Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights

The contribution of IPRs to the biotechnology ecosystem and economic growth in developed and emerging economies: examining the literature and evidence

Meir Perez Pugatch, David Torstensson & Rachel Chu

Pugatch Consilium

June 2012

Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights

The contribution of IPRs to the biotechnology ecosystem and economic growth in developed and emerging economies: examining the literature and evidence

Meir Perez Pugatch, David Torstensson & Rachel Chu

Pugatch Consilium

June 2012

Contents

Executive summary 4

List of abbreviations & definitions 6

Introduction 7

1 Current discussions and debates on IPRs 10

1.1 Review of the existing body of knowledge 10

2 The strategic use of IPRs during the R&D process in the biotechnology ecosystem 28

2.1 Biotechnology patenting activity 28

2.2 Technology transfer and licensing 35

2.3 Partnerships and collaboration 39

3 The role of IPRs in promoting biotechnology R&D activities and economic development: implications for emerging and developing economies 43

3.1 Emerging economies, IPRs, FDI and technology transfer 43

3.2 The growing recognition and use of IPRs in emerging and developing economies 47

4 Conclusions and thoughts on the way forward 56

Figures

Figure 1: Number of biotechnology patents filed under PCT, 1977-2009 30

Figure 2: Number of biotechnology patents filed under PCT, 1977-2009 30

Figure 3: Number of biotechnology patents filed under PCT, 1977-2009 31

Figure 4: Number of biotechnology alliances for research or technology transfer, 1990 to 2005 40

Figure 5: Inward foreign direct investment stock, annual, 1980-2010 US Dollars at current prices and current exchange rates in millions 44

Figure 6: Patent Rights Index, 1960-2005 46

Figure 7: Strength of pharmaceutical IPRs vis-à-vis foreign direct investment in clinical research 47

Tables

Table 1: Summary of existing evidence and main findings 27

Table 2: Biotechnology patents Top 10 regions, 2004-2006 38

Executive summary

1) This report was commissioned by the Biotechnology Industry Organization (BIO).

2) This report examines the role played by IPRs in both upstream and downstream phases of the research, development and commercialization of biotechnology products and inventions in developed, emerging and developing economies.

3) The report provides a review and analysis of the existing body of knowledge concerning the role of IPRs more generally as well as specifically in biopharmaceutical and biotechnological innovation.

4) The key findings discussed in the literature include:

   - There is a growing body of evidence suggesting a positive link between economic development and growth, technology transfer, increased rates of innovation and the strengthening of IPRs. This is particularly strong in certain knowledge-intensive sectors such as biopharmaceuticals.
   - Much of the international debate on biopharmaceutical innovation focuses on downstream issues: whether IPRs stand in the way of commercialization and whether they enable or delay access to medicines in developing countries. This discussion is usually placed in the context of the "North-South" divide (i.e. developed vs. developing world) and the extent to which the use of IPRs benefits or damages developing countries.
   - The discussion on the use of IPRs in upstream innovation (or the relationship of IPRs and biotechnology innovation in the context of biotech SMEs and universities) is often theoretical in nature and only at times based on data and collected evidence. Some international debates on IPRs relating to the upstream R&D process also examine the issue of ownership of genetic innovations and biologic materials and so-called research exemptions.
   - Recent empirical studies and surveys seem to significantly ease ongoing concerns about the extent to which the patent system may be used in a manner that slows or hinders access to biotechnological research and innovation. Still, there is a relative paucity of direct evidence and data on the roles that IPRs play in stimulating biotech research and innovation.

5) Based on these findings, the report discusses and explains the impact of IPRs on biotechnological innovation in the upstream process. It provides an examination of existing and new evidence on how SMEs, universities, spin-offs and biopharmaceutical manufacturers are using IPRs (chiefly patents) in their day-to-day operations.

6) The report outlines how IPRs have encouraged collaboration between biotechnological entities and, as a result, enabled further research and development of new biotechnologies, specifically in emerging and developing economies. In particular, technology transfer mechanisms such as Bayh-Dole styled frameworks are discussed in the context of emerging and developing economies.

7) The key findings that have emerged from this report include:

- IPRs, especially patents, are actively facilitating and contributing to upstream and downstream biotechnology activities in both developed and developing countries.
- Today, not only mature economies but also major emerging economies are making growing use of the patent system to facilitate biotechnology research and commercialization.
- Accordingly, biotechnology alliances for research and technology transfer have increased markedly since the early 1990s.
- Case study analysis suggests that strengthening IPRs and introducing technology transfer frameworks based on IPRs in combination with other reforms can have a positive and sustained impact on innovation, economic development and growth, biopharmaceutical R&D and access to biotech products in emerging economies.

8) Based on these findings the report makes the following recommendations:

- **Focus the spotlight on upstream phases –** Understanding the relationship and interaction between IPRs and the upstream phases of biotech R&D is as important as discussing the role of IPRs in the commercialization of these technologies and products. Therefore, attention should also be devoted to upstream processes, not least in international discussions.
- **A closer look at the nuts and bolts –** In this context, we need to deepen our understanding of the mechanics and mechanisms by which IPRs can be used strategically in order to enhance the R&D process.
- **An enhanced architectural mindset –** Policymakers should consider the architectural setting and how the use of IPRs during the upstream process can be optimized.
- **The needs of emerging economies –** Given the growing positive impact of IPRs in emerging and developing economies, there is a real need to increase our awareness and body of knowledge about frameworks, best practices and specific experiences with the use of IPRs during the upstream phases of R&D.
- **An international observatory of best practices –** It is worth creating an international observatory that maps both knowledge as well as instruments that could help galvanize entities around the world to make greater use of IPRs during the upstream phases of biotech R&D.

List of abbreviations & definitions

CL	Compulsory license
EMA	European Medicines Agency
FDA	US Food and Drug Administration
FDI	Foreign direct investment
FTC	Federal Trade Commission
GM	Genetically modified
ICT	Information and communications technologies
IP	Intellectual property
IPRs	Intellectual property rights
LDC	Least developed country
NGO	Non-governmental organization
NIH	US National Institutes of Health
OECD	Organization for Economic Co-operation and Development
PCT	Patent Cooperation Treaty
PRO	Public research organization
R&D	Research and development
SME	Small and medium enterprises
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USTR	US Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Additional definitions

Upstream process[1]	The range of research and development activities which relate to the pre-market and development stages of a product or technology.
Downstream process	The range of activities that relate to the market and post-market phases (including commercialization) of a new product or technology, or the further development of an existing technology or product already available to the market.

[1] A similar distinction between upstream and downstream research is used by the OECD both in relation to biotechnology as well as in broader discussions on IPRs and competition. See for example, OECD (1997), *Policy Roundtables, Competition Policy and Intellectual Property Rights*, OECD 1997, p. 278; as well as OECD (2002), *Genetic Inventions, Intellectual Property Rights, and Licensing Practices*, OECD Paris.

Introduction

In its 2009 flagship publication *The Bioeconomy to 2030*, the OECD outlined the extent to which the use of biotechnologies offers solutions to many of the biggest challenges facing mankind in the 21st century.

In three key areas – agriculture, health care and industrial production – the OECD saw biotechnologies as having a profound impact on both the size and composition of global economic output. The report stated that:

> Biotechnology offers technological solutions for many of the health and resource-based challenges facing the world. It can increase the supply and environmental sustainability of food, feed and fibre production, improve water quality, provide renewable energy, improve the health of animals and people, and help maintain biodiversity by detecting invasive species.[2]

Yet in many ways this bioeconomy is already upon us.

Since the mid-1990s bioengineering and the commercialization of GM crops has led to large and sustained increases in the number of hectares planted to GM crops. In 1996 globally this number was close to zero; a decade later this had increased to over 70 million hectares.[3] In fact in many South American countries GM crops now account for the majority of arable land planted. For instance, in Paraguay GM crops cover 89% of all arable land.[4]

With regards to the life sciences and biomedical and biopharmaceutical innovation, biotechnology also has grown significantly in importance and stature over the past thirty years. To begin with the number of biological drugs account for a rising share of total biopharmaceuticals approved: in 2011 alone the FDA approved a total of 30 new drugs, of which 24 were new molecular entities and 6 were new biologics.[5] Just as importantly, biotechnologies are increasingly part of the discovery, clinical and pre-marketing studies on traditional small molecule drugs. This includes biotech processes such as pharmacogenetics, gene sequencing and diagnostics through the identification of biomarkers. Perhaps most significant of all, the path to a new type of clinical and therapeutic environment – based on the personalization of medicines and medical treatments – is in large measure based on advances in biotechnology. Here pharmacogenetics and gene sequencing play a crucial role.

---

[2] OECD (2009), *The Bioeconomy to 2030: Designing a Policy Agenda, Main findings and policy conclusions*, OECD Paris.
[3] Beuzekom, B. & Arundel, A. (2009), *OECD Biotechnology Statistics 2009*, OECD 2009, pp. 76-7.
[4] Ibid.
[5] Mullard, A (2012), “2011 FDA drug approvals”, *Nature Reviews Drug Discovery* 11, 91-94 (February 2012).

Highlighting the growing importance of the biotechnology sector to the global economy, an increasing number of governments at all levels have, or are, putting in place policies to promote and encourage growth in their biotechnology and life science sectors. In both developed and emerging economies biotech is seen as a source of future job creation and economic expansion. Examples include initiatives in Ireland, Singapore, India, China, and a number of American states including Massachusetts and California.[6] Altogether, biotechnology, which 30-40 years ago was a relatively small and niche scientific specialism, is now at the heart of social and economic development.

However, biotechnological and biopharmaceutical R&D processes are complicated and highly technically demanding. There are a number of factors that together build an environment conducive to biotechnological R&D. Examples of such factors include: adequate levels of human capital and infrastructure; the research and development capacity of a given country or region; the regulatory and clinical environment; market incentives and market access for R&D; and finally the existence and strength of IPRs. Together these factors interact and provide many of the conditions in which biomedical and biotechnological innovation can develop.

Today there is much controversy surrounding the extent to which one of these factors – IPRs – contributes to promoting upstream innovation as well as ensuring access to these products once they have been developed, particularly in emerging and developing economies. Often these debates have become as emotional as they are rational, encompassing economic, legal and health issues, and even questions of business ethics and morality. As such, the purpose of this report is to examine empirical evidence – existing as well as new – on the role played by IPRs in both upstream and downstream biotechnology research and development.

Some of the key questions to be addressed include:

- How have IPRs affected innovation and the development of new biotechnologies?
- Do IPRs contribute to growth in partnerships and other models of collaboration between biotechnology R&D actors such as universities, SMEs and pharmaceutical manufacturers?
- What are the economic implications for emerging and developing economies of the current use of IPRs as a basis for enhancing their biotechnology R&D infrastructure?

The report has been divided up into four main sections.

Section 1 provides a comprehensive review and analysis of the existing body of knowledge concerning the role of IPRs more generally as well as specifically in biopharmaceutical and

[6] For full details and a number of country specific examples see Chu, R. & Pugatch, M. (2010) *From Test Tube to Patient – National Innovation Strategies for the Biomedical Field*, Stockholm Network, London.

biotechnological innovation. In addition to the existing body of knowledge on IPRs, this section also describes the key debates and positions taken by some of the most important international stakeholders and research organizations regarding the role of IPRs in biopharmaceutical and biotechnological innovation. These include organizations such as the OECD, the WTO and WHO as well as independent research institutes and think tanks that specialize in research on IPRs and IP environments.

Section 2 discusses, details, and explains the impact of IPRs on biotechnological innovation in the upstream process. It provides an examination of existing and new evidence on how SMEs, universities, spin-offs and biopharmaceutical manufacturers are using IPRs (chiefly patents) in their day-to-day operations.

Section 3 discusses how IPRs have contributed to economic development, R&D capabilities and public-private partnerships in developed, emerging and developing economies. In particular, technology transfer mechanisms such as Bayh-Dole styled frameworks are discussed and detailed in the context of emerging and developing economies.

Section 4 summarizes the paper’s findings on the role played by IPRs in biotechnology R&D and offers a few concluding thoughts on the current evidence and on future areas of research.

1 Current discussions and debates on IPRs

Since the TRIPS agreement established a new international legal architecture for intellectual property, there has been a great deal of public controversy and debate surrounding the role of IPRs. This has been both generally as well as specifically in relation to the biotechnological and biopharmaceutical field.

Traditionally, debates on the role played by IPRs have been quite theoretical in nature. More often than not discussions have only partially been based on hard evidence. However, over the last decade, a substantial empirical literature has been built on the wider economic effects of IPRs as well as their specific effects on innovation, technology transfer, and international trade.

A good deal of this literature has been sector specific studies of how IPRs affect knowledge and R&D intensive segments or sectors of an economy such as ICT, biopharmaceuticals and the chemicals industry.

The studies and discussions on IPRs and the biotechnological and biopharmaceutical fields are either quite broad or tend to focus mainly on downstream aspects of biotechnological innovation, i.e., commercialization, manufacturing and market access. There have been some specific discussions of the role of IPRs in upstream biotechnological research – particularly in the area of pharmacogenetics – but these have been mainly theoretical in nature.

Governmental and or international organizations, NGOs and independent research institutes and think tanks have produced a good deal of this research either independently or in partnership with academics and academic institutions. Depending on their specific interests (beliefs, objectives and missions) these bodies examine IPRs more broadly or focus specifically on one or two areas.

1.1 Review of the existing body of knowledge

This subsection is structured around five key areas of debate relating to IPRs more generally; IPRs and biopharmaceutical innovation and access; and patents and access to biotechnological research and innovation:

- IPRs, FDI, trade and economic development;
- IPRs and innovation;

- IPRs and biopharmaceutical innovation;
- IPRs and access to medicines; and
- Patents and access to biotechnological research and innovation.

IPRs, FDI, trade and economic development

The economic impact of IPRs at both the macro and micro level has been a topic of growing interest to economists and social scientists. The literature encompasses theoretical as well as evidence-based discussions about how patents, trademarks, copyrights and other forms of IPRs contribute to or limit FDI, economic growth and trade flows. Primarily econometric in nature, this literature also includes a number of surveys and country-specific case studies.

Much of this economic, econometric and survey analysis suggests that there is a strong and positive correlation between IPRs, FDI, trade and economic development. The exact impact of IPRs depends on a country's stage of development, income level and technical capabilities.

Below is an outline of some of the most significant studies over the past 20 years that have found this positive correlation between the level of IP protection in a country or region and corresponding levels of FDI, trade and economic development.

The literature reviewed has been divided up into those studies that examine IPRs and FDI/trade flows, and studies that examine IPRs and broader economic development.

IPRs, FDI and trade

Through a survey of US multinationals, Lee and Mansfield (1996) found that a country's system of IP protection significantly influences the volume and composition of US FDI.[7] The study suggests that if the percentage of firms regarding protection in a particular country as inadequate falls by 10 percentage points, US FDI there might increase by about $140 million per year. Moreover, the results indicate that the percentage of a firm's investment devoted to sales and distribution outlets or rudimentary production and assembly facilities is directly related to the perceived weakness of the country's IP protection.

Similarly, Primo Braga and Fink (1998) examined the potential implications of stronger IPRs on FDI flows.[8] The authors review and analyze a range of available empirical evidence on the relationship between IPRs and FDI. The evidence comes either from surveys of foreign investors in industrial countries or from econometric work evaluating the impact of different levels of IP

---

[7] Lee, J.Y. & Mansfield, E. (1996), "Intellectual Property Protection and US Foreign Direct investment", *Review of Economics and Statistics*, Vol. 78, Vol. 2, pp. 181-86

[8] Primo Braga, C. & Fink, C. (1998), "The Relationship Between Intellectual Property Rights and Foreign Direct Investment", *Duke Journal of Comparative and International Law*, Vol. 9, pp.163-187

protection on a cross-section of countries. The study finds that surveys of foreign investors in industrial countries confirm a positive link to the strength of existing IPRs. However, it is not clear how strong this link is or how important the protection of IP is compared to other factors, such as tax incentives, quality of infrastructure, cultural ties, skills availability and input prices. Finally, the study finds that legal reform must be followed by adequate resources for the administration and enforcement of IPRs for it to achieve its full potential. The study concludes that there is growing evidence that IPRs affect FDI decisions around the world.

Smith (2001) added to this evidence by looking at the effect of IPRs on sales and licensing by American affiliates in 50 countries across the world.[9] Overall, the study found that IPRs increase both US affiliate sales and licenses, particularly among countries with strong imitative abilities, as measured by R&D and education statistics.

Park and Lippoldt (2003) complemented and built on this evidence, finding that the effect of IPRs on FDI varies by levels of economic development, but that overall IPRs tend to have a positive impact on inward and outward FDI.[10] For instance, non-LDC developing countries that are members of the WTO (and are thus signatories to the TRIPS agreement) have higher levels of FDI than non-members. Conversely, membership in the WTO did not seem to have as significant an impact on levels of FDI for LDCs.

Taking a different regional-comparative approach, Blyde and Acea (2003) analyzed the effects of strengthening IPRs on the volume of FDI by comparing Latin America with other regions.[11] Through economic and statistical modeling, the authors found that strengthening IPRs has a greater effect on FDI flows to developing countries than to high-income countries. According to the simulation, there would be an increase in FDI inflows to Latin America of around $20 billion (in 1995 figures) following full TRIPS implementation. Because patent obligations would be phased in over time, this effect would emerge over the long term.

Nunnenkamp and Spatz (2004) also found evidence linking the strength of a country's IPRs to levels of FDI.[12] The study explores how industry characteristics and host-country conditions affect the extent to which IPRs are related to FDI. It also examines whether stronger IPRs raises both the quantity and the quality of FDI. Overall the study finds that host country and industry characteristics have an important say in the relationship between the protection of IP and FDI. Specifically, IPRs have a weaker effect in countries with strong pull factors (i.e., proximity to

[9] Smith, P.J. (2001) "How Do Foreign Patent Rights Affect US Exports, Affiliate Sales and Licenses?", *Journal of International Economics* 55(2): 411–39.
[10] Park, W.G. and Lippoldt, D. (2003) *The Impact of Trade-Related Intellectual Property Rights on Trade and Foreign Direct Investment in Developing Countries*. Paris: OECD.
[11] Blyde, J. & Acea, C. (2003), *How does Intellectual Property Affect Foreign Direct Investment in Latin America*?, Institute for the Integration of Latin America - Integration, Trade and Hemispheric Issues Division, Occasional Paper 19.
[12] Nunnenkamp, P. & Spatz, J. (2004), "Intellectual Property Rights and Foreign Direct Investment: A Disaggregated Analysis", *Review of World Economics*, Vol. 140, No. 3, pp.393-414

investing country), and have a stronger effect where local imitative capacity is moderate. This effect is strongest in less developed countries. It finds that the strength of IPRs has the strongest effect on FDI in technology intensive industries, and a weak effect in sectors with low technology intensity. Finally, it finds that host countries cannot only attract more FDI, but may also derive more benefits from FDI (especially R&D expenditure by US affiliates) by strengthening IPRs.

Finally, Robbins (2006, 2008) attempts to quantify the intangibles market (commercial use of IP-based products and services) in the US, via estimation of the total receipts of royalties and license fees in the US industry.[13] The author estimates the magnitude of US earned corporate income in 2002, by type of IP: for licensing of patents and trade secrets it is around $50 billion dollars, for licensing of trademarks around $20 billion, $10 billion for the licensing of copyrights, and $10 billion for the licensing of franchises. The majority countries paying for trade in intangibles with the US included: France, the United Kingdom, Switzerland, and Japan. Top countries earning income from trade in intangibles with the US included: Japan, Germany, Korea, United Kingdom and Canada. The leading royalties-receiving industries included: computer and electronic product manufacturing ($23,317 million, representing 4.3% of all royalties), chemical manufacturing, including pharmaceuticals ($20,482 million, or 3.1%), transportation equipment manufacturing ($9,406 million, or 1.1%), and publishing industries ($4,755 million, or 2.2%). The study concludes that IP-based activities and transactions are one of the most significant components in the US economy in the international trading arena.

IPRs and economic development

The literature linking IPRs with economic development has grown considerably over the past decade with a number of case studies and broader analyzes available.

In a major study Falvey et al (2004) uses panel data for a sample of 80 developed and developing countries over the period 1975-1994 to estimate the impact of level of IP protection on economic growth.[14] The level of development is measured by initial GDP per capita. IP protection is measured using the Ginarte-Park index. The authors find that the impact of levels of IP protection on growth depends upon the level of development: IPRs are positively and significantly related to growth for low- and high-income countries, but this relationship is not as strong for middle-income countries. The study concludes that high- and low-income countries are likely to benefit most from stronger IPRs. It suggests that middle-income countries do not see the same benefit because of the costs of discouraging imitation in these countries.

---

[13] Robbins, C. A. (2006, 2008), *Measuring Payments for the Supply and Use of Intellectual Property*, International Association for Official Statistics (IAOS) Ottawa: Canada
[14] Falvey, R., Foster, N. & Greenaway, D. (2004), "Intellectual Property Rights and Economic Growth", Internationalisation of Economic Policy Research Paper No. 2004/12

Gamberdella et al (2006) analyzed the value of patents in Europe measured by: monetary value of patents; economic and social impact of patents (particularly, share of patents used for commercial and industrial purposes, patent licensing and creation of new firms from patents); relationships between patents, R&D and innovation; and inter-industry differences.[15] Overall the authors found that: the value of patents is highly skewed (a small number of patents account for a large share of the total value, in which value is of the patent itself as an asset, and not the patented invention); the value of patents has increased faster than GDP in practically all countries; many patents are not used (including in the scope of licensing activities and the creation of new firms); and increases in R&D are driven mostly by genuine increases in innovation productivity rather than strategic patenting.

In a study for the US Chamber's GIPC, Pham (2011) examined the economic contribution of IP intensive companies to the US economy.[16] The author estimates that in 2008 IP intensive companies employed close to 20 million workers, accounting for over 16% of total US employment. Based on this the study finds that IP intensive companies generated a third of total US economic output.

In a similar vein to the GIPC study, the Economics and Statistics Administration and United States Patent and Trademark Office (USPTO) (2012) began the process of developing a set of metrics to map and measure which sectors of the US economy rely on and utilize IPRs the most.[17] This study finds that IP intensive industries make a large contribution to US GDP and employment. In total these industries directly and indirectly account for over 40 million jobs or 27% of total US employment.

It is also important to note that some studies have expressed a more skeptical view of the link between IPRs and economic development. For example, an analysis by Kumar (2007) of the impact of IPRs on economic and technological development, using Asian countries as case studies, argues that lax IPRs in countries such as Japan, South Korea, Taiwan and India played a positive role in their economic development.[18] However, this study relies substantively on the development of India's generic, non-research based, pharmaceutical industry as an example of the benefits of weak IPRs. Furthermore, the author acknowledges that IPRs were strengthened in Japan, South Korea and Taiwan as a result of both the maturation of their domestic technological capabilities as well as greater international commercial ties and ensuing market pressure, in particular with the US.

[15] Gambardella, A., Giuri, P. & Mariani, M. (2006), *The Value of Patents for Today's Economy and Society*, Tender No. MARKT/2004/09/E, Lot 2, DG Internal Market, Final Report, July 2006
[16] Pham, ND (2011), *Employment and Gross Output of Intellectual Property Companies in the United States*, GIPC 2011.
[17] Economics and Statistics Administration & United States Patent and Trademark Office (2012), *Intellectual Property and the U.S. Economy: Industries in Focus*, US Department of Commerce 2012.
[18] Kumar, N. (2007), "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries", *Economic and Political Weekly*, Vol. 38, No. 3, pp.209-215, 217-226

IPRs and innovation

Although innovation is inherently a difficult process to define and quantify, rates of innovation can be measured by a number of variables including: patenting, licensing activities, royalties, technological development and absolute diffusion of new technologies and know-how. Increased levels of patenting suggest that individuals and companies see a clear value in their research and wish to protect and disseminate it. Similarly, licensing activity (and accompanying royalty income) suggests the adoption, dissemination and use of technologies and processes otherwise not available or developed by a given entity or in a given country. International and trans-national licensing is of particular importance as it signifies the transfer of technologies from one country to another.

The importance of patenting and licensing as a proxy for innovation is illustrated by their frequent use in economic analysis and country comparisons of rates of innovation. Over the last decade a substantial body of literature has emerged detailing the interaction between IPRs and rates of innovation. By and large these studies find that there is often a positive impact of introducing IPRs (such as patents) on domestic innovation. Frequently this exceeds the short term gains that local companies may have from the ability to freely imitate foreign technologies, particularly in emerging economies.[19]

Furthermore, economic analysis at both the macro and micro levels of rates of patenting, licensing activity and technology transfer in countries that have strengthened their IPRs suggests a positive link between higher levels of innovation and stronger protection of IP. However, it should also be noted that IPRs do not work in a vacuum. Much of the literature describes how stronger IP protection is more likely to positively affect rates of innovation when combined with other policies and development (e.g., improved infrastructure, education and human capital, technical R&D capability and absorptive capacity, etc.) at both the macro and micro levels.

This subsection is divided into those studies that isolate the effects of patents and those studies that look at a broader set of IPRs and their impact on innovation. Studies focusing on biopharmaceuticals and biotechnology are listed separately in the next subsection.

Patents

Maskus et al (2004) examine the impact of patent rights or other forms of technology protection on technology flows through FDI and licensing.[20] The authors also explore substitution effects

[19] See, for example, Chen, Y. & Puttitanun, T. (2004), "Intellectual Property Rights and Innovation in Developing Countries", Journal of Development Economics, Vol. 78, pp.474-493

[20] Maskus, K., Saggi, K. & Puttitanun, T. (2004), "Patent Rights and International Technology Transfer through Direct Investment and Licensing", Paper prepared for the conference, *International Public Good and the Transfer of Technology after TRIPS*, Duke University Law School, 2003

between level of FDI and of licensing in the context of stronger IPRs. The study finds that the existing empirical evidence suggests the impact of stronger IPRs could be large and positive in developing economies with the ability to absorb technology. It also finds that stronger IPRs drive multinational firms away from FDI and toward licensing only in higher technology industries. In lower technology industries, the study finds that it is more likely that stronger patents would induce firms to shift towards greater use of FDI, rather than licensing.

In an exhaustive and detailed study Chen and Puttitanun (2004) examined IPRs and their impact on domestic innovation and imitation activities in developing countries.[21] The study develops and applies a model that embodies the trade-off between imitating foreign technologies and encouraging domestic innovation in a developing country's choice to introduce protection of IP. It uses a panel of data for 64 developing countries. The strength of IPRs is measured using the Ginarte-Park index. Innovation by domestic firms is measured using the number of patent applications filed at the USPTO by developing countries' residents. The model also incorporates other variables, including measures of economic freedom, education, population and international trade. The study finds that the positive impact of introducing IPRs on domestic innovation is greater than the positive impact of not introducing protection and retaining the ability to imitate foreign technologies, particularly in emerging economies. The work concludes that even if strategic behavior or pressures from developed countries are not a concern, a developing country may still want to offer strong IPRs for domestic economic considerations.

In a similar vein to earlier work cited above in relation to FDI, Branstetter et al (2005) examine how technology transfer within US multinational firms to affiliates changed in response to a series of reforms of IPRs undertaken by 16 countries over the 1982-1999 period.[22] The study analyzes the effects of patent reform on the royalty payments and R&D expenditures of US multinational affiliates, as well as the level and growth rate of patent filings by non-residents. It uses firm- and affiliate-level data from US multinational firms operating in 16 countries. Patent reform is measured along five dimensions: patentable subject matter; scope of protection; length of protection; enforcement of patent rights; and administration of patent system. The study finds that royalty payments for technology transferred to affiliates increase at the time of reforms, as do affiliate R&D expenditures and total levels of foreign patent applications. For affiliates of parent companies that used US patents extensively prior to reform, increases in royalty payments following reform exceed 30%.

There are some studies that find a less positive relationship between IPRs and innovation. For example, Boldrin et al (2011) examine the role of patenting in technological innovation.[23] The study applies a theoretical framework and two scenarios: scenario 1 "monopoly" (existence of

---

[21] Chen, Y. & Puttitanun, T. (2004)
[22] Branstetter, L. et al (2005), *Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from US Firm-Level Panel Data*, US Dept of Commerce, Bureau of Economic Analysis/NBER
[23] Boldrin, M et al (2011), "Competition and Innovation", *Cato Papers on Public Policy*, Vol. 1 2011.

patent law and enforcement along the lines as in the US) versus scenario 2 "competition" (where patents are loosely enforced and only awarded for brief periods). The authors provide a few examples of large technology corporations and suggest their innovative capacity decreased once they became a "monopolist". In conclusion, the authors argue that there is a stronger case that competition can be more effective in promoting innovation as it may be conducive for good economic performance and good management practices. Similarly, Sakakibara and Branstetter (2001) examined whether expanding the scope of patent protection results in more innovative effort by firms, using Japan and the 1988 patent reform as a case study.[24] Overall, the authors found that Japanese firms have been mainly unresponsive to patent reform and finds no evidence of an increase in innovative effort or output that could be attributed to patent reform. However, these two studies' conclusions are largely based on isolated cases or on a theoretical discussion of patenting and not on any economic or statistical evidence on the actual effect patenting has on innovation.

Broader IPRs environment

Park and Lippoldt (2005) assess the effect of strengthened IPRs in developing countries on international licensing activity.[25] Overall, the study finds a net positive effect of strengthening IPRs on licensing activity, which is found to be strongest with respect to patent rights and the existence of effective enforcement. Furthermore, where developing countries have moved to address weaknesses in these areas in recent years, they have tended to experience increased inward licensing of IP assets.

Xu and Chiang (2005) examine international technology diffusion through trade and patenting, exploring different patterns of technology absorption based on country income level.[26] The study utilizes a sample of 48 countries for the period 1980 to 2000 and divides the sample in three groups according to real GDP per capita. It models international technology spill-overs from three sources: international trade, international patenting and human capital level in recipient countries. The effects of such spill-overs are measured as the average annual growth rate of total factor productivity. In line with much of the economic literature this study finds that the type and rate of technological and innovative spill-over IPRs contribute to depends on the level of development and absorptive capacity of a given country. The study finds that rich countries benefit from domestic technology and foreign technology embodied in imported capital goods; middle-income countries enjoy technology spill-overs from foreign patents and imported capital goods; and poor countries benefit mainly from foreign patents. It also finds that government

[24] Sakakibara, M. & Branstetter, L. (2001), "Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms", *RAND Journal of Economics*, Vol.32, No.1, pp.77-100

[25] Park, W.G. & Lippoldt, D. (2005), *International Licensing and the Strengthening of Intellectual Property Rights in Developing Countries during the 1990s*, OECD Economic Studies, No. 40, 2005/1

[26] Xu, B. & Chiang, E. (2005), "Trade, Patents and International Technology Diffusion", *Journal of International Trade and Economic Development*, Vol. 14, No. 1, pp. 115-135

policies on IPRs and trade openness have large effects on foreign technology spill-overs in middle- and low-income countries.

Léger (2006) studies the relationship between the strengthening of IPRs in developing countries and the level of innovation in these countries.[27] The author uses regression analysis to determine the relationship between key economic and political determinants and the influence of these factors on innovation in selected developing and industrialized countries. The factors considered are: 1) demand-pull factors (public demand for new products and services); 2) technology-push factors (advancements in technology which create new products and services); 3) macro-economic stability; 4) political instability; 5) access to capital; 6) cost of capital; 7) competition; 8) IP protection; and 9) human capital and education. The study finds that the factors most influential on innovation, in both developing and industrialized countries, are technology-push factors (measured as past investments in R&D as a percentage of GDP). The next most influential factor is IP protection (measured by several indices), followed by human capital and education. The order of factors was almost identical for developing and developed countries.

In a case study analysis, Dutta and Sharma (2008) explore the effect of TRIPS implementation on innovation in India.[28] The authors utilized data sets on R&D spending of Indian knowledge intensive firms from 1989 to 2005 to determine whether the signing of TRIPS and commencing reforms of IPRs were successful in increasing innovation. The authors find that after TRIPS implementation Indian firms increased their R&D expenditure on average by 20%. The article also finds that patenting in the US by Indian firms has also increased after TRIPS, and to a greater extent in Indian knowledge-intensive industries. They conclude that the immediate short-term effects of the TRIPS agreement in India show promising trends about the ability of stronger IPRs to create incentives for greater R&D and transfer of technology.

Finally, Park and Lippoldt (2008) find that IPRs stimulate technology transfer, particularly the transfer of technology-intensive goods, services and capital.[29] The authors use regression analysis to analyze the relationship between IPRs and technology transfer, and the relationship between IPRs and innovation in a large set of countries. The study also finds that IPRs can directly and indirectly stimulate local innovation by stimulating the transfer of technologies that foster it.

---

[27] Léger, A. (2006), "Intellectual Property Rights and Innovation in Developing Countries: Evidence from Panel Data", Proceedings of the German Development Economics Conference, Berlin

[28] Dutta, A. & Sharma, S. (2008), *Intellectual Property Rights and Innovation in Developing Countries: Evidence from India, Enterprise Surveys,* World Bank, http://www.enterprisesurveys.org/About-Us

[29] Park, W. G. & Lippoldt, D. (2008), *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

IPRs and biopharmaceutical innovation

The relationship between IPRs and biopharmaceutical innovation is together with copyright on the internet perhaps the most contentiously debated topic in the literature. Proponents argue that IPRs are essential to pharmaceutical and biotechnological innovation and provide innovators with the necessary incentives to continue to invest in research and to develop new drugs. Critics claim that pharmaceutical IPRs stifle innovation and raise the cost of drug development.

The below section has been divided up into country-specific case studies and broader ranging theoretical and/or empirical discussions.

Country case studies

Pazderka (1999) investigated the impact of the strengthening of IPRs on corporate R&D spending in the pharmaceutical industry in Canada.[30] The paper studies trends in pharmaceutical R&D spending in Canada before and after 1987 (the year in which Bill C-22 restored full patent protection to prescription drugs; after two decades of policies favoring compulsory licensing). The author finds a dramatic acceleration in corporate pharmaceutical R&D spending after 1988 – between 1988 and 1997, spending increased 3.4 times. However, this increase also took place in the context of a commitment by the Pharmaceutical Manufacturers Association of Canada (PMAC) in conjunction with the patent reform to double the R&D-to-sales ratio between 1984 and 1996. The study concludes that the strengthening of patent protection led to a change in trend in pharmaceutical spending. Although it suggests that patent reform was not the exclusive factor driving the rise in R&D spending, it facilitated an increased willingness on the part of pharmaceutical companies to invest in R&D.

In contrast, using Mexico as a case study Zuniga and Combe (2002) evaluate the economic impact of patent protection on pharmaceuticals, finding that dynamic gains are not being felt as a result of patent reform.[31] The authors argue that following patent reform, Mexico experienced a deterioration in the trade balance (although this was already a trend) and an increase in FDI. However, no significant change was noted in licensing activity. Furthermore, R&D mainly shifted from imitative to generic-focused activities.

Like Pazderka, Ryan and Shanebrook (2004) find a more positive correlation in their case study analysis of Jordan and the effects of reforms of IPRs in the late 1990s and early 2000s.[32] The study finds that: Jordanian GDP increased from 2.8% in 1997 to 3.5% in 2001; health-services

[30] Pazderka, B. (1999), "Patent Protection and Pharmaceutical R&D Spending in Canada", *Canadian Public Policy*, Vol. 25, No.1, pp.29-46

[31] Zuniga, M.P. & Combe, E. (2002), "Introducing Patent Protection in the Pharmaceutical Sector: A First Evaluation of the Mexican Case", *Revue Region et Developpement*, No. 16

[32] Ryan, M. & Shanebrook, J. (2004), *Establishing Globally Competitive Pharmaceutical and Biomedical Technology Industries in Jordan: Assessment of Business Strategies and the Enabling Environment*, IIPIl August 2004

employment grew 52% from 1997 levels; the multinational pharmaceutical presence expanded with many firms doubling or tripling their headcount; medical tourism increased to two-thirds of total tourism revenues in Jordan; the number of clinical trials multiplied; and drug exports from local firms grew by 30%.

In a more wide-ranging analysis Lanjouw and MacLeod (2005) examined whether introducing patent rights in developing country markets via the TRIPS agreement has stimulated greater R&D investment in neglected diseases.[33] The study is based on both statistical data and survey evidence during the period of implementing the TRIPS agreement (1995-2005). It examines trends in indicators of R&D (NIAID grants, literature citations and patenting in the US) targeting diseases concentrated in lower income countries. Special focus is paid to India, based on the argument that India-based scientists would have a comparative advantage in R&D targeting developing countries and hence, new R&D activity would be most apparent there. The survey evidence focuses on a pair of surveys carried out in 1998 and 2003 of India-based scientists on how much of their work is related to developing country markets. According to the data, patenting activities targeting previously neglected diseases sped up in the early 2000s (although it is still relatively low compared to overall pharmaceutical patenting). In the case of India, pharmaceutical patenting by India-based inventors grew rapidly in the period (to over 2% of all patenting in the US) as did pharmaceutical R&D expenditure. However, the survey results indicate that, while 16% of this expenditure was directed towards neglected diseases in 1998, this percentage dropped to 10% in 2003. The results suggest that the impact of the TRIPS agreement has been a steady increase in pharmaceutical R&D activity in some areas of neglected diseases, by both OECD-based and domestic companies, such as in India. However, the latest R&D activity by domestic companies is not necessarily focused on neglected diseases, but rather on global products.

Finally, Pugatch et al (2007) examined examples of technology transfer activities in the developing world.[34] The paper suggests that there is a growing body of evidence that IPRs are, and have been, important for the promotion of innovative, inventive and technology transfer activities in developing countries, including in industrial sectors like pharmaceuticals and biotechnology. Examining a number of commercialization initiatives arising from public-private partnerships in China, India and across South East Asia, Africa and South America, the paper concludes that research bodies consider IPRs to be an important platform in their ability to successfully commercialize their innovations and bring new products to market.

[33] Lanjouw, J. & MacLeod, M. (2005), *Statistical Trends in Pharmaceutical Research in Poor Countries*, Commission on Intellectual Property, Innovation and Public Health, WHO

[34] Pugatch, M., Davison H. and Diamant R., (2007), *Promoting Technology Transfer in Developing Countries: Lessons from Public-Private Partnerships in the Field of Pharmaceuticals*, Stockholm Network London.

Broader theoretical and empirical work

In an empirical analysis with case study examples Wertheimer et al (2001) examined the importance of incremental innovation in the fields of pharmaceuticals.[35] Detailed examples are provided for several classes of drugs: Antihistamines, Beta-Blockers, Calcium Channel Blockers, Cephalosporin Antibiotics, Non-Steroidal Anti-Inflammatory Drugs, Oral Contraceptives, Diabetes Medications, Atypical Antipsychotics, Anesthetics and Endocrine Therapy for Breast Cancer. Based on these examples, the paper argues that incremental innovation has resulted, over time, in striking improvements in existing drug therapy and patient care, and in some cases in reduced total costs for therapy.

Lippoldt (2006) provides evidence on the relationship between IPRs and FDI in the pharmaceutical sector, studying it in the context of increasing globalization and improved protection for IP in the developing world.[36] The author analyzes several evidence-based studies on the impact of the strength of IP protection on the volume and nature of inward investment and imports, focusing on the studies' findings in the pharmaceutical sector. The study finds a positive relationship between IPRs and FDI in the sector. It concludes that the strength of IPRs is one important factor – among others – influencing trade and investment decisions in the pharmaceutical sector.

Qian (2007) adds nuance to the debate finding that patent protection and economic development together are positively related to domestic R&D expenditure.[37] Patent protection together with economic freedom and education are also found to have a positive relationship with domestic R&D spending (this is only found in OECD countries). Furthermore, the study finds that above a certain level of IP protection, further increases in protection are eventually associated with a decline in innovative activities.

IPRs and access to medicines

The extent to which IPRs affect access to medicines in developing countries (be it positively or negatively) is a topic of intense debate and attention. In the international community this is a topic of increasing interest, particularly to the WHO which has conducted a number of studies over the last half decade. Although there has been some discussion about the role of IPRs at the upstream level in relation to R&D into type II and III diseases that disproportionately affect low

---

[35] Wertheimer, A., Levy, R., O'Connor, T. (2001), "Too Many Drugs? The Clinical and Economic Value of Incremental Innovations" in *Investing in Health: The Social and Economic Benefits of Health Care Innovation* (Research in Human Capital and Development, Volume 14), Emerald Group Publishing Limited, pp. 77-118

[36] Lippoldt, D. (2006), *Intellectual Property Rights, Pharmaceuticals and Foreign Direct Investment*, Groupe d'Economie Mondiale de Sciences Po

[37] Qian, Y. (2007), "Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection", 1978-2002, *Review of Economics and Statistics*, Vol. 89, No.3, pp.436-453

income countries,[38] generally the issue of access to medicines pertains to existing, fully developed drugs and medical technologies.

While this report does not focus on the above debate, a few examples may be given in order to illustrate the international and academic discussion on this issue.

Borrell (2004) examines the impact of patents on drug prices across developing countries.[39] The study uses sales data on HIV/AIDS drugs in a sample of 34 low and middle-income countries between 1995 and 2000. The study finds that the average daily dose price of any ARV "cocktail therapy" is higher when it includes products under patent regime. In addition, the study suggests that multinational drug firms have tiered their prices to per capita income across countries when drugs are under patent regime. Additional studies by Li (2008) and Scherer and Watal (2001) reach a similar conclusion.[40]

On the other hand, Attaran (2004) examines the link between patents in developing countries and access to medicines.[41] The author concludes that patents for essential medicines are uncommon in poor countries (less than 2%) and cannot explain why access to those medicines is often lacking, suggesting that poverty, not patents, imposes the greater limitation on access to essential medicines. Specifically, Attaran found that in the 65 countries surveyed, where the majority of people in the developing world live, patents and patent applications exist for essential medicines 1.4% of the time (300 instances out of 20,735 combinations of essential medicines and countries). He further notes that since it is only a subset of patents that are absolutely fundamental to generic manufacturers (normally, a patent on the active pharmaceutical ingredient, and for medicines containing two such ingredients, a patent on their co-formulation), there are only 186 fundamental patents or applications, or 0.9% of the total. Therefore, the article finds that there are no patent barriers to accessing generic essential medicines in 98.6% of the cases studied.

Similarly, Glynn (2009) analyzed the impact of measures that aim to countervail patent protection, such as parallel trade, on access to patented medicines.[42] The study examined the effects of price convergence on access to medicines in EU Member States. Based on Member

---

[38] See: Lanjouw, J. & Cockburn, I. (2001), "New Pills for Poor People? Empirical Evidence after GATT", *World Development*, Vol. 29, No.2, pp.265-289; WHO Consultative Expert Working Group on Research and Development: Financing and Coordination, (2012), *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, WHO; Borrell, J.R. & Watal, J. (2003), *Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries*, Center for International Development, Harvard University, Work Paper No. 92, Revised Version

[39] Borrell, J. R. (2004), *Pricing and Patents of HIV/AIDS Drugs in Developing Countries*

[40] Li, X. (2008), *The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement: A Comparative Study of China and India*, UNU-WIDER Research Paper No. 2008/36; Scherer, F.M. & Watal, J. (2001), *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, Commission on Macroeconomics and Health Working Paper

[41] Attaran, A. (2004), "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?" *Health Affairs*, Vol. 23, No. 3, pp. 155-66

[42] Glynn, D. (2009), "The Effects of Parallel Trade on Affordable Access to Medicines", *Eurohealth*, Vol. 15, No. 2, pp. 1-5

State GDP per capita and population size, it estimates and compares potential sales under two scenarios: in the cases of a single EU price (under which the ability of the patent holder to set different prices in different countries is effectively denied), and of differentiated prices (under which patent holders are entitled to exercise their right to determine the price of their product). The paper finds that a single EU price (i.e., resulting from parallel trade) would reduce the number of patients with affordable access to patented medicines, compared to optimally differentiated prices. On the assumptions of an overall EU population of 482 million, it finds that over 100 million would not be supplied if a single EU price were to be adopted. Furthermore, gross profits of manufacturers would be reduced by about 25%. Therefore, the article concludes that constraining parallel trade, by prohibiting repackaging and requiring traceability throughout the supply chain, would reduce the risk to patient safety and improve affordability of medicines across the EU as a whole.

Patents and access to biotechnological research and innovation

Scientific breakthroughs in biotechnology and gene mapping during the 1980s and 1990s brought to the fore a number of questions relating to the scope of patent protection that should be provided to early stage biotechnological innovations.

In this context there are on-going debates concerning the extent to which broader patent protection can slow down the rate of innovation and diffusion of biotechnology research, specifically during the upstream phases.

In fact, one could argue that the common thread that underlines these debates is the fear that patent protection may be used in a manner that would monopolize the 'essential' building blocks of biotechnological research (such as genes).[43]

Consequently, different theoretical studies often focus on potential negative effects that patents can have or have had on biotechnological innovation. For example, Hettinger (1995) offered a theoretical discussion of the proliferation of biotechnology and genetic patenting.[44] The author argues that the patenting of biotechnology – in particular genes and organisms – has not contributed to biotechnological innovation and should be discouraged. More recent work, such as Clark et al (2000) and Gold et al (2007), while taking a more nuanced view, have also come to the conclusion that future biotechnological innovation will be dependent on collaborative models of innovation rather than models based on IPRs.

---

[43] See for example the recent US Supreme Court Case *Prometheus v Mayo*. The Court overturned existing patent claims held by Prometheus Laboratories. The patents in question relate to a test enabling physicians to set levels of medication for treating autoimmune disorders affecting the digestive system. The Court argued that the patents did not in fact do more than describe naturally occurring phenomena, which in themselves are not patentable. The verdict raised concerns in the biotechnology industry over future application of the ruling and its implications for lower level courts and patent examiners.

[44] Hettinger, N (1995), "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics", *Boston College Environmental Affairs Law Review*, Vol. 22, Issue 2

Yet since the mid-1990s, and particularly over the past decade, a number of evidence-based studies have questioned these judgments and begun to provide more concrete data on the impact patents have on upstream biotechnological research and innovation.

In fact this new evidence suggests that, by and large, the patent system does not hinder or prevent access to biotechnological research and innovation.

For example, Walsh et al (2003) surveyed scientific researchers, members of the legal community and biomedical managers in the US on the effect patents have on biomedical R&D activities.[45] The survey found that despite the sharp increase in overall patenting, patenting of research tools and upstream patenting, very few research projects had been cancelled or suffered long delays.

Adding to their previous work Walsh et al (2005) surveyed both industry and academic biotechnology scientists on the impact IPRs and material transfer agreements (MTAs) had on their research.[46] (MTAs are used by academic institutions to protect the value of their own IP assets as well as to reduce exposure to third-party lawsuits.) The authors found that the existence of patents had a negligible impact on their research causing delays of over 1 month in only 1% of cases. In contrast, MTAs had a more substantive – albeit still relatively limited – effect causing delays of over 1 month in 8% of cases.

In an in-depth report the US National Academy of Sciences (2006) on behalf of the National Institutes of Health reviewed how the granting and licensing of IPRs (chiefly patents) on research relating to genetics and proteomics (relating to human and health research) has affected R&D in these fields.[47] The NAS conducted a literature review, public hearings and a survey of research scientists. The Academy found that patents have not had an adverse effect on scientists' access to research or technology tools or placed costly and undue burdens in the acquisition of needed IP assets.

Likewise, Adelman and DeAngelis (2007) examined the impact of biotechnology patenting on rates of innovation, finding that the cumulative growth in biotechnology patenting during the period studied had not had an adverse impact on biotechnology innovation.[48] The study analyzed US biotechnology patenting between 1990 and 2004, and over 52,000 patents in total.

[45] Walsh, E. et al (2003), "Working Through the Patent Problem", *Science*, Vol 299, February 2003.
[46] Walsh, E. et al (2005), "Patents, Material Transfers and Access to Research Inputs in Biomedical Research", Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions,
[47] NAS, Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, National Research Council, (2006), *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*, National Academic Press, Washington DC.
[48] Adelman, D.E. and DeAngelis, K.L. (2007), "Patent Metrics: The Mismeasure of Innovation in The Biotech Patent Debate", Arizona Legal Studies Discussion Paper No. 06-10.

The US FTC (2009) reached a similar conclusion when studying competition issues relating to the introduction of follow-on biologic drugs.[49] As part of the report the Commission examined the extent to which patenting has contributed to or hindered innovation in biotechnology. The FTC found no reason why the patent system should not be continued to be relied upon to stimulate biotechnology innovation.

Lei et al (2009) surveyed a number of agricultural biologists in the US and obtained results comparable to Walsh (2003, 2005).[50] The purpose of the survey was to gauge the role and effect of patenting on research. The survey found that a plurality of respondents did not find that patents themselves are a hindrance to research. Rather, administrative processes such as MTAs were seen as blocking access to research tools.

Finally, Nicol (2010) examined the effect of patents on upstream biomedical innovation and the use of collaborative arrangements in the field, taking Australia as a case study.[51] Like the other surveys cited above, it too finds third party patents to be a relatively limited hindrance in research activities. The study utilized a survey of various actors in different sectors of the biomedical industry, including firms, universities, research institutes and hospitals. Three types of collaborative arrangements were considered: cross licensing, patent pools and clearinghouse mechanisms. The study finds that 75% of participants did not identify an undue burden resulting from third party patents (although many participants were not engaged in licensing activities). Furthermore, the study finds limited knowledge of collaborative mechanisms, except in drug discovery and pharmaceuticals sectors. The work concludes that further study is needed as participating entities mature and licensing becomes more relevant.

Section summary

This section has sought to outline the major contemporary debates relating to IPRs both generally and specifically to biotechnology and biopharmaceutical R&D. The key findings discussed in the literature include:

- There is a growing body of evidence suggesting a positive link between economic development, technology transfer, rates of innovation and the existence of IPRs. This is particularly strong in certain high-tech sectors such as biopharmaceuticals.
- Much of the international debate on biopharmacutical innovation focuses on downstream issues: whether IPRs promote or hinder innovation and to what extent they enable or

[49] FTC (2009), *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, FTC 2009
[50] Lei, Z. et al, (2009), "Patents versus patenting: implications of intellectual property protection for biological research", *Nature Biotechnology*, Vol 27, No 1, Jan 2009.
[51] Nicol, D. (2010), "Collaborative Licensing in Biotechnology: A Survey of Knowledge, Experience and Attitudes in Australia", *Biotechnology Law Report*, Vol.29, pp.465-483

delay access to medicines in developing countries. This discussion is usually placed in the context of the "North-South" divide (i.e., developed vs. developing world) and the extent to which the use of IPRs benefits or damages developing countries.

- The discussion on the use of IPRs in upstream innovation (or the relationship of IPRs and biotechnology innovation in the context of SMEs and universities) is often theoretical in nature and only at times based on data and collected evidence.
- Recent empirical studies and surveys seem to significantly ease ongoing concerns about the extent to which the patent system may be used in a manner that slows or hinders access to biotechnological research and innovation. Still, there is a relative paucity of direct evidence and data on the roles that IPRs play in stimulating biotech research and innovation.
- Some international debates on IPRs relating to the upstream R&D process also examine the issue of ownership of genetic innovations and biologic materials and so called research exemptions.

Table 1 summarizes the body of evidence reviewed and the major conclusions drawn.

Table 1: Summary of Existing Evidence and Main Findings

IPRs, FDI, trade and economic development)	- Much of the economic, econometric and survey analysis suggests that there is a positive correlation between IPRs, FDI, trade and economic development. - The literature often finds that there are variations in the impact of IPRs depending on a country's stage of development, income level and technical capabilities.
IPRs and innovation	- Economic analysis at both the macro and micro level of licensing activity, rates of patenting and technology transfer in countries that have strengthened their IPRs suggests a positive link between higher levels of innovation and stronger IPRs. - As above this literature also suggests that stronger IPRs are likely to encourage innovation in combination with other policies and development (e.g., infrastructure, education, improved technical R&D capability, etc.) at both the macro and micro level.
IPRs and biopharmaceutical innovation	- Country-specific analysis and broader studies suggest that IPRs (in conjunction with other policy measures) can have a positive impact on biopharmaceutical innovation.
IPRs and access to medicines	- Studies of patenting in developing countries suggest that few essential medicines are under patent protection in developing countries. - Other studies suggest that patent protection on medicines (e.g., HIV/AIDS anti-retrovirals) raises the cost of these medicines.
Patents and access to biotechnological research and innovation	- Recent empirical studies and surveys seem to significantly ease ongoing concerns about the extent to which the patent system may be used in a manner that slows or hinders access to biotechnological research and innovation. - Still, there is a relative paucity of direct evidence and data on the roles that IPRs play in stimulating biotech research and innovation

Source: Pugatch Consilium analysis (2012)

Based on these findings, the following sections will provide additional material and evidence on how IPRs are actively being used within the upstream research and commercialization process by biotech entities such as SMEs, universities and research institutes. It will also relate these trends and place them in the wider context of IPRs being an important variable in the encouragement of FDI, economic development and innovation, as illustrated by the economic literature surveyed.

2 The strategic use of IPRs during the R&D process in the biotechnology ecosystem

How do companies, universities and research organizations specializing in biotech use IPRs in their R&D?

This section details how IPRs are impacting biotechnological innovation. Specifically, it examines how biotech entities – at both the upstream and downstream level – have made and are making use of IPRs in their research activities. In particular, three areas of research related activities are focused on:

- Biotechnology patenting activity;
- Technology transfer and licensing by biotechnology entities; and
- Partnerships and collaboration between biotechnology entities and/or larger entities such as biopharmaceutical manufacturers.

The manner in which biotech entities make use of IPRs provides a good indication of how these entities view the value of IPRs and the extent to which they play a significant role in their business strategies and incentivize upstream R&D.

2.1 Biotechnology patenting activity

As outlined in the preceding sections, a number of studies view patenting activity as a good proxy for innovation. Increased levels of patenting suggest that individuals and companies see a clear value in their research and wish to protect and disseminate it. Patenting, in this light, is thus an integral part of innovation.

This section will suggest that in the biotechnology and biopharmaceutical sectors much of the evidence points to patenting being an essential component of the innovation process. Biotech companies, universities and research institutes use patents as a way of not only gaining protection for their innovations, but also: securing capital investment; obtaining scientific citations; acquiring knowledge about their competitors' R&D activities; and publicity for their R&D activities.

Biotechnology patenting rates

Patenting has increased sharply over the past few decades as large segments of the global economy have shifted away from traditional manufacturing and industrial production to knowledge-based industries and high-tech production. For example, from the mid-1980s to the mid-2000s, the total number of patents granted by the USPTO increased by 6% per year.[52] Similar increases have been experienced at all major patenting offices globally.

In the biotechnology sector this growth in patenting has been even more pronounced. In fact, biotechnology patenting applications have far outpaced the general rise in patenting applications. For instance, from 1993 to the mid-2000s, the growth of biotechnology-related applications to the EPO was 14.3% a year compared with 8.3% for all patent applications.[53]

Looking at the total number of biotechnology patents filed globally over the past 40 years, the scale of this growth is even more impressive. In 1977, measured by patent applications filed under the PCT, there were 12 biotechnology patents filed globally.[54] By 2009 this had increased to 9,339 patents – a mind-boggling increase of over 77,000%. Figure 1 summarizes this rise globally, for the OECD, the US and EU27.

Figure 1 illustrates how much of the increase in patenting took place within the OECD. In particular, the US and the EU27 have accounted for the vast majority of biotechnology patenting globally. For example, in 2009 out of a total of 9,339 patent applications filed through the PCT, 6,448.5 patents, or 69%, were applied for by an inventor resident in either the EU27 or US.

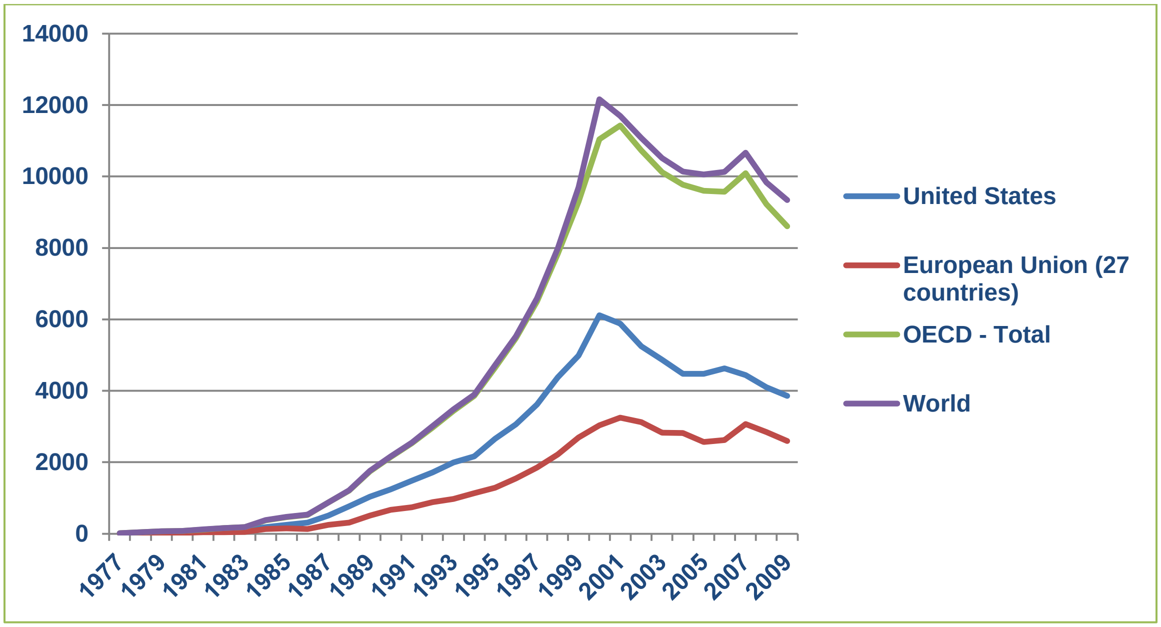
Still, this is not to say that biotechnology patenting outside the OECD did not experience significant growth. In fact, in the BRIC economies, as well as a number of other Asian and Latin American 'tigers', biotechnology patenting increased substantially over the same time period. Below Figures 2 and 3 provide an overview of this rise for ten major past and present emerging economies: Brazil, India, Russia, Singapore, Taiwan, Argentina, Israel, Japan, Korea and China. (China, Japan, Korea and Israel are listed separately in Figure 3 given that their biotechnology patenting activity grew more strongly than the other countries during this period.)

[52] Barrone, E. (2005), "Intellectual Property Rights and Innovation in SMEs in OECD Countries", *Journal of Intellectual Property Rights*, Vol. 10, January 2005, 34-43

[53] Ibid.

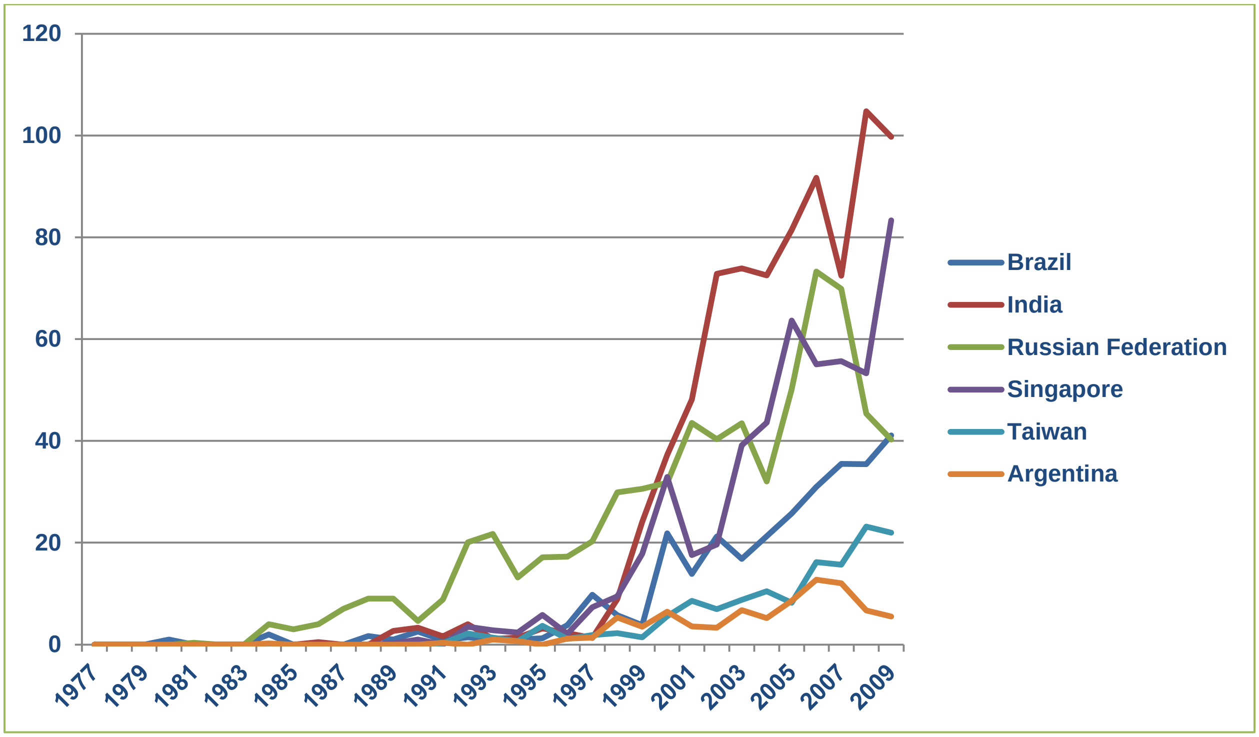
[54] OECD Patent statistics, OECD.Stat, Patent Applications filed under the PCT, Biotechnology. Data accessed March 2012.

Figure 1: Number of biotechnology patents filed under PCT, 1977-2009



Source: Pugatch Consilium analysis based on OECD data (2012)[55]

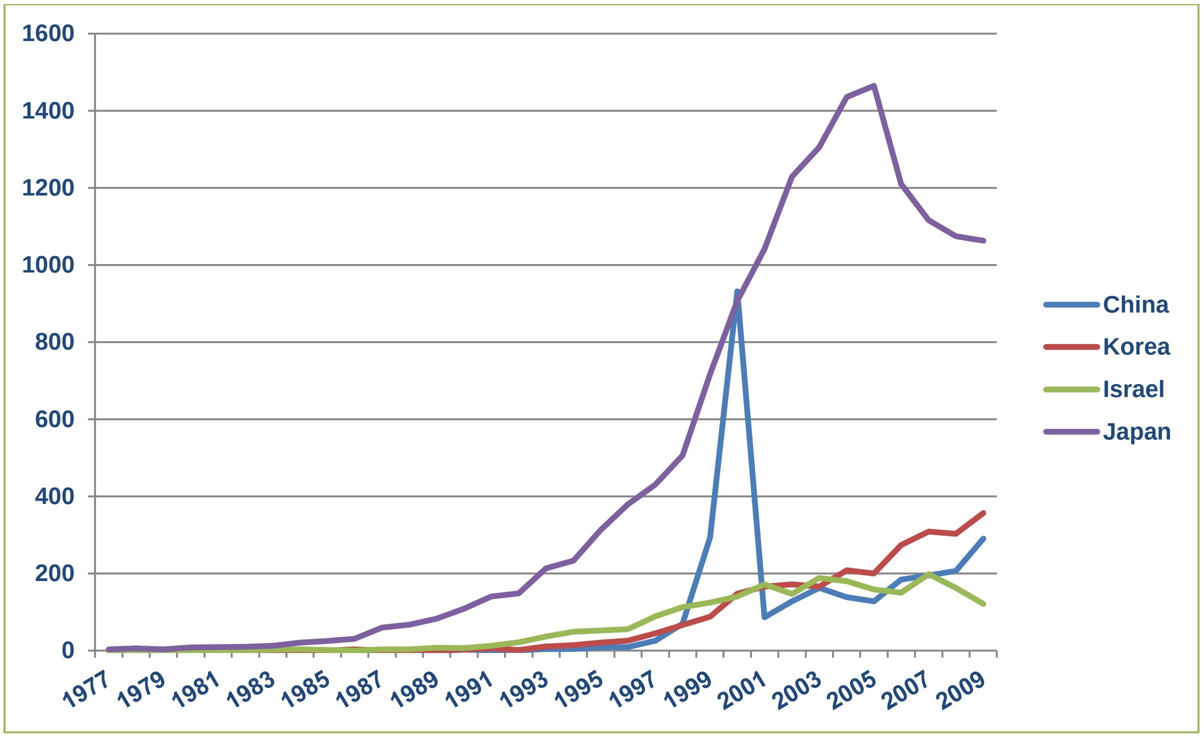
Figure 2: Number of biotechnology patents filed under PCT, 1977-2009



Source: Pugatch Consilium analysis based on OECD data (2012)[56]

[55] Ibid.
[56] Ibid.

Figure 3: Number of biotechnology patents filed under PCT, 1977-2009



Source: Pugatch Consilium analysis based on OECD data (2012)[57]

Figures 2 and 3 show a steady and substantial rise in biotechnology patenting applications by these countries. In particular, Japan, China, India, Korea and Singapore have experienced strong and sustained growth levels in biotechnology patenting.

What has caused this global rise in patenting? At the macro level there are a number of factors including: globalization and the decision by many firms to patent in foreign locations; the increased importance of knowledge-based industries within the global economy; outsourcing to foreign countries (for which products and technologies must be protected); TRIPS and the international focus on IPRs and better enforcement; court cases, specifically *Diamond v Chakrabarty* (1980), which was important for biotechnology patenting in the US; the growth of technology transfer through the US Bayh-Dole Act and similar legislation globally; and perhaps above all, a number of scientific breakthroughs that fundamentally changed the upstream and downstream research process.[58]

Indeed, the global growth in biotechnology patenting captured in the above figures correlates with the significant growth and development of biotechnology as a substantive research and commercial field in itself. Scientific breakthroughs such as genetic engineering, the ability to create monoclonal antibodies and the mapping of the human genome have opened up new areas

[57] Ibid.
[58] For a detailed discussion and outline of these factors see Barrone (2005).

of research, and the pace of discovery in basic biomedical science has accelerated dramatically over the last few decades.

For biotech entities the importance of some of these factors – particularly technology transfer legislation and private-public frameworks – cannot be overstated. Below subsection 2.2 and section 3 will discuss the impact of technology transfer mechanisms on the commercialization of upstream research. Biotech entities – particularly at the upstream level – are now actively engaged in commercializing their R&D and reaping the rewards in term of licensing revenues and royalties. While not uniform, this is also a process that is rapidly spreading across the world.

The sustained and substantial increase in biotechnology patenting since the late 1970s strongly suggests that biotech entities globally have come to see a value in protecting their individual R&D and IP through patenting. Before turning to the ramifications of this increase in patenting and concomitant increase in licensing activity, it is worth examining how biotech entities at the micro level view patenting and the protection of their IP. Indeed, a number of surveys and studies of biotech entities (particularly SMEs) in both developed and emerging economies provide further insight into how patenting affects biotech entities' R&D and business decisions.

The role of patenting within biotechnology entities – Korea and Switzerland

The following pages provide an overview of how biotechnology SMEs in Korea and Switzerland view patenting for their business and R&D.

Switzerland and Korea are two good examples for a number of reasons. First, there are high quality and recent biotech survey and patent data available for both. Second, both countries have seen sharp increases in both the number of biotech entities and the patenting activity of these entities. Finally, the two countries are regionally, culturally and economically very different, providing diversity to the analysis. Korea is an Asian tiger, and a good example of a fast-growing and dynamic emerging economy. Switzerland is an example of a mature, developed economy.

Korea

A 2010 survey of Korean biotech SMEs by researchers at the Korea Institute of Intellectual Property and Seoul National University illustrates how patenting is a multifaceted instrument used by biotech entities for a number of purposes. Korea is a particularly revealing case study for a number of reasons.

First the Korean economy has seen tremendous growth and development over the past 30 years. In 1980 GDP per capita measured at purchasing power parity (PPP) was under $5,000. By the first quarter of 2012, this had reached close to $30,000.[59] Similarly, during this period the Korean economy saw annual GDP growth rates often exceeding 10% and in the last few years over 5% per year.[60] In addition, Korea has rapidly moved towards a more knowledge-based economy producing higher value and technologically more sophisticated goods and services.

Second, Korea implemented a host of IP-related reforms aimed at encouraging innovation and technology transfer (including a Bayh-Dole style framework, which will be discussed in greater detail below). Chief among these were the Korean Technology Enhancement Act of 2000 and the establishment of the Korea Technology Transfer Center.[61]

Third, during the past decade Korea has seen tremendous growth in its biotechnology sector, particularly of SMEs. Between 1999 and 2006 the number of biotech SMEs increased by almost 10 times, growing from 70 in 1999 to 600 in 2006.[62]

The 2010 survey found that close to all (96%) of the SMEs surveyed had searched and used patent information. Moreover, respondents explained that there were three main reasons for the use of patent information: to avoid duplicative or redundant R&D activities; to observe research trends in related fields; and/or to monitor their competitors' performances.[63]

Close to all respondents (95%) had filed patent applications. In fact, the mean number of patent applications both domestically and internationally was quite substantial at 11.59 and 4.98 respectively.[64]

Revealingly, patenting was sought for a number of strategic and business reasons including: commercial exploitation; preventing competitors from obtaining patents with similar technologies; and as a basis for partnerships and attracting funding.[65]

Switzerland

Similar sentiments can be seen in Switzerland. Switzerland is an excellent example of a country that has successfully encouraged the emergence of a vibrant and innovative biotechnology sector in a relatively short time-frame. The success and growth of the Swiss biotechnology industry has

---

[59] Trading Economics, South Korea GDP per capita PPP, (Accessed May 2012), http://www.tradingeconomics.com/south-korea/gdp-per-capita-ppp

[60] Trading Economics, South Korea GDP Annual Growth Rate, (Accessed May 2012), http://www.tradingeconomics.com/south-korea/gdp-growth-annual

[61] Park, J. & Moultrie, J. (2010), "Understanding university academics' knowledge interactions in different disciplines: evidence from universities in South Korea", conference paper, *Opening Up Innovation: Strategy, Organization and Technology*, Imperial College, London, June 2010.

[62] Kang, K.N. & Lee, Y.S.(2010), "Patent activities in Biotech SMEs", *Tech Monitor*, Nov-Dec 2010.

[63] Ibid. p. 39.

[64] Ibid.

[65] Ibid.

largely been the result of government-backed initiatives through the National Sciences Foundation and its nine-year program SPP BioTech launched in 1992. In particular, the successful development of the Swiss biotechnology industry was aided by the promotion of technology transfer through networks of tech transfer offices and the establishment of the Swiss Technology Transfer Association (swiTT). This program sought to promote technology transfer and the commercialization of biotechnology through start-ups, venture capital partnerships and spin-offs.[66] Since the formalization of technology transfer programs in Switzerland, the number of biotech start-ups has shot up from 5 in 1995 and 3 in 1996 to an average of 11.4 between 1997 and 2010.[67]

The importance of patenting for these biotech entities can be seen both on a macro level in increased rates of patenting as well as on the micro firm-specific level. At the macro level, since 2001, Switzerland has seen the number of biotechnology patents per capita increase by over 300%; far higher than other top biotech countries.[68]

On the micro level a survey of Swiss biotech entities by the Swiss Federal Institute of Intellectual Property in 2003 reveals not only that biotech entities have a number of strong motivations for patenting, but that these also vary in strength depending on the size and composition of the entity (for example, corporate versus public research body).

When asked about the motivations behind seeking patent protection, protecting one's technology from imitation was given the highest rank by half of the sample.[69] This was followed by preventing competitors' patent applications.

Interestingly, all sized companies (measured by employing less than 50, 50-250, or over 250 people, respectively) viewed patenting as important for their cooperation with other companies. This was particularly the case for large companies. For small companies, patents were viewed as a way of attracting venture capital.[70]

The Korean and Swiss surveys illustrate how biotech entities view patenting as an important element of their R&D and commercial strategies. Specifically, the ability to prevent competitors from imitating an inventor's products was cited as a key factor in seeking patent protection. There is a risk that mechanisms such as compulsory licensing and/or patent exemptions which reduce this protection may limit incentives to innovate at the upstream and downstream levels. While the use of compulsory licensing for exceptional or emergency circumstances is regarded as acceptable under international legal conventions relating to IPRs, its use for non-humanitarian

---

[66] Swiss Biotech (2010), *Report 2010*, p. 6.
[67] Ibid. p. 8.
[68] Ibid. p. 10.
[69] Thumm, N. (2003), *Research and Patenting in Biotechnology – A Survey in Switzerland*, Swiss Federal Institute of Intellectual Property, p. 22.
[70] Ibid. p. 23.

objectives, such as cost containment and industrial policy, is not. Indeed, it is this aspect of compulsory licensing and too broadly defined exemptions that risk damaging the strength of protection on patents relevant to the medicines that are licensed in this way. This issue is further discussed in relation to India below in section 3.

2.2 Technology transfer and licensing

Since the mid-1980s, the upstream R&D process has been heavily influenced by the spread and growing use of technology transfer frameworks throughout the world. These frameworks (often modeled on American legislation; described below) allow universities and publicly funded research institutions to commercialize and utilize the IP created through their research efforts.[71]

The establishment of technology transfer mechanisms can have a number of positive results including:

- the generation of revenue in the form of licensing fees and royalties to academic institutions and start-ups;
- the commercialization of research; and
- the growth and development of industrial clusters, mostly in and around major universities and technology corridors.

A number of countries that have a well-established, fluid and well-functioning system of technology transfer have also experienced growth in licensing activities and revenues for related biotech entities. Indeed, many universities, research-based SMEs and start-ups are actively engaged in producing, commercializing and licensing their research.

The US was one of the pioneers, putting in place a legislative framework for promoting and encouraging technology transfer, partnerships and collaboration between industry, universities and federally funded institutions. Since the early to mid-1980s and the passage of the Patent and Trademark Amendment Act of 1980 (Bayh-Dole Act), the Stevenson-Wydler Technology Innovation Act and their subsequent amended acts (Federal Technology Transfer Act of 1986 and Technology Transfer Commercialization Act of 2000), American universities and federal research bodies have been allowed to commercialize and utilize the IP created through their research efforts.

A number of academic and industry studies show how Bayh-Dole has had a tremendous impact on university patenting activity. For example, the university share of total patenting in the US

[71] This increased use of IPRs, such as patents, by universities and publicly funded institutions is one of the factors contributing to the significant growth in patenting activity (not least in the biotechnology and biopharmaceutical sphere) described above.

increased from 0.69% of total patents to just under 5% in 1996.[72] Moreover, in a range of 117 industries (including pharmaceutical drugs) this increase in patenting was from a contraction of 87% in 1969 to an increase of 1,648% in 1996. Even today under the current adverse economic conditions, the positive effects of Bayh Dole are being felt. In 2010 university related patenting, licensing, and start-ups were still strong with close to 19,000 patent applications filed, over 4,000 licenses executed, and 650 start-ups formed.[73]

Other countries have followed in the footsteps of the US.

These include Japan, which introduced the Law for Promoting University-Industry Technology Transfer in 1998. This legislation enabled the establishment of Technology Licensing Offices (TLOs). A number of universities (including the University of Tokyo, Nihon University, Kansai OTT and Tohoku Technoarch) have received approvals for offices of technology transfer.

Similarly, Germany introduced its version of a Bayh-Dole framework in the late 1990s and early 2000s. This framework was quite similar to existing policies at the Max Planck Society (Germany's largest non-university public research organization dedicated to basic research), which since the 1970s had its own version of technology transfer mechanisms.[74]

China has also strengthened existing legislation (most notably the 1996 Act for Promotion of Technology Transfer and various reforms in the early 2000s) to promote technology transfer and commercialization of academic research.[75] (The introduction of Bayh-Dole style frameworks in emerging economies, such as China and Taiwan, and the effect they are having on biotech innovation, will be discussed in more detail below in section 3.)

In line with the increase in general patenting activity and wider introduction of technology transfer mechanisms, licensing and licensing income has seen sharp increases. In the decade between 1996 and 2006, licensing income by US universities more than quadrupled. Significantly, a large portion, between 50-75%, of this income has been estimated as emanating from research in the life sciences.[76] The importance of the life sciences to universities' technology transfer activities and licensing is illustrated by the wider trend of large academic

[72] Shane, S. (2004), "Encouraging university entrepreneurship? The effect of the Bayh-Dole Act on university patenting in the United States", Journal of Business Venturing, 19, pp. 127-151

[73] AUTM, 2010 Licensing Survey, http://www.autm.net/AM/Template.cfm?Section=FY_2010_Licensing_Survey&Template=/CM/ContentDisplay.cfm&ContentID=6872 (Accessed November 17 2011)

[74] Buenstorf, B. & Geissler, M. (2009), "Not invented here: Technology licensing, knowledge transfer and innovation based on public research", *Papers on Economics and Evolution*, Max Planck Institute of Economics, Evolutionary Economics Group, p. 12-3.

[75] DeVol, R.C. et al (2011), *The Global Biomedical Industry: Preserving US Leadership*, Milken Institute, p. 40.

[76] Roessner, D. et al (2009), *The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007*, pp. 30-1. Report prepared for the Biotechnology Industry Organization. Data cited based on AUTM surveys and figures. See footnote 6. This is based on a breakdown of the largest universities licensing portfolios and respective income for each academic discipline.

institutions, such as the University of California, Stanford University, and MIT, today being some of the largest biotech patent-generating entities in the US.[77] In many cases these entities have replaced large multinational biopharmaceutical manufacturers. For example, by 1999 the campuses of the University of California had replaced Merck as the top recipient of biotechnology patents. Moreover, American universities continue to innovate and dominate international biotech patenting scores. For instance, the Milken Institute in 2006 devised a composite index (measures included biotech patents, impact, science linkage etc.) ranking the top biotech patenting universities globally.[78] Tellingly, there were only four non-American universities in the top-20 with only one in the top-10.

In other countries as well, licensing has grown in line with the introduction and existence of technology transfer mechanisms. For example, the German Max Planck Society has generated close to €15-20 million in licensing income per year since 2000.[79] Here too, a significant proportion of licensing income is derived from research in the life sciences.

Much of the funds generated through university licensing and technology transfer activities are reinvested into the university and its research activities. For example, in the US the academic institutions that generate the largest amounts of licensing income have specific policies in place to reinvest the majority of this income into university and research activities. For instance, the University of California allocates all funds remaining after expenses and inventors' share to the campuses and research laboratories responsible for the licensed technologies.[80] In 2011 income distributions relating to campus inventions (i.e. total licensing and royalty income less payments to joint holders and legal and direct expenses) totaled $164.6 million.[81] Out of this total nearly 70% was reinvested into the university, according to a set formula divided up into a specific research allocation, general fund and campus allocation.[82]

Similarly, Northwestern University – in 2010 the US academic institution with the largest amount of licensing income at $180 million – has a policy of distributing 35% of net income to the departments in which the inventor serves as well as to the specific research undertaken by the inventor.[83] Thirty percent of net income is distributed to the inventor and 35% is used by the university in its general technology transfer and commercialization activities.

---

[77] Edwards, M.G. et al (2003), "Value creation and sharing among universities, biotechnology and pharma", *Nature Biotechnology*, Vol. 21, No. 6, June 2003
[78] DeVol, R.C. et al (2006), *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization*, Milken Institute, p.91.
[79] Max Planck Innovation, Success Stories, Licensing, http://www.max-planck-innovation.de/en/success_stories/successful_track_record/licensing/ (Accessed April 2012)
[80]University of California, (2011) *Technology Transfer Annual Report 2011*, p. 25.
[81] Ibid.
[82] Ibid.
[83] Northwestern University, Innovation and New Ventures Office, Royalty Distribution Policy: http://invo.northwestern.edu/policies/royalty-distribution-policy (Accessed May 29 2012) This policy is in place for inventions supported by the University's TTO after 1999.

Technology transfer and licensing in biotechnology

Technology transfer

Evidence suggests that the introduction of technology transfer mechanisms has also been a key driver in increasing patenting and licensing activity in the biotechnology sector. For example, this can be seen in the increased importance of biotechnology clusters in biotech innovation and patenting. In a number of regions globally, biotech entities have grown up and around universities. Examples include the greater Boston area in Massachusetts, the Bay Area in San Francisco, biotech corridors in Southern California, as well as the Medicon Valley in Denmark and Sweden and Nordrhein-Westfalen in Germany. Today these clusters account for a growing share of R&D activity and IP outputs measured by patenting.

Table 2 provides an overview of the top-10 regions measured by biotechnology patenting for the period 2004-2006, all of which contain significant biotech clusters.

Table 2: Biotechnology patents top-10 regions, 2004-2006

Region	Country	Biotechnology patents	Share (%) of total Globally
San Jose-San Francisco-Oakland	U.S.	1,510	5.5
Boston-Worcester-Manchester	U.S.	1,422	5.2
New York-Newark-Bridgeport	U.S.	1,090	4
Washington-Baltimore-Northern Virginia	U.S.	811	3
Tokyo	Japan	729	2.9
San Diego-Carlsbad-San Marcos	U.S.	782	2.9
Los Angeles-Long Beach-Riverside	U.S.	613	2.2
Philadelphia-Camden-Vineland	U.S.	587	2.2
Nordrhein-Westfalen	Germany	506	1.9
Hovedstadsregionen	Denmark	454	1.7

Source: Milken Institute (2011)[84]

Licensing

Increased patenting and technology transfer of biotechnologies has increased licensing income for upstream and downstream entities. The best and most extensive data exist for the US where, for example, upfront license fees have more than tripled from $20,000 to $70,000 since the late

[84] DeVol (2011). Cited verbatim, p. 27.

1970s when biotech entities first became more involved in licensing.[85] Similarly, sponsored research fees and license maintenance fees have doubled and quadrupled respectively.[86]

As for commercialization and downstream licensing involving biotech entities, this also has increased dramatically. Biotechnology entities today are responsible for more of the research and development of new drugs and medical technologies than ever before. A number of blockbuster drugs were developed through licensing and partnership agreements between universities, biotech entities and large multinational pharmaceutical manufacturers. Examples include Procrit, Epogen and Avonex, which had combined sales of over $7.5 billion in 2002.[87]

Furthermore, surveys and case study analysis suggests that to many biotech entities licensing is an important source of income and driver of their research. For example, in Korea just over a quarter of biotech SMEs surveyed in 2010 had experience in licensing patents and technology transfer.[88] Significantly, the survey also revealed that use of licensing varied across biotechnological sub-fields. For instance, in the sub-field of biopharmaceuticals, biotech SMEs were the most likely of all sub-fields to have experience in licensing; 36% of biopharmaceutical SMEs had experience in licensing versus 27% in bio-chemicals and only 17% in bio-foods.[89]

Accompanying this increase in technology transfer and licensing activity among biotech entities has also been a rise in the number of partnerships and alliances involving biotech entities. The following subsection will provide an overview of these partnerships and collaboration models at both the upstream and downstream levels.

2.3 Partnerships and collaboration

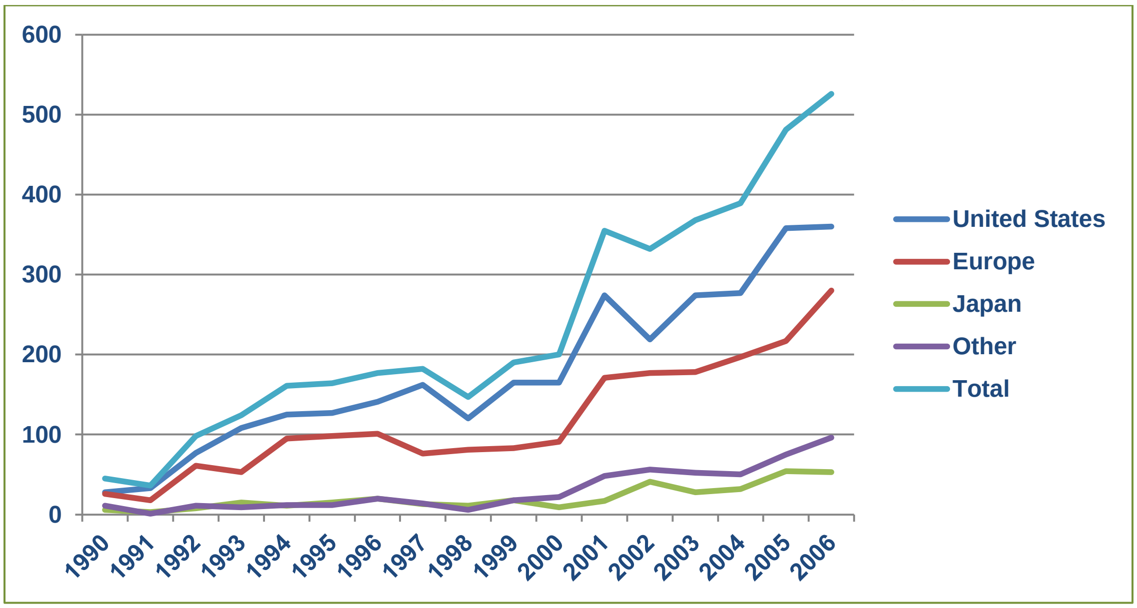
Partnerships and collaboration agreements between biotech entities (including universities) and large biopharmaceutical manufacturers are now part and parcel of the drug development process. IPRs are a central part and driver of these partnerships. As this subsection will outline, the increase in biotechnology patenting described above has been accompanied by an equally strong increase in partnering and collaboration between biotech and biopharmaceutical entities. IPRs, such as patents, are used to generate attention and income to biotech entities and form much of the basis for the R&D activities by commercial upstream biotech entities. For example, as the above cited surveys from Korea and Switzerland illustrate, a strong patent portfolio is a way for biotech SMEs to attract funding and capital from venture capital investors.

[85] Edwards et al (2003)
[86] Ibid.
[87] Ibid.
[88] Kang and Lee (2010)
[89] Ibid.

As with increased technology transfer and licensing between upstream entities and biopharmaceutical manufacturers, the development of these partnerships has been part of, and has contributed to, the long-term structural changes the pharmaceutical R&D process has undergone since the 1980s. The older R&D model – common from the 1950s to the mid-1980s – was a model based on full vertical integration from drug discovery through to clinical development, regulatory affairs, manufacturing, and marketing.[90] Generally speaking there was a clear distinction between upstream and downstream research. The majority of downstream research was conducted by integrated pharmaceutical manufacturers and upstream research took place at not-for-profit universities, research institutes, government laboratories and hospitals. In contrast, the model in use today – although still evolving – sees biotech entities as an intermediary and a partner between both upstream and downstream actors.[91]

There has been a steady increase in the number of research collaborations and alliances, and in technology transfer over the last two decades. Figure 4 shows the increase in partnerships and alliances from 1990 to 2006 globally as well as for three key regions: the US, Europe and Japan.

Figure 4: Number of biotechnology alliances for research or technology transfer, 1990 to 2006



Source: UNU-MERIT CATI database in OECD *Biotechnology Statistics* (2009)[92]

From Figure 4 the upward trajectory and growth path is very clear. In 1990 no region had close to 100 alliances; 15 years later in 2005 the global total had reached over 500 with significant growth having taken place in all regions.

[90] Cockburn (2004)
[91] Ibid.
[92] OECD (2009), *Biotechnology Statistics*, OECD Paris, p. 94.

Interestingly, the regional variation suggests that, although still clearly the biggest home to alliance-making, after 2000 the US saw its relative dominance decline. The portion of alliances involving a US-based partner decreased from over 85% of alliances during the late 1990s to just over 70% during the mid-2000s. During the same period, the European share increased from 46% to close to 50%.

Highlighting the globalization and spread of biotechnologies (as illustrated by increased patenting activity in the sections above) the share of non-European, non-US and non-Japanese partners more than doubled from just over 7% to close to 16% of the total.[93]

Although since 2006 the number of alliances has declined somewhat (due to the ongoing economic downturn in the US and large parts of the developed world), agreements are still being made. Figures for post-2006 activity indicate that collaborative R&D deals and alliances have flattened somewhat and have hovered at around 600 globally in the period 2007-2011.[94] In 2011 that figure had dropped slightly to just under 600 for the year.

Biopharmaceutical manufacturers are now also contracting and engaging biotech entities at a much earlier stage of the research process and partnering with universities directly.

At the macro level this shift towards greater direct partnering on upstream and pre-clinical research is illustrated by the recent growth in pre-clinical licensing deals. Between 2007 and 2010 the number of pre-clinical licensing deals fluctuated between 80 and 90 per year. In 2011 that number jumped markedly up to over 110.[95] This increase suggests that biopharmaceutical manufacturers now see the need and possibility of further engagement and partnership earlier in the research process.

At the micro level this international trend is illustrated by a number of recent deals and partnerships.

For example, in 2011 Pfizer entered into a drug discovery and development partnership with University of California, San Diego, potentially valued at $50 million.[96] This is part of Pfizer's broader strategy of engaging directly with academic researchers and universities through its Centers for Therapeutic Innovation.

Illustrating both the globalization of biotechnology research and international use of IPRs is the recently signed partnership agreement between US-based Lauren Sciences and BGN

[93] Ibid. All figures from OECD.
[94] Cartwright, H. (2012), "A Review of Deal Making in 2011", *Pharma Deals Review*, Vol. 2012 Issue 1, pp. 15-7, PharmaVentures Ltd, Oxford.
[95] Ibid.
[96] Ibid.

Technologies, the technology transfer company for Ben-Gurion University of the Negev (BGU), Israel. The partnership relates to the licensing of a Parkinson's drug delivery platform. Lauren Sciences will develop the technology which is envisioned for use in the treatment of central nervous system (CNS) diseases such as Parkinson's and Alzheimer's. The platform (V-Smart technology) was developed by researchers at Ben Gurion University. The University holds a number of international patents relating to the technology.[97]

Section Summary

This section has outlined the following trends:

- IPRs are being used by biotech entities in their day-to-day operations and businesses.
- Evidence and data on the strategic use and leveraging of IPRs by biotech entities in the upstream and downstream R&D processes strongly suggest that IPRs are central to biotech innovation.
- Increased biotechnology patenting, licensing and R&D partnerships and collaborations have risen more or less in unison over the last several decades.

Apart from macro data on patenting activity, licensing agreements and number of partnerships and collaborations, the section also provides specific case study analysis and micro data in the form of surveys from biotech entities in both developed and emerging economies. These surveys provide specific insight into how biotech entities are making use of IPRs in their research and outreach activities.

[97] See: *Globes Israel Business Arena*, "BG Negev licenses Parkinson's drug delivery platform", April 11 2012, http://www.globes.co.il/serveen/globes/docview.asp?did=1000740755&fid=1725 (Accessed April 2012)

3 The role of IPRs in promoting biotechnology R&D activities and economic development: implications for emerging and developing economies

Building on the previous section's discussion of the role played by IPRs and technology transfer in the generation and commercialization of biotechnology research, this section will in more detail discuss the implications of this evidence in the context of emerging and developing economies.

Specifically, this section will provide concrete examples of how many countries have used and are successfully using IPRs and technology transfer mechanisms to build up their own national biotechnology capabilities.

3.1 Emerging economies, IPRs, FDI and technology transfer

Flows of FDI are widely acknowledged as being a relatively good proxy for technology transfer and knowledge diffusion; FDI is a market-based channel by which knowledge and intangible assets are disseminated.[98] Apart from capital flows, FDI therefore also suggests flows of technology and knowledge.

Above in section 2, Figures 2 and 3 showed the increase in biotechnology patenting from the late 1970s to 2009 in 10 emerging and developed markets (Brazil, India, Russia, Singapore, Taiwan, Argentina, Israel, Japan, Korea and China). These figures showed a sustained and broad increase in biotechnology patenting in most if not all of these countries, particularly Japan, China, Korea, India and Brazil.

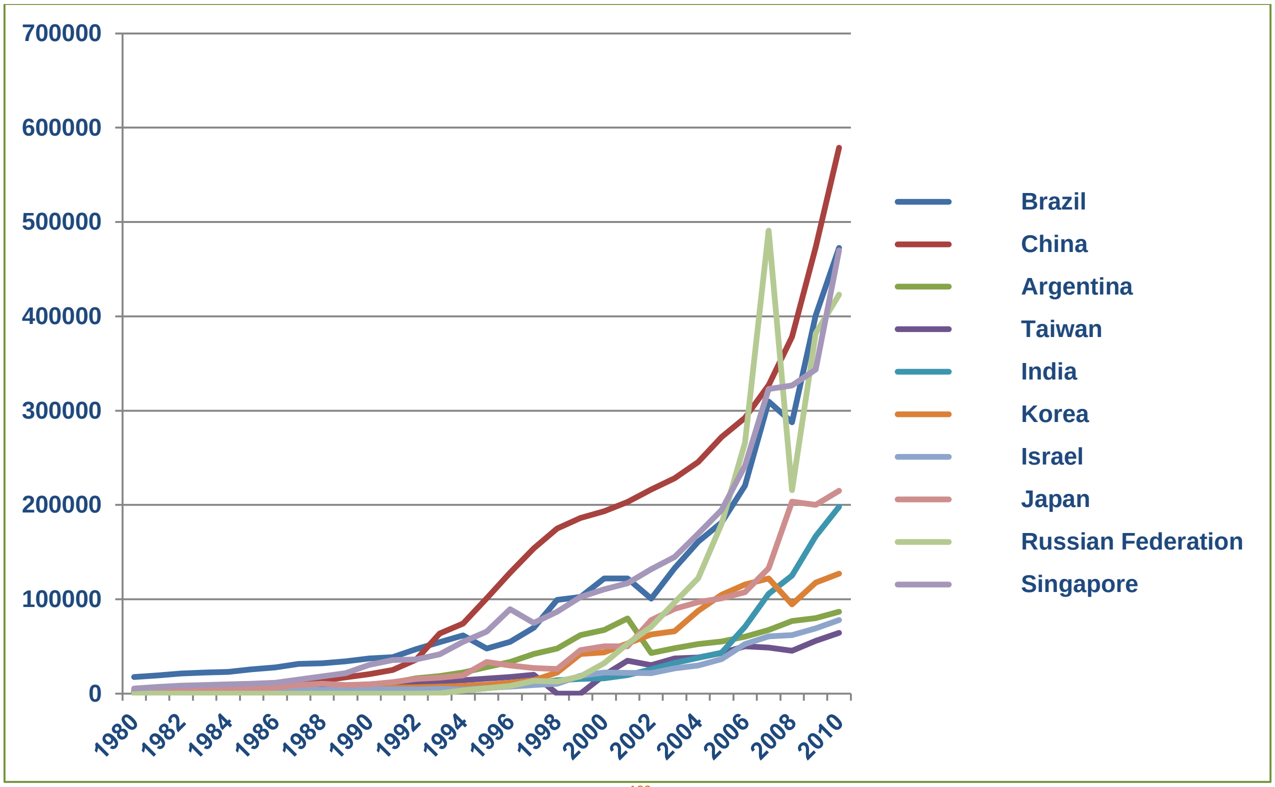
---

[98] Cavazos, R. et al, (2010), *Policy Complements to the Strengthening of IPRS in Developing Countries*, OECD Trade Policy Working Papers, No. 104, OECD Publishing, p. 11-3

Complementing these figures, below Figures 5 and 6 show increases in FDI and changes to the national IP environment in these countries respectively as measured by the Patent Rights Index (PRI).[99]

Together these two measures put in context the rise of biotechnology patenting by illustrating how these 10 countries during the same time period also strengthened their IPRs as measured by the PRI, and simultaneously saw substantial increases in technology transfer (as illustrated by inward FDI flows).

Figure 5: Inward foreign direct investment stock, annual, 1980-2010 US Dollars at current prices and current exchange rates in millions



Source: Pugatch Consilium analysis based on data from UNCTAD[100]

[99] The PRI is probably the most widely used and the most acceptable standard for measuring the cross-national strength of IPRs The index measures the cross-national strength of patent rights in 122 countries for the period from 1960 to 2005. The index was coded on the basis of five categories of patent law:
(1) Extent of coverage;
(2) Membership in international patent agreements;
(3) Duration of protection;
(4) Enforcement provisions;
(5) Restrictions on patent rights.
The index ranges from 0 (weakest level of patent protection) to 5 (highest level of patent protection).

[100] United Nations Conference on Trade and Development, UNCTAD STAT, Inward foreign direct investment stock, annual, 1980-2010, (Database accessed April 2012).

Figure 5 shows how inward FDI has increased substantially in all of the listed countries. In the early 1980s, FDI was close to zero in most, if not all, of these countries. By 2000 there had been a noticeable increase in virtually all countries, with China in particular outpacing the others. A decade later and FDI rates have taken off in all countries bar Argentina. Today countries such as Brazil, Singapore, China and Russia attract between $40 and 60 billion annually in FDI.

During the same time period, national IP environments and patenting protection – as illustrated by Figure 6 below – increased substantially in many of the same countries. As outlined in section 1, there have been a number of recent important economic studies of the positive effect reforms of IPRs can have on FDI, technology transfer and licensing activities in emerging and developing economies.[101] Cumulatively these studies are providing a rich and empirical body of research that, by and large, suggests that strengthening IPRs combined with other policy measures can have a positive economic effect, increasing knowledge transfer and economic development in emerging and developing economies.

Figures 5 and 6 help concretely illustrate this body of empirical literature and strongly suggest that IPRs and technology transfer mechanisms in combination with other policies can have a beneficial effect on innovation, economic growth and knowledge transfer.

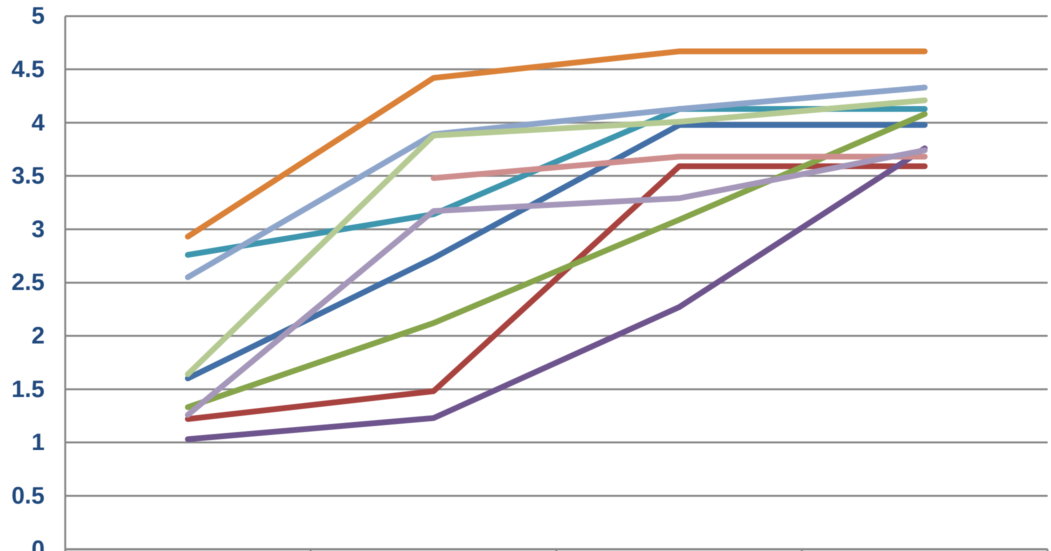
Figure 6 shows how the PRI score has increased substantially in all but one country listed (Russia). In particular, China, India, Brazil, Japan and Korea saw significant increases in their PRI scores since the 1960s.

Of note is that China, India and Brazil in the 10-year period 1995-2005 more than doubled or almost doubled their PRI rating. Significantly, during this time period as illustrated above by Figures 2, 3 and 6, both biotechnology patenting and technology transfer (as captured by inward FDI) increased substantially.

---

[101] See section 1: Park & Lippoldt (2008), Park & Lippoldt (2003), Xu & Chiang (2005), Park & Lippoldt (2005), Branstetter et al (2005), and Nunnenkamp & Spatz (2004).

Figure 6: Patent Rights Index, 1960-2005



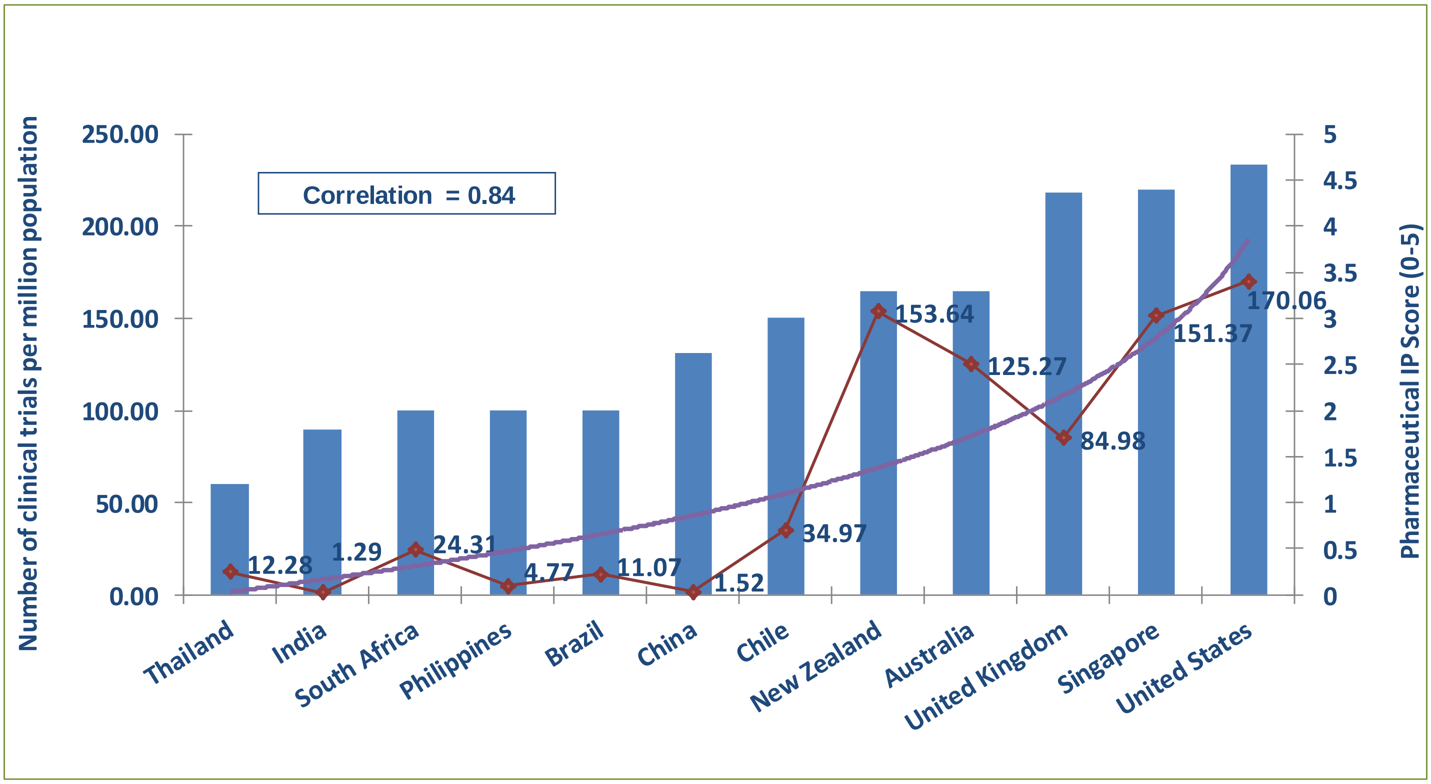
	Average 1960–1990	1995	2000	2005
Argentina	1.6	2.73	3.98	3.98
Brazil	1.22	1.48	3.59	3.59
China	1.33	2.12	3.09	4.08
India	1.03	1.23	2.27	3.76
Israel	2.76	3.14	4.13	4.13
Japan	2.93	4.42	4.67	4.67
Korea	2.55	3.89	4.13	4.33
Russian Federation		3.48	3.68	3.68
Singapore	1.64	3.88	4.01	4.21
Taiwan	1.26	3.17	3.29	3.74

Source: Park[102]

The correlation between stronger national IP environments and the level of biopharmaceutical FDI is also visible with regard to investments in the clinical development of biopharmaceutical products. For example, Pugatch and Chu (2011)[103] measured this correlation in 12 developed and developing countries – four of which are ones examined by the PRI – using the Pharmaceutical IP Index as a measure of IP protection. Overall, the results in Figure 7 show that countries with a more robust level of pharmaceutical IP protection, including emerging economies, tend to enjoy a greater level of clinical trial activity by multinational research-based companies. In other words, by improving their level of protection of pharmaceutical IPRs (together with other factors), developing countries may also be exposed to higher levels of biomedical FDI.

[102] Park, W.G. (2008), "International patent protection: 1960–2005", *Research Policy* 2008, p. 2-3.
[103] Pugatch, M.P. and Chu, R. (2011), The strength of pharmaceutical IPRs vis- à -vis foreign direct investment in clinical research: Preliminary findings, *Journal of Commercial Biotechnology*, Vol.14, No.4, pp.308-318

Figure 7: Strength of pharmaceutical IPRs vis-à-vis foreign direct investment in clinical research



Source: Pugatch and Chu[104]

3.2 The growing recognition and use of IPRs in emerging and developing economies

As mentioned above there are a number of fast-growing dynamic economies around the world that are implementing and shaping policies on IPRs that promote biotechnology research, technology transfer and partnerships and collaboration.

Significantly, a number of these initiatives have had and are having a positive impact on economic development, job creation and access to biotech products such as GM foods and biological drugs and medical technologies.

The previous subsection outlined the macro trends for 10 emerging and developing economies; the following subsection will provide a more detailed analysis of six countries (Taiwan, Brazil, Jordan, China, Singapore and India) at varying points of both the economic and biotechnological development process.

[104] Park, W.G. (2008), "International patent protection: 1960–2005", *Research Policy* 2008, p. 2-3.

Taiwan

As illustrated by the increase in patenting and biotechnology patenting activity outlined in section 2 above, Taiwan has been quite successful in building a research infrastructure that is conducive to biotech innovation.

One of the factors that contributed to this growth was the introduction of a Bayh-Dole style framework in the late 1990s and early 2000s. Specifically two pieces of legislation – the Fundamental Science and Technology Act and the Government Scientific and Technological Research and Development Results Ownership and Utilization Regulations passed in 1999 and 2000 respectively – provide universities and non-profit research institutions control over the IP they create through their research. The legislation was intended to promote entrepreneurship and the transfer and eventual commercialization of upstream research.

A 2010 study of the effects of this legislation on university patenting activity provides a concrete and detailed example of the positive effect the introduction of technology transfer mechanisms can have.[105] The study examines patents granted to 174 Taiwanese universities during the period of 2004 to 2009 and compares this to the period preceding it. Strikingly, the study finds a sharp and sustained increase in university's patenting activity: patenting increased from 446 patents in 2004 to 1,581 by 2009.[106] This is an impressive increase of 354%. As importantly, apart from a slight drop in 2007, this growth has been progressive and sustained year after year.

Moreover, many of the universities and research institutes that were the most active in patenting had also introduced dedicated technology transfer offices and administrators. The study finds that the top-10 general (non-technological or military) universities had designated divisions or offices overseeing their patenting.[107]

Brazil

Although by international comparison it is still fairly limited, Brazil has over recent years seen real growth in the use of IPRs by its universities and public research bodies. For example, between 2000 and 2007 patenting by universities more than quintupled, from 60 patents to 325.[108] During the same time period, patenting by PROs increased from 20 to 39.

However, with regard to biotechnological innovation Brazil is one of the biggest producers of biotech agricultural crops in the world, ranking only second to the US on number of hectares

[105] Lo, S. (2010), "Innovation and Patenting Activities at Universities in Taiwan", International Conference on Engineering Education ICEE-2010, Poland 2010.
[106] Ibid. p. 3.
[107] Ibid. p. 5.
[108] WIPO, (2011), *World Intellectual Property Report 2011, The Changing Face of Innovation*, WIPO Geneva p. 151.

under cultivation.[109] Since the 1970s, innovation in agricultural biotech has primarily been led by the Brazilian Agricultural Research Corporation (EMBRAPA). Founded in 1973, this body is to "provide feasible solutions for the sustainable development of Brazilian agribusiness through knowledge and technology generation and transfer".[110]

In 1996 following Brazil's adoption of the TRIPS agreement, EMBRAPA introduced IP regulations and a technology transfer platform which committed the institution to using IPRs in its practices and placed a significant emphasis on the commercialization of research. The "Institutional Policy for the Management of Intellectual Property" stated that EMBRAPA should maximize use of IPRs through either technology transfer or licensing of its research. Furthermore, the institute should seek legal protection (in the form of IPRs) for its research and should only release and make available its proprietary knowledge under specific circumstances approved by its Intellectual Property Committee.[111] As part of these new policies and guidelines, the institute also set up a central unit to deal with technology transfer

Significantly, since the introduction of these new regulations EMBRAPA's IP portfolio – patents in particular – has increased substantially. Between 1996 and 2006, the company applied for 190 patents with the Brazilian Patent and Trademark Office (INPI) and made 65 international patent applications.[112] EMBRAPA has also increased the number of cultivations registered in Brazil. Between 1999 and 2009, 1,687 cultivars were registered in Brazil with EMBRAPA holding the title to 357 cultivars, or just over 20% of the total.[113]

In addition to agricultural biotechnology, there are a number of specific examples of success in biomedical technology transfer where companies and research bodies have made use of existing Brazilian technology transfer legislation. For example, case study analysis and surveys of five biotech companies in the state of Sao Paolo, Brazil, in the mid- to late-2000s show that the introduction of patent protection in 1996 prompted a wave of patenting and innovation.[114] Most notable is the case of Ache Laboratorios, which waited until patent protection was available to bring to market a biodiversity-based anti-inflammatory technology.

---

[109] James, C. (2011), "Global Status of Commercialized Biotech/GM Crops: 2011", International Service for the Acquisition of Agri-biotech Applications

[110] EMBRAPA, About, http://www.embrapa.br/english (Accessed April 2012)

[111] Lele, U. et al (eds) (1999), *Intellectual property rights in agriculture: the World Bank's role in assisting borrower and member countries*, World Bank Washington DC, p. 47.

[112] Buainain, A.M. & de Souza, R. (2008), "Intellectual property and innovation in agriculture and health", RECIIS – *Elect. J. Commun. Inf. Innov. Health*. Rio de Janeiro, v.2, n.2, p.56-65, Jul.-Dec., p. 60.

[113] Teixeira, F., (Head, Technology Innovation Office, EMBRAPA), (2010), "Use of Plant Variety Protection by National Research Centers Brazilian Agricultural Research Corporation (EMBRAPA), Brazil", UPOV Seminar 2010.

[114] Ryan, M. (2010), "Patent Incentives, Technology Markets and Public-Private Bio-Medical Innovation Networks in Brazil", *World Development*, Vol. 38, Iss. 9, pp. 1082-1093

Jordan

Jordan provides a good example of how strengthening IPRs can have a positive impact on economic development and economic growth. There are a number of studies that have examined the effect of these reforms on the Jordanian economy as well as more specifically on the biopharmaceutical sector.[115]

Jordan's IPRs related reforms began in the mid- to late-1990s and culminated with the accession to the WTO and TRIPS in 2000 and signing of a FTA with the US in 2001. Subsequent to these reforms, Jordan's environment for the protection of IP improved considerably. For instance, as measured by the Patent Rights Index (scale of 0-5), Jordan's score more than tripled from below 1.0 in 1995 to just under 3.5 in 2005.[116]

Furthermore the implementation of the IPRs-related provisions of these agreements has coincided with a remarkable rise in economic output. Since 2000, GDP per capita at PPP rose from under $3,000 to $5,500 in 2010.[117] Annual growth averaged 6.7% per year between 2000 and 2008, only falling off sharply in 2009-2010 as the global financial crisis hit the world economy.[118] In the prior decade 1990-2000, growth had only exceeded 6% twice.

More specifically in the biopharmaceutical sector, Jordan experienced sustained growth in research and increased access to biopharmaceuticals. Prior to the reforms of 2000 and 2001, there were no clinical trials or clinical research conducted by multinational biopharmaceutical manufacturers in Jordan.[119] By 2006, six companies were carrying out 13 pre-market launch clinical research trials involving 3,600 patients. Similarly, due to the weak nature of Jordan's IPRs, very few drugs were introduced by multinational manufacturers prior to 2001. In contrast, during the five-year period (2001-2006) following the introduction of the reform package, close to 80 drugs were introduced onto the Jordanian market.[120]

China

Critics of IPRs often put forth China as an example of how a relatively weak environment does not necessarily result in low levels of investment or foreign interest. While it is certainly true that China is still home to some of the world's highest rates of counterfeiting and piracy, this

[115] See: Cavzos et al (2010).
[116] Ibid.
[117] Trading Economics, World Bank Indicators, GDP per capita at PPP (US dollar) in Jordan, http://www.tradingeconomics.com/ (Accessed April 2012)
[118] Ibid. GDP growth (annual %) in Jordan
[119] Ryan, M.P. (2007), *Intellectual Property Reforms, Pharmaceuticals, and Health Competitiveness in Jordan: Misunderstanding and Misinformation from Oxfam International*, GWU Law School, 2007 3.
[120] Ibid. p.4.

argument overlooks the fact that China has made remarkable strides in reforming and strengthening its IPR environment.

For example, as measured by the Patent Rights Index, China's patenting environment has improved markedly over the past half century. Between 1960 and 1990, China averaged a score of 1.33.[121] By 1995, this had risen to 2.12 and by 2005 this had reached 4.08. This latter figure was just under that of Australia (4.17) and well above fellow BRICs such as Brazil (3.59) and India (3.76). Other studies have also found that China's IP environment has improved and has been a factor in increasing FDI. For example, Awokuse and Yin find that increased levels of IP protection stimulate China's imports, particularly for knowledge-intensive products.[122]

With regards to technology transfer and IP commercialization, Chinese universities have been encouraged since the mid-1980s to manage and use inventions produced by their researchers, although formal ownership was retained by the state. As mentioned above, a number of IPRs reforms began in the 1990s, culminating in the 2002 "Opinion on Exerting the Role of Universities in Science and Technological Innovation".[123]

Combined with the substantial growth and development of the Chinese economy over the last few decades, the results of this relative freedom for universities and researchers to pursue commercial ventures has been a sharp increase in university patenting, patent and technology transfers and number of spin-offs.

University patenting has increased dramatically and been a major contributor to China's rise as one of the world's top patenting nations. In 2006, resident university patent applications totaled 17,312, representing just under 15% of total resident applications.[124] Since 2000, university patenting has increased by almost 50% per year.

Technology transfer has also increased. The number of patent transfers rose from 298 in 1999 to 532 in 2002. During the same period technology transfers also increased from about 4,000 to 5,600.[125] University spin-offs have also increased in large part due to an incentive structure that allows researchers to retain at least 50% of income from commercialized technologies.[126]

---

[121] Park, (2008), p. 2.
[122] Awokuse, T. & Yin, H. (2010), "Does Stronger Intellectual Property Rights Protection Induce More Bilateral Trade? Evidence from China's Imports", *World Development*, Volume 38, Issue 8, August 2010, pp. 1094–1104
[123] Graff, G.D. (2007), "Echoes of Bayh-Dole? A Survey of IP and Technology Transfer Policies in Emerging and Developing Economies" in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K, p. 176.
[124] WIPO (2011), p. 151. However, the rise in patenting by Chinese universities should be treated with some caution. Many Chinese universities and research institutes have explicitly had a policy of promotion and evaluation based in part on number of patent applications. According to some studies patenting has become a substitute for peer-reviewed publications. See Guo, H (2007), "IP Management at Chinese Universities", in Krattiger, A et al (eds)
[125] Nezu, R. et al, (2007), *Technology Transfer, Intellectual Property Rights and University-Industry Partnerships: The Experience of China, India, Japan, Philippines, the Republic of Korea, Singapore and Thailand*, p. 10, WIPO.
[126] Ibid.

Singapore

Singapore has over the past several decades developed into a hub of both general innovation as well as in biotechnology. The links between industry and university research in all areas have been strong since the early 1980s when governmental-sponsored R&D programs were first put in place. The result has been a vibrant and well-functioning technology transfer relationship between industry and universities as well as industry and government-sponsored agencies such as the Agency for Science, Technology and Research (ASTAR).

At the university level, National University of Singapore (NUS) has had an influential technology transfer office set up since the early 1990s. Up to the mid-2000s this office had facilitated more than 700 patent applications, 84 licensing agreements (with revenues of US$1.44 million), and equity in lieu of royalties reaching US$4.85 million.[127]

ASTAR is the Singapore government's main research agency and has been a major contributor to the growth of R&D activities in the country. The agency has a number of institutes specializing in the life sciences, engineering and materials. Between 2006 and 2010, the agency filed over 1,100 patents and secured industry funding of over SGD219 million.[128]

With regard to biotechnology, Singapore is one of the leaders in Asia. Over the last decade Singapore has built up an active biomedical science system from almost no base prior to 2000. As part of the national Biomedical Science Initiative, it has developed programs in a range of disciplines, including bioprocessing, chemical synthesis, genomics and proteomics, cell biology, bioengineering, nanotechnology, computational biology, clinical pharmacy, medical imaging and bioinformatics. Efforts to amass national talent and attract foreign scientists and researchers involve scholarship and fellowship programs, as well as boosting salaries and funding support, and diversifying the structure of grant schemes to permit exploratory research.

Singapore has also created a specific body to liaise between universities, public research institutes and industry needs, called the Biomedical Sciences Industry Partnership Office.[129] This body seeks to catalyze and promote partnerships between industry and public sector research, linking upstream public sector research with downstream commercialization partners.

As was illustrated above in Figure 2, biotechnology patenting has increased substantially in the past few decades, growing from zero in the 1980s and early 1990s to over 83 patents applied for under the PCT in 2009.[130] University patenting has been a growing part of this. For example,

---

[127] Ibid. p. 11.
[128] Agency for Science, Technology and Research, Singapore (2011), *A*STAR Yearbook 2010/2011*, ASTAR 2011, p. 9.
[129] See: http://www.bmsipo.sg/about-us/ (accessed April 2012)
[130] Figure 2; OECD 2012.

according to the 2006 Milken Institute composite index cited above, the National University of Singapore came in 76th out of 100 and had a relatively high patent score of 18.2.[131]

Singapore has also seen the growth and development of several biotech clusters. Singapore's main biocluster, Biopolis, comprises 25 domestic and international firms and five biomedical research institutes and is in close proximity to the National University of Singapore and the Singapore Science Parks. It has over 2,000 private and public researchers.[132] These factors allow Biopolis to provide shared state-of-the-art infrastructure, resources and services catering to the full spectrum of R&D activities and to create economies of scale. Building up a high quality biomedical research base has allowed Singapore to attract a number of multinational pharmaceutical companies, which are now supporting the further development of a domestic biomedical industry, particularly in fields of biologics and translational and clinical research.

India

Like China, India is often subject to criticism for its IP and regulatory environment. This is particularly the case with counterfeit and substandard medicines and the issuing of compulsory licenses. For example, in early 2012 the Indian patent authorities authorized the use of a compulsory license for the generic domestic production of the cancer drug Nexavar.[133] The issuing of the license – which is the first license issued for cancer related treatments – highlights the legal and regulatory challenges biopharmaceutical manufacturers face in protecting their intellectual property in India.

While these problems are of a serious nature and could potentially undermine India's reforms to IPRs, viewed over the long-term India's IP environment has in fact improved over the past several decades.

For example, as measured by the Patent Rights Index, India's patenting environment has improved from an average score of 1.03 between 1960 and 1990, to a score of 3.76 in 2005.[134] During this time period, India also saw substantial rises in its FDI as well as substantial increases in economic growth and rates of innovation.

A significant factor contributing to these developments has been the implementation of the TRIPS agreement. For example, surveys of knowledge-intensive Indian firms suggest that post TRIPS there was an average increase in R&D expenditure by 20%.[135] Moreover the same study found that patenting in the US by Indian firms also increased after TRIPS.[136]

---

[131] DeVol et al (2006), p.92.
[132] Ibid. p. 282.
[133] Bajaj, V. and Pollock A. (2012), "India Orders Bayer to License a Patented Drug", *New York Times*, March 12 2012.
[134] Park (2008), p. 2.
[135] Dutta and Sharma (2008)
[136] Ibid.

With regards to rates of patenting by universities and public research organizations (PROs), India has also experienced substantial increases in the last decade. For example, measured by university patent applications under the PCT by a range of middle- and low-income countries between 1980 and 2010, India had a share of 7%.[137] This puts India in third place, just behind Brazil at 8%, but far below China, which dominates patenting by middle- and low-income countries at 64% of the total.[138]

However, with regard to PROs, India is much closer to China's share, measured as a percentage of the total PCT university patent applications for low- and middle-income countries. Between 1980 and 2010, India had a share of 36%, just under China's 41%.[139] The majority of these patent applications were tied to just one organization: the Council of Scientific and Industrial Research (CSIR). The CISR is the largest domestic patentee and has since the early 1990s accounted for 80% of public sector patents.[140]

As the university patenting figures suggest, in comparison with China technology transfer and university patenting rates are quite low. Indeed, very few Indian universities have functioning TTOs. In light of this fact, India has since the mid-2000s explored developing its own private-public Bayh-Dole style framework to encourage further patenting and innovation.[141] The Protection and Utilisation of Public Funded Intellectual Property Bill was introduced in 2008 and sought to increase creativity, innovation and access to these innovations. Essentially, the bill would allow research institutions and universities to retain the title to their IP. The bill was reported out of committee in 2010, but actual legislation is still not in place as the issue is still being publicly debated.[142]

Overall, with regards to its IP environment India has made some real progress since 2005 and the implementation of TRIPS. Levels of patent protection have increased as have rates of FDI, R&D investment and patenting. However, this progress risks being undermined and many of these positive developments undone by a lack of clarity and direction on where India's level of IP protection is headed. In particular, as mentioned above, the worrying trend of the enhanced use of compulsory licensing risks setting back Indian progress on the protection of IP.

---

137 WIPO (2011), p. 149.
138 Ibid.
139 Ibid.
140 Ibid. p. 152.
141 Sampat, B. (2009), *The Bayh-Dole Model in Developing Countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property*, Policy brief Number 5, October 2009, ICTSD-UNCTD.
142 Spicy IP (blog site), "Indian "Bayh Dole" and a Painful End to the Pursuit of Pleasure", August 10 2010. http://spicyipindia.blogspot.com/2010/08/indian-bayh-dole-and-painful-end-to.html (Accessed April 2012)

Section Summary

This section has provided both a macro and micro analysis of how IPRs and technology transfer have and are currently being used in emerging and developing economies.

At the macro level, this section makes the following findings:

- Since the early 1980s, rates of FDI (a proxy for technology transfer) have increased sharply in many emerging economies such as China, Brazil, South Korea, India, Singapore and Taiwan.
- During the same time period, the strength of patent protection in these countries has increased across the board.
- Countries that have strengthened their protection of IP also show greater levels of biopharmaceutical FDI, including relatively higher amounts of clinical trial activity by multinational research-based companies.
- These trends reflect the findings of a growing body of empirical literature that IPRs (together with other policies) can increase economic development, FDI and innovation.

At the micro level, the section makes the following findings:

- A number of case study examples illustrate how IPRs and technology transfer mechanisms are being implemented and utilized in emerging and developing economies.
- Many of the countries studied have seen accompanying increases in rates of innovation as measured by patenting (biotechnological and otherwise), wider economic development and access to biotech products.
- Many countries (e.g., Singapore) have seen the value of technology transfer mechanisms and have built formalized umbrella organizations to promote more partnerships between industry and upstream public research bodies in the biotech sector.

Together these macro and micro findings complement much of the empirical literature on the effect of IPRs described in section 1, which find that IPRs and technology transfer mechanisms in combination with other policies can have a beneficial effect on innovation, economic growth and knowledge transfer.

4 Conclusions and thoughts on the way forward

The debate over the role of IPRs as an incentive to innovation is as old as it is intense. There are a number of different views of the impact IPRs have, ranging from those who view it as an essential component of technological and social progress to those who view IPRs as being more of a barrier to innovation.

Nevertheless, as illustrated by the review of contemporary thinking in section 1, there is a growing body of empirical and economic evidence on the value IPRs (in combination with other policy and economic reforms) have for increasing innovation (biotechnological and otherwise), technology transfer, economic development and access to high-tech goods and services in developed, emerging and developing economies.

However, most of this literature focuses primarily on the impact of IPRs on downstream research. This is a rather limited scope given that the evidence presented in this report suggests there is room to include a discussion played by the role of IPRs in upstream research, particularly in the biotech sector.

First, there is a growing need to take a more holistic approach to the subject matter and tie together existing strands of evidence on IPRs' effect more generally as well as specifically on biotechnological upstream and downstream research.

Second, there is a need to internationalize and publicize the practical and technical aspects of the use of IPRs in upstream research by biotech entities. As was noted in the Introduction, the bio-economy is in many ways already upon us today and it is of real importance that policymakers, scientists and researchers around the world have a detailed understanding of what drives biotechnological innovation in the real world and how IPRs play a role in this.

This report makes the following recommendations:

- **Focus the spotlight on upstream phases –** Understanding the relationship and interaction between IPRs and the upstream phases of biotech R&D is as important as discussing the role of IPRs in the commercialization of these technologies and products. Therefore, attention should also be devoted to upstream processes, not least in international discussions.

- **A closer look at the nuts and bolts –** In this context, we need to deepen our understanding of the mechanics and mechanisms by which IPRs can be used strategically in order to enhance the R&D process.
- **An enhanced architectural mindset –** Policymakers should consider the architectural setting and how the use of IPRs during the upstream process can be optimized.
- **The needs of emerging economies –** Given the growing positive impact of IPRs in emerging and developing economies, there is a real need to increase our awareness and body of knowledge about frameworks, best practices and specific experiences with the use of IPRs during the upstream phases of R&D.
- **An international observatory of best practices –** It is worth creating an international observatory that maps both knowledge as well as instruments that could help galvanize entities around the world to make greater use of IPRs during the upstream phases of biotech R&D.