drug in the late 1990s at USD 897 million, with the average development costs increasing 5.8 times in constant dollars between the 1970s and the 1990s.[6] R&D expenses contributed substantially to this increase in costs. For example, clinical testing costs rose 8.6 times during this period, an increase related to "greater emphasis on development of treatments for conditions associated with chronic and degenerative diseases, increasing clinical trial sizes, rising subject recruitment costs, and more procedures performed per subject" [Tufts (2003)].

Most of the pharmaceutical sector R&D takes place in the most advanced economies, but there is an increasing volume of R&D activity in developing countries that have created a favourable regulatory environment (including with respect to IPRs). This is an important development for these countries because multinational pharmaceutical firms can play a significant role in technology transfer through the interaction of the parent firm and affiliates, which can in turn have positive effects on the national economy (e.g., via productivity-enhancing application of new technologies). Several countries have

[6] The study, conducted by Tufts Center for the Study of Drug Development, covered 68 drugs from 10 pharmaceutical firms. The total cost refers to the fully capitalised cost to develop a new drug, including studies conducted after receiving regulatory approval. Such post-approval studies are often mandated in the case of drugs put on a fast-track for approval [*Psychiatric News*, 1 August 2003, Vol. 38, No. 5].

implemented national strategies to encourage pharmaceutical and biotechnological FDI with a view to promoting further technology transfer to their national economies through spillovers or local partnerships.[7] Where they have been successful in the pharmaceutical sector, such strategies have tended to hinge in part on the strengthening of IPR regimes.

Singapore is an interesting case in that it has a quite successful strategy to attract and develop biotech and pharmaceutical R&D activities, one with an explicit element of IPR protection.[8] This has born fruit. For example, in 2005, GlaxoSmithKline announced a USD 100 million expansion of existing facilities, Pfizer opened a USD 350 million plant, and Novartis opened its Institute for Tropical Disease (a public-private partnership with the Singapore Economic Development Board). In addition to implementation of measures to ensure TRIPS compliance, Singapore took further steps to enhance IPRs in the context of its free trade agreement with the United States (2003). Among other changes in the IPR regime, Singapore moved: to provide for extension of patent terms in cases where applicants faced delays in granting of patents or marketing approval; to limit parallel imports of pharmaceutical products (unless the intellectual property owner already markets the patented product in Singapore); and to extend the five year data exclusivity period for applicants (originators) from the date of application to the date of marketing. Moreover, Singapore signed on to a voluntary statement opting out of recourse to a WTO provision concerning possible use of compulsory licensing for imports (under certain conditions).[9]

Business decisions to invest are complex and based on a variety of considerations, with higher level considerations sometimes trumping lower level concerns.[10] While an effective IPR regime may not be sufficient in-and-of itself to attract pharmaceutical FDI, an inadequate IPR regime can be in some cases a deal-breaker for a technology firm that is looking to invest. As IPR standards improve in countries around the world, the competitive advantage that provision of basic IPR protection affords to a given investment destination shrinks. Some investors have come to require a basic level of protection. On the other hand, depending on the technology concerned, it may be that a strategy of trade secrecy can adequately protect a firm's intellectual property, even in the face of some weakness in the local IPR system. In some cases, factors such as market scale (i.e., access to a large market) or strategic positioning prove to be dominant factors motivating investment.[11] Such factors, for example, may help to account for the large number of

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7 With respect to strategy, government policies to promote technology transfer via FDI may have a greater likelihood of success if they focus on boosting incentives to source locally (e.g., through well-designed supplier development programmes that prepare local firms to meet the needs of multinational firms) rather than through regulation or legislation directly mandating technology transfer [World Bank (2006)].

8 Pharmabiz (2005), *New policies spur pharma, biotech growth in Singapore*, 14 April, article posted on-line at www.pharmabiz.com .

9 For more on this, see the WTO web site FAQ on compulsory licensing, TRIPS and public health, available at: http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm .

10 The choice of whether and where to invest depends on locational advantages of the home and foreign markets and the profitability of internalising production or selling or licensing the technology to another firm that is active in the market [Braga and Fink (1998)]. The extent of protection for intellectual property rights can constitute an important locational advantage.

11 In a survey on investment issues affecting the world's largest 1,000 firms, business leaders characterised the most critical risks to their corporations as they invest abroad [A.T. Kearney (2003)]. At the top of the list were government regulation, country financial risk, currency risk, and risk of political and social disturbances (each of which cited by 60% or more of respondents). Theft of intellectual property was cited by 17% of the respondents and ranked 12th on the list of concerns.

pharmaceutical FDI projects in China (which has had a mixed performance on IPR enforcement since its entry into the WTO in 2001).[12]

Moreover, variation in IPR strength may influence not only the volume of FDI but also the nature of the projects (e.g., for distribution, production and/or R&D). For example, an analysis of data from a 1995 EBRD enterprise survey in Eastern Europe and the republics of the former Soviet Union found that weak IPR regimes tended to discourage foreign investors in technology-intensive sectors that rely heavily on IPRs [Smarzynska (2002)]. In all sectors, weak IPR regimes tended to deter investors from undertaking local production and rather focus on distribution of imported products. An earlier study of intellectual property managers from 94 major U.S. firms (including several pharmaceutical companies) revealed that IPRs mattered less for protecting sales and distribution outlets, than for protecting production and R&D facilities [Mansfield (1994) and Lee and Mansfield (1996)]. The proportion of FDI invested in production and R&D facilities was positively and significantly related to the perceived strength of IPRs. In addition, firms tended to regard strong IPRs as being more important for decisions concerning transfer of advanced technology than for FDI decisions as a whole.

Using regression analysis, Park and Lippoldt (2003) considered the relationship of an index of the strength of patent rights during the 1990s to FDI and trade.[13] Overall, the analysis revealed a positive relationship.[14] For pharmaceuticals, a 1% increase in the indicator for patent rights in the destination market was associated with about a 0.24% increase in the stock of US outward FDI in the market (Table 3). The results are perhaps a bit surprising in that the coefficients for the pharmaceutical sector are somewhat smaller than those for industry as a whole. One possible explanation may be related to variation in the propensity to invest abroad depending on the nature of the investment.

Generally, R&D has traditionally been done in the home market [OECD (2006b)]. Given that the pharmaceutical sector is particularly R&D-intensive and that proximity has in the past been an important factor in R&D locational decisions, it may have been the case that there was a certain lack of responsiveness in pharmaceutical R&D investment to improved IPRs in foreign markets.[15] On the other hand, for other types of investment by the pharmaceutical industry (e.g., distribution) there may have been less "stickiness" in investment decisions and better responsiveness to local changes in the regulatory environment (including IPRs). Such a segmentation of investment strategy by type of investment may account (at least partly) for the smaller, but still significant coefficients found with respect to patent strength and FDI in the sector.

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12 Among the top 10 locations for pharmaceutical FDI projects during January 2002 to February 2005, China ranked second with 44 projects. The US ranked first with 52 FDI projects in the sector. Other countries ranked as follows: India (30), Ireland (29), Spain (27), Canada (27), UK (23), Singapore (23), Brazil (22) and Germany (18). ["Pharma pulls in $15bn", 12 April 2005, on-line edition available as of 15 September 2006 at: www.fdimagazine.com]

13 Trade and FDI were measured as percentages of GDP in each destination market. The index of patent rights strength took into account such elements as membership in relevant international treaties, restrictions on IPRs, available means of enforcement, duration of protection and sectoral coverage of patent rights. See also Lippoldt (2006) for a further elaboration of the results of this study.

14 For the least developed countries, the estimates by Park and Lippoldt were not statistically significant for the sectors shown in the table.

15 Mansfield (1994, p. 10) singles out the chemical industry as whole, noting "chemical firms are reluctant to transfer relatively new or advanced technology to other than wholly owned subsidiaries."

Table 3. Estimates of the relationship of FDI and imports to strength of patent protection, 1990–2000

Economic indicator and sector of origin	Country of destination	Coefficient estimate	N	R^2
I. US outward FDI				
All Industries	All Countries	0.568*	224	0.13
	Developing Countries	0.708*	127	0.12
Pharmaceuticals	All Countries	0.242*	153	0.12
	Developing Countries	0.361*	77	0.16
II. Imports				
All Industries	All Countries	0.315**	154	0.46
	Developing Countries	0.243*	83	0.55
Pharmaceuticals	All Countries	0.436**	154	0.44
	Developing Countries	0.372*	83	0.56

Source: Derived from Park and Lippoldt (2003), Tables 7 and 8.

Notes: The coefficient estimates measure the relationship of the economic indicators to the destination country's strength of patent rights, controlling for various factors such as other economic influences (e.g., level of GDP per capita) and unobserved country-specific factors. The coefficients were calculated using regression analysis and a pooled sample of observations across countries. The coefficients can be viewed as indicating in percentage terms the average change in the respective sector's outward-FDI-stock-to-GDP ratio or imports-to-GDP ratio per 1% change in an index of patent rights for the destination country. The asterisks indicate that each coefficient is statistically significant. N denotes the number of observations and R2 the fraction of the variation in the data explained by the model.

In the same study, Park and Lippoldt (2003) assessed the relationship between imports and the strength of patent rights (Table 3). Here as well, they found a positive relationship, with the coefficients for pharmaceutical products being somewhat higher than those for industrial goods as a whole. The positive relationship is in line with the notion that as IPRs were strengthened during the 1990s, firms were better able to appropriate a return on their technological investments and therefore had greater incentive to export into these markets.

Conclusion

The pharmaceutical sector is facing a changing economic environment characterised by the deepening of globalisation for OECD countries and the increasing integration of many developing countries into the mainstream of the international economy. One dimension of this changed environment is an international strengthening of IPRs. Given the critical role that technological innovation plays in the sector and the role that IPRs play in the ability of the pharmaceutical sector to capitalise on that innovation, it is not surprising to find a positive relationship between IPRs and FDI in the sector. The strength of IPR protection appears to be one important factor – among others – influencing trade and investment decisions in the sector.

The pharmaceutical sector is already among the most geographically diversified in terms of the location of affiliates [UNCTAD (2005)]. It is likely that pharmaceutical firms will continue to internationalise and seek to capitalise on new market opportunities around the world. In this context, one might expect some deepening and geographic diversification of FDI as firms seek to exploit locational advantages of sites around the world and thereby contain costs or position themselves strategically. Moreover, as IPR standards in some developing countries begin to approximate those in OECD countries, one could reasonably anticipate further geographic diversification in the types of investment, including with respect to R&D.

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