

# **Leveraging the Private Sector for Public Health Objectives**

**A Briefing Paper for DFID on Technology Transfer in the Pharmaceuticals Sector**

Cheri Grace

September 2004

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The DFID Health Systems Resource Centre (HSRC) provides technical assistance and information to the British Government's Department for International Development (DFID) and its partners in support of pro-poor health policies, financing and services. The HSRC is based at the London offices of the Institute for Health Sector Development (IHSD) and is managed by an international consortium of seven organisations: Aga Khan Health Services Community Health Department, Kenya; CREDES-International, France; Curatio International Foundation, Georgia; IDS (Institute of Development Studies, University of Sussex, UK); IHSD (Institute for Health Sector Development, UK); IHSG (International Health Systems Group, Harvard School of Public Health, USA); and the Institute of Policy Studies, Sri Lanka.

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Title: Leveraging the Private Sector for Public Health Objectives: A Briefing Paper for DFID on Technology Transfer in the Pharmaceuticals Sector

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# 1 Abbreviations and Acronyms

API	Active pharmaceutical ingredient
ARV	Antiretroviral
DFID	Department for International Development
DNDi	Drugs for Neglected Diseases Initiative
EU	European Union
FDI	Foreign direct investment
GMP	Good manufacturing practice
GSK	GlaxoSmithKline
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
INTECH	Institute for New Technologies of the United Nations University
IP	Intellectual property
IPR	Intellectual property rights
IPTT	Initiative on Pharmaceutical Technology Transfer
JPMA	Japanese Pharmaceutical Manufacturers Association
LDCs	Least-developed countries
MDR TB	Multidrug-resistant tuberculosis
MMV	Medicines for Malaria Venture
MNC	Multinational corporation
NIH	National Institutes of Health
OECD	Organisation for Economic Co-operation and Development
PPP	Public-private partnership
R&D	Research and development
TB	Tuberculosis
TDR	Tropical Diseases Research Department, World Trade Organization
TRIPS	Trade-related aspects of intellectual property rights
TT	Technology transfer
UNCTAD	United Nations Conference on Trade and Development
US	United States
VL	Voluntary licensing
WHO	World Health Organization
WTO	World Trade Organization



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## 2 Executive Summary

Technology transfer (TT) is defined here as the dissemination of knowledge and expertise in the pharmaceutical sector from developed country organisations to organisations in developing countries. Recognising that technology transfer is potentially a very important activity for the international community to encourage, particularly when such transfers further public health objectives, this briefing paper documents a variety of TT experiences and analyses the motivations behind the enabling agreements. These experiences range from those that occur spontaneously, sometimes between relatively equal partners engaging in more of a technology exchange, to those taking place in countries with industries in more nascent stages of development, as well as those where public bodies sometimes impose obligations or offer incentives, including through public-private partnerships (PPPs), to bring parties together.

On the obligation side, the TRIPS agreement is weak on imposing technology transfer obligations in developed countries as a legal requirement, although the statements referring to TT as an objective may be used as an interpretative device, either to inform the application of other parts of the TRIPS Agreement, or as the basis for political objection to the manner in which the Agreement is being interpreted and applied by developed members. On the incentive side, developed country examples where governments have offered incentives to industry to engage in TT are limited. However, non-governmental and international organisations have been active in this field, and their engagement well noted in the examples.

Regardless of where the TT experience fits within the 'spontaneous/purely commercial' versus PPP continuum, sustainable arrangements have required a solid business rationale for engaging in any such technology transfers. Many of the technology transfer experiences have involved an element of public funding or technical support that serve to 'sweeten' the deal, making it a sound business investment for the technology donor and/or recipient.

It is difficult to generalise about the kind of incentives that can be offered to bring together such TT deals, since the appropriate incentive and the business case it supports, will differ according to such (usually difficult to uncover) factors as the particular company's history and past investments, perceived competitive advantages and future strategic goals. In some instances, the business case for the participating firms may be immediately obvious, short-term, and easily attributable to the TT experience. Alternatively, the business case may be more subtle and long term – for example, a response to public pressure or a desire to fulfil overall company strategic objectives.

As for how changing intellectual property (IP) can be expected to impact TT, as long as the institutional and governance structures are aligned with increasing protection of IP, then we might expect to see more willingness of firms to license and contract out increasingly important/proprietary technologies to developing country firms.<sup>1</sup> However, the opposite argument has also been made – that strong intellectual property protection is liable to stifle technology transfer as technology owners exploit their market power. The technology/patent-holder will no doubt need to consider all types of costs and benefits when choosing the most appropriate contractual/ownership mode and the degree of technology that can be successfully transferred.



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## 3 Background

This briefing paper is part of a series of studies commissioned by the UK Department for International Development. It focuses on answering emerging policy questions related to access to medicines and is aimed at documenting technology transfer experiences between developed and developing country firms in the pharmaceutical sector, and unpacking the motivations behind such agreements.

### Definition of TT

The NIH defines TT as ‘the exchange of information, materials or intellectual property rights between (and among) government, academic, or industry laboratories, to facilitate further research and commercialisation’. The United Nations definition is more process orientated, and talks of a ‘process of sharing knowledge, skills, expertise and know-how’, divided into four categories: Technoware, including physical objects and equipment; Humanware, including skills and human aspects of technology management and learning; Infoware, including designs, blueprints, and document-embodied knowledge on information and technology; and Orgaware, including organisational knowledge needed to operate a given technology. The TT experiences covered in this review are primarily limited to firm-to-firm transfers, but often involving a non-profit or international organisation as a third party.

### Technology transfer and access to medicines

Why the focus on technology transfer? Proponents of TRIPS argue that, by aligning with the prevailing IP protection standards in the world’s developed countries, developing countries stand to gain through increased trade and investment with the multinationals (and presumably, technology transfer and technological development that comes with this). Opponents of TRIPS argue that technology transfer is not automatic with increased multinational corporation (MNC) interaction, and anyway, multinationals have neither by incentive nor obligation been compelled to delocalise their activities to the south.<sup>2</sup>

Yet, technology transfer is potentially a very important activity for the international community to encourage. As a potential source of technological catch-up and growth in developing countries, such transfers can encourage economic development. When they occur in the pharmaceutical sector, and particularly for drugs for diseases of the poor, they can also contribute towards public health objectives. This briefing paper focuses on TT experiences that have the potential to encourage capacity development in the pharmaceutical sector of developing countries and/or the potential to deliver products that meet public health objectives. The goal is to help understand how to



create an environment where such transfers can occur spontaneously, and in those cases where they do not occur spontaneously, how to develop obligations and/or incentives for technology suppliers and recipients to engage with one another.



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## 4 Purpose and Scope of the Briefing Paper

The purpose of this briefing paper is to begin a process whereby technology transfer experiences that either benefit public health or have the potential to encourage industrial capacity development can be documented and better understood. Specifically, it addresses the questions: What types of obligations or incentives have caused MNCs and firms in less developed countries to engage with one another? How can donors capitalise on these incentives, or develop such incentives, where the technology transfer would benefit public health? What effect is changing IP likely to have on the incentives for technology transfer?

The Terms of Reference did not call for an exhaustive analysis of all the components that influence or result from technology transfer. The scope of the paper is also primarily confined to firm-to-firm technology exchange and transfers, which inevitably limits discussion of all the TT forms that can help facilitate technological development and contribution to public health. However, it was decided that this briefing paper should scope out those experiences that can be easily documented, without the need for conducting more expensive in-country case studies.<sup>3</sup>

The paper also does not extensively cover the enabling environment that is conducive to technology transfer and technology spillovers. Similarly, it only briefly touches upon the role of IPRs, technology transfers and technology spillovers in economic development. Extensive reviews on this subject can be found on the United Nations Conference on Trade and Development (UNCTAD) website and recent empirical research can be found on the website for DFID's Development Research Centre at the London Business School Centre for New and Emerging Markets, for example.<sup>4</sup>

This briefing paper does not rely on country-level empirical data collection, although extensive interviews were conducted with informants in order to confirm and supplement information gleaned from written reports. It was primarily a desk-based exercise, focused on a cost-effective means of gathering information from available reports, studies, and interviews to answer a set of specific questions posed by DFID. What is new about this paper is the way that it brings together and analyses these pieces of information, from quite varied sources, to answer these specific questions.

## 4.1 Methods

Methods included a literature review, including academic, press, and equity analyst reports from the major investment banks. The research assistance of Kate Hurtig and Rabiya Hussain was helpful in gathering this literature. Interviews were held with the following categories of people: academics, pharmaceutical equity analysts, individuals within research-based MNCs, the International Federation of Pharmaceutical Manufacturers' Association, an individual from the US National Institutes of Health, individuals from the World Health Organization (WHO) and from non-profits who participate as brokers and technology donors in technology transfer deals, and individuals from other UN agencies who are knowledgeable in the subject areas covered. A conference on the subject of technology transfer sponsored by the International Federation of Pharmaceutical Manufacturers Associations provided useful information as well.

Helpful comments were received on an early draft of this paper in May/June 2004 from: Nel Druce, Deputy Director of the Institute for Health Sector Development; Professor Lynn Mytelka, Director of INTECH; Maciej Gajewski, Policy Research Analyst, International Federation of Pharmaceutical Manufacturers Associations; and Andreas Seiter of the World Bank. A second draft went through a formal review process, benefiting from feedback submitted by Hannah Kettler of the Gates Foundation; Andrew Creese at WHO; Abdul Barkat, Professor of Economics, University of Dhaka; Professor Richard Mahoney, University of California, San Diego; and Krisana Kraisintu, former Director of Government Pharmaceutical Organization of Thailand and currently working in three African countries to transfer technology for antiretroviral (ARV) drug production.

## 4.2 Format of the paper

The paper begins with a discussion of the technology transfer obligations on developed country signatories to the World Trade Organization, as stipulated in the TRIPS agreement. The initiatives that developed country governments, international and non-profit organisations have put into place to foster technology transfer are described. Since the best prospects for encouraging more TT may lie in recognising where TT already works and in capitalising on these successes, the majority of the paper focuses on documenting existing agreements and uncovering the motivations that have led to their development. Finally, the impact of IP on the prospects for increased technology transfer is discussed. Annex A provides a detailed mapping of the technology transfer experiences from which the paper's findings have been drawn.



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# 5 International Obligations and Programmes to Encourage Technology Transfer

## 5.1 Technology transfer obligations in TRIPS

The principal provisions of the TRIPS Agreement relevant to technology transfer include the Preamble, Articles 7 and 8, and Article 66.2 and its reaffirmation in Paragraph 37 of the Doha Declaration.

In its statement of objectives in Article 7 of the TRIPS Agreement, the transfer of technology is established as a core value of the Agreement, along with the promotion of innovation: 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology'. However, this statement refers to the effects of the operation of the TRIPS Agreement, and not to specific obligations. Since the general objectives are not made more concrete by the imposition of specific obligations on developed members or technology holders, legal enforceability is a problem. However, the statement of objectives may be used as an interpretative device, to inform the application of other parts of the TRIPS Agreement. It may also be used as a basis for political objection to the manner in which the Agreement is being interpreted and applied by developed members.

Article 66.2 of the TRIPS Agreement is the most concrete manifestation of an express obligation on developed members to encourage technology transfer in favour only of least developed members through the establishment of incentives to private enterprises. However, even the language used in Article 66.2 is 'soft', talking of non-specific 'incentives' to 'promote and encourage' and to 'enable'.<sup>5</sup>

## 5.2 Initiatives to foster TT

Technology and its transfer can be thought of like any economic market with agents on the demand side and on the supply side. Under perfect market conditions, no intervention would be necessary. However, market conditions for some types of TT are often not perfect. For example, there may be information asymmetries or high transaction costs acting as barriers (especially information and seek costs).

Governments, international bodies and non-profits can help facilitate TT by reducing market failures or by providing incentives to engage.

### **5.2.1 Working Group on Trade and Transfer of Technology**

At the World Trade Organization (WTO) Ministers meeting in November 2001 in Doha, a Ministerial Declaration provided for the establishment of a Working Group on Trade and Transfer of Technology, with a mandate to examine the relationship between trade and technology transfer, and to make recommendations on steps that might be taken within the scope of the WTO to increase flows of technology to developing countries. The Working Group has held several meetings, and the Secretariat has prepared two reports for members. The reports seem to view the solution to lower rates of development as dependent upon a stable investment and IP climate, an environment into which foreign direct investment (FDI) will flow, along with improved education and training, with the assumption that FDI is the best means for transferring technology. Given the lack of consensus and/or concrete proposals coming from this Working Group, it has been suggested that the Group, while reflecting a concession to developing country demand, may be a largely symbolic act.<sup>6</sup>

### **5.2.2 Incentives offered by WTO member governments<sup>7</sup>**

The developed members of WTO have provided modest incentives to the private sector to promote technology transfer in the pharmaceuticals and public health sector, including tax advantages that may accrue from participation in public-private partnerships and direct or indirect government financial participation in clinical testing programmes, such as in relation to human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) vaccines.

#### **Canada**

The government of Canada has a variety of programmes in place to encourage the commercial export of Canadian technology abroad; two examples are the Canadian International Development Agency's (CIDA) Industrial Cooperation Programme and Canada's contribution to the International Model Forest Network (IMFN). CIDA's Industrial Cooperation Programme provides financial support to Canadian businesses planning sustainable business activities in developing countries in a variety of sectors. It reduces the risks to Canadian firms by sharing the costs unique to doing business in developing countries and those associated with providing training, the participation of women, and a clean environment. Canada also exports its knowledge of forestry management to the rest of the world through the IMFN.



## EU

The European Communities submitted a paper to the Working Group on Trade and Transfer of Technology on the subject of 'Transfer of Technology to developing and least-developed countries'. In this submission, the EU points to the importance of creating incentives to encourage FDI and foster business partnership (thereby putting technology owners and recipients in contact). The paper states,

*In parallel, developed countries can help improve the overall capacity of LDCs and create an enabling environment for FDI by means of appropriate domestic policies and capacity building programmes. Developed countries authorities also have a role to play through cooperation activities, support to joint research initiatives, expertise on public utility sectors, and support to regional integration.<sup>8</sup>*

The presentation only points to these suggested activities; it does not detail how and whether the EU has implemented or will implement any of them.

## IPTT

The South African government is planning to launch the *Initiative on Pharmaceutical Technology Transfer* (IPTT) to promote the production of off-patent pharmaceuticals to treat disease endemic to the developing world. It is expected that the government would enter into contracts to buy the resulting products, which would ensure that prices were kept low. The IPTT has its roots in the Doha Declaration, which includes an undertaking that developed countries would promote TT to least-developed countries. IPTT is a cooperative partnership with the industry, under which the government would negotiate TT arrangements and encourage local companies to use the technology to upgrade their production facilities.

### 5.2.3 Initiatives involving multi-laterals and non-profits

## UNCTAD

UNCTAD's work on TT spans several decades, and includes case studies and normative work, as well as analytical work on the relationship between investment and TT. UNCTAD has also developed concepts of technological capacity-building and technology partnerships. UNCTAD's Compendium of existing measures contains a selection of 35 multilateral and 25 regional and interregional instruments that make provisions related to technology transfer and capacity-building. When bilateral agreements are included, the number exceeds 80. UNCTAD's current work includes extensive policy analysis embracing global trends, particularly in the UNCTAD World Investment Report, which examined the question of linkages between foreign enterprises and backward linkages with the domestic economy through affiliates.

UNCTAD is involved in a joint project with UNIDO on evaluating the impact of TRIPS on technology transfer issues in developing countries.<sup>9</sup>

### *WHO (TDR), MMV and DNDi*

The Tropical Diseases Research Department of WHO and the Medicines for Malaria Venture are not explicitly set up to transfer technology. However, their contribution in this area, in the context of ensuring access to drugs for neglected diseases, has been substantial, as documented in Annex A.

Similarly, the Drugs for Neglected Diseases Initiative (DNDi) is a \$250 million initiative begun with Médecins Sans Frontières and a group of developing countries to research diseases ignored by western drugs companies. Technology transfer and exchange occurs at the research stage. The six founding partners include the Indian Council of Medical Research, L'Institut Pasteur (France), the Kenya Medical Research Institute, Médecins Sans Frontières, the Ministry of Health of Malaysia and the Oswaldo Cruz Foundation (Brazil). WHO/TDR will participate in the meetings of the Scientific Advisory Committee of DNDi as an observer to provide expert scientific and technical advice as required.



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# 6 Technology Transfer Experiences

This section documents a wide range of TT experiences, from those that have occurred on a spontaneous commercial basis as well as those that have been facilitated by some sort of broker – usually a government, international organisation, or non-profit – who may also provide finance and technology transfer (e.g. technical assistance) as well.

## 6.1 Goals of TT

TT goals of various partners in the arrangement will differ. When the WHO, government bodies or non-profits are involved, goals may include: benefiting public health; ensuring public availability of new technologies; utilising intellectual property rights (IPR) appropriately as an incentive for commercial development of technologies; attracting new research and development (R&D) resources; obtaining return on public investments; and stimulating technological and economic development. The private sector partners may share some of these goals, but in all the examples covered in this review except for one,<sup>10</sup> there was also a definite business case. Without a strong business case, the sustainability of the TT deal may be at risk as soon as other more profitable opportunities arise.

## 6.2 Basic conditions conducive to TT

There are some common preconditions that affect the willingness of MNCs to enter into transfer of technology agreements. First of all, firms will not want to enter into any arrangement that will expose them to major legal or technology risks. Secondly, there also needs to be a supportive business and scientific environment in the recipient country that is conducive to such arrangements. That environment should include skilled workers, economic and political stability, IP protection, a supportive regulatory environment (e.g. customs), market size and potential, and a well-developed national infrastructure of natural resources and transport.<sup>11</sup> Although it has been suggested that the ability of developed world governments to influence decisions in this area through general incentives will be limited,<sup>12</sup> clearly the examples in this section demonstrate that well-targeted and well-designed incentives, such as those that include tailored financing and skills transfer, can direct specific partners towards joint realisation of access to medicines objectives.

### 6.3 Scope of TT experiences investigated

Pharmaceutical companies have been involved in numerous programmes focusing on transferring health technologies and know-how to developing countries. These programmes cover a wide spectrum of the value chain,<sup>13</sup> including: R&D alliances to develop new medicines; clinical trials programmes; transferring technology for production to domestic manufacturers (involving quality assurance, process maintenance, or regulatory compliance, for example); training activities in disease management and control strategies for physicians, pharmacists and other medical professionals; and creating healthcare systems and structures in developing countries.

Annex A summarizes the TT experiences investigated for this paper. Only those TT examples involving developing country firms have been included. Thus, for example, the Lapdap partnership for a malaria drug will not be touched upon in this paper, as it is a PPP involving GlaxoSmithKline (GSK), WHO, DFID and others, but has no developing country component (apart from as the beneficiary of the eventual product). However, the Aventis partnership, also a PPP involving WHO and a research based MNC, is covered, since this PPP has an explicit goal to transfer technology to developing country firms.

### 6.4 Private sector incentives to engage in technology transfer

Motivations for engaging in technology transfer agreements will vary by company, according to the particular product portfolio, company history and resources and capabilities, for example. These motivations are also likely to change over time.

However, there are some generalisations that are typically true for all private companies. Although the company and its employees may hold a philanthropic interest in helping achieve access to medicines, employees are also under significant pressure to meet earnings expectations, and this leads to assessing TT deals in the same way as they would a commercial deal, i.e. whether the deal has the potential to earn a reasonable return for the company. This return may be immediately obvious, short-term, and easily attributable to the TT experience. Alternatively, it may be more subtle and long-term – for example, a response to public pressure or a desire to fulfil overall company strategic objectives.

**Business case examples uncovered during the course of this paper, from the perspective of the technology donor, (usually a research-based MNC) are cited below.**

- Historically, many countries had regulations regarding ‘local content requirements’ or ‘local presence’ of one sort or another, in order to be able to sell in the country. This was the rationale for Eli Lilly setting up domestic



manufacturing operations in Egypt, for example.<sup>14</sup> However, such requirements are questionable under WTO rules, and consequently some MNCs have pulled out of domestic manufacturing in some countries, while other facilities remain because the business prospects have become attractive over time.

- Similarly, some domestic manufacturing has historically been established as a way to ingratiate the MNC with a local government/regulator. This was a consideration in Novartis' decision to use the malaria drug, Coartem, as a beachhead into China.<sup>15</sup>
- MNCs may choose to locate production in a developing country in order to create a strategic location, such as one that is proximate to other countries it wants to serve in the region.<sup>16</sup>
- Another MNC rationale for transferring manufacturing technology to developing country manufacturers is to provide for a source of contingency supply. Manufacturing partners can help out when the research-based MNCs' capacity cannot meet demand. In the example of Eli Lilly's decision to transfer technology to developing country suppliers, the need for contingency supply was linked to the need for speed. Lilly needed to get supply from firms who had existing vacant capacity that could be easily converted for the purpose of making tuberculosis (TB) drugs. Lilly could not have met the timescales required to satisfy the WHO demand projections.<sup>17</sup>
- Patent holders may choose to engage in TT as a response to public pressure. For example, in 1995, Aventis (then Hoechst Marion Roussel) abandoned production of the sleeping sickness drug, eflornithine, because it was not making a profit. It took years of international pressure to find a way to restart production of the drug. When this international pressure coincided with the media attention around the launch of Bristol-Myers Squibb's (BMS) Vaniqa, an eflornithine-based product intended to remove women's facial hair, Aventis and BMS became involved with WHO, in a deal that includes TT to developing country firms to manufacture drugs for sleeping sickness, including eflornithine.<sup>18</sup>
- Investor pressure provides a similar motivation. Calpers, the world's largest pension fund, put pressure on GSK to allow more generic companies to produce copies of its AIDS drugs for patients in developing countries. The fund asked GSK to evaluate potential licensing deals for its AIDS drugs and report back to shareholders within three months.<sup>19</sup> The Calpers letter echoed many of the concerns also raised by a group of leading European investors. Motivation for the letter was reported to be a concern as to whether a popular backlash about AIDS in Africa would limit the industry's ability to charge high prices in rich countries.

- A choice to engage in TT may also be made in order to appease a domestic regulator. For example, in October 2003, South Africa's Competition Commission issued a statement saying that Glaxo and Boehringer Ingelheim had broken competition rules by charging excessive prices for AIDS drugs in the country. The Commission said it would recommend that generics companies be allowed to make copies of the drugs and that the two companies be fined 10 per cent of the sales of their AIDS drugs in South Africa.<sup>20</sup> This was likely to be one of the reasons why GSK chose to make its ARV licences available to multiple companies.
- Companies can get a tax write-off if they donate patents.<sup>21</sup>
- Technology transfer arrangements can be driven by a desire to reduce costs or reduce taxes. For example, clinical trials costs for Elli Lilly's TB drugs have been reduced through a clinical trials technology transfer in Tomsk, Siberia. Similarly, Singapore is a popular location for pharmaceutical production partly due to tax advantages.
- Technology donors may also transfer technology as part of an obligation for receipt of IPR from a publicly funded programme. For example, technology recipients from NIH programmes, who have licensed compounds made from natural materials, are required to go back to the originating country and reach an agreement with government authorities to share benefits arising from the compound. For example, the NIH isolated the anti-cancer compound, calanolide A, from the bark of a tree found in Malaysia. It then licensed the rights to this technology to the private firm, Medicam, and required Medicam to reach an agreement with the national government from where the resources came to share the benefits arising from the technology. Medicam and the Malaysian government subsequently agreed that Medicam would enter into a joint venture with a Malaysian firm, Sarawak, transferring technology for production of the product.<sup>22</sup>
- Research-based companies may be incentivised to engage in TT with developing country firms as part of the larger trend towards outsourcing non-core activities.<sup>23</sup> Since the development or manufacture of a non-core product would not be fully mainstreamed strategically or functionally, then the additional cost of conducting the activity in-house might be high relative to the transaction costs of transferring the activity to another company. This is the motivation for many of the companies working with the TDR division of WHO.
- The above is closely related to the idea of how products are handled during their life-cycle. Research-based MNCs want to keep tight control over the entire supply chain of a blockbuster drug during its high growth phase, from R&D through to manufacturing, as highly proprietary blockbuster drugs are considered to be key to the company's competitive advantage and profits. However, once products have reached maturity, production may be outsourced to other firms. Eli



Lilly has an entire product division that develops the global strategy for their portfolio of older products, for example.<sup>24</sup>

- MNCs may be motivated to use TT of a commercially unimportant product or technology as a low-risk way of testing out a new market or new partner firm. This was part of the motivation when Novartis chose to use the development and manufacturing of the malaria drug, Coartem, as a first step to working with Chinese firms.<sup>25</sup>
- Finally, NGOs assert that a motivation for some PPP projects (which are also TT projects) has sometimes been the development of products that will benefit rich countries as well as poor ones – the tuberculosis vaccine, for example. And although a vaccine and better treatment for kala azar (leishmaniasis) will help people in developing countries, it is also of strategic interest to Western countries, the US in particular, because of the risk to military personnel. (The cutaneous version of the disease, dubbed ‘Baghdad Boil’, has infected 150 US soldiers serving in Iraq, according to newspaper reports.)<sup>26</sup>

## From the perspective of both technology donor and recipient

- From the perspective of a research-based MNC, out-licensing for products that are mature or less commercially interesting frees up management time and focus for higher priority products. Since all the major research-based companies are publicly listed, they have the incentive to optimise their R&D pipeline and portfolios, because the market judges them on this basis. Drugs with limited market potential in developed countries are therefore not attractive to them, whereas a developing country-based firm, with a potentially lower cost base and lower required return to shareholders, may have more freedom and desire to pursue such niche opportunities. GSK

*has an important programme of ‘know-how’ transfer to local manufacturers whereby we outsource production of products as part of a carefully managed production cycle aimed at freeing up GSK production capacity for the development of new drugs. Transfer of production traditionally occurs post-patent expiry for products which local operating units consider of strategic and/or commercial importance in local or regional markets. They continue to be GSK branded products and sold and marketed by the company. Production, however, is handled by a third party contractor, with the necessary regulatory and technical support from GSK to ensure compliance with local and international standards.<sup>27</sup>*

- The Director of Medicines for Malaria Venture also stated that this was a common motivating factor for the firms they work with. For example, development and

production of malaria products is usually not commercially interesting to major pharmaceutical companies, but it may be interesting to developing country producers, especially if they receive help in deferring development costs, receive help with registration and with bringing the dossier up to an international level – this is the TT that MMV provides.<sup>28</sup>

- Any technology transfer partnership that can have a positive impact on the value chain of both companies will have good prospects. Benefits may include increased access to scientific centres of excellence, to funding, or to developing technology and new skills; and potential access to targets or final products for global distribution.
- Any partnership that reduces risk would also be of value, for example, providing up-front funding of early research, fixing profit margins or guaranteeing sales volumes, reducing expenses by sharing costs, or speeding up drug registration through government partners.

### **Developing country firms may be motivated to enter into technology transfer arrangements for:**

- Funding
- Assets other than funding, such as raising the firm's profile, demonstration/proof of technology, access to data, training, know-how, introduction to new markets. For example, Shanghai Desano (China) received the know-how of producing ARVs from Cipla (India). Shanghai Desano's motivation is to increase their international profile, consistent with their goal to develop their export base in Africa and Latin America.<sup>29</sup>
- The need to utilise excess capacity – increasingly likely as Indian firms must switch from their role as technology copiers, and must find ways to re-employ scientists and production capacity. For example, the brochure distributed by Eli Lilly describing their TT partnerships for production of TB drugs, states that Lilly will give manufacturing firms in S Africa, China & India the technology to 'convert existing facilities' for the production of these drugs.
- Access to new machinery, training, know-how and business partnerships that can be useful for more profitable drugs. For example, Eli Lilly is providing a liophilization machine for freeze-drying the injectable TB drug solution. Production of injectables is more difficult than oral forms.<sup>30</sup> The liophilization machine itself, plus the know-how for producing injectables, is a valuable skill that technology recipients can use for other, more profitable, product categories.

Similarly, technical assistance provided to developing country firms in order to bring the



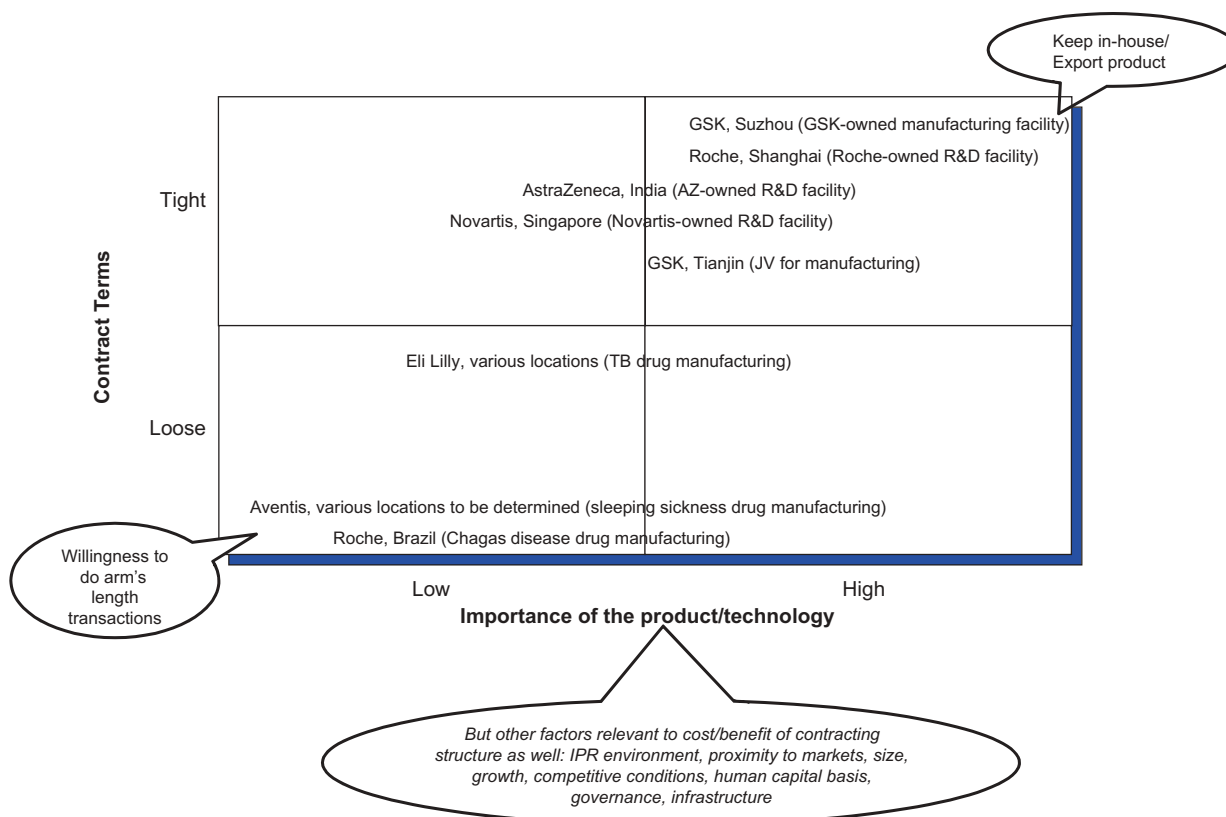
registration dossier of a new, neglected disease product up to the standards set by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) can be helpful to the firms when developing dossiers for other disease areas. Help with bringing manufacturing quality up to good manufacturing practice (GMP) certification can be helpful in a similar way. These benefits were mentioned specifically as those that MMV can offer to firms who partner with them to develop and manufacture malaria drugs.

## 6.5 The impact of changing IP on technology transfer: theory and practice

Transaction cost theory predicts that, other costs being equal, a patent owner would choose to keep research, development and production of more proprietary products and/or technologies completely in-house, particularly in an environment of insecure IP protection.<sup>31</sup> If keeping everything in-house is not possible, then the patent owner's first choice would generally be to engage with other firms via very tight relationships (where equity/ownership arrangements and duration of the working relationship are structured to align the incentives of all parties). The contractual tendencies observed during the course of this paper do seem to support transaction cost theory.<sup>32</sup> For example, the hepatitis B medication, lamivudine, is a commercially and strategically important product for GSK in China, reaching number two in Glaxo's sales revenues in China for 2002. With sales growth averaging 18 per cent per year, it is now the leading product on the Chinese market for hepatitis B. Rather than license out production of this important product in what can be argued is a relatively insecure IP environment, GSK has built a greenfield GSK-owned site in the eastern Chinese province of Jiangsu which conducts all stages of the manufacturing process. Similarly, it should not be surprising that many of the R&D facilities (dealing with sensitive and proprietary products) set up by MNCs in developing countries are owned (rather than contracted).

As illustrated in the figure below, this ownership structure contrasts with the relatively loose arrangements being sought by Aventis for production of commercially unattractive sleeping sickness drugs, and Roche for production of the drug for Chagas disease, for example. Aventis is looking for partners willing to manufacture the drugs and essentially looking to contract with these firms 'at arm's length', transferring the technology over to the partners completely, with no residual ownership. Similarly, following Roche's donation, the Brazilian government will set up a manufacturing plant in the state of Acre (Amazon region) and start producing Bezonidazole with the know-how of Roche. All rights related to benzonidazole have been handed over to the Brazilian government.

## Mapping of TT Experiences: Contractual Trends



Although transaction costs are an important consideration in determining contractual modes and degree of technology transfer, the technology/patent holder will no doubt need to consider all types of costs and benefits when choosing the most appropriate contractual/ownership mode for such transfers. As for the influence of IPR on contractual modes, other costs being equal, we might expect to see more willingness of firms to license and contract out technologies to developing country firms, as the IPR situation in developing countries becomes increasingly secure. However, some have argued the opposite – asserting that strong intellectual property protection is liable to stifle technology transfer as technology owners exploit their market power.<sup>33</sup> The answer to this dichotomy of views may be found in market conditions. Large countries with a high level of pre-existing technological capabilities are more likely to attract licensing opportunities as the IPR environment is enhanced, whereas smaller and medium-sized countries, and those with lower technological capabilities, are unlikely to be able to attract licensing regardless of the IPR situation. Another factor to consider is the degree to which the institutional environment – that is, the formal laws as well as the informal norms that guide behaviour – are supportive of enhanced IP protection. For example, despite the presence of patent law since 2002, China has been criticized by MNCs as a country having poor supporting institutions for IPR.<sup>34</sup> Thus, IP laws are only one of many factors that may influence contracting modes and degree of technology transfer.



## 6.6 Scope for further work

This briefing paper provides a wide and relatively shallow mapping exercise of technology transfer experiences in the pharmaceutical sector, focusing on those experiences that further public health objectives or have the potential to encourage industrial capacity development. More detailed case study work would be needed to understand whether these arrangements have actually benefited public health and have encouraged capacity development in the pharmaceutical sector in developing countries. Such a study would need to:

- uncover the contractual basis/ownership structures through which the agreement has been concluded
- analyse the characteristics of the market where the technology is destined, including substitutability with other technology in the domestic market, pre-existence of subsidies or other forms of protections, the degree of competition in the product market and the effect on competitor entry
- look at the characteristics of the firms offering and receiving the technology, e.g. minimum quality requirements of the technology recipient
- identify any trends/patterns in ownership structures, product types, or part of the value chain in which these relationships operate.





missing examples, as the TT experiences which involve some kind of assistance/collaboration with international or government organisations are bound to get more press and be easier to track down than those relationships that are purely commercial or those that are more limited in scope, for example multitudes of packaging arrangements between MNCs and local firms in developing countries.

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
<i>Examples where the technology 'recipient' firm is dealt with 'at arm's length' and usually involves an intermediary as broker, funder or additional technology donor</i>				
1. India (firms have not yet been found)	Aventis <sup>35</sup>	Pentamidine, melarsoprol and eflornithine – all for treating sleeping sickness	Manufacturing and other	<p>On May 3, 2001, WHO and Aventis announced a partnership to combat African trypanosomiasis or sleeping sickness. Aventis has committed \$25 million to supporting WHO's activities over a five-year period. The project involves three related efforts – drug donation, disease management and control, and research and development. Aventis will arrange for the production of three of the five drugs used to treat sleeping sickness, in the amounts forecasted by WHO. With the financial support of Aventis, WHO intended to control activities and accelerate disease surveillance in African countries most affected. Also, Aventis will fund new research into African trypanosomiasis.</p> <p>By the end of the five-year period, Aventis has committed to transfer the production technology for these products and provide technical assistance to developing country firms, who would find such a niche opportunity commercially attractive, and with the goal of helping to provide a sustainable source of supply for these drugs.</p>
2. India, China, S. Africa	Eli Lilly <sup>36</sup>	Multidrug-resistant tuberculosis (MDR TB)	Manufacturing	<p>The Lilly MDR-TB Partnership is a uniquely comprehensive initiative with the Green Light Committee of the World Health Organization, the U.S. Department of Health and Human Services' Centres for Disease Control and Prevention (CDC), Brigham and Women's Hospital (BWH), an affiliate of Harvard Medical School, the International Council of Nurses (ICN) and Purdue University to increase the number of trained personnel and drugs available to treat the expanding crisis of MDR TB.</p> <p>Lilly has invested in its own facilities to enable it to double its current production of capreomycin, one of the essential drugs used to treat MDR TB. Finally, Lilly is providing both capreomycin and cycloserine at a fraction of their cost to WHO Green Light Committee-approved DOTS-Plus<sup>37</sup> treatment programmes around the world.</p> <p>Lilly has signed technology transfer agreements with companies in India (Shasun Chemical and Drugs, Ltd.) and South Africa (Aspen Pharmacare Holdings, Ltd) and is negotiating a similar agreement in China (Zhejiang Hisun Pharmaceutical Co., Ltd.). In addition to making available the necessary manufacturing know-how, Lilly is providing financial assistance for the purchase of equipment (liophilization equipment, necessary for the freeze-drying step of injectable production) and/or conversion of manufacturing facilities and technical training for various stages in the manufacturing processes. Currently, the companies are in various stages of facility conversion and initial production. The first validated production could occur within the next six months with shipments for disbursement to WHO-approved MDR TB DOTS-Plus programmes occurring before the end of 2004.</p> <p>Possible incentives for technology recipients to engage are: access to know-how and grants for equipment for producing injectable drugs (know-how and equipment that is useful for other product categories); demonstration of ability to work with an MNC (useful for other product</p>

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
				<p>categories); using excess capacity. Possible incentives for Lilly to engage, as technology donor: divesting from commercially uninteresting business; (similarly) avoiding the need for further investment into capacity; getting speedy access to contingency supply from firms who had 'vacant supply ready to go' (whereas Lilly could not have met the timescales for matching supply with WHO's projected demand, which would have been bad from several respects, including PR). Eli Lilly has subsequently worked with these firms to source other products (active pharmaceutical ingredient (API) and formulations). Implication: using the TB drugs as a test case for working with the firms would have been a relatively low-risk way to begin a working relationship.</p> <p>In December 2003, Purdue University broke ground for its new manufacturing facility, the Allen Chao Center for Industrial Pharmacy, which will produce Seromycin (cycloserine). University officials also visited Lilly's manufacturing partners in India and China to determine training requirements for both facilities and to meet with local universities in those countries to discuss possible collaborative efforts. In May, Purdue University will be hosting its first training for five employees of Zhejiang Hisun Pharmaceutical Co. Ltd. (China) and four employees from Shasun Chemical and Drugs, Ltd. (India), in West Lafayette, Indiana. The university will train employees in Good Manufacturing Practices and proper regulatory documentation.</p> <p>Lilly has also established a Center of Excellence for the training of medical personnel in the treatment of MDR TB to help prevent further spread of the disease and is leading an effort to establish a comprehensive surveillance programme to monitor development of resistance against the antibiotics used to treat MDR TB.</p>
3. China	Novartis	Coartem	Development and Manufacture	<p>Coartem is an antimalarial licensed by Novartis from a Chinese firm. Novartis always recognised that this product would have limited commercial potential and this made it ideal for the company's first experiment in working with China, where it has since become one of the largest multinationals in operation. The capacity and relationships built through the development of Coartem are now being used for other products Novartis manufactures and markets in China. Novartis receives public relations benefits from the deal. Also, WHO provides technical support and funding (for development), demand forecasting and a credit line for governments to purchase the product.<sup>36</sup></p>
4. Bihar State, India – Institute for One World Health (IOWH)	Farmitalia (taken over by Pharmacia)	Leishmaniasis	Development and eventually manufacture	<p>With little more than \$10 million from the Gates Foundation, The Institute for One World Health has just started a large and pivotal human experiment in Bihar, India, that's testing a drug to treat kala azar. Known medically as leishmaniasis, kala azar is carried by the sand fly and kills an estimated 200,000 people annually. Twelve million people are thought to be infected, mainly in India.</p> <p>In the 1990s the World Health Organization received a donation of paromomycin from Farmitalia the Italian pharmaceutical firm holding the licence. Farmitalia was not interested in developing the drug on its own because of paromomycin's lack of potential to become profitable, given the</p>

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
				expense of conducting clinical trials and the poor economic status of people most in need of it. WHO began with Phase I and II trials on the drug, but ran out of funds and had to stop. IOWH came to WHO, looking for a project. WHO suggested they take over the trials and continue to Phase III, which they did.
5. Shanghai Desano	Cipla		Manufacturing	Shanghai Desano (China) received the know-how of producing ARVs from Cipla (India). Shanghai Desano's motivation is to increase their international profile, consistent with their goal of developing their export base in Africa and Latin America. <sup>39</sup>
6. Aeras Global TB Vaccine Foundation	Various institutes in developing countries and a South African vaccine manufacturer	TB vaccines	Research and manufacturing	Aeras announced in February 2004 that it would begin Phase II trials of two new vaccines against tuberculosis. The project has enlisted partnerships with scientists, academic institutions, governments, and companies in Europe, in South Africa and other developing countries, and in the US. A clinical research site is already in operation in Cape Town, South Africa, where more than 9000 volunteers are enrolled in a clinical trial. Other sites are being considered in Peru and India. Aeras is also partnering with The Biovac Institute in Cape Town to manufacture vaccines for future Phase I and II clinical trials.
7. Various, primarily Indian manufacturers	Wyeth	Pharmaceuticals, vaccines, consumer health	Clinical trial and manufacturing expertise	Over 100 Wyeth products are manufactured in developing countries; some supply entire regions. There are 16 pharma plants, 3 vaccine plants and 2 biopharm plants – some of these are owned affiliates and some are third party suppliers. Main areas of TT: product/process know-how (technical documents); knowledge of products and processes; scientific knowledge; transfer of equipment; regulatory and quality requirements; training of personnel. Examples include Ghana, where Wyeth is sponsoring clinical trials for treatment of river blindness at Hohoe Hospital (in partnership with WHO) in which Wyeth provides the resources for pre-clinical analysis, data management, medical writing, regulatory filings, etc. In Gambia Wyeth is providing a newly developed pneumococcal conjugate vaccine for a five-year clinical trial. In South Africa the company is sponsoring a clinical trial with 40,000 children to assess the public health value of a pneumococcal conjugate vaccine in preventing pneumonia that results in hospitalisation. In India, Wyeth has nine third party suppliers and two owned plants, both of which produce hormonal.
8. TB Alliance	Chiron Corp.	TB	Manufacturing rights	Chiron donated most of the commercial rights to the drug compound dubbed PA-824 to the TB Alliance. Chiron didn't have any reason to take this forward and their goal was to get that drug developed, said Alliance spokeswoman Gwynne Oosterbaan. 'Chiron had every incentive to hand it over to us.' <sup>40</sup>
9. Medicines for Malaria Venture <sup>41</sup>	Ranbaxy & Roche/MMV & Korean firm	Various malaria products	Manufacturing & R&D	Various R&D projects targeting new malaria medicines with researchers and scientists from developing countries, as well as biotech and pharmaceutical companies from China and South Korea. MMV may offer the following to the partnerships: offset costs of development; provide access to 'biology of disease' malaria expertise; provide technical assistance related to bringing registration dossier up to international standards, including



Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
				<p>ICH-level clinical trials and GMP certification.</p> <p>In Korea, WHO identified a small firm interested in growing their African presence. There is also a small anti-malarial market in Korea, but big enough that a small company may be interested. There was also an incentive for the Korean company to learn about drug development and the development of the regulatory dossier.</p> <p>In the Ranbaxy deal, Ranbaxy gets the developed world market and MMV gets the developing world. The new head of R&amp;D at Ranbaxy was instrumental to getting the deal done. MMV offsets the cost of R&amp;D. In the press release, the CEO said 'Collaborative research is one of the identified growth drivers of Ranbaxy. Developing a new medicine for Malaria affords Ranbaxy an opportunity to provide better health care options in this segment. We are delighted to join hands with MMV in this venture to enhance our social responsibilities cause.'</p> <p>A recent agreement was signed between Chongqing Holley Holding, a Chinese pharmaceutical company, Sigma-Tau, an Italian pharmaceutical company, MMV and the University of Oxford for the international development of the anti-malarial drug, dihydroartemisinin-piperaquine (Artekin). Unlike the conventional chloroquine and sulfadoxine-pyrimethamine treatments artemisinin, from which the drug is derived, has not yet produced any known cases of resistance. 'Not only should this antimalarial be effective,' said Dr Christopher Hentschel, CEO of Medicines for Malaria Venture, 'our goal is also to be able to make it available at a cost that's affordable for people living on less than a dollar a day.'</p> <p>A mefloquine artesunate fixed-dose combination is being developed by the Far Manguinos factory (government factory) in Brazil, with assistance from DNDi and the TDR division of WHO. DNDi/TDR facilitates the deal and the development process and has provided manufacturing technical assistance as well.</p> <p>The total malaria market is worth approximately \$200-300 million per year. This is not commercially interesting to majors, but may be interesting to developing country producers. especially if they receive help in deferring development costs, with registration and with bringing the dossier up to an international level – this is the TT that MMV provides! Learning how to bring the dossier up to ICH standards can be helpful to the firm in other disease areas. GMP certification (gained through working in accordance with MMV standards) can help as well. MMV can also offer malaria experts. The Chinese have malaria expertise, but Indians and Koreans do not.</p>
10. Various	U.S. National Institutes of Health (NIH) <sup>42</sup>	Various	Various	<ul style="list-style-type: none"> <li>- ddl _ PROTEIN, S.A. de C.V., Mexico</li> <li>- Meningococcal vaccine – Programme for Appropriate Technology in Health and WHO, produced by Serum Institute, India for sub-Saharan Africa</li> </ul>

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
				<ul style="list-style-type: none"> <li>- Thymosin B, Lee's Pharmaceuticals, Hong Kong</li> <li>- Calanolide A, Sarawak – Medicam, Malaysia. NIH isolated the anti-cancer compound, calanolide A, from the bark of a tree found in Malaysia. It then licensed the rights to this technology to the private firm, Medicam, and required Medicam to reach an agreement with the national government from where the resources came to share the benefits arising from the technology. Medicam and the Malaysian government subsequently agreed that Medicam would enter into a joint venture with a Malaysian firm, Sarawak, transferring technology for production of the product.</li> <li>- Rotavirus vaccine, Bharat Biotech, INDIA</li> <li>- Other negotiations for commercialisation licences with companies in China, South Africa, and India.</li> </ul>
11. Firms in Africa	Thai firms	ARVs	Manufacturing	The Thai state producer, the 'Government Pharmaceutical Organisation', has offered technical help to Ghana, Zimbabwe and Zambia to set up pilot manufacturing plants. Zambia hopes eventually to sell ARVs to 13 neighbouring countries. <sup>43</sup>
12. Ten countries – five in Africa and five in Latin America	Brazil government	ARVs	Manufacturing	Brazil is giving \$100,000 technology transfer grants to ten countries to help develop local generics industries for AIDS drugs. <sup>44</sup>
13. Government of Brazil	Roche <sup>45</sup>	Benzonidazole (benzonidazole is the API for Radamil and has been produced by Roche in Basel), Chagas disease	Manufacturing	The goal of the Roche partnership with the Brazilian government is to provide a sustainable, low-cost supply of a drug that treats a disease endemic to Latin American countries, particularly Brazil. The drug for treating Chagas disease is benzonidazole, and it is not under patent. Roche has donated the legal rights and technology for producing the drug to the Brazilian government, without any compensation to Roche. This gives Brazil control over their own production as well as the ability to establish direct supply agreements with other governments. Following the company's donation, the Brazilian government will set up a manufacturing plant in the state of Acre (Amazon region) and start producing the drug with the know-how of Roche.
14. Institute for One World Health and developing country producers, yet to be identified	Celera	ARVs	Development & eventually manufacture	Celera was not interested in pursuing development of the new protease inhibitor, known as K777, so Celera gave the drug to IOWH in an 'irrevocable, exclusive' licence that waived all potential royalties if it ever succeeds. IOWH now needs to enlist scientists to perfect the drug, conduct animal tests, complete human trials, seek regulatory approval, and then strike a deal with a manufacturer to produce and distribute the drug in developing countries on a two-tiered pricing schedule <sup>46</sup> .

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
15. Nepal state producer	Japan Pharmaceutical Manufacturers Association (JPMA) / Japan International Cooperation Agency	TB	Manufacturing	<p>With the cooperation of the Nepal Department of Health, the Japan International Cooperation Agency constructed a TB Clinic Centre in 1989 and sent TB specialists to Nepal. However, problems with a consistent supply of TB medicines were impeding treatment success. Consequently, JPMA negotiated a contract with DOH Nepal in December 1992 to supply the anti-TB medicine rifampicin, in capsules in the first instance, with the intention of supplying the raw materials (free of charge) for domestic rifampicin production once the Nepal state pharmaceutical factory had received production training. It should be noted that, in Japan, there are few TB patients and anti-TB drugs are used for domestic use only, so that neither the product nor the API is exported commercially.</p> <p>JPMA sent technicians to Nepal several times, to transfer the capsule-filling technology and GMP. JPMA's member companies also agreed to fund production training for Nepal technicians in Japan. The technology transfer to the Nepal state pharmaceutical factory was completed by 1998. The TB cure percentage was more than 85 per cent for the districts that had implemented DOTS. Consequently, the contract between JPMA and Department of Health, Nepal was considered to be completely fulfilled in 1998.</p> <p>JPMA is not aware of the current situation regarding production and supply of rifampicin in Nepal. Japan is no longer providing the raw material, and a representative of JPMA supposes that the Nepal government is currently importing the raw materials of rifampicin from India and China, then making the finished product in Nepal.<sup>47</sup></p>
Examples where the technology donor owns or part-owns the firm to which the technology is transferred and where no intermediary is involved (commercial transactions)				
16. Suzhou plant, GSK-owned R&D facility in the eastern Chinese province of Jiangsu	GSK	Anti-infective drugs, including lamivudine, a treatment for hepatitis B	R&D and manufacturing	<p>Construction began in 1998 and the facility was made operational in 2001. 'Glaxo hopes that a comprehensive system of patent recognition and respect for IPRs is slowly emerging in China. This belief was the main reason behind the company's decision to build the new factory in China' (from <a href="http://www.pharmaceutical-technology.com/projects/suzhou">http://www.pharmaceutical-technology.com/projects/suzhou</a>). The plant is geared especially for the Chinese market and will produce a range of products, including, Heptodin (lamivudine) and antibiotics. It will also serve as the mainland China-based headquarters for sales and marketing. The new facility will cost approximately £85 million. Lamivudine is an important product for GSK in China, as it has high sales for hepatitis. (Note: This TT experience is not directed at a separate firm, but rather, the facility is owned by Glaxo.)</p>
17. Roche-owned R&D facility in Shanghai, China	Roche	Various less proprietary products now, moving on to more proprietary products within five years	R&D	<p>In the Zhangjiang High-Tech Park, this is Roche's fifth R&amp;D centre in the world and its first R&amp;D facility in a developing country. It is also the first wholly owned and operated R&amp;D centre set up in Shanghai by a MNC pharmaceutical company. 'After the R&amp;D centre gains more experience within the next five years, it will become more active in participating in Roche's global projects' (China Daily, 19 January, 2004). 'Looking to the long-term, our aim is for the group to discover and optimise new molecules – active ingredients of potential new drugs – which address</p>

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
18. Chiron-owned Indian branch in a joint venture with Aventis and alliance with local firm, Panacea Biotec	Chiron vaccines	Vaccines	R&D & manufacturing	<p>important unmet medical needs and can be marketed worldwide, including China', quoted from China Daily, Roche Group President Jonathan Knowles'. (Note: This TT experience is not directed at a separate firm, but rather, the facility is owned by Roche.)</p> <p>Chiron is doubling its manufacturing capacity for its rabies vaccine in India, making India its regional base. The company also wants to use India as a prime resource for clinical research and the introduction of new vaccines. 'We've recognised the importance of India, the great health challenges there and its very good skills base. There's a very good opportunity to fulfil health need and it also makes good business' said John Lambert, president of Chiron Vaccines in <i>Scrip</i> magazine, 21 March, 2003.</p> <p>Chiron also expects to do clinical research and introduce new vaccines such as its influenza vaccine and certain meningitis vaccines.</p>
19. Tianjin joint venture in China	GSK	Over the counter (OTC) products initially, expanding into respiratory aerosols and Avandia for diabetes	Manufacturing	<p>GSK (via its legacy companies) has a long history of joint ventures in China, starting with discussions with Smith, Kline &amp; French in 1983 which resulted in the first Tianjin joint venture in 1987 – one of the three most successful foreign pharmaceutical businesses in China throughout the 1990s. In 1996 it reached a production level of more than 1.2 billion capsules per year, mostly of OTC-type products such as Contac (for colds) and Fenbid (the non-steroidal ibuprofen).</p> <p>Glaxo completed a manufacturing joint venture in Chongqing, which became operational in the late 1980s. This factory fills aerosols for the respiratory product lines Ventolin, Becotide and Beconase, but inhaled therapy remains under-utilised in China, and the market performance of these lines has been a long, slow development.</p> <p>In 1997, SmithKline Beecham approved a second manufacturing joint venture in Tianjin. This became operational in January 2001 with the launch of Avandia.</p>
20. Bangalore, Astra Zeneca (AZ)-owned R&D facility	Astra Zeneca	TB	R&D	<p>In 2001 AZ invested US\$10m in an R&amp;D facility to target TB discovery research – developing new diagnostic tests and new therapies. This opened in June 2003. In addition to the \$10m initial capital investment, the company is spending another \$10m on state-of-the-art equipment and has committed a minimum of \$5m a year from 2001 to 2005 to support the research programme. More than 60 scientists recruited from leading research institutions around the world currently work at the facility, and the company plans to recruit more international experts over the coming years.</p>
21. Singapore, Novartis-owned R&D facility	Novartis	TB & dengue fever	R&D	<p>Basic and conceptual research for identification of targets, develop screening assays, &amp; prepare compounds for TB and dengue fever up to readiness for clinical testing. Will offer teaching and training opportunities for postdoctoral fellows and students from Asian countries and elsewhere.</p>

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
<i>Examples where firms are contracted 'at arm's length', but need no intermediary assistance and are more appropriately called technology exchange rather than technology transfer</i>				
22. South Africa, Aspen Pharmacare	GSK, [Boehringer Ingelheim, Bristol-Myers Squibb]	ARVs	Licences for manufacturing, but suspected minimum degree of TT to go with the licences	<p>Possible motivations for the GSK voluntary licence deal can be surmised from press articles surrounding the first and the expanded voluntary licensing (VL) offer. The first VL offer came, coincidentally, just six months after 39 companies backed down in a landmark court battle with the South African government. Cipla was lobbying the South African government to issue compulsory licences for ARVs<sup>48</sup> and there was a parallel patient-led compulsory licence effort that was in the works in South Africa.<sup>49</sup> There was also an article in the press (7 March, 2001)<sup>50</sup> that talked of Aspen's plans to enter into an agreement with Hetero (Indian generics manufacturer) to distribute Hetero's copies in South Africa, if South Africa won its lawsuit against the research-based pharmaceutical companies, allowing for importation of generic drugs. Such an announcement obviously lent credibility to any compulsory licence threat. Criticism surrounding the conditions of the first offer included GSK setting a high royalty payment in order to establish a precedent for such deals, and imposing 'draconian' conditions on distribution of the drugs.</p> <p>The second VL came about, coincidentally, following a series of articles in the newspapers: South Africa's Competition Commission was threatening to fine patent holders who had violated competition rules by offering the VLs on an exclusive basis. There were also calls from investors (Calpers), mentioned in the text earlier. Any one of these events, or a combination of them, quite possibly led to the VL deals struck between GSK, Aspen, and now other firms in South Africa. The terms of the new VL agreement can be found on <a href="http://www.essentialdrugs.org/ledrug/archiver/200312/msg00017.php">http://www.essentialdrugs.org/ledrug/archiver/200312/msg00017.php</a>.</p> <p>One implication of the new agreement is that the four generics companies who will receive the VLs from GSK and Boehringer Ingelheim will be able to sell triple-drug antiretroviral therapy to governments in sub-Saharan Africa, thereby getting around access problems exacerbated by the domestic legislation in some of these countries that is in excess of that required by TRIPS.</p>
23. Ranbaxy	GSK	Various	R&D	<p>Certain R&amp;D activities will be outsourced. GSK says it has hired Ranbaxy to 'research molecules that may become the building blocks for drugs.' BBC News, 23 October, 2003. 'Under the new alliance, Ranbaxy will identify promising potential drugs and perform early clinical trials in India, while GSK takes care of the later stage development. GSK will have sole commercial rights outside India, although Ranbaxy may – if consent is forthcoming – take part in joint promotion in the US or Europe.'</p> <p>A JP Morgan report said 'GSK expects to benefit from Ranbaxy's expertise in medical and process chemistry while Ranbaxy expects to bolster its new drug delivery system skills. While GSK will provide validation targets and perform lead optimisation, Ranbaxy will be involved in subsequent stages like compound optimisation. However, the onus of clinical development and commercialisation rests with GSK. Ranbaxy will be made lump-sum payments on a</p>

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
				<p>molecule-by-molecule basis and will receive royalties based on sales, after the product is commercialised. Revenues from the project are expected to flow from 2010 onwards. The arrangement with GSK does not preclude Ranbaxy from other tie-ups and does not restrain Ranbaxy from pursuing its independent research efforts. Ranbaxy has taken a decision to limit such tie-ups to ensure that not more than 25 per cent of its drug discovery scientists are involved in such projects. This is not exactly TT but it's not 50/50 either, as GSK is driving the strategy and product criteria and is designating the milestones, so it's more like contract research. This allows GSK to maintain control, but it also means they have to put in more money.</p> <p>Goldman Sachs said that GSK has first rights of refusal on Ranbaxy leads, within a defined R&amp;D area. GSK has commercial rights outside India; Ranbaxy will commercialise the product domestically as well as in other markets where Ranbaxy has the sales and distribution infrastructure (subject to GSK's agreement).</p>
24. India, Dr Reddy's	Novartis			Novartis has in-licensed NCE <sup>51</sup> candidates from Dr Reddy's and has hired Dr Reddy's to do research on a diabetes molecule (not really TT, but rather an example of a contract R&D).
25. India, Bharat Biotech	Wyeth	Vaccines	Manufacturing	Wyeth Lederle has contracted with Bharat Biotech for production of the HibTITER vaccine. This is the first example of an Indian company manufacturing a vaccine for big pharma, through contract manufacturing.
26. Brazil, Fiocruz	GSK Biologicals	Vaccines	Manufacturing	In late 1998, GSK Biologicals formally agreed a technology agreement with Biomanguinhos, the vaccine producer entity of the Brazilian Government Foundation, Fiocruz, for the phased transfer of technology HIB (Haemophilus influenza B) vaccine. Under the agreement, GSK has undertaken to transfer all the information, technology, processes and technical assistance needed (including training of Fiocruz staff by GSK Biologicals) to enable Fiocruz to produce the finished vaccines for sale in Brazil's public sector in return for agreed royalties.
27. Brazil, Fiocruz	GSK	ARVs	Manufacturing and clinical trials	Under a separate agreement, GSK is planning to transfer technology to Fiocruz's pharmaceutical arm, Farmanguinhos, linked to volume take-off around the phased introduction of manufacturing of three of GSK's ARVs over a ten-year period. Under a key separate agreement with GSK Bio, GSK will also conduct clinical trials around its HIV vaccine in Brazil.

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
<i>Examples that do not fit above, e.g. where the TT is more skills-based, or is not being transferred firm-to-firm, but by other means</i>				
28. Botswana – The African 29. Comprehensive HIV/AIDS Partnerships (ACHAP)	Merck	Stocrin and Crixivan	Other (Building Skills)	ACHAP is a \$100 million partnership between the Government of Botswana, the Gates Foundation and Merck that aims at providing solutions and resources for all aspects of HIV/AIDS prevention, treatment and care. The goal of the project is to demonstrate the feasibility of a targeted, comprehensive approach, and to apply the lessons learned in other countries and similar contexts. In addition, Merck will supply at no charge to the government of Botswana whatever is required in the way of Merck's ARVs.
29. Kampala, Uganda – Infectious Diseases Institute	Pfizer		Other (Building Skills)	Pfizer and the Pfizer Foundation are building a regional treatment and training institute in Kampala, Uganda to strengthen local capacity in HIV/AIDS care. The facility will provide the latest standards of HIV/AIDS care and treatment to thousands of patients each year, and train healthcare professionals from all over Africa. Start date, October 2004.
30. Various: the SHARE programme	Abbott, Agouron, Boehringer Ingelheim, GSK & Roche		Other (Building Skills)	A multinational programme that teaches doctors, healthcare workers, resource planners and public health experts about prevention and management of HIV infection. The programme principally focuses on the clinical care and prevention of HIV infection. The aim of the programme is to support the professional growth of healthcare providers, including physicians, nurses and other healthcare workers.
31. 'TB free'	Aventis		Other (Building Skills)	Together with the Nelson Mandela Foundation, Aventis established the TB free programme, a \$15 million effort committed to increase the detection and treatment rates of TB in South Africa. TB free aims at training volunteers to support patients' compliance during the six months treatment in line with the WHO DOTS strategy.
32. Krisana Kraisintu, former Director of Government Pharmaceutical Organization of Thailand and currently working in three African countries to transfer technology for ARV production.	Firms in Eritrea, Democratic Republic of Congo and Tanzania	ARVs	Ms. Kraisintu offers technical assistance to build capacity for secondary ARV production. Royalties from sales go towards an orphanage foundation set up by Ms. Kraisintu in the countries where she works.	Eritrea: Ms. Kraisintu is a consultant to the government, supporting its aim to manufacture essential drugs for local use and export, and will soon start an ARV production line, where APIs will come from India initially and then China.  Democratic Republic of Congo, Bukavu: a PPP between Pharmakina, a German/French owned company and GTZ, with Ms. Kraisintu as consultant, to help produce ARVs to treat employees. The project is rather slow due to fighting, but production is expected to start in October 2004.  Tanzania, Arusha: with Tanzania Pharmaceutical Industries, 40 per cent owned by the government. A German medical aid organisation (a non-governmental organisation) called Action Medeor supports the project. The APIs come from China and Ms. Kraisintu is in the process of preparing for production.

Developing country & firm technology recipient	Technology Donor	Product	TT type (Manufacturing, R&D or other)	Description
<p>33. Joint declaration between the Federal Republic of Nigeria, the Federative Republic of Brazil, the Kingdom of Thailand, the People's Republic of China, the Republic of Ukraine and the Russian Federation on the scope of the fight against HIV/AIDS.</p>		<p>ARVs and medicines for opportunistic infections; R&amp;D and production of vaccines and microbicides; development and production of raw materials vaccines and biologicals manufacturing; R&amp;D of rapid tests; CD 4 tests; viral load and genotyping.</p>	<p>Convening technical meetings during the course of this year to establish and implement a working agenda for the development of a common strategy to fight the HIV/AIDS epidemic</p>	<p>The agreement was announced at the 2004 HIV/AIDS conference in Bangkok and the parties agree to 'act in a concerted way to establish common strategies and develop simultaneous actions in the fight against the pandemic of HIV/AIDS'.</p>

Note: Several of the entries in this table have been informed by a note from the Geneva Pharma Forum, ICC Varembe, 18 March, 2004, entitled 'Examples of Technology Transfers from the Pharmaceutical Companies'.



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'Reflection paper on transfer of technology to developing and least-developed countries', communication from the European Communities and their member states, presentation to the Working Group on Trade and Transfer of Technology, 14 February, 2003

## Notes

- 1 Other costs and benefits being equal.
- 2 Incentives are quite the opposite, evidenced by the increased centralisation that has occurred with increased trade liberalisation; such centralisation is focused on capturing increased economies of scale and on avoiding the increased effort and costs associated with upgrading developing country scientific and industrial capabilities. As for obligations, although there is an explicit obligation on WTO developed member countries to offer technology transfer to less developed members as they implement enhanced IP protection, the enforceability of this obligation is weak.
- 3 During the course of the research, it was discovered that a series of country-level case studies on TT within the pharmaceutical sector are currently being conducted by INTECH, focused on India, Cuba, and Nigeria, among other countries, and using examples of a wide range of TT channels, not just firm-to-firm channels. (Personal communication, Professor Lynn Mytelka – INTECH Director.)
- 4 The following links may be useful to readers interested in exploring these subjects further:  
<http://www.unctad.org/Templates/StartPage.asp?intltemID=2983&lang=1>  
<http://www.iprsonline.org/resources/technologytransfer.htm>  
[http://www.london.edu/cnem/\\_Working\\_Papers/\\_working\\_papers.html](http://www.london.edu/cnem/_Working_Papers/_working_papers.html)  
<http://people.brandeis.edu/~jefferso/RDandFDI.pdf>
- 5 Abbott 2002
- 6 Abbott 2002
- 7 Several of the entries in this section come from presentations made to the Working Group on Trade and Technology Transfer, and are available at the following URL:  
[http://www.wto.org/english/tratop\\_e/devel\\_e/dev\\_wkgrp\\_trade\\_transfer\\_technology\\_e.htm](http://www.wto.org/english/tratop_e/devel_e/dev_wkgrp_trade_transfer_technology_e.htm)
- 8 'Reflection paper on transfer of technology to developing and least-developed countries', communication from the European Communities and their member states, presentation to the Working Group on Trade and Transfer of Technology, 14 February 2003
- 9 Presentation by Mr. Khalil Hamdani to the first session of the Working Group on Trade and Transfer of Technology
- 10 Example number 15 in Annex A, involving the Japan International Cooperation Agency
- 11 Hughes 2002
- 12 Hughes 2002 and Farrell 2004
- 13 The term 'value chain' here refers to the range of processes/functions within an industry that bring products and services from the formulation/discovery stage through to the consumer. See Porter 1985, chapters 1 and 2, for more detail on the firm value chain concept and on the structural analysis of industries.
- 14 Presentation given by Mike Okopski of Eli Lilly at the International Federation of Pharmaceutical Manufacturers Associations meeting in Geneva, April 2004
- 15 Grace 2003
- 16 Hawkins 2004

- 17 Mike Okopski, Eli Lilly
- 18 Moon 2001
- 19 See <http://www.aidsmap.com/news/newsdisplay2.asp?newsId=2026> and [http://www.ethicalcorp.com/content\\_print.asp?ContentID=463](http://www.ethicalcorp.com/content_print.asp?ContentID=463)
- 20 Financial Times Intelligence report 2003
- 21 Associated Press 2004
- 22 Mark Rohrbaugh, NIH Director, personal communication
- 23 Rob Ridley, Director TDR at WHO, personal communication
- 24 Mike Spink, Director of this division at Eli Lilly, personal communication. Also see Hughes 2002 (GSK document that discusses the same)
- 25 Grace 2003
- 26 Bernard Pécoul, Executive Director of the 'Access to Essential Drugs' project at Médecins Sans Frontières, quoted in Mandelbaum-Schmid 2004. See <http://www.essentialdrugs.org/edrug/archive/200405/msg00011.php>
- 27 Hughes 2002
- 28 Chris Hentschel, MMV Director, personal communication
- 29 Jean-Francois Deçhamp, personal communication
- 30 Morgan Stanley 2003 and confirmed in conversation with author
- 31 Maskus 2003
- 32 Although definitive trends would require more analysis of data that would probably be impossible to get due to its commercial nature.
- 33 Correa 2003
- 34 The Japanese Manufacturers Association cites lengthy registration approval processes and regulatory discrimination between local and overseas firms as barriers to foreign investment. (Morgan Stanley 2004)
- 35 Alain Aumonier, Aventis, personal communication
- 36 Mike Spink and Mike Okopski, Eli Lilly, personal communication
- 37 DOTS-Plus is an extension of WHO's DOTS programme (Directly Observed Therapy – Short course), an intensive six-month treatment protocol, often requiring daily dosing of capreomycin and three-times daily dosing of cycloserine
- 38 Grace 2003
- 39 Jean-Francois Deçhamp, formerly with Médecins Sans Frontières, personal communication
- 40 See Associated Press 2004
- 41 Chris Hentschel, Director MMV, personal communication
- 42 Mark Rohrbaugh, NIH Director, personal communication
- 43 See <http://www.essentialdrugs.org/edrug/archive/200308/msg00065.php>. See also entry 32 of this Annex for details of technology transfer work that a former GPO director is undertaking in Africa.
- 44 See <http://www.essentialdrugs.org/edrug/archive/200308/msg00065.php> and <http://www.essentialdrugs.org/edrug/archive/200007/msg00014.php>
- 45 Maria Vigneau, Director, External Relations HIV/AIDS, Hoffman-La Roche, personal communication
- 46 See <http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/>

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47 Mr. Miyazawa, JPMA, personal communication and 'Crossing national borders in pursuit of health: international cooperation projects of Japan Pharmaceutical Manufacturers Association', 2002, JPMA

48 On 8 March 2001, Cipla formally requested the South African Department of Trade and Industry to issue compulsory licences for several HIV/AIDS drugs.

49 See <http://www.essentialdrugs.org/edrug/archive/200110/msg00023.php>

50 See <http://lists.essential.org/pipermail/pharm-policy/2001-March/000753.html>

51 NCE is a New Chemical Entity, a drug compound that meets novelty criteria, as defined in national laws