Bad Medicine

Patents: Obstacles or Facilitators of Access to Knowledge

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Intellectual Property Rights are state-mandated monopolies

Notion of IPR is built on a contradiction:

in order to promote the development of ideas, it is necessary to reduce the freedom with which people can use them

"The relentless march of intellectual property rights needs to be stopped and questioned. ... Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents."

UNDP Human Development Report 1999

"The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky; the patent system provides the incentive necessary to investigate thousands of new compounds and to invest an average of several hundred million dollars in R&D".

IFPMA: Workshop on TRIPS, Jakarta, May 2000

IPR laws have always been a compromise between these two, in the last few decades the resolution of the contradiction has tended to favour the latter

Facilitator of Creativity?

- **Creation is facilitated by a temporary monopoly: validity when laws geared to benefit the individual artisan or author**
- **But intellectual products, today, are social products**
- **Individual creators cease to be the beneficiaries: replaced by corporate interests**
- **IPRs place enormous power at the disposal of a handful of corporations: to determine the direction of research**

➔Handful of Pharmaceutical corporations can decide the kind of drugs that will be developed

Increasing Concentration of Pharma Industry

Percent share by value in World Pharmaceutical Market

	1987	1990	1994	1997	2000
Number 1 manufacturer	3.42	3.99	4.9	4.6	7.3
Top 10 manufacturers	27.50	28.70	31.8	36.2	45.7

Source: IMS Data, cited in J. Morris: Pharmaceuticals Global Insights,

Top Performing Companies

Company	Revenues Rank	1999 Profit as % of Revenue
Microsoft	216	39.4
Cable and Wireless	315	38.8
E.I. du Pont	123	27.6
Eli Lilly	485	27.2
Telefonos de Mexico	482	26.1
Volvo	305	25.8
Intel	116	24.9
Glazo Wellcome	349	21.3
Roche Group	239	20.9
Petronas	311	20.8
Bristol-Myers Squibb	206	20.6
R.J.Reynolds Tobacco	436	20.6
Novartis	192	20.5
Pfizer	285	19.6
Textron	428	19.2

TRIPS Agreement designed to safegaurd "Rent Incomes" in sectors where initial production costs are high but reproduction costs are low

Overturned the very basis of trade negotiations where classically the developing nations were considered victims and special considerations were taken to remedy their problems.

Concept of IPRs has come a full circle:

- ☞ **from the initial notion of the protection of an individual's rights and the notion of disclosure of information**
- ☞ **to protection of the rights of corporations and a bar on the free flow of information.**

High Risk Activity?

Seductive argument that:

- ☞ **invests huge amounts in R&D**
- ☞ **new product development is risky business**

Converted IPRs into the "holy cow" of trade negotiations, that nobody dare tamper with.

Profitability by Industrial Sector (1999)

Sector	Net Profits % of Assets	Net Profits % of Revenue
Pharmaceuticals	14.7	18.3
Beverages	11.1	10.1
Tobacco	8.0	8.5
Specialty Retailers	6.0	2.6
Telecommunications	5.5	10.2
Computers, Equipment	4.9	6.6
Food	4.8	2.2
Aerospace	4.1	4.3
Petroleum Refining	4.0	3.6
Forest & Paper Products	3.8	4.2
Food & Drug Stores	3.7	1.9
Chemicals	3.6	3.3
Wholesalers	3.5	1.2
Airlines	3.4	3.4
Electronics, Electrical	2.9	3.0
General Merchandisers	2.8	1.4
Energy	2.3	2.2
Publishing, Printing	2.3	2.5
Motor Vehicles & Parts	2.2	2.2
Utilities: Gas & Electric	2.1	2.5
Entertainment	2.0	5.6
Health Care	1.9	2.8
Diversified Financials	1.5	11.1
Mail, Package,Delivery	1.1	1.7
Securities	0.9	10.7

Profits of Top Global Pharmaceutical Corporations (1999)

	Company	Revenues $ million	Profits $ million
1	Merck	32,714	5,890
2	Johnson & Johnson	27,471	4,167
3	Novartis	21,609	4,432
4	Bristol_Myers Squibb	20,222	4,167
5	Astra-Zeneca	18,445	1,143
6	Roche Group	18,349	3,837
7	Pfizer	16,204	3,179
8	Glaxo Wellcome	13,738	2,930
9	Smithkline Beecham	13,562	1,704
10	American H P	13,550	-1,227
11	Aventis	13,438	-1,035
12	Abbott Laboratories	13,178	2,446
13	Warner Lambert	12,929	1,733
14	Eli Lilly	10,003	2,721

If profit margins were to have been less by a third — a benefit of about 11 billion dollars could have been passed on to consumers. That is, more than the projected 10 billion dollars that are required to provide access to anti-AIDS drugs to all HIV positive patients in the world!

This is profiteering, driven by rent incomes and not legitimate returns on investment.

- Those who need drugs the most are the least likely to be able to pay for them
- The income poor, wherever they live, spend higher proportion of total medical costs on drugs
- In developing regions larger % of drug costs are paid for privately

Comparison of Private Expenditure on Drugs

	Per capita (US $)	% GDP	Pvt. as % of Total
Sub-Saharan Africa	8	0.9	65
Asia	12	0.6	81
Middle East	27	0.7	74
Latin America	26	0.9	72
Mkt.Economies	138	0.6	40

Innovations for Whose Benefit?

- **Drugs which sell in the market have little relation with the actual medical needs**
- **Research and patenting in pharmaceuticals are being driven by the search for the next "blockbuster" drug**
- **The frantic search for the next "blockbuster" skews drug development in favour of new drugs for which there are buyers who are willing to pay prohibitive amounts**
- **More and more drugs being introduced are "copycat" drugs that address "lifestyle" needs and not medical needs.**

Assessment of New Drugs Introduced Between 1981-2000

Category	No.	%
Major therapeutic innovation in an area where previously no treatment was available	7	0.31
Product is an **important therapeutic innovation** but has certain limitations	67	2.96
Product has **some value** but does not fundamentally change the present therapeutic practice	192	8.51
Product has **minimal additional value**, and should not change prescribing habits except in rare circumstances	397	17.59
Product may be a new molecule but is **superfluous** because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a me-too product	1427	63.23
Product without evident benefit but with potential or **real disadvantages**	58	2.57
Editors **postpone their judgements** until better data and a more thorough evaluation of the drug is available	109	4.83

Source: Prescrire

What, then, Justifies such High Research Costs?

- Many new drugs are initially researched in public funded institutions: Beta-blockers, H2-blockers, Taxol, ACE inhibitors - groups which spawned "blockbusters"
- Industry driven by rent incomes will bypass the needs of the income poor
- Drugs developed in the 1950s and 1960s to treat tropical diseases have begun to disappear: termed as "orphan" drugs.
- Industry argues that patented drugs constitute less than 10% of drugs that are being used in developing countries.
- But the reason why so few commonly used drugs in developing countries are under patents is not because new drugs are not necessary, but because pharma-ceutical countries do not develop appropriate drugs

Patents make for Bad Science

- Protection extends to protection of test data
- Industry argues that granting data exclusivity for test data is crucial, since the development of these data is expensive
- Trend also towards less disclosure of information when patents are filed.
- Pendulum shifting away from the concept of "full disclosure"
- Studies submitted in support of applications for new licenses for drugs in which side-effects had been shown were less likely than others to be published
- Clearly, patents have ceased to be a vehicle of dissemination of knowledge and have become the tools to constrain its spread — quite the antithesis of what good science requires.

Patents Retard Domestic Industries

- **Domestic industries outside the developed countries have been able to develop in places where strong patent production has not been allowed.**
- **Issue is not just that it allowed cheaper versions of patented drugs to be sold, it also led to the development of world class manufacturing facilities in a developing country.**
- **Today the campaign on access draws strength from :**
  - ➔ **Indian Companies offering anti-AIDS drugs at one tenth to one fortieth of global prices**

This could not have happened if the TRIPS accord had been signed in 1975 and not in 1995! It is this that we stand to lose as we move towards "harmonised" standards

- **TRIPS accord was not pushed through to access markets of developing countries: India accounts for 0.8% of the global market in value terms, in contrast to 53%, 20% and 18% for the US, Europe and Japan**

- **TRIPS agreement became a necessity to protect the markets of large pharmaceutical companies in the developed world against competition from cheaper generic drugs manufactured in countries like India and Brazil**

- **TRIPS in other words is not about "free" trade, but has to do with protection of markets in developed countries**

The Way Forward

☞ To recapitulate:

➔ financial returns for large pharmaceutical companies is evidence of profiteering

Patenting leads not only to high prices but also to:

➔ the wrong kind of research,

➔ to inhibition of research,

➔ to stifling of domestic industries in developing countries.

☞ A system which perpetuates such a situation needs to be taken apart and be replaced by a new system, that brings back a balance between the rights of the inventor and public interest

☞ Need to develop different mechanisms to promote innovation