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## TRIPS and the pharmaceutical industry: Prescription for profit?

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### Abstract

The impact of global patent regulation in the form of the WTO's TRIPS Agreement has far reaching effects for the research based pharmaceutical industry and global public health. This paper explores the role of accounting in reinforcing the primacy of capital interests over global public interest by its ability to capture and measure an abstraction - knowledge. This commodification of knowledge serves to transfer the responsibility of the global health agenda to the market. However, this market based solution is not sensitive to many important issues faced by governments in relation to the global pharmaceutical research and development agenda, such as 'neglected diseases'. The terms and global nature of the TRIPS Agreement effectively constrains the ability of governments, particularly in least-developed countries, to address their individual public health issues. The adoption of TRIPS presents significant challenges and opportunities in an era of globalisation for both the pharmaceutical industry and policymakers.

### Keywords

TRIPS, intellectual property, research and development, intangible assets

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# **TRIPS & the pharmaceutical industry: prescription for profit?**

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**Key Words:** TRIPS, intellectual property, research and development, intangible assets.

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# **TRIPS & the pharmaceutical industry: prescription for profit?**

## **ABSTRACT**

The impact of global patent regulation in the form of the WTO's TRIPS Agreement has far reaching effects for the research based pharmaceutical industry and global public health. This paper explores the role of accounting in reinforcing the primacy of capital interests over global public interest by its ability to capture and measure an abstraction - knowledge. This commodification of knowledge serves to transfer the responsibility of the global health agenda to the market. However, this market based solution is not sensitive to many important issues faced by governments in relation to the global pharmaceutical research and development agenda, such as 'neglected diseases'. The terms and global nature of the TRIPS Agreement effectively constrains the ability of governments, particularly in least-developed countries, to address their individual public health issues. The adoption of TRIPS presents significant challenges and opportunities in an era of globalisation for both the pharmaceutical industry and policymakers.

*The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed – in every country – of the economic and social consequences of the TRIPs Agreement (UNDP Human Development Report 1999)*

## **Introduction**

Innovative drug treatments have offered cures from illnesses previously considered life-threatening, have improved lifestyles and diminished the effects of ageing on those fortunate enough to be able to afford treatment. In a time when international trade liberalisation is seen as a panacea for economic underdevelopment, The World Trade Organization (WTO) through the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement has constrained the ability of developing and least-developed countries<sup>1</sup> to address domestic public health issues by limiting their access to affordable drugs.

The TRIPS Agreement affords drug companies' exclusive patent rights on pharmaceutical innovation for 20 years, but limits the ability of developing and least-developed countries (LDC) to determine their national health issues (diseases) that allow for the import, production and marketing of low cost copies of patented medicines (generic drugs). Safeguards within the agreement that allow for compulsory licensing and parallel importing have not stopped the US Government threatening trade sanctions or

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<sup>1</sup> The implications of the antimony, developing/less developing or undeveloped, is not stated but these terms are used in this paper as they are consistent with the literature. The TRIPS Agreement differentiates between developed, developing and least-developed countries in terms of their respective economies.

initiating WTO disputes against countries where domestic legislation has been less protective towards pharmaceutical companies (Oxfam, 2001).

Underpinned by the ideology of neo-liberalism, incorporating free-market globalisation and trade-led development, the WTO through the TRIPS agreement provides a mechanism for companies to make monopolistic profits for a guaranteed time frame. In the case of the research based pharmaceutical industry, companies are granted intellectual property rights over certain pharmaceutical products. From an agency perspective, there is an expectation that the industry, in pursuit of profit, will provide social welfare outcomes as positive externalities through innovation. This suggests that the public interest in terms of global public health, can be served through market based solutions. The position taken by pharmaceutical companies is based on the economic rationalist argument of research and development cost recovery which requires support from patent protection. However this view, and the expensive lobbying to gain political sway by the pharmaceutical industry, ignores the real and present public health problems faced by developing and LDCs. In an era of economic globalisation, ease of technology and information transfer, patent protection underpins corporate profitability in a competitive global environment. As the economic power of global corporations increases, so to does their political and intellectual reach.

“[T]he complex interdependencies between the economic, social, political, and rhetorical patterns ... place accounting in a milieu of concrete, material conditions of human life where acts of power and acts of exclusion (victimization) are contemporaneous”

(Arrington, 1990, p.5). Accounting in this context is a device which serves the vested interests of powerful groups. In the case of pharmaceutical innovation the accounting discourse of costing and profitability has reoriented a means-end rationality to an ends-mean rationality. Instead of an ex ante expectation, justification of patent protection relies on ex post calculations and legitimisation. The quoted 'cost' of bringing a new drug to market is US\$802 million (DiMasi et al, 2003). "[T]he elegance of a single figure provides a legitimacy that, at least in certain Western societies, seems difficult to disrupt or disturb" (Miller, 1994, p.3). Economic justifications for patent protection using accounting techniques prevail. In practice, accounting techniques define, measure and value abstractions, identified as intangibles. In this way, accounting facilitates the commodification of knowledge through the ability to 'account for' intangible assets that subsequently provide a conduit or "gateway to capital" (Drahos, 1996). The perception of accounting as an objective neutral device subtly reinforces the dominance of capital over social welfare issues. The ideological hegemony of free market trade liberalisation affects the process of what is accounted and how, which has been demonstrated to impact on local communities (Cooper et al, 2003).

The TRIPS Agreement highlights the tensions between the interests of various governments, powerful multinational corporations and the 'public interest', as well as the role of multilateral organisations in mediating these issues. In order to explore these themes this paper is structured as follows: first we provide an overview of intellectual property rights and examine the interests of various dominant players and their position in relation to the TRIPS Agreement. This will be followed by a discussion of the

inequities presented by the adoption of the Agreement, particularly in relation to health issues faced by developing and LDCs.

### **Intellectual Property Rights**

Intellectual property (IP) is a property right in an abstract object. Examples include copyright, trademarks and patents which serve to mediate property relationships between individuals by objectifying an intangible. In developing a philosophical understanding of IP, Drahos (1996, p.1) concluded that, a “property form that allows private hands to capture important abstract objects creates, among other things, many person dependent relationships in a society. It swells the growth of private power”.

Intellectual property rights (IPR) are a distinctive form of power and the exclusive nature of these rights allows dominion or sovereignty over an abstraction - knowledge. This right should be termed and treated as a privilege and the holders of that privilege subsequently have duties to society (Drahos, 1996). The rationale for IPR largely rests with the economic argument that individuals, as self-maximisers, will only devote resources to the creation of abstract objects if there is a suitable incentive or reward. IPR allow for monopolistic pricing. This incentive has the expected outcome of generating creativity, knowledge and innovation. The subsequent diffusion of this knowledge is reliant on market based mechanisms, which may fail.

Patents, as a form of intellectual property, protect inventions that satisfy the criteria of novelty and inventiveness for a limited duration (Drahos, 1996). Originally, patent law

clearly distinguished between discovery and invention. Discoveries were revealed knowledge compared to the creativity and originality involved in an invention. This dichotomy has been somewhat blurred with the rulings on patent rights in biological material (including genes) (Drahos, 1996). The indefinite nature of abstract objects lends this role of defining the criteria to interested actors and players. Accounting facilitates the quantification of qualitative characteristics. By objectifying knowledge as an intangible asset, it is defined in such a way that a number represents a concept. Once defined and counted “differing or distinguishing attributes are no longer visible” (Robson, 1992, p.688). In the case of pharmaceuticals, there are two intangibles, patents and research and development costs (capitalised or expensed). In both cases the investment consists of information or knowledge generated about a drug’s safety and effectiveness rather than the physical properties of the compound (Kuhlik, 2004). Costing, or the ascription of numbers to these concepts, is used as a legitimization for the high price of on-patent drugs.

In an emergent global environment dominated by multinational corporations the power attached to IPR is mediated through multilateral organisations, supported by governments with vastly differing interests. In relation to public health, the WTO’s introduction of the TRIPS Agreement has further highlighted issues of power, the inequities exacerbated by the conferral of IPR and the contested domain in which they exist.

## WTO and TRIPs

The WTO, the primary rule-making body for international trade, is premised on a notion that if developed, developing and LDC's co-operate and equitably share in economic expansion, a prosperous world economy will result (Jawara & Kwa, 2004). Consistent with this view, the articulated primary purpose of the TRIPS Agreement is

..to reduce distortion and impediments to trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade (Preamble to the TRIPS Agreement).

The TRIPS Agreement, negotiated during the Uruguay Round of multilateral trade negotiations, is seen as having equal status as trade in goods covered by the General Agreement on Tariffs and Trade (GATT) and the trade in services covered by the General Agreement on Trade in Services (GATS). These three agreements have been described as the three pillars of the WTO (Otten and Wager, 1996). These agreements are binding on all WTO Member States. The TRIPS Agreement aims to set minimum standards in intellectual property protection. The application of the Agreement requires Member States to modify domestic laws for consistency with the standards.

Prior to the TRIPS Agreement, patent protection, especially in developing and LDCs, was perceived as inconsistent or non-existent. Where patent protection did exist, in many cases, the regimes varied in relation to domestically produced or imported pharmaceutical drugs. TRIPS has sought to overcome this issue by mandating a term of patent protection of 20 years, as well as requiring Member States to make patents available for domestic pharmaceutical inventions. Recognising the economic inequalities amongst Member

States, the Agreement sets out a staggered time-frame for compliance. Originally, developed countries were required to comply by 1996, developing countries by 2000 and least-developed by 2006. In 2001 at the 4<sup>th</sup> WTO Ministerial Conference in Doha (Doha Declaration) the implementation regime was extended and some of the provisions were clarified. LDCs now have until 2016 to comply with TRIPS. The Doha Declaration also affirmed sovereign rights to protect public health. The flexibility of some of these provisions was codified allowing for generic drug manufacture, under special provisions, through the granting of compulsory licenses and parallel importing (Correa, 2002).

The TRIPS Agreement reflects the changing nature of society and the increasing importance of technological innovation and globalisation. This ideological stance is embodied in the TRIPS Agreement under Article 7 through aspirational statements in the text such as

...[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The assumption that free market globalisation and harmonisation of laws ultimately serve to solve social issues is problematic. As studies of globalisation have demonstrated, facilitating capital or information flows to stimulate economic growth does not necessarily result in mutual benefits between and within nations (Cooper et al, 2003). The public interest, as such, is not served unanimously by market based solutions relying on economic incentives. Nor is it served by a multilateral organisation that is anti-democratic and prioritises corporate profits over social objectives (Jawara & Kwa, 2004).

Although member states appear to be equal – one nation one vote – meetings are often held with only a small group of members. Committees filter out interested decision makers and skew the outcomes in favour of the vested interests of the powerful. As with TRIPS, initial negotiations did not include most pharmaceutical importer nations, some states were misinformed and most nations were threatened by US trade power (Drahos & Braithwaite, 2004). “TRIPS had all the transparency of a one-way mirror, with only the US and EC knowing exactly what was going on” (Drahos & Braithwaite, 2004, p. 29).

The TRIPS Agreement has profound implications for the research based pharmaceutical industry, that will benefit from increased global patent protection; the manufacturers and consumers of generic medicines, whose future is uncertain under the TRIPS Agreement; and governments, who are charged with the responsibility to adopt TRIPS as well as meeting the economic and public health objectives of their nations.

### **The Pharmaceutical Industry**

The research based pharmaceutical industry has frequently been criticised over a number of issues, especially concerning pricing and profitability (Scherer, 2001). In 2002 the world drug market was valued at US\$406 billion, of which 20% was attributable to the developing world, and the proportion in LDCs much less (Commission on IPR, 2002). Differential pricing, bio-piracy, the nature of clinical testing and ‘evergreening’<sup>2</sup> practices have all attracted less than favourable attention to the industry.

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<sup>2</sup> Evergreening is the practice of making minor improvements to existing drugs and re-patenting to extend the advantages of monopoly pricing (Anon., 2002).

The debate surrounding the global extension of IPR through TRIPS has seen the pharmaceutical industry emerge as one of the main lobbyists (Commission on IPR, 2002). The global, research based pharmaceutical industry is represented by the International Federation of Pharmaceutical Manufacturers Association (IFPMA), a non-profit, non-government organisation. This association represents 60 companies (IFPMA, 2004) and is a strong and powerful lobby group. In the US, where the majority of research based companies are located (see Appendix 1), PhRMA represents the leading research based pharmaceutical and biotechnology companies and is rather disparagingly referred to as 'Big Pharma' by its critics. In terms of corporate social responsibility and philanthropy, the industry lobby group directs these critics to the "estimated \$2.7 billion in financial assistance and donated medicines" provided since 1998 by the major pharmaceutical companies (IFPMA, 2003). The issue of donated medicines is controversial. Research has demonstrated that these medicines are not 'free' and activists argue that it hampers country specific solutions. In the long-term, donations are neither sustainable solutions, nor entirely appropriate (Health Action International, 2003). Misuse of pharmaceuticals, whether through weak healthcare systems or overuse facilitates drug resistance and long-term problems in the provision of healthcare (Kremer, 2002).

The emergence of multinational corporations as dominant players in global pharmaceutical markets has led to standardisation and an accentuation of inequalities (Merson, 2000). In many cases, corporations use IPR and licensing agreements to disguise the structuring of a global knowledge cartel to effectively dominate markets

rather than being controlled by them. (Drahos & Braithwaite, 2004). The scale of investment required for innovation and research has resulted in the concentration and centralisation of research teams in the applied market (Merson, 2000).<sup>3</sup> The pharmaceutical industry estimates that R&D for each new product, which includes product failure and opportunity costs, is US\$802 million or about 30% of the total cost. Manufacturing costs on the other hand are relatively small. This production cost means that generic drugs can be manufactured and priced well below drugs under patent. The long time-frame of patented drugs and market exclusivity is rationalised by the need to cover the costs of research and development including the risk of product failure (Kettler & Collins, 2002).

Why do developing countries object so strongly to TRIPS? Its essential flaw is to oblige all countries, rich and poor, to grant at least 20 years' patent protection for new medicines, thereby delaying production of the inexpensive generic substitutes upon which developing country health services and poor people depend. And there is no upside: the increased profits harvested by international drug firms from developing-world markets will not be ploughed back into extra research into poor people's diseases – a fact some companies will in private admit (OXFAM in Commission on IPR, 2002).

The underlying assumption that strong IPR encourage innovation is the rationale for the implementation of the global protection offered by TRIPS. For developing nations this is manifested in the belief that fostering IP will encourage foreign direct investment, technology transfer and inputs necessary for R&D capacity (Kettler & Collins, 2002). This potential may be realised in the large, industrialised countries with extant technological and manufacturing capabilities e.g. Brazil and India. Notwithstanding the

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<sup>3</sup> Of the 284 approved medicines in the nineties in the US, 93% originated from the private sector. The estimate of total R&D expenditure by the pharmaceutical industry exceeded US\$4.5 billion in 2002 (IFPMA, 2004) (see Appendix 2).

required investment, companies in these countries would also “need to move along a steep and rapidly evolving learning curve” (Kettler & Modi in Kettler & Collins, 2002, p.22). However, even given R&D potential and capabilities, research would probably be directed toward commercially viable products treating rapidly developing global diseases.

### **Public Health Issues**

Global IPR in pharmaceutical products are conferred to promote improved public health outcomes in the short and long-term, whether through improved accessibility or trade-led development. Therefore an important issue for analysis is whether the objective of global improved public health is being met. There is a prevailing myth in developed nations that research and innovation will ultimately assist poorer countries, however the health issues of the developing and LDCs are not necessarily paralleled with their richer cousins. For some diseases, such as HIV/AIDS, cancer and diabetes, the advances made in the developed world could assist in the developing and least-developed world. Sadly, where virtually unheard of treatable diseases, such as leishmaniasis and Chagas disease afflict thousands of people (Commission on IPR, 2002), research and innovation is minimal or non-existent and relies on government and private (non-pharmaceutical) philanthropy. This highlights the inequities in resources and opportunities for countries at different stages of development.

In 2000 the Millennium Development Goals (MDG) were adopted by the United Nations General Assembly with the mandate to reduce by the year 2015 the “dehumanising conditions of extreme poverty” (Greenhill, 2002 p.2). Part of this mandate includes

reducing by two-thirds the under five mortality rate, reducing by three-quarters the maternal mortality rate and to combat HIV/AIDS, malaria and other diseases. Patent protection, especially if it involves increasing price and decreasing choice of pharmaceuticals, has the potential to hamper efforts to improve public health and achieve these goals.

Some provisions of the original TRIPS Agreement exposed unintended consequences of a global IP regime. After lobbying by affected countries, the Doha Declaration affirmed sovereign rights to protect public health and acknowledged inequities by altering the special provisions of TRIPS relating to compulsory licensing and parallel importing.

We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics (Paragraph 1, Doha Declaration on TRIPS and Public Health)<sup>4</sup>.

Therefore,

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health...[It] should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health and, in particular, to promote access to medicines for all (Paragraph 4 Doha Declaration on TRIPS and Public Health).

Accordingly,

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme emergency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis,

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<sup>4</sup> The original agreement restricted the scope of this paragraph to the three specified diseases. "Epidemics" covers any health problem including those prevalent in developed as well as developing countries (Correa, 2002)

malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency (Sub-paragraph 5 (c) Doha Declaration on TRIPS and Public Health).

Compulsory licenses allow for production of pharmaceuticals without the permission of the patent holder and can be both a short and long-term measure (Correa, 2002). Protection of public health through the issue of compulsory licenses is only a feasible option if there are the manufacturing capabilities in that country sufficient to provide generic drugs. There is a large disparity in the manufacturing capacities of developing nations and the TRIPS Agreement (Article 31(f)) originally restricted manufacturing under compulsory licenses to “predominately for the supply of the domestic market”. In August 2003 this restriction was waived allowing countries with minimal or non-existent manufacturing capabilities to import drugs produced under compulsory license elsewhere. Under this parallel importing regime, an ‘eligible importer’ may notify at any time that it will use the system in whole or in a limited way, for example, only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use (WTO, 2003).

However, invoking the compulsory licensing provisions is fraught with difficulties as exemplified by the recent, well publicised South African experience. With an HIV/AIDS epidemic and prohibitive drug pricing fuelling an inability to procure patented drugs, alternative solutions were sought by the South African Government (Baskaran & Boden, 2005). The response from the pharmaceutical industry was to report South Africa to the US Government and trade reprisals were threatened. The US also placed South Africa on a watch list of countries that may be contravening TRIPS. There was also a caution from

the UK and the European Union (Baskaran & Boden, 2005). Despite these pressures South Africa moved forward and imported cheap generic HIV/AIDS medicines. This prompted legal action by a group of 40 pharmaceutical companies supported by the South African Pharmaceutical Manufacturers' Association who argued the South African Government were violating their patent rights by enacting a law to make medicines more affordable. However, pressure from global criticism and the requirement to produce documents relating to costs and pricing the pharmaceutical companies withdrew their action (Mowjee, 2003).

Parallel importing, as a solution, relies on the existence of a market large enough for production to be economically viable by an eligible exporter. Manufacture of generic pharmaceuticals also relies on the existence of a drug to copy. Underscoring this issue is the impact of IP regimes in developed countries that provide a powerful incentive to research in the areas that affect only those in developed nations at the expense of global health. Consider, however, the diseases which afflict the developing world where demand is high but the ability to pay is low.

**Table 1: Sales by geographic area (PhRMA Member Companies 2002)**

<u>Geographic Region</u>	<u>US\$</u> (in millions)	<u>Share</u> %
Africa	549.8	0.3
U.S & Canada	142,551.6	74.0
Latin America	4,583.7	2.4
Asia-Pacific	3,043.8	1.6
Australia & New Zealand	1,555.8	0.8
Western Europe	26,565.1	13.7
Central & Eastern Europe	1,712.1	0.9
Middle East	1,362.3	0.7
Uncategorised	4,542.7	2.4

Source: PhRMA (2004) Profile Pharmaceutical Industry 2004: Focus on Innovation.

The table above clearly demonstrates the concentration in developed countries of ability to pay for research based pharmaceutical products. Lack of market opportunities relegate many diseases of the developing and least-developed nations a low commercial priority (Kettler & Collins, 2002). These infectious and communicable diseases are known as “neglected diseases” (Kettler & Collins, 2002, p.10). A study by Troiller et al (in Cohen, 2002) of 1,393 drugs approved in the period 1975 –1999 found that just over 1% were specifically for tropical disease and tuberculosis. Research in neglected diseases has been initiated through some public private partnerships e.g. Medicines for Malaria Venture (MMV). Interestingly, the biggest change in funding for has come from foundations, such as the Gates Foundation (Cohen, 2002). Another source of R&D is the non-profit pharmaceutical company, One World Health, which procures dormant IP rights from major, for-profit pharmaceutical companies and collaborates with various NGO groups to

provide research and medicines. In return the pharmaceutical companies have philanthropic exposure and as well as a tax write-off in the US (Rogers, 2003).

Recognising that the impact of IP regimes, as well as being country specific, are disease specific, the public health issues fall into two broad categories – those diseases specifically mentioned as epidemics in the Doha Declaration and those communicable and infectious diseases unique to developing and least-developed nations, the *neglected diseases*.

### ***Epidemic Diseases***

The three diseases specifically illustrative of an epidemic are HIV/AIDS, malaria and tuberculosis (TB). Interestingly these three diseases are common to the developed world in some form and are already on the research and development agenda. In the case of HIV/AIDS, it is the single biggest cause of mortality world-wide (IPR, Commission, 2002). TB, a virtually eradicated disease in the developed world, has made a resurgence as a co-disease with HIV/AIDS and thus attracts research attention. Malaria, although uncommon in the developed world, attracts research into prophylactic treatment for travellers (Commission on IPR, 2002).

Malaria, as an example, kills approximately 1,222,000 people annually and 88% of those are from Africa (WHO, 2003). Malarial control in endemic regions relies on diagnosis and prompt treatment, otherwise the disease advances rapidly (TDR, 2004) Although several drugs are available, the only treatment for many people is a medicine developed

in 1934, Chloroquin, and the new strains of malaria are resistant to this older treatment. Artemisinins, developed from traditional Chinese herbal medicines has proved an effective treatment, however to avoid parasitic resistance a combination therapy is recommended (Arrow, 2004). Although malaria is treatable using a combination of drugs, the lack of a viable economic market to offset the cost of newer antimalarial drugs prevents their use (Cohen, 2002).

### *Neglected Diseases*

The term *neglected diseases* is used by health lobby groups to indicate a group of diseases that attract little or no research and development, and in some cases, a cessation of manufacture of drugs or vaccine. This term is highly emotive and the IFPMA has contested the use of this term based on the fact that it lacks a clear and precise definition for policy decisions (IFPMA, 2003). In 2001, in a joint study with WHO, the pharmaceutical industry identified African trypanosomiasis, leishmaniasis and Chagas disease as truly neglected. These diseases are categorised as such because effective treatment is not available. But there is another list, those diseases which have treatments but for reasons of access and affordability are not available. This list includes leprosy, onchocerciasis, lymphatic filariasis and schistosomiasis<sup>5</sup> (Appendix 3). Measles, a common disease not generally considered life threatening in developed countries, is also considered worthy of attention in developing countries (Médecins Sans Frontières in Commission on IPR, 2002).

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<sup>5</sup> Acute respiratory infections, tuberculosis, HIV/AIDS and malaria also fall into this category, however, the last three have already been discussed in the previous section.

The lack of availability of medicines therefore rests to some extent with market failure and to some extent public policy failure because of the political nature of governmental research agenda (MSF, 2001). The context and conditions surrounding the advent of disease cannot be understated, especially in terms of long term eradication. Leishmaniasis, an example of a neglected disease, consists of a group of fatal parasitic conditions related to environmental changes and degradation. The treatment, SSG, was developed in 1930 and requires a one month hospital stay. For many, hospitalisation for a month is impossible, the drug is expensive and resistance to the treatment is rising (Cohen, 2002). Therefore, in addition to the general health implications, the disease severely constrains productivity (TDR, 2004).

Notwithstanding the recognition that the health issues facing the developing world are a combination of many factors including public policy and institutional frameworks, IPR hamper efforts to improve public health in the following ways,

1. Research and development, unless philanthropic, is not commercially viable where there is a limited market in terms of ability to pay for expensive under patent medicines.
2. Where drugs or the market to encourage research and development exist, such as for HIV/AIDS, cancer or diabetes, the drugs and vaccines are still unaffordable. Even generic copies may be unaffordable for patients in LDC's.

3. Generic manufacturing, although providing a cheaper alternative is still market driven and this practice will be further constrained by compulsory licensing and parallel importing provisions after the full implementation of TRIPS post- 2016.

### **Accounting and Accountability**

The commodification of knowledge serves to transfer the responsibility for health outcomes to the market. A global IP regime therefore, assumes global health outcomes will be achieved through economic globalisation. “Intellectual property rights are rule governed privileges that regulate the ownership and exploitation of abstract objects”(Drahos, 1996, p.5). In this conceptual form the privileges have the potential to be “liberty intruding” (Drahos, 1996, p.5) by providing dangerous levels of private power. When these rights are conferred on things of universal social importance and become object related, the holder of these rights then has the power to mediate the relationship between the object and the person, thus shifting the object-dependent relationship to a person-dependent relationship (Drahos, 1996). And this,

[E]xtensive, possibly global power, will probably be concentrated in the hands of those who through their sufficient scientific/technological capabilities and superior capital resources, are able to capture, through the property mechanism for abstract objects, resources upon which there is a universal reliance (Drahos, 1996, p.161)

This abstraction, intellectual property, becomes both a source of capital and a source of power. This power is demonstrated by the concentrated handful of pharmaceutical companies that through patents receive the privilege of monopolistic profits. Accounting is a mechanism through which power is exercised, rather than being a neutral technology

to provide information, (Miller, 1994). The symbolic and ritualistic aspects of accounting assist in justifying the agendas, methods and goals of organisations (Graham and Neu, 2003).

[A]ccounting technologies help structure the institutional field within which the supra-national organizations operate, influencing their goals and performance by shaping what is both thinkable and possible. In this way, these organizations serve to propagate accounting technologies, but are simultaneously constituted by them. ...[A]ccounting and accountability mechanisms create a particular form of social distinction. ... This social distinction is the asymmetry of wealth and power that exists across international boundaries (Graham and Neu, 2003, pp. 451-2)

Patent protected monopolistic profits are presumed to be an incentive for innovation. This 'means-end' rationality is reoriented by the use of accounting techniques. The ex ante expectation becomes an ex post legitimation for patent protection. The argument, reoriented in this way, effectively situates the power of defining the forum and agenda to the vested interests of the industry. The goal of profit maximisation gains primacy and drives the argument. The argument, framed in terms of economic rationalism, is in effect 'repackaged' and becomes an 'ends-means' rationality. Accounting is not a neutral device and is "an attempt to intervene, to act upon individuals, entities and processes to transform them and to achieve specific ends...[to do so] accounting practices create the costs and returns whose reality actors and agents are asked to respond to" (Miller, 1994, p.1).

Accounting defines and constructs a 'cost'. Accounting rules prescribe the "real-ization" (Hines, 1988, p. 252) of this cost, which can be either expensed or capitalised and

subsequently amortised or written down for impairment. Accounting also provides organisations with the ability to ascribe a value to an abstraction, an intangible asset. The accounting treatment for intangible assets, whether patents or R & D, affects accounting profit calculation. This figure in the public domain is used as a measure of performance. In a controversial industry, ‘performance’ attracts attention from policy-makers and critics.

The difficulty in directly linking profitability and pharmaceutical R & D is exacerbated by the complex structure of many research based pharmaceutical companies. Companies that comprise this industry are also involved in many other related activities, including veterinary products, medical supplies and nutritional products. This presents difficulties in isolating particular costs and products. Adding to this opacity is the practice of increasing R & D investments as profit opportunities expand, so supranormal profit opportunities dissipate. Policy interventions aimed at reducing industry profits and prices are subsequently preempted (Scherer, 2004). Despite the fact that accounting treatment for patents and R & D varies, most western generally accepted accounting principles only allow capitalisation of development costs once future economic benefits are ensured<sup>6</sup>. The International Accounting Standard IAS38 Intangible Assets<sup>7</sup> is clear that all costs defined as research must be expensed.

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<sup>6</sup> Under the International Accounting Standards (IAS 38), the treatment of R&D will be harmonised amongst countries adopting these new standards. However, the majority of the leading pharmaceutical companies (see Appendix 2) are domiciled in the US. The US has, as yet, made no firm commitment to adopt International Accounting Standards.

<sup>7</sup> Interestingly, the accounting regime under International Accounting Standards will be harmonised and the TRIPS Agreement is a push for harmonisation of legal regimes covering intellectual property. The International Accounting Standards Board is also no stranger to corporate lobbying, for example IAS 39.

Development costs may be capitalised if certain criteria are met. For the pharmaceutical industry where the development component accounts for approximately 70% of the total R&D budget (IFPMA, 2004) this accounting treatment is significant. These criteria include the ability to demonstrate the use or sale of the resulting asset and specific identification of future benefits including a market (Oxley, 2004). Marketing or regulatory approval (see below Phase IV) is considered an indication of satisfying the five accounting recognition criteria (Friend et al, 2004). Product development, besides being a large cost component, is also time-consuming. Different phases of development also exhibit different risk profiles in terms of expected success. The US system is the most rigorous and is outlined below.

**Table 2: Development stages required by FDA**

STAGE	PROCESS	TIME (yrs)
Preclinical Testing	Laboratory and animal studies	3.5
Investigational New Drug Application (IND)	Permission to test in people	
Clinical Trials		
Phase I	Test on 20-80 normal healthy volunteers	1
Phase II	100 -300 volunteers affected by disease	2
Phase III	1,000 – 3,000 patients in clinics and hospitals	3
New Drug Application (NDA)		2 (average)
Phase IV	Evaluate long-term effects	

Source: Drug Discovery, Development and Approval Process<sup>8</sup>

The development process will differ between drugs and also across markets. To assess market viability at any stage requires an assessment of risks and the probability of

<sup>8</sup> [www.fda.gov/oc/ohrt/ohrt\\_approval\\_process.shtml](http://www.fda.gov/oc/ohrt/ohrt_approval_process.shtml)

benefits. The contestability of this assessment is highlighted by the fact that Phase IV clinical trial expenditure is arguably a marketing cost (Oxley, 2004). The accounting treatment for purchased R&D and patents differs from internally generated research. An intangible asset is deemed to be created under IAS38 because the criteria for capitalisation is presumed to be satisfied since development risk is factored into the purchase price. The recent scale and number of mergers, acquisitions and collaborations in the research based pharmaceutical industry results in a significant accounting issue regarding intangible assets and subsequent amortisation or impairment (Friend et al, 2004).

Internal cost calculations for research and development are used to justify patent protection. These calculations are based on estimates and opportunity costs (Di Masi et al, 2003) and also ignore the contribution of government funded research and tax incentives. The shifting of marketing expenditure into the development phase further distorts the cost. The information used for the calculation of the average figure of US\$802 million is not publicly available and requires many estimates compounded by the use of valuation techniques requiring further estimation, such as discount rates. Therefore, of the quoted US\$802 million only half is a true cash cost (Bonduelle & Pisani, 2004). Also, the sample for calculating the average cost is based on the development of treatments for chronic and degenerative diseases, which are more expensive to test (DiMasi et al, 2003).

[T]his matter could be resolved simply, if the drug companies were to open their books and reveal their actual investments in research and development

(R&D). Implausibly they claim that this information would give away trade secrets and must remain proprietary – though when it suits their political agenda, they make all sorts of announcements about costs (Anon.,2002, p.5).

Accounting systems provide a mechanism through which power is exercised and highlight issues of social welfare and distribution (Miller, 1994). R&D costs influence international and national resource allocation and provide inputs into public policy studies and decision-making (DiMasi et al, 2003). In turn, actors in the research based pharmaceutical industry locate their decisions and rhetoric within an accounting discourse. As an example, profitability studies have attempted to demonstrate that supranormal profits are not sustained in the pharmaceutical industry (DiMasi et al, 2003; Scherer, 2001). Pharmaceutical firms exploit profit opportunities by investing further in R&D and promotional activity to reduce returns to deflect scrutiny or policy interventions aimed at reducing profits or pricing (Scherer, 2001).

“[Accounting] deflects attention away from contradictions and tensions that would otherwise translate into social conflict and change by reducing the matter of business ethics to cases of individual corruption. And it presents as universal the partisan interests of corporations, by masking the frequent incompatibility of social and corporate interests under a rhetorical gloss that allows the comfortable cohabitation of social responsibility and corporate profitability” (Neimark, 1995, p. 88).

Financial accounting is underpinned by neo-classical economics. The notion of the market having the responsibility for pharmaceutical innovation rests on the assumption that this public good will satisfy the needs and issues of health in a global environment. This public good has become a private good facilitated by the TRIPS Agreement and free

market rationality is failing, particularly in relation to health crises in LDCs as is so often the case, when the economic system “pits profits against people” (Neimark, 1995, p.81). This is demonstrated so overwhelmingly by the case in South Africa where financial accounting pressures were central to the case made by drug companies (Baskaran & Boden, 2005; Mowjee, 2003).

“The foundational assumption of classical and neo-classical economics, that self-interested behaviour combined with market competition will adequately protect the public interest, seems less and less tenable at the very moment that free market economics is emerging as the unchallenged international orthodoxy” (Neimark, 1995, p. 83).

Private ownership of knowledge provides the pharmaceutical industry with the power to mediate relationships between R&D and health outcomes. Where this mediation role is conferred to a profit seeking entity, accountable to the interests of private capital, then the public health issues have the potential to be subverted to economic rationality. Under the TRIPS Agreement, the role of mediator is expanded to include global public health issues which are located within an economic incentive framework. Knowledge, as a public good, ultimately becomes shareholder gain by commodification – the gateway to capital (Draho, 1996).

### **Conclusion**

Pharmaceutical firm profits have frequently been in the spotlight (Meyer et al, 2000). The pharmaceutical industry in the US often top the Fortune 500 rankings for profitability and most research based pharmaceutical companies devote more revenue to profits than to R&D (Public Citizen, 2002).

The TRIPS Agreement grants the rights to monopolistic profits as an incentive for the creation of knowledge. As a global agreement on patented pharmaceuticals, extends the obligation to global welfare including improved health outcomes. The abstract notion of property rights is commodified through accounting discourse. Accounting plays a legitimating role in the economic justification for product prices, not to mention a rhetorical role in identifying, measuring and valuing IPR. It also plays an ideological role as a gateway to capital (Drahos, 1996). Accounting, because of the centrality of notions such as ‘costs’ in trade-resolution mechanisms, “operates as an embedded technology to adjudicate and apportion the spoils of such disputes” (Graham and Neu, 2003). This perspective, that of the primacy of capital interests, supports market based solutions to social problems.

Inasmuch as accounting discourse and the research based pharmaceutical industry are unable to solve global health problems, it is clear that practitioners and policymakers should consider the complicity of accounting in an increasingly unjust world (Tinker and Gray, 2003). This consideration should involve a critique of global agreements that reinforce, echo and amplify the power and interests of capital providers and attempt to provide market based solutions to promote the public interest.

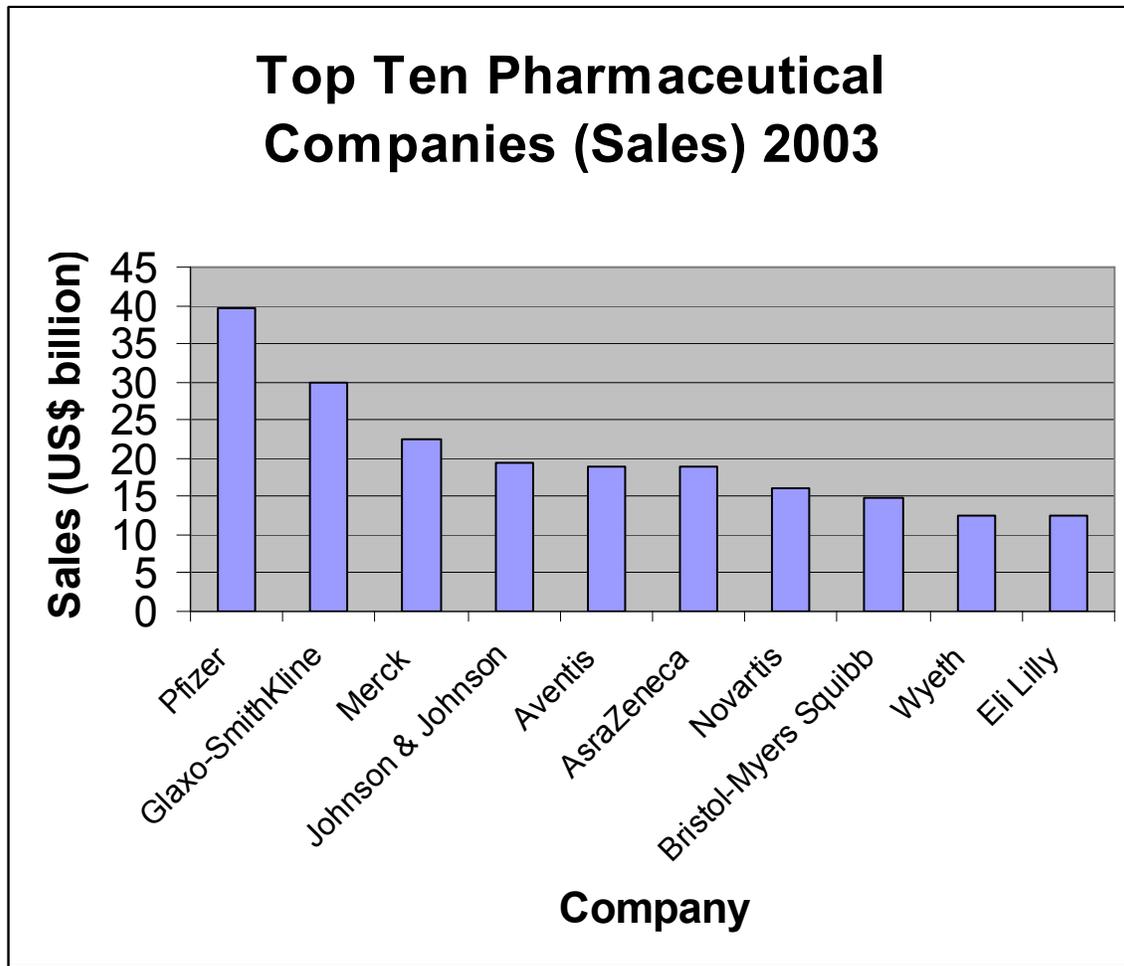
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## Appendix 1: Top 10 Pharmaceutical Companies 2003



Source: Sellers, L.J (2004) Pharm Exec 50, *Pharmaceutical Executive*, May.

**Appendix 2: Top 12 Pharmaceutical Companies R&D Expenditure 2003**



Source: Sellers, L.J (2004) Pharm Exec 50, *Pharmaceutical Executive*, May.

**Appendix 3: Burden of disease in DALY's\* by cause and mortality stratum  
in WHO regions**

<b>Disease</b>	<b>Total (,000)</b>	<b>Africa (,000)</b>	<b>Americas (,000)</b>	<b>Eastern Mediterranean (,000)</b>	<b>Europe (,000)</b>	<b>South East Asia (,000)</b>	<b>Western Pacific (,000)</b>
Tuberculosis	35 361	8 230	902	2 876	1 653	15 729	5 948
HIV/AIDS	86 072	66 772	3 220	1 600	1 620	10 834	1 965
Malaria	44 716	39 165	110	2 204	19	2 755	433
African trypanosomiasis	1 535	1 494	0	39	0	0	0
Leishmaniasis	2 090	383	44	248	6	1 358	50
Chagas disease	667	0	662	0	0	0	0
Leprosy	199	23	18	25	0	118	13
Onchocerciasis	484	470	2	10	0	0	0
Lymphatic filariasis	5 777	2 011	10	122	1	3 219	411
Schistosomiasis	1 702	1 334	74	227	1	7	55
Measles	27 058	15 567	0	2 988	257	7 060	1 170

Source: World Health Report 2003 Annex Table 3 Burden of Disease in DALY's by cause, sex and mortality stratum in WHO regions, estimated for 2002.

\*DALY (Disability Adjusted Life Year ) is a summary measure of population health used to represent the health of a population in terms of mortality and non-fatal outcomes in a single figure e.g. if a person dies with a disability (weighted at 0.2) dies at age 60 (life expectancy =80) the burden of the disease would be 20 DALY + (60X 0.2) DALY = 32 DALY (Nord, 1999)