Prescription for profit: is the pharmaceutical industry is [sic] making a killing?

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Abstract
The research based pharmaceutical industry, with the support of the World Trade Organization's Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) has secured its longterm profitability. Using an economic rationalist argument of recovering research and development costs, pharmaceutical industry representatives have successfully argued for greater patent protection. This paper seeks to demonstrate how a powerful cartel of major global pharmaceutical companies through multilateral agreements and economic mechanisms protect their 'bottom lines'. The commodification of research and development resulting in the private ownership of intellectual property serves to transfer the responsibility for the health agenda to the market. This limits the ability of governments, particularly in least-developed countries, to address their individual public health issues. By ameliorating the business risk presented by countries producing or importing generic medicines, the TRIPS Agreement has effectively rendered national health issues subservient to corporate profitability.

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Prescription for Profit: Is the Pharmaceutical Industry is Making a Killing?

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Key Words: TRIPS, intellectual property, research and development.

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ABSTRACT

The research based pharmaceutical industry, with the support of the World Trade Organization’s Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) has secured its long-term profitability. Using an economic rationalist argument of recovering research and development costs, pharmaceutical industry representatives have successfully argued for greater patent protection.

This paper seeks to demonstrate how a powerful cartel of major global pharmaceutical companies through multilateral agreements and economic mechanisms protect their ‘bottom lines’. The commodification of research and development resulting in the private ownership of intellectual property serves to transfer the responsibility for the health agenda to the market. This limits the ability of governments, particularly in least-developed countries, to address their individual public health issues. By ameliorating the business risk presented by countries producing or importing generic medicines, the TRIPS Agreement has effectively rendered national health issues subservient to corporate profitability.
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 globalisation is seen as the 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 least-developed countries (LDC)\(^1\) to address domestic public health issues by limiting their access to affordable drugs.

The TRIPS agreement not only affords drug companies exclusive patent rights for 20 years, but also undermines the ability of developing and 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 threatening trade sanctions or initiating WTO disputes against countries where legislation has been less protective towards pharmaceutical companies (Oxfam, 2001).

Society grants a right to the research based pharmaceutical industry to make monopoly profits for a guaranteed time frame. And in return, there is a positive obligation on this industry to provide innovation through research and development. The position taken by pharmaceutical companies is based on the legitimate economic rationalist argument of covering these research and development costs, and encouraging further research and innovation from behind the protection of patents. 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 LDC. As the economic power of global corporations increases, so to does their political and intellectual reach (Kuttner, 2000). Economic justifications for patent protection using accounting technologies prevail. Accounting defines and measures abstractions, known as intangibles, and uses the subsequent estimates of future economic benefits for valuation and amortisation\(^2\). The quoted “cost” of bringing a new drug to market is US$800 million (Bonduelle and Pisan, 2004) and as Miller (1994, p.3) asserts “the elegance of a single figure provides a legitimacy that, at least in certain Western societies, seems difficult to disrupt or disturb”

Issues surrounding the TRIPS Agreement highlight the tensions between the interests of various governments and powerful multinational corporations 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 stated 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 least-developed countries. This discussion leads to an examination of the use of accounting technologies and how they facilitate the interests of the pharmaceutical industry at the expense of the health and welfare of developing and LDC.

Intellectual Property Rights

Intellectual property (IP) is concerned with property rights in abstract objects, such as copyright, trademarks and patents. As such it mediates property relationships between individuals. 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 allows monopoly pricing (pricing above marginal cost) and this reward will foster the desire to generate creativity or knowledge. The subsequent diffusion of this knowledge is reliant on market-based mechanisms which may ultimately fail. Patents, as a form of intellectual property, protect inventions that satisfy the criteria of novelty and inventiveness for a limited duration (Drahos, 1996). The indefinite nature of abstract objects lends this role of defining to interested actors and players. Accounting facilitates the quantification of a characteristic of the object that is a quality. The object, an intangible asset, is defined in such a way that the number ascribed stands for the concept (Robson, 1992). Once defined and counted “differing or distinguishing attributes are no longer visible” (Robson, 1992, p.688). Patenting allows monopoly pricing for a period which is determined by the length of the intellectual property regime. In the case of pharmaceuticals, research and development costs are used as a legitimation for the high price of an on-patent drug. According to the industry, the cost to bring a new drug to market is in the range of US$800 million (Bonduelle & Pisani, 2004).

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).

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

**WTO and TRIPS**

As part of their commitment to the WTO, Member States are expected to conform to the provisions of the TRIPS Agreement. The primary purpose of this Agreement is...

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 (UNAIDS/WHO, 2000).

Prior to the TRIPS Agreement, many developing and LDC did not provide patent protection for pharmaceuticals, whether produced locally or imported. Where patent protection did exist there was much inconsistency in the term of patent protection. 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 economic inequalities amongst Member States, the Agreement sets out a time-frame for compliance. Originally, developed countries were required to comply by 1996, developing countries by 2000 and least-developed by 2006 (UNAIDS/WHO, 2000). In 2001, at the 4th WTO Ministerial Conference in Doha (Doha Declaration), the implementation regime was extended and some of the provisions were clarified.

The TRIPS Agreement reflects the changing nature of society and the increasing importance of technological innovation and spread of ‘globalisation’. This ideological stance is embodied in the TRIPS Agreement under Article 7 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 TRIPS Agreement has profound implications for the research based pharmaceutical industry which will benefit from increased patent protection, the manufactures and recipients of generic medicines and the public health needs of, particularly, LDC.

The Pharmaceutical Industry

In an ideal world, privileges such as IP rights would be the means to an end. The process of conferring these rights to individuals or corporations should result in a contribution to society in terms of improved healthcare. Accordingly, the IP rights regime is designed to allow companies to use a proportion of profits from monopoly pricing for further research, not to bolster the bottom-line. Patents allow companies 20 years of monopoly profits and the practice of ‘evergreening’, or making minor improvements and re-patenting existing drugs, ensures continued profits (Anon., 2002) beyond the original patent period. The pharmaceutical companies have a powerful influence in the development of IP policy and subsequently the profit motive has the potential to subsume the primary health objective.

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 least-developed countries was much less (IPR Commission, 2002). The major researchers in pharmaceutical R&D are public research institutions, contributing primarily in research and the early development phases. Private pharmaceutical companies, although investing in all stages dominate the processes of development, production and commercialisation in developed countries (Kettler & Collins, 2002). Drugs bought to market are often funded by the government, either by directly funding basic research or supporting the initial, riskier areas of research e.g. through universities, or providing tax incentives (Anon, 2002).

The debate surrounding the global extension of IP rights through TRIPS has seen the pharmaceutical industry emerge as one of the main lobbyists (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, 2003) 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, 2004). The issue of donated medicines, however, is not without controversy. Research that has demonstrated that these medicines are not “free” and activists argue that it hampers country specific solutions. In the long-term donations are not sustainable solutions and are never in the quantities required (Health Action International, 2003). Misuse of pharmaceuticals, whether through weak healthcare systems or overuse facilitates drug resistance and long-term problems in the

http://aux.zicklin.baruch.cuny.edu/cpa2005/papers.htm/8282moerman.htm
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provision of healthcare (Kremer, 2002).

The emergence of multinational corporations as key dominators in global pharmaceutical markets has led to standardisation and an accentuation of inequalities (Merson, 2000). The scale of investment required for innovation and research has resulted in the concentration and centralisation of research teams which dominate the applied market (Merson, 2000). 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). The pharmaceutical industry states that R&D for each new product, which includes product failure and opportunity costs, is US$800 million or about 30% of the total cost. Manufacturing costs on the other hand are relatively small. This cheap production cost is the reason generic drugs are manufactured and priced well below the 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).

The underlying assumption that strong IP rights encourage innovation is a rationale for the implementation of TRIPS. For developing and LDC this is manifested in the belief that fostering IP will encourage foreign direct investment, technology transfer and inputs necessary for R&D capacity (Kettler, 2002). This potential may be realised in the large, industrialised countries with extant technological and manufacturing capabilities e.g Brazil and India. However research has demonstrated that, besides the required investment, these companies would "need to move along a steep and rapidly evolving learning curve" (Kettler & Modi in Kettler & Collins, 2002, p.22). Also, even given R&D capabilities, research would probably be in commercially viable products treating rapidly developing global diseases.

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 IPR, 2002).

Public Health Issues

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).[3]

Given that IP rights are conferred to promote healthcare in the short and long term, an important issue for analysis is whether this primary objective is being met. IP rights conferred globally, via TRIPS, should have the primary objective of promoting healthcare world-wide. This assumption implies equitable resources and opportunities for countries at all stages of development. There is a prevailing myth in developed nations that research and innovation in these countries will ultimately assist poorer countries. This would be the case if the health issues of the developing and LDC were 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 leishmaniaisis and Chagas disease afflict thousands of people (IPR Commission, 2002), research and innovation is minimal or non-existent and relies on government and private (non-pharmaceutical) philanthropy.

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.

The issue of public health and the provision of pharmaceuticals in developing and LDC are complicated by two issues. The first is the definition or criteria of what is considered 'developing' in this context. When considering developing nations and capacity, diversity exists with respect to scientific and technological capabilities. As an example, India and China have strong capabilities, demonstrated in their ability to produce generic drugs, as opposed to nations in sub-Saharan Africa with a non-existent or weak capability. Also, social and economic circumstances and the disparities between the rich and poor are not homogenous, thus the impact of IP policies in one country may be vastly different in another (IPR Commission, 2002). The second is the scope of health issues, defined in the Doha Declaration as HIV/AIDS, malaria and tuberculosis and other epidemics (Paragraph 1). To affirm the sovereign right to protect public health, the TRIPS Agreement allows for generic drug manufacture, under special provisions, through the granting of compulsory licenses and parallel importing (Correa, 2002).

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health...[S]hould 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, 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. 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 and Boden, 2004). The response from the pharmaceutical industry was to report South Africa to the US 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 and Boden, 2004). Despite these pressures South Africa moved forward and imported cheap generic HIV/AIDS medicines. This prompted legal
action by a group of 39 pharmaceutical companies, who argued the South African Government were violating their patent rights. However, under pressure from global criticism and the requirement to produce documents relating to costs and pricing, the pharmaceutical companies withdrew their action (Baskaran and Boden, 2004)

Where manufacturing capacity is weak or non-existent, the other option available to LDC is parallel importing. However, as a market driven solution, even if production capabilities exist in an exporting country the market may not be large enough for production to be economically viable, thus still preventing access to generic pharmaceuticals by the eligible importing countries. Manufacture of generic pharmaceuticals also relies on the existence of a pharmaceutical to copy. Underscoring this issue is the impact of IP regimes in developed countries that provide a powerful incentive to research in areas that will provide a substantial return at the expense of global health. Consider, however, the diseases which afflict the developing and LDC where demand is high but the ability to pay is low.

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

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


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 LDC, 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 unknown 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 travelers (IPR Commission, 2002).

Malaria, as an example, kills approximately 1,222,000 people annually and 88% of those are from Africa (WHO, 2003 (a)). Malarial control in endemic regions relies on diagnosis and prompt treatment, otherwise the disease advances rapidly (WHO, 2004) Although several drugs are available, the only treatment for many people is a medicine developed in 1934, Chloroquine, 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[^5] (Appendix 3 & 4). 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 IPR, 2003). The lack of availability of medicines therefore rests to some extent with market failure and to some extent public policy failure as the government research agenda is a political exercise (MSF, 2001).

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). Thus, besides the general health implications, the disease severely constrains productivity (WHO, 2004).

Notwithstanding the recognition that the health issues facing the developing world are a combination of a number of factors including public policy and institutional frameworks, IP rights hamper efforts 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 least-developed countries.
3. Generic manufacturing, although providing a cheaper alternative still is market driven and this practice will be constrained after the implementation of TRIPS post-2016.

**Making a Killing?**

The commodification of research and development resulting in the private ownership of intellectual
property serves to transfer the responsibility for the health agenda to the market. "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 abstract object becomes a source of capital and a source of power. Patents provide a "gateway to capital resources" and provide a strong motivation for accumulation (Drahos, 1996, p.158). This power is demonstrated by the concentrated handful of pharmaceutical companies that have the privilege of monopoly profits. How is accounting implicated in legitimating this power in capital? Accounting technologies are implicated as both a means and a justification for patent protection.

Accounting technologies provide organisations with the notion of a cost that is either expensed or capitalised and subsequently amortised or written down for impairment. Accounting provides organisations with the ability to ascribe a value to an abstract object, an intangible asset and to create a bottom-line profit. This profit is the return to shareholders, the providers of capital. The commodification of R&D and knowledge and accounting measurement and recognition rules facilitates and provides this conduit. The accounting treatment for R & D varies but most Western generally accepted accounting principles only allow capitalisation of the development component once future economic benefits are ensured[6]. The new International Financial Reporting Standard IAS 38 Accounting for Intangibles is clear that no intangible may be recognised for research. Development costs can be capitalised if certain criteria are met. For the pharmaceutical industry where the development component accounts for approximately 70% of total R&D budget (IFPMA, 2004) the 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 is considered an indication of satisfying the five criteria (Phase IV) (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

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

Source: Drug Discovery, Development and Approval Process
www.fda.gov/approval_process.shtml

http://aux.zicklin.baruch.cuny.edu/cpa2005/papers.htm/8282moerman.htm

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The development process will differ from drug to drug and also markets. To assess market viability at any stage will require an assessment of risks and the probability benefits. The contestability of this assessment is highlighted by the fact that Phase IV clinical trial expenditure is arguably marketing costs (Oxley, 2004). The accounting treatment for purchased R & D differs from internally generated research. An intangible asset is deemed to be created under IAS 38 because the criteria for capitalisation is presumed to be satisfied since development risk is factored into the purchase price. The 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).

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). Research and development calculations are used in the justification of product costing and are based on estimates and opportunity costs (Anon, 2002) 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 which forms the rationale for high prices. The information used for the calculation of the average figure of US$800 million is not publicly available and requires many estimates compounded by the use of valuation techniques requiring further estimation, such as discount rates. Of the quoted US$800 million only half is a true cash cost (Bonduelle & Pisani, 2004). Once a figure for costs has been calculated, this in turn is used as a justification for patent protection.

[T]his matter [R&D expenditure justifies high prices and IP protection] 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).

Employing accounting in this way emphasises its transformative capacity. It has the capacity “to alter the way in which it can be thought of and acted upon (Miller, 1994, p.2). Accounting systems provide a mechanism through which power is exercised and highlights issues of social welfare and distribution (Miller, 1994). 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 least-developed countries. 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, Financial accounting pressures were central to the case made by drug companies to justify high prices (Baskaran and Boden, 2004).

Another consideration is the issue of ownership. Much basic or fundamental research is contributed to by government sponsored or academic research. Whilst the pharmaceutical industry develops these products to bring to market, private ownership of the development phase effectively provides the pharmaceutical industry the power to mediate relationships between public research and health issues. 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, including those neglected diseases.

Conclusion

Over the last decade or more, pharmaceutical firm profits have been frequently in the spotlight (Meyer et al, 2000). The pharmaceutical industry in the US often top the Fortune 500 rankings for profitability and eight of the top 10 pharmaceutical companies devote more of their revenue to profits than to R&D (Public Citizen, 2002).

Society has granted the rights to monopoly profits in return for pharmaceutical innovation. The TRIPS Agreement is a global agreement and as such this positive obligation extends to global health issues. The abstract notion of property rights is accounted for as an intangible asset in accounting discourse. The private ownership of IPR and the accounting treatment of those rights and associated R&D costs are important when IPR are protected by global legal frameworks and granted to profit seeking entities. Accounting plays a legitimating role in the economic justification for product prices, not to mention an enabling role in valuing IPR. It also plays an ideological role as a gateway to capital (Drahos, 1996). The monopoly profits privilege shareholders, the providers of capital, by capturing the abstract notion of intellectual property rights through the definition and measurement of a future economic benefit. Considering the pharmaceutical industry is one of the most profitable world-wide they are ‘making a killing’ economically, potentially at the expense of global health issues with the full implementation of the TRIPS Agreement.
References
