

# From a Satellite Looking Down at our use of Patents in the Great Planetary Scheme of Things

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## **Patents, by Providing more Research and Development, Benefit the People of the World. Except for...**

Patents allow inventors to have unique access to a market for a set period of time, giving the inventors monopoly control and/or market exclusivity on the sale of their innovation. The monopoly control provided by patents not only provides for a return on the relatively high cost of research and development that went into the innovation, but also provides rather high profits as a result of the monopoly and its duration. Excess profits serve to attract capital investors who then create jobs in the biotechnology industry, increase the rate of research, and cause new innovations in drug treatments and therapies to be undertaken, subsequently benefiting the people of the world. Except though... except for the people who comprise the majority of the world's population: socially and economically underprivileged people of the world, who live for the most part in less-developed countries. Because of this, the challenging question was raised by Solomon Benatar in an article addressing human rights and biotechnology: "If drugs for malaria, tuberculosis, many tropical diseases and HIV/AIDS have not been made available to billions in poor countries is it likely that the poor will benefit from advances in biotechnology?"[1].

## **Where in the World is the Pharmaceutical/Biotechnology Industry? The Transnational Operation of the Industry.**

Pharmaceutical/biotechnology companies cannot be pinpointed to one location as they function, as any transnational corporation would, globally. Operations are carried out depending on where labor is cheapest,

raw materials are the least expensive, where taxes can be most easily evaded, as well as where market regulations are the least strict. As Bodenheimer describes "...a pharmaceutical company might have its corporate headquarters in the United States, produce its drugs in Ireland, assemble its capsules in Brazil, and sell the products in Bolivia" [2]. In his description the "core", or the regions of capital accumulation, are mainly in the more developed countries and are where the majority of research and development occurs. The "periphery" are described as the exploited regions of the world, the less-developed countries, whose main functions are production and assembly. The rulers of the global economy have also been described as a transnational alliance of elite classes from around the world [18]. Institutions such as the World Bank and the International Monetary Fund (IMF) support corporations by lending billions of dollars to third world elites who in turn, because of their large debts, support the profit-making of corporations. Unfortunately, profits from these corporate organizations are achieved through decision-making without public consultation and have historically been achieved by introducing policies that harm human-rights, labor rights and the environment, especially in third world countries [18]. The other concerns regarding this set-up are the same as those for any transnational corporation. The mobility of the pharmaceutical industry compared to the relative immobility of governments means that because the industry is seeking out the cheapest labor and the lowest taxes, governments have few means of maintaining stable employment and collecting required taxes [6].

Not only is the pharmaceutical industry difficult to locate in any single place around the world, it is also difficult to isolate from other transnational capital, a characteristic of its world-wide pervasiveness and strength. Interlocks, mergers and acquisitions serve

to make the industry a force indistinguishable from other transnational capital such as: oil companies, Coca-Cola, and even the New York Times [2,3]. In this sense, the transnational pharmaceutical industry is difficult to discuss tangibly as a separate and distinguishable entity, requiring it instead to be addressed along with other transnational capital.

## **Patents and Social Responsibility...**

### **The Corporate Struggle to Prevent Antiretroviral Accessibility During an HIV/AIDS Crisis in South Africa.**

In many cases, governments may be acting on behalf of the pharmaceutical industry. In the United States during the 1997 to 1998 election campaigns, the pharmaceutical industry spent almost \$12 million in soft money, Political Action Committee and individual pharmaceutical company campaign contributions according to the Centre for Responsible Politics [3]. These large contributions came at a time when the U.S. government was supporting the pharmaceutical firms in abolishing the health initiatives of the South African government that made the antiretroviral drugs more accessible to South Africa's population. Antiretroviral drugs are drugs that target HIV, have the possibility of prolonging infected people's lives indefinitely and as well, have been shown to drastically reduce the transmission of HIV from mother to child. Drugs that fight HIV/AIDS, although being physically close to the many millions of people living with HIV/AIDS in South Africa (the subsidiaries of international pharmaceutical firms produce these drugs in South Africa), are far from being accessible financially to infected people and their families. This is still true now, despite the fact that in April 2001 the 39 pharmaceutical firms suing the South African government for patent violations finally dropped their case [19]. Bond has published a report and analysis on the situation in South Africa from 1996 to 1999 in the International Journal of Health Services and his report is discussed in this section to highlight the role of globalization on the health of poor people [3]. The "Medicines Act", established in 1996 in South Africa, included an Essential Drug List, based on 90-95% of the most common and detrimental conditions, and contained a clause allowing the importation of generic substitutes for the essential drugs specified. This clause included allowing the importation of some of the antiretroviral drugs, for example AZT, ddI and ddC, that had been developed by the U.S. National Institute of Health, and were produced by some of the large pharmaceutical firms. The clause allowing the importation of these generic substitutes was legal according to the World Trade Organization (WTO) Trade in Intellectual Property Rights (TRIPS) rules, and similar

measures have often been used by European nations and the U.S. to attempt to import generic substitutes at times of health emergencies, for example during the potential Anthrax threat in the U.S. [1].

Yet at a time when 25.1 million people out of a total 36.1 million living with HIV/AIDS worldwide lived in Sub-Saharan Africa, a lawsuit claiming intellectual property rights violation was issued by the pharmaceutical firms, backed by the U.S. government, thereby tying up the law in African High Court between mid-1997 and April 2001. In April, 2001 a deteriorating public image, in an industry that spends more money on marketing than on research and development [2,4], and international criticism and protest finally prompted the firms to drop the case [19].

Although funds for research and development were cited by the industry as the reasons they pushed for their monopoly patents, in this case, Sanjaya Lall's studies inform us that where there is inelastic demand for a drug, as would be the case for a drug involved in a life-threatening virus with soaring new infection rates, the profits earned are so great as to be extremely socially irresponsible [6]. In this case, the funding for the development of some of the drugs implicated, came from the U.S. National Institute of Health and thus from U.S. tax dollars.

### **Consuming More Than We Need – Patents and Marketing Measures are not Designed to Promote the Balance of Health Needs**

Drug "dumping", exporting harmful drugs into countries that lack strict drug reinforcement and the excessive marketing of unnecessary or damaging drugs, has been heavily documented [4,5] and prompted the World Health Organization to release its list of essential drugs. The decision makers in drug purchases are often doctors and not the consumers themselves, so marketing can produce a lack of reliable information or as Lall has put it, "promotion creates powerful monopoly positions, confuses the flow of correct information, may induce inappropriate prescribing and generally leads to considerable social waste" [6]. The reason it is so important that a person's income not be wasted on unnecessary or expensive drugs is that ill people are more likely to be poor and expensive medications detracts income from food, adequate housing and other such important expenses. Lall has noted that, in the countries where there is a governmental health system, the consumer's identity may also be separate from the purchaser, the state. In this situation, the best interests of society; to balance health expenditures among pharmaceuticals, testing, screening, hospitals, care staff, and other social expenditures; coincide with the interests of the biotechnology industry, which is conversely driven by market forces that call for the maximum

usage of commodities that will profit them.

Patents and promotion have a common vision - that of establishing and maintaining a secure position of monopoly control. Technological innovations and monopoly patents have provided a way, during periods of economic crisis that occur as a result of economic overproduction and stagnation, to render the pharmaceutical industry “almost crisis proof” [7]. Marketing measures serve to establish a monopoly position long after the patent has expired. Periods of low consumer demand in the world economy are dealt with through promotions and patents; to insure that the industry remains profitable and suffers minimal setbacks throughout a crisis.

Overall, Lall has also found that the pharmaceutical industry faces little risk in research and development when compared with other industries. Yet pharmaceutical pricing policies are based on the monopolistic principles of “what the market can bear” rather than on the socially responsible one of lowering prices after recovering research costs [6]. The fact remains that patents reduce competition. For example, smaller firms that cannot afford the high cost and time-consuming process of litigation will simply sell their innovations to the giant firms for a set amount. This reduces competition and so works in turn to keep the price of drugs and therapies high. As far as health goes, pharmaceuticals and biotechnology really only fit into a continuum of health needs; ranging from good nutrition, adequate housing, clean air and water; to education, and qualified health care workers. Just as a person with limited resources may have to divert income for expensive drugs from that spent on food, lifestyle and other social spending or else go without medication; the state has an allocated budget for social spending and health care and must divert from other necessary endeavors to fund pricey biotechnology. Either way, as a result of the high prices brought on by patents, impoverished people will not receive necessary medication or will become more impoverished or else governments will go further into debt and into economic control of unaccountable organizations, such as the International Monetary Fund and the World Bank [1].

The Ontario government has so far ignored Myriad Genetics Laboratory’s demands on breast cancer genetic susceptibility tests, which involves screening for genes only in Myriad’s own labs in the U.S. at about five times the current price; in doing so the government has thereby “taken steps toward charting a path that balances societal and commercial interests in the area of genomics” [12]. It is important to grasp then that without continual resistance, although for society’s sake high-costing patented biotechnology should be balanced among many other health and social factors,

resources will be allocated in an unbalanced way to biotechnology.

### **North, East, South, West: the compass guiding scientific research is pointing to Profit**

“Scientific knowledge emerges from a process that [is] intensely human, a process indelibly shaped by human virtues, values and limitations... Science is a social enterprise... [and] takes place within a broad social and historical context, which gives substance, direction, and ultimately meaning to the work of individual scientists...” [8, cited in 1].

What is driving research endeavors if not the collective needs of people? An economic and political compass is guiding scientific research, driven by the “logic of capitalist expansion” [7]; where, instead of accountability to society, research is steered towards earning profits for shareholders. In this way, the research endeavors undertaken by scientists are likely to be determined by market forces rather than real human need. This ideology coincides with the ideology of benefiting society only at opportune times, or as McKinlay has termed it: “There is only a ‘coincidental relationship’ between the production of goods and services in accordance with the logic of capitalism and any resulting improvements in the health and general welfare of mankind.” Such forces embedded in the direction of scientific research are exemplified in that “sixty six percent of the USA Government’s expenditure on research and development is on military research [9]. Ninety percent of global expenditure on medical research is on diseases causing 10% of global burden of diseases, [10] and of 1233 new drugs developed between 1975-1997 only 13 were for the tropical diseases” [1]. Not only is most of the revenue spent on research not for the majority of people’s health problems; a large portion of the research is also not even spent on drugs that are new or innovative in the sense that they are useful to society. These drugs, as a result of molecule manipulation, allow patents to be obtained for drugs of no value to society, what Thomas Bodenheimer has dubbed the “me too” drugs [2]. This type of research is uneconomical and wasteful as there is much research needed in other areas of healthcare and social expenditure.

Since the market revolves around research on commodities that can be bought and sold, the importance of research into non-profitable aspects of health, such as long-term environmental and lifestyle studies and measures, have remained minimal [2,11,12]. This may produce genetic screening and gene-based therapies that are marketed as “magic bullet” solutions to disease and used; at best, excessively; and, at worst; marketed and used as replacements for other measures.

As Donald Willison and Stuart Macleod have noted: "...modifiable behavioural factors, such as obesity, inactivity and smoking account for over 70% of the cases of stroke and colon cancer, over 80% of coronary artery disease and over 90% of adult-onset diabetes"; ignoring the importance of these areas in healthcare would be both costly and inefficient in addressing the majority of the problem [12]. Market forces and the success of shareholders being the determinants of research focus instead of societal health needs results in a heavily promoted approach to diseases as drug and biotechnology-oriented, when evidence suggests socio-economic factors simply cannot be ignored. Scientific research is, in this way, given direction and shape in the context of the political and economic structures of the world.

## **Research Process – Effects of the Biotechnology Industry**

As stated above, the market may have a profound effect on the focus of research but what are the effects on the research process itself? Willison and MacLeod have looked at whether or not patents are benefiting society, by first outlining how research could be carried out with benefits to society. "By granting time-limited market exclusivity, patents create the potential for inventors to generate high returns on successful innovations. In exchange, the inventor provides a complete description of the invention so that others may build on the technology to create improvements or other breakthrough discoveries." [12]. Yet, as government research funding through grants becomes more scarce, researchers are forced to turn to the private sector; thereby creating a lack of objective scientific knowledge or what Baird has termed a lack of "a body of independent scientists without commercial affiliation who can provide more objective input and opinion when society has to deal with choices posed by developing technologies" [11]. The few high profile cases in the past of physicians or scientists covering-up undesired results, or even forging results, has been connected to the large financial motive present. As Bodenheimer states, "Science is supposed to be objective, but when money is at stake, subjectivity may certainly come to the fore" [2]. To demonstrate how the market can affect the research process, Willison and Macleod [12] have cited a survey of 100 Universities in the U.S. with the greatest amount of funding from the National Institute of Health in 1998 [13]: "In a survey of over 2100 life scientists, about 20% of respondents reported delays in publication of 6 months or more to allow for patent application, to protect their scientific lead, to slow dissemination of undesired results, to allow time for patent negotiation or to resolve disputes over the ownership of intellectual property." They have also cited a survey

that concentrated on geneticists in 50 U.S. Universities with the maximum government funding [14]: "47% of geneticists who asked other faculty for additional information, data or materials regarding published research reported denial of at least 1 request in the preceding 3 years. In 28% of cases, respondents were unable to replicate published research as a direct result of this refusal to share information. The rate of denial of requests for data was equivalent to that reported by non-geneticists. However, geneticists were more likely to report that the withholding of data impeded progress of their research (58% v. 38% respectively)." These findings were especially prevalent where there was more academic-industry research partnerships and commercialization of university research. Since secrecy and lack of educational dispersal throughout academia is not the way to improve on an innovation or to find new and ground-breaking discoveries, these effects of industry on scientific research can be viewed as paralyzing, or at best dulling, to reaching societal benefits. As Baird has pointed out, "the opinions of academic researchers with investments in biotechnology firms, or with appointments on their boards or as consultants, cannot be accepted as objective, but this is not often taken into account" [11].

## **Can They Put a Patent on Someone's Brain?**

### **What is Deemed Worthy of Patents is Consistently Tested Under the Law, with Repercussions on Research.**

For now, human beings cannot be patented for ethical reasons. It could be speculated though that, in the future when such technology is developed, some human organs created and developed in the laboratory would be eligible for patent protection. Could these organs include the entire human brain – or would that be going too far? How far patent protection can go is partly based on ethical issues and public consensus and partly on the many legal interpretations of current laws. Regarding laws, we have section 2 of the Patent Act of Canada that says that an "invention" comprises "any new and useful art, process, machine, manufacture, or composition of matter" [15]. The dynamic relationship between the theory of what a patent is meant to include and this interpretation by law is elucidated by Willison and MacLeod: "to qualify for a patent, the invention must be deemed useful, novel and not obvious. The utility criterion requires that a clear application is known. Novelty means that the invention has not been described before in the literature. The criterion of non-obviousness demands creativity on the part of the inventor" [12]. They have noted that where these criteria came into consideration was, for



example Pfizer, a company that patented Viagra - a drug used for erectile dysfunction, was denied a patent on the entire class of phosphodiesterase-5 inhibitors for erectile dysfunction on the grounds of “obviousness”, since the knowledge for this class of drugs already existed in the literature.

These criteria are only guides though in the highly contentious fields of biology and ethics. Where the distinction between life forms that constitute property, such as molecules, micro-organisms or non-human animals, are still highly debatable and controversial among the public. A case in 1980 in the U.S., where the U.S. Supreme Court ruled in a 5-4 split decision that “the genetic modification of a bacterium to break down oil spills was consistent with ‘a new composition of matter,’” set the precedent for the majority of the rational behind today’s patent decisions; components of an organism, its DNA sequences and genes, may well be patented if a whole organism can. Canada, although having issued patents for certain yeasts and molds, has drawn the line at so-called higher life-forms such as seeds, plants and non-human animals although in the U.S., Europe and Japan, such patents have already been issued [16]. A Federal Court of Appeal ruled earlier this year that the Harvard Oncomouse, a mouse susceptible to cancer and so used in cancer research, fit the criteria of “non-obviousness” and was described by a justice Marshall Rothstein as “a new and useful ‘composition of matter’” and so an “invention” according to the patent act [17]. The decision of the Court of Appeal has been appealed to the Supreme Court and is currently under review.

In the general distinction between discoveries, “upstream discoveries” are very broad discoveries, for example on the H2-receptor responsible for gastric acid secretion, and “down stream” applications are more specific, for example the development of H2-receptor antagonists; before 1980, the discoveries eligible for patents were only the specific tests or therapies that made use of the “upstream discoveries” [12]. For the purposes of research and the goals of maintaining useful and innovative new inventions, it has been noted by Willison and Macleod that “an excessively broad patent – particularly on an upstream discovery - might block or place severe constraints on the ability of others to develop new tests or therapies that build on the patented invention” [12]. If companies are able to place very broad patents, for example on higher life-forms or “upstream discoveries”, more lawsuits and time-consuming court appeals from possible intellectual property rights violations would result. Many researchers who lack the funds to deal with the litigation may decide not to research in a greater number of areas and so, such broad-patents may very well discourage and impede important research endeavors.

## Who will make Drugs Without the Large Financial Incentive? And Other Questions...

On top of lawsuits, threats of trade sanctions and trade constraints were used against the South African government as the government attempted to install WTO-legal imports of generic HIV/AIDS drugs [3]. Could this have been an isolated incident? The evidence tells us otherwise. Previously, there had been U.S. government threats of foreign aid cuts to Bangladesh in the early 1980’s when Bangladesh attempted to prohibit import of non-essential drugs. Then there was, similar to South Africa, trade pressure on Thailand when they attempted to provide affordable antiretrovirals for people with HIV/AIDS [3]. Trade pressure and threats of foreign aid cuts, by developed countries on less developed ones, make it difficult for governments of less developed countries to implement policies that would make necessary drugs affordable to populations.

Bodenheimer has noted that, as the corporations work transnationally, resistance is also required to be transnational in scope in a way that is united across the world [2]. Bond has drawn upon the importance of active dissent and criticism, especially during election campaigns, to cause the necessary embarrassment that would incite a political will for change [3]. Since reforms will not come about voluntarily international organizations with public interests, consumer critics and grassroots activism will be invaluable to the dissemination of information and the political pressure to bring about a change to the current system. As a broad solution, Bodenheimer suggests placing the control of essential discoveries and research endeavors under the control and supervision of the majority of the world’s people. Making research and discoveries more publicly accountable, for example to an international organization that concerned itself with human rights, would ensure that it is the majority of people around the world that benefit from discoveries [2]. In this way, the answer to the question “Who’ll make drugs without the large financial incentive?” is that organizations with human interests in mind, if empowered, could make necessary drugs without the wasteful spending on unneeded promotion and without making the huge, socially irresponsible profits; thereby achieving wider benefits with less wasteful spending.

Willison and Macleod have outlined reforms proposed here in Canada by the Ontario government regarding Canada’s Patent Act:

- Narrow the scope of gene patents.
- Create clear exemptions for experimental and noncommercial clinical use of a patented invention.

- Introduce a morality clause, the basis on which a patent may be challenged.
- Make provision for a separate ethics review panel.
- Create a faster, less expensive dispute-resolution mechanism.
- Permit compulsory licensing of genetic diagnostic and screening tests, giving government authority to require the patent holder to license the test to another firm, under reasonable conditions.

...stating that these reforms still fail to address the industry's "bias toward products that will maximize a return on investment" and so stressing that the federal and provincial government's continued funding for all types of research, including the kind that are non-profitable, would be required [12].

## References

1. Benatar, Solomon R. (2002, September 20). Human rights in the biotechnology era  
1. BioMed Central International Health and Human Rights, 2, (3) 1-11. [http://www.biomecentral.com/1472-698X/2/3/]
2. Bodenheimer, T.S. (1985). The transnational pharmaceutical industry and the health of the world's people. In J.B. McKinlay (Ed.), Issues in the Political Economy of Health Care (pp187-216). NY/London: Tavistock Publications.
3. Bond, P. (1999). Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians. International Journal of Health Services, 29 (4), pp765-792.
4. Thrupp, L.A. (1984). Technology and planning in the third world pharmaceutical sector: the Cuban and Caribbean community approaches, International Journal of Health Services, 14, (2), pp189-216.
5. Glucksberg, H. and Singer, J. (1982). The multinational drug companies in Zaire: their adverse effects on cost and availability of essential drugs. International Journal of Health Services, 12, (3).
6. Lall, S. (1980). The Multinational Corporation – Nine Essays. London: Macmillan.
7. McKinlay, J.B. (Ed.). (1985). Issues in the Political Economy of Health Care. NY/London: Tavistock Publications.
8. National Academy of Science, National Academy of Engineering, Institute of Medicine. (1994) On being a scientist (2<sup>nd</sup> ed.). Washington, DC: National Academy Press.
9. Sivard, R.L. (1996). World social and military expenditure. Washington, DC: World Priority Press.
10. WHO Geneva. (1996). Investing in health research and development. Report of the ad hoc committee on health research relating to future intervention policies.
11. Baird, P.A. (2000). Genetic Technologies and Achieving Health for Populations. International Journal of Health Services, 30 (2), 407-424.
12. Willison, D. and MacLeod, S. (2002, August 6). Patenting of genetic material: Are the benefits to society being realized. eCMAJ, 167, (3). [http://www.cmaj.ca/cgi/content/full/167/3/259]
13. Blumenthal D, Cambell E.G., Anderson M.S., Causino N, Louis K.S. (1977). Withholding research results in academic life science. Evidence from a national survey of faculty. JAMA, 277, (15), 1224-8.
14. Cambell, E.G., Clarridge, B.R., Gokhale M, Birenbaum L, Hilgartner S, Holtzman NA, et al. (2001). Data withholding in academic genetics: evidence from a national survey. JAMA, 287, (4), 473-480.
15. David Gambill. (2002). Court Allows Patent on Harvard Mouse. Canada Law Book. http://www.canadalawbook.ca/headline52\_arc.html.
16. CBC News Online Staff. (2002, June 6). Patents OK for higher life forms. http://cbc.ca/stories/2002/06/06/cloning\_patents020606
17. CBC News Online Staff. (2000, Aug. 4). Court allows genetically altered mouse patent. http://cbc.ca/storyview/CBC/2000/08/03/mousepatent000803
18. Danaher, Kevin. (2001) 10 Reasons to Abolish the IMF & World Bank. New York: Seven Stories Press.
19. BBC News. (2001, Apr. 19). SA victory in Aids drugs case. http://news.bbc.co.uk/1/hi/world/africa/1285097.stm

