The Impetus for and Potential of Alternative Mechanisms for the Protection of Biotechnological Innovations

Prepared for

The Canadian Biotechnology Advisory Committee
Project Steering Committee on Intellectual Property
and the
Patenting of Higher Life Forms

By

Pat Roy Mooney

March 2001

This publication is also available electronically on the World Wide Web at the following address: cbac-cccb.ca
This publication is also available in alternative formats on request.
Contact the Canadian Biotechnology Advisory Committee (CBAC) at the numbers listed below.

For additional copies of this publication, please contact the:

Canadian Biotechnology Advisory Committee (CBAC)
235 Queen Street
7th Floor - Room 744B
Ottawa ON K1A 0H5

Tel: (613) 957-7715
Toll free : 1 866 748-CBAC (2222)
TTY : 1 866 835-5380
Fax: (613) 946-2847
Web: cbac-cccb.ca
E-mail: info@cbac-cccb.ca

Opinions and statements in this publication do not necessarily reflect the CBAC views and positions.

The Impetus for and Potential of Alternative Mechanisms for the Protection of Biotechnological Innovations

for the

Canadian Biotechnology Advisory Committee

Prepared by Pat Roy Mooney, RAFI

I. Context:

In the last two decades intellectual property (IP) has become a powerful, though imperfect, instrument to establish temporary technological monopoly and advance market share. IP has been a major force in the growth and consolidation of the biotechnology industry. In the 1980s the US government took significant steps to accommodate patents on living organisms and their components by re-defining laws to allow for exclusive monopoly patents on biological products and processes. At the World Trade Organization and through bilateral trade agreements the biotech industry has lobbied vigorously to advance the US IP regime around the world.

Despite the push to harmonize, expand and enforce stronger IP laws, patents are often a headache for the biotech industry. IP laws, especially as they apply to biological products and processes, are characterized by confusion and uncertainty. The application of patent law to living materials has resulted in immense and costly legal battles between enterprises competing for ownership of strategic genes, traits and processes. In order for patents to have economic value, corporations must defend their patent claims and enforce licensing requirements under civil law. As patentable subject matter grows in number and in complexity so are patent applications.

Critics claim there are too many patents being granted for too long, and, further, that the subject matter being monopolized is too often someone else's innovation. Instead of promoting the useful arts, patents are criticized for stifling innovation and hindering competition. The concerns are not just technical, but go further to question the morality of a legal system seen as fundamentally inequitable and piratical. Twenty-year monopolies granted by national authorities in record numbers are seen as jeopardizing basic human rights, threatening food security and marginalizing public sector research.

It is in this context that industry is seeking new and additional mechanisms - technological and regulatory - to secure their control of biotechnology in the 21st century.

II. The Impetus for Options:

Industry's discomfiture with the present intellectual property system, then, can be summarized as follows:

1. **Practically unreliable** - The science, the IP process, and the courts are too unpredictable to allow enterprises to count on IP as a means of protecting inventions and markets.
2. **Politically unpredictable** - Between "Post-Seattle Syndrome", political turn-abouts in the European Union, mounting opposition from UN Agencies and the Human Rights Commissioner, and a backlash among developing countries, the biotech industry does not trust governments to "stay the course". For the first time since the Seventies, legislative reversals are feared.

3. **Technologically untrustworthy** - Some new technological advances seen designed to disassemble or circumvent biotech patents. This points the way to what could become a profitable move toward lawful patent piracies that) in the current political environment) governments would be reluctant to confront.

Each of these concerns is summarized briefly below.

1. **Practical/Cost constraints:**

The Canadian patent system is being positioned to mimic the US system. Since the USA is the technological leader in life sciences, this report will reference the US situation in order to suggest the direction in which Canada is moving unless a distinctly different path is chosen.

It is extraordinarily difficult to monitor and monopolize a technology that is advancing so quickly. The volume of life sciences data is doubling every six months.[1] In the face of rapid technological change, the patent system has become overburdened. (See chart.) IBM acquires 10 new patents every working day.[2] The complexity of biological patents is also daunting and increasing. In 2000, the US Patent & Trademark Office received one biotech patent application that was the equivalent of 400,000 pages in length.[3]

Complexity has led to a massive leap in transaction costs. The legal costs of obtaining a patent approach US$10,000, and it typically costs US$1.5 million (per side) to litigate a patent.[4] Operating costs at the US Patent Office now exceed US$1 billion.

The number of intellectual property lawyers in the United States, for example, is growing faster than the amount of research.[5][6] Since 1995 in the USA, the number of intellectual property lawsuits reaching federal courts has risen ten times faster than other legal actions. There were 8,200 cases in 1999 alone[7]. Because patents are civil law, these costs fall on the industry. Were it only a matter of cost, the larger companies would probably see the expense as a useful barrier to entry for smaller enterprises. Indeed, the costs are a barrier. Start-up biotech “boutiques” are reported to be budgeting as much for patent litigation as they are for research expenditures. But even the largest enterprises cannot be assured that the courts will be on their side. Twelve of every one hundred biotech patents end up in court. Forty-six per cent of all US biotech patents that are challenged in court are overturned and some legal experts suggest that a still larger percentage would be rejected if they were challenged. Nor can dominant patent-holders be certain that a much smaller enterprise does not have a "submarine" patent that will surface to hold their market ransom at the point of commercialization. For the world's biggest biotech companies, these uncertainties are unacceptable.

2. Political concerns:

Compounding the functional uncertainties and costs associated with IP, the industry is now discovering that "patents on life" are politically contentious. Whereas once, IP stirred no interest whatsoever in the media or in parliaments, recently a public debate has emerged.

In 2000, the President of the USA and the Prime Minister of the UK jointly expressed concern that the biotech industry would have patent monopoly over the human genome. Religious leaders shared this concern. The 1999 United Nations’ Human Development Report (the one that annually declares Canada to be "the best country in the world" according to our Prime Minister) concludes, “the relentless march of intellectual property rights needs to be stopped and questioned.”[8] In August 2000 the United Nations Sub-Commission for the Protection of Human

Rights recognized that the World Trade Organizations' Trade-Related Intellectual Property Agreement could infringe on the rights of poor people and their access to both seeds and pharmaceuticals.[9] In November 2000, a blue-ribbon panel of ethicists and scientists brought together by the UN Food and Agriculture Organization (FAO) concluded that IP had gone too far and is a threat to food security. Most recently, three cabinet ministers (for trade, justice and the environment) in Sweden announced their alarm over the scope of gene patenting. A number of governments within the European Union are now banding together to challenge an EU patent directive that, they believe, goes too far in permitting the patenting of living material. Originally, the directive was only opposed by The Netherlands and Austria. As of this writing, it is understood that Sweden, Italy and France will join the opposition ranks and many anticipate that Germany will side with those against the directive. In February 2001 Oxfam UK joined an international campaign waged by civil society organizations to force multinational drug companies to make life-saving drugs available to poor countries. The campaign specifically attacks the WTO for using trade sanctions against poor countries that fail to enforce 20-year monopolies on drugs.[10] South Africa's court battle with the world's leading pharmaceutical houses over the patents and prices for AIDS-related drugs has also drawn world attention to the patent issue. Media reports now appear on a daily basis in Europe and elsewhere debating the merits and morality of intellectual property in biotechnology.

The industry and its investors must worry that mounting political opposition to patents could lead to legislative changes that threaten their IP and the market premises based upon their IP.

3. Technological complications:

Compounding practical and political constraints, the biotech industry has discovered some significant technological problems as well.

At one level, the industry appears to have overreached itself in patenting "too much too often". In December 1999, when the USA granted its six millionth patent (since it began counting in the 1830's), three human genomics enterprises allowed that they collectively had human gene applications totaling over three million claims. The applications were based on the assumption that the human cell line contained at least 100,000 genes. When the first genetic map, "The Book of Life" was unveiled in February 2001, researchers concluded that there might only be 30,000 to 40,000 genes. The revelation immediately called into question the scientific credibility and capability of the patent applicants - as well as the competence of patent examiners.

Revelations in the Book of life have posed other complications for the patent system. British researchers announced that homosapiens share half their genes with the banana, for example, while US scientists said that half our genes could be found in ringworms. The conclusion must be that some gene patents on plants could actually have implications for people. In fact, a cold tolerance gene found in arctic char might also be in arctic moss or in the Inuit scientists doing the lab work. Science has skewed the boundaries of species and kingdoms.

At another level, the cost and uncertainty of IP - and the potential for patents to thwart innovation - has encouraged some companies to "invent around" the patent system altogether. The chief scientific officer at Bristol-Myers, has said there are more than 50 proteins possibly involved in cancer that his company is not working on because the patent holders either would not allow it or were demanding unreasonable royalties.

Another biotech company may have a solution. Athersys, a company based in Cleveland, has developed a technique for randomly turning on genes inside a cell. Cells are exposed to low-level

radiation that causes a random break in a chromosome. The company then inserts a genetic "on" switch into the break. This turns on a nearby gene and causes the production of the associated protein. By automating this process with respect to a vast number of cells, the company ends up with a collection that produces virtually every protein. It can then search this collection for a cell producing a particular protein of interest. Athersys maintains that since the protein is produced without isolating or even knowing anything about the gene, the protein can be used without infringing other patents on the gene.[11] The technology could provide a major enterprise such as Bristol- Myers Squibb (which is collaborating with the Cleveland firm) with the freedom to continue drug discovery by circumventing IP.

These three areas of concern to the biotech industry make it clear that companies have an incentive to search for alternative or additional monopoly mechanisms.

Perhaps, the incentive for change is still greater because the reasons for patents are less urgent now than they were in 1980 when the US Supreme Court ruled that microorganisms were patentable.

III. The Potential for Alternatives:

The biotech industry is now exploring a number of new mechanisms that could either supplement or even replace IP as the "vehicle of choice" in establishing technological supremacy in specific markets. These include:

1. **Biological monopolies** - Terminator and other sterility or trait-control technologies that make it difficult or impossible for customers to replicate the biomaterial without returning to the inventor.
2. **Biosensors** - Satellite and other DNA-detectors that will be able to identify marker genes or sequences at any point in the product life cycle.
3. **Regulatory or Contract controls** – Laws (including trade secrecy and contract law) that are more enforceable than IP regimes and that – through government enforced regulation – protect private monopolies on the grounds of public or environmental safety.

Each of these strategies is summarized briefly below.

1. Terminator/trait control technologies:

Because patents on more technologies are unreliable and because litigation is both expensive and uncertain, transnational enterprises would be more than happy to find more reliable systems of monopoly control. New Enclosure mechanisms are being developed. Among them, *negative* technologies ("Traitor Tech") are attractive because of their built-in exclusivity and long-range controls. One prominent variation of Trait*or* Tech are the "Terminator" patents. The Terminator version causes the planted seed to become sterile at harvest time so that farmers cannot save the seed for another growing season. Other Trait*or* technologies offer positive or negative traits in plant varieties that can only be activated or de-activated by the application of proprietary chemicals. Advanced industry strategies include the development of seeds that can be regrown but only if farmers purchase specialty chemicals that rejuvenate dormant seeds.

2. Biosensors:

The biosensor industry, including gene-chip technologies, grossed US$400 million in 1998 but is expected to reach US$ 6.3 billion by 2005.[12] The potential for remote and hand-held DNA monitoring devices usable in the crop, cannery or kitchen, is enormous and could ultimately rival patents as a mechanism for ensuring contract control of technologies. Some recent developments that point in this direction:

- GPS (Global Positioning System) are becoming an important tool in identity preservation (IP), if an experimental program in Australia succeeds. In Tasmania, 600 agricultural fields are being assigned special identification numbers associated with their unique GPS coordinates. Backers of the plan are pushing for all Tasmanian fields to be numbered in an effort to expedite information exchanges between growers, wholesalers, government, and consumers. (And patent lawyers?)
- Similarly, the Argentine government has launched an "eye in the sky" to halt tax evasion by using satellite imagery to monitor their crops.[13]
- GeneScan Europe AG and Motorola are developing a new DNA detection tool for genetically modified crops. By utilizing Motorola's eSensor DNA detection system (the "scan gun"), the eSensor could lead to "on site" analyses via a hand-held device. The eSensor uses organic molecules to form electronic circuits that can detect numerous DNA targets simultaneously.[14]
- AviGenics, a US biotech company plans to create a strain of chicken genetically engineered to have an extra large breast to yield more meat, with a DNA copyright tag inserted among its genes to stop anyone breeding it without permission.[15]

Some of he new technological strategies are designed to prevent GM products from infecting conventional crops. The results can still be worrisome. Researchers have recently announced a "safe sex seed" that would lead to a genetic modification of maize in order to resist foreign genes. In other words, if Monsanto has a sexually transmitted disease, the rest of the world has to wear a condom. Working with *teosinte*, a University of Wisconsin-Madison scientist has found a molecular barrier that is capable of completely locking out foreign genes.[16]

In another strategy, Northland Seed and Grain (USA) has patented a method of doing business - the rather pedestrian process to establish the pedigree of non-GM varieties from the farmer purchased seed to household refrigerator sale (PCT WO/0048454). [17]

3. Regulation/Contracts:

Yet another New Enclosure strategy comes in the form of government-enforced public safety requirements. Biosafety protocols can be used to impose monopoly under the assumption that the necessity to feed the world or safeguard the environment warrants the risk of employing a complex and potentially hazardous technology. Because of the risk, governments could legislate a private monopoly for the inventor company to manage the innovation. This would not be the first time that the state has guaranteed monopoly in the name of the public good.

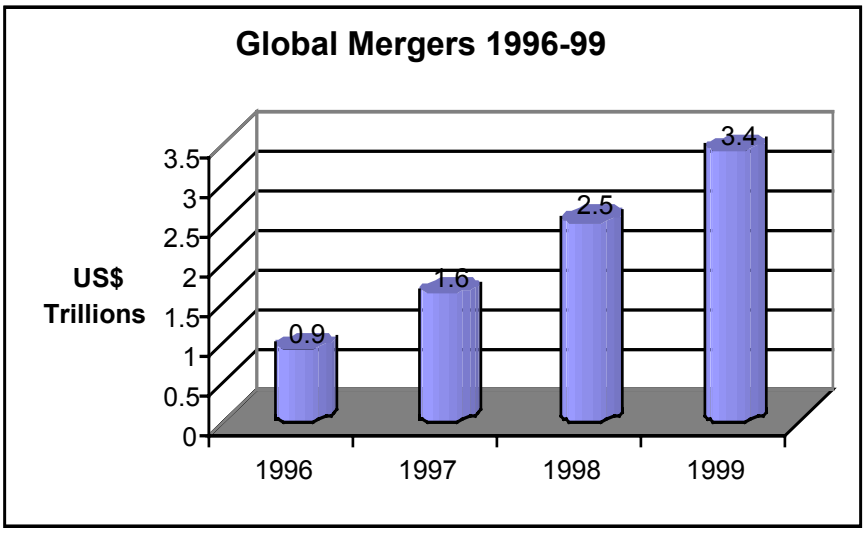
Another strategy involves reliance on contract law. Many companies now see contracts as a more reliable strategy. Pharmacia (Monsanto), for example, has employed extraordinary measures to prevent farmers from saving the company's patented GM seed – including the use of Pinkerton detectives to monitor rural areas. The company has prosecuted vigorously to prevent farmers from saving seed. Farmers are required to sign a licensing agreement. Oklahoma's Secretary of Agriculture, Dennis Howard, recently commented: "After reviewing Monsanto's 2001 Technology Agreement, I would discourage any farmer from signing this document. Not only does this contract severely limit the options of the producer, it also limits Monsanto's liability.

Marketing agreements and contracts are only effective if they serve to protect the interests of all parties involved. The protection of the Monsanto contract is strictly one-sided…."[18]

IV. The Conditions for Change:

It is arguable that IP is no longer essential - or, at least, the sole effective mechanism - to achieve these ends. The notes below summarize the present situation.

1. Private sector changes may make IP unnecessary:



The role of IP – and the feasibility of alternatives – has to be understood in the light of a number of other enterprise developments including mergers and alliances.

Mergers reduce the need for patent monopolies: Intellectual property is intended partly to control competitors and partly to control customers. But, if the number of competitors is reduced to a handful of giant enterprises through mergers and acquisitions, much of the argument for patents dissipates. Attached to this report are tables summarizing the global market share of the top ten enterprises in 1999 in the major industrial sectors concerned with biotechnology. The figures indicate a trend toward oligopolistic markets on a world scale.

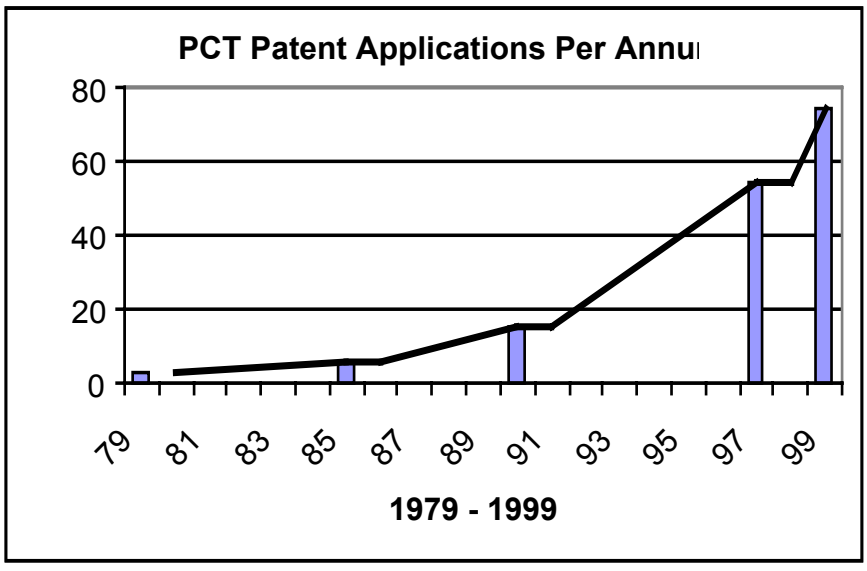
- When the US Supreme Court approved "life patenting" in 1980, no single seed enterprise was significant on the world stage. Today, the top ten companies control 31% of the commercial seed market worldwide.
- About the same time. 65 pesticide manufacturers were considered dominant in the research and development of new biocides. No single enterprise was seen to dominate. In 1999, the top ten enterprises controlled more than 90 per cent of the global market.
- The top ten veterinary medicine enterprises now control 68% of the world market.
- Whereas in the late Seventies, the top 20 pharmaceutical houses held barely 5% of the global drug market, the top ten in 1999 controlled over 51% of world sales.
- For all the talk of diversity, 6 major companies held 32% of all agricultural biotechnology patents issued by the USA to the end of 1998 and only 30 private and public research entities held 15 or more (of the 3092 patents) each.

The extent of corporate mergers grew from a record US$0.9 trillion worldwide in 1996 to a breathtaking US$3.5 trillion in 2000.[19] Most observers find such figures incomprehensible. The total of world mergers in 2000 amounts to a sum roughly equivalent to 10 per cent of total world output (the combined GDP of every country) in the mid-1990s.[20] Global mergers in the last two years of the bygone decade exceeded the total of the previous eight years.

This represents an enormous concentration of power. It is a sign of the pace of change that the securities and investment industries have only lately begun to monitor worldwide mergers. In 1974, the annual value of US acquisitions stood at less than US$12 billion. In 1988, the tally soared to US$330 billion, before dipping slightly in the recession years that immediately followed. In 2000, the US merger figure was well above US$1.7 trillion.[21]

By no means has all this activity been fuelled (or even primarily initiated) by the biotech industry. Petroleum and automobile industry mergers, as well as financial and informatics (telecoms and media) industry mergers, have led the field. At the mid-point of 2000, cross-border mergers were up 26 % over the previous record-shattering year with a tally in excess of US$1.9 trillion. Half a trillion dollars' worth of these mergers were in the informatics sector.[22]

But the biotech-related industries (including food and health as well as other bio-based products) have not been a bystander. According to a UNDP study, mergers in the global biotech industry (excluding pharmaceuticals, for example) rose from just US$9.3 billion ten yeas ago to more than US$172 billion in 1998.[23] Roughly estimated, mergers in the pharmaceutical sub-sector, that reached US$80 billion during the period 1994–97, have probably exceeded US$400 billion today. In the first six months of 2000, drug company mergers added up to just under US$100 billion.[24] At the beginning of 2000, Glaxo Wellcome and Smithkline Beecham (two UK drug firms) agreed to the (then) world's largest drug industry merger (US$76 billion). Days later, Pfizer snapped up Warner-Lambert (two US drug majors) in a still bigger deal valued at US$90 billion.[25] Only Merck among the world's top ten drug companies is not thought to be a potential buyer or seller. Mergers in the agribusiness industry (including food processors and retailers as well as ag input companies) leapt dramatically in 1999 when DuPont bought the world's largest seed company, Pioneer Hi-Bred, for US$7.7 billion. Monsanto, however, led in agricultural biotechnology



mergers with its purchases of almost US$8.5 billion in seed company stocks since the mid-decade point. Now Monsanto itself has been acquired by Pharmacia & Upjohn (to be called Pharmacia)

in a deal valued at US$37 billion. In the first half of 2000, the pace of mergers in the food sector increased with almost US$150 billion in acquisitions.[26] With some deals still to be confirmed, the estimate for mergers in 2000 in this sector is now US$250 billion.

Alliances reduce the need to use IP to create market entry barriers: Corporate mergers are only one way companies are taking over more territory and technology. But, there are other strategies. In order to avoid anti-combines laws or nationalist policies, companies increasingly form alliances to share patents, know-how and turf in less-regulated ways. Between 1996 and 1998, the world's largest transnationals established more than 20,000 such alliances. The top 20 pharmaceutical houses, for example, had 375 alliances with biotech boutiques in 1998 compared to only 152 a decade earlier. Almost all of them were 'cross-border' arrangements. Since the early 1990s, corporate revenues drawn from these alliances have doubled and now account for about 20% of company income in Europe and 21% for the US *Fortune 500.*[27]

Because of the protection provided by alliances, the extent of global concentration in pharmaceuticals or in agribusiness appears modest according to the conventionally applied monopoly rules monitored by most countries. But what are the implications, and what was the deal, when Monsanto agreed to market its smashingly successful arthritis drug with Pfizer? The new arthritis treatment is actually outselling Pfizer's famous Viagra. To argue that the top ten drug houses have 51% of the global market does not impress a monopoly commission that is focused narrowly on asthma or cardiovascular sub-markets. Neither are anti-combines officials interested in monitoring the whole seed or pesticides industry when they perceive the competition to be waged between maize breeders or broad-leaf herbicide manufacturers rather than across technologies. Governments have shown little interest in – or capacity for – cross-sectoral technology analysis. The monopoly now arising is within a biotechnology industry that governments don't even understand to exist. These enterprises share a common *bio*technology that links human genomics with human pharmaceuticals with veterinary medicines with crop chemicals with plant germplasm with cosmetics with household cleaning products. The biotech industry is much wider than the competition monitoring agencies.

There are, however, other factors working against the patent system that companies must also consider.

2. Public Sector changes have surrendered the field:

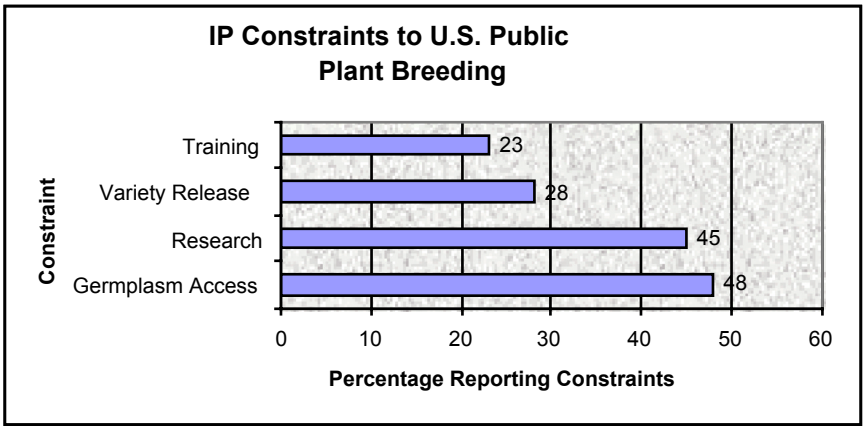
There was a time when the academic community could have argued that public sector research and development was an effective instrument to keep the private sector "honest" and socially beneficial. This may no longer be the case. Public funding for agricultural development - including research - is withering everywhere. Annual foreign aid for agriculture in the South fell by 57% between the publication of the pro-agriculture *Our Common Future* (The Brundtland Commission report*)* in 1988 and The World Food Summit of 1996 (from $9.24 billion down to $4 billion, in 1990 dollars). World Bank loans for agriculture and/or rural development in general plummeted by 47% between 1986 and 1998 (from $6 billion to $3.2 billion, in 1996 dollars).[28]

The aid community's declining interest in agriculture is reflected in the South's own lack of commitment. On average, the South spends barely 7.5% of total government budgets on agriculture. Only a tiny fraction of this goes to research.[29] The disinterest in agriculture is incomprehensible. Seventy-five per cent of the "$1 poor" (those living on one dollar or less per day) are in rural areas of the world. Rapid urbanization not

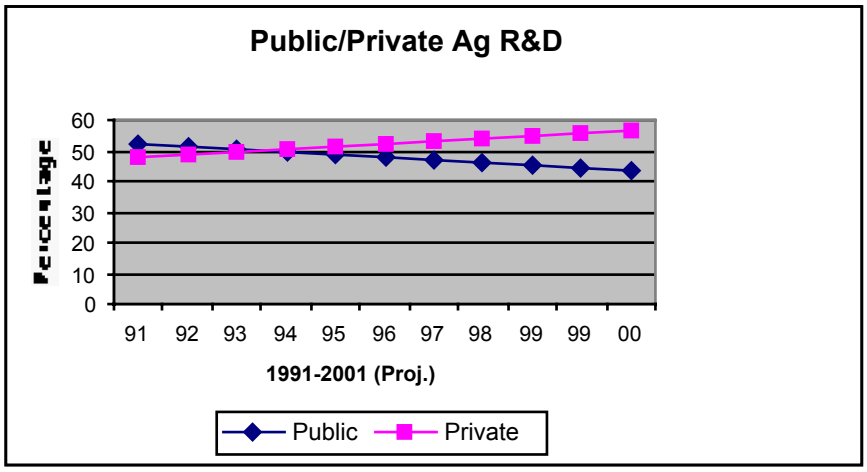
withstanding, even in 2025, about two-thirds of the "$1 poor" will still be rural.[30] Even though farmers feed the urban poor, rural areas have access to hardly half the public services available to urbanites.[31] Almost a quarter of the entire world's population is fed by farmers who save their own seeds and struggle for survival themselves.[32]

But, if public investment is vanishing, private agricultural R&D is booming. In the OECD, private R&D totaled $7 billion in 1993 - up sharply from $4 billion in 1981. Private investment in research during this period represented an annual growth of 5.1%. Conversely, publicly performed agricultural R&D rose just 1.7% per annum, from $5.7 billion in 1981 to $6.9 billion in 1991.[33] Well behind population growth.

Yet, private and public researchers perform markedly different duties. First, little private research takes place in the South. Corporate R&D in the South typically account for no more than 10-15% of total agricultural research in these countries.[34] Secondly, only 12% of corporate research goes to farm-level technologies. In contrast, 80% of public research is (at least theoretically) oriented to the farmer. Food processing and post-harvest research dominates private research, accounting for 30-90% of all private R&D. [35] In other words, less than $100 million of corporate R&D is farmer-focused while more than $5.5 billion in public funding is (ostensibly) devoted to improving farm production. There is no chance whatsoever that private companies will - or will want to - take over this important research from public breeders.
Private biotech also dominates public biotech. In the agricultural field, private biotech is spending about US$1.5 billion per annum compared to about US$1 billion in the public sector around the world. Aid-based funding for agricultural biotechnology in the South is probably less than US$80 million of which, the CGIAR accounts for $25-$30 million.[36] Once again, the research orientation in the private sector is very different from that of public researchers.

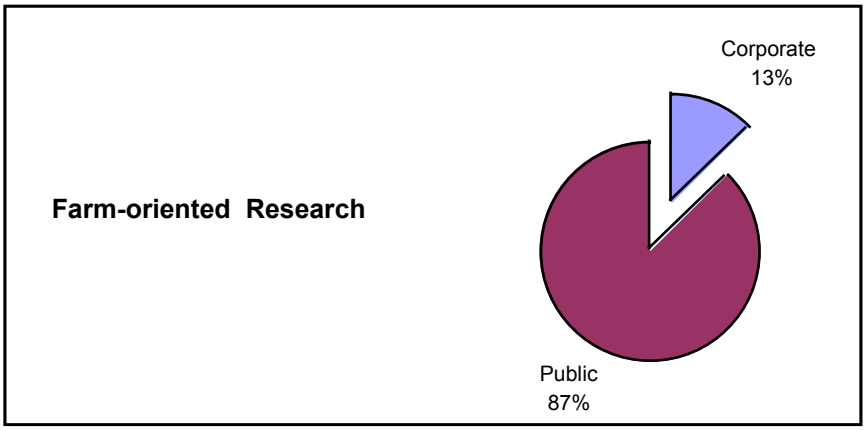


The world's agricultural research is experiencing a dramatic re-orientation toward post-harvest and food processing technologies. The decline in public research, therefore, should be no surprise. Public research is farm-based; corporate research is factory-based. Half a century ago, farmers (and their suppliers) accounted for 57% of the consumer's food purchasing budget - which assured farmers majority control over agricultural policy. At the end of the century, the farmers' share of the consumer budget had shrunk to 28%.[37] Farmers' Rights (adopted as a concept by FAO in 1989 and by UNCED in 1992) have dwindled accordingly.



Today it is common for universities to pay exorbitant legal fees to defend their intellectual property. According to the Association of University Technology Managers annual report, dozens of major universities – Brandeis, West Virginia, Tufts, and Miami among them – spent more on legal fees in FY 1997 than they earned from all licensing and patenting activity that year." [38] As companies were raking in close to $100 billion in royalties, U.S. universities, in 1997, earned only $611 million in licensing fees - hardly half of one per cent of total patent revenues.[39]

The doubts surrounding the usefulness of the patent system for the public sector also include concerns regarding Plant Breeders' Rights (Plant Variety Protection) legislation. Canada only adopted this legislation ten years ago but the United States has had PBR for three decades. One



recent survey among public breeders in the USA revealed that 23% of respondents felt that academic training was constrained by the legislation; 28% felt that the law inhibited varietal release; 45% said that it hurt research and 48% claimed that it reduced their access to breeding material. (See chart.)

V. The need for a new bargain between society and science:

The social contract achieved between industrial inventors and society at the time of the Vienna World's Fair of the 1870's is no longer valid. It is time to re-open the negotiations in order to be

certain that society benefits and that science is able to innovate responsibly. Governments that ignore the growing controversy swirling around technological monopolies do so at their peril.

Between 1980 and 1994 – a period that began with the US Supreme Court's decision to allow 'life patenting' and ended with the GATT Uruguay Round – the share of global trade involving high-tech (patented) production rose from 12% to 24% and now accounts for more than half of the GDP of OECD countries.[40] This does not take into account that the overwhelming majority of agricultural commodities produced and traded by OECD countries are also 'protected' by patents and/or Plant Breeders' Rights (plant variety protection). Perhaps the most telling development is that the number of annual patent applications made via the Patent Cooperation Treaty has skyrocketed from barely 3,000 in the mid-1970s to over 76,000 in 1999 (see Chart.) Half of all royalties and licensing fees paid to inventors in the mid-1990s went to corporations in the USA. Nothing better illustrates that patent monopolies are a strategy to deny others access to markets than the estimate by WIPO (World Intellectual Property Organization) that 90% of all cross-border licensing payments – and 70% of all licensing fees – are made between subsidiaries of the same parent transnationals.[41] In its 2000 Human Development Report, the UNDP estimates that 90% of the patents related to high technologies are held by global enterprises.[42]

In 1992, several scientific, industrial and civil society organizations joined to form a non-consensus dialogue process. What became known as the Crucible Group was galvanized by the approval of two 'species' patents – on soybeans and cotton – that appeared to grant exclusive monopoly control of the biotech development of the crops to Monsanto. The Group was also spurred into consultations by the seemingly uncontrolled acceptance of patents on genes and on indigenous knowledge. Civil Society Organizations warned that intellectual property regimes had become rudderless and ruthless and that there were no longer any 'rules of the game'. They argued that patents were no longer incentives to innovation but bargaining chips big firms used to trade turf among themselves and to exclude smaller enterprises. Patent litigation costs – then estimated at about US$225,000 per combatant – had turned intellectual property into a non-tariff barrier to market entry for smaller innovators. They speculated that if trends continued, we would see patents become stock market negotiable assets – possibly even develop their own 'trading floor' – and that the sacred embargoes against patents on pure science, methods of doing business, and mathematics would all erode.

In 1998, US courts confirmed that methods of doing business – specifically trading practices and investment strategies – were patentable. In effect, it is now possible to patent Wall Street. In 1999, a San Francisco-based investment bank announced plans to create a patent futures market by 'securitising' corporate patent portfolios and selling notes to investors. At the same time, a virtual trading floor in patent licences was created by Yet2.com so that companies such as 3M, Allied Signal, Boeing, Dow, Dupont, Ford, Honeywell, Polaroid, and Rockwell could 'exchange' patented technologies. Breaking the tradition that all inventors are created equal before the patent office, the Japanese government has announced plans to grant venture capitalists and major IP (intellectual property) investors 'various preferential treatments'.[43]

While the media have been mesmerized by the antics of dot com entrepreneurs like Amazon in trying to patent chunks of the Internet and its functions, the most amazing intellectual property claims have continued to come from the biotech industry.

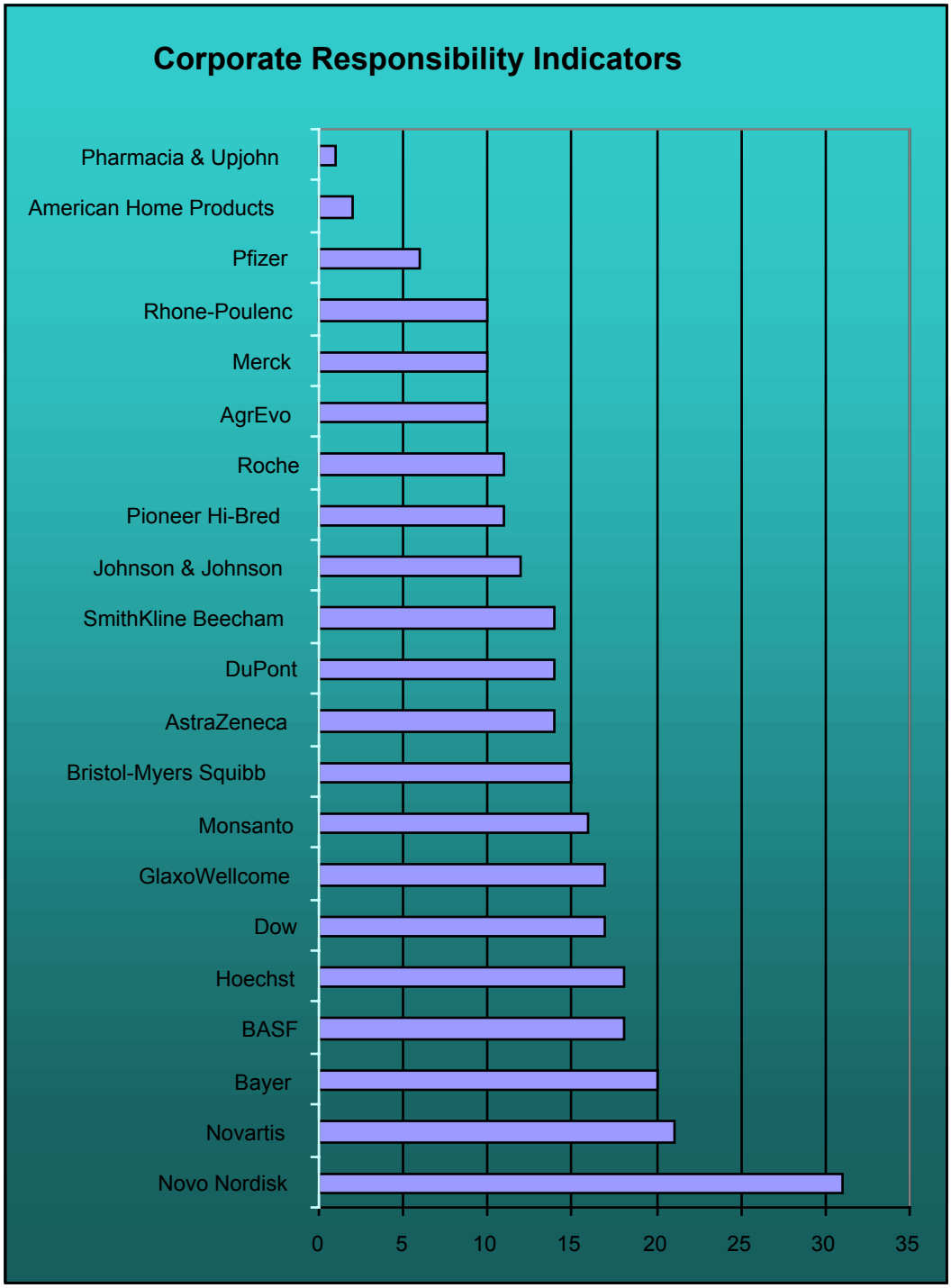
Some claims amount to 'driftnet' patenting. Not only in human DNA, but also in the rainforests, the fields, and the beaches of Canada's and the world's indigenous peoples, biotech companies are scavenging for unique (unpatented) diversity and placing claims on it without the slightest notion of how it might be useful – or how others have used it for thousands of years. At the end of

the 1990s, Heritage Seed Curators of Australia and RAFI identified 147 cases where patent or Plant Breeders' Rights claims had been made on plant material without apparent justification. Almost all the possible abuses identified were based on a search of the Australian records and amounted to at least 6% of all plant variety applications in that country since legislation first made such claims possible. Similar studies of plant claims in other countries – perhaps especially in New Zealand, Israel, South Africa, and the European side of the Mediterranean – would be likely to yield similar scandals.

In 1990, total revenues from patent licences amounted to US$15 billion. By 1998, licencing fees garnered US$100 billion, and some experts predict revenues of half a trillion dollars per annum by 2005. For the first time in economic history, patents are achieving a political profile their assignees could regret.

A recent independent British study of the global biotech industry has shown that the level of confidence in the leading companies is low. The following table indicates how the companies were assessed in total in 12 relevant policy areas.

Engaging Stakeholders: The Life Sciences Report, 2000
Life and Science: Accountability, Transparency, Citizenship, and Governance in the Life Sciences Sector;



Endnotes:

[1] *IBM news release*. "IBM announces $100 Million investment in the Life Sciences Revolution," August 16, 2000.
[2] Anonymous, "Patent Wars," *The Economist*, 8 April 2000.
[3] Aharonian, Greg. "PTO Gets 400,000 page biotech patent application," *Internet Patent News Service*, 23 February 2001.

[4] Ibid.

[6] Barton, John H., "Reforming the Patent System," *Science*, Volume 287, Number 5460, 1933-1934, March 17, 2000.
[7] Mullaney, Timothy J., and Spencer E. Ante, 'Info Wars', *Business Week*, June 5, 2000, p. 107.
[8] United Nations Development Programme, United Nations Human Development Report 1999, New York: Oxford University Press, July, 1999.
[9] Sub-Commission on Intellectual Property Rights and Human Rights, Commission on Human Rights, United Nations, "Resolution on Intellectual Property Rights and Human Rights," E/CN.4/Sub.2/2000/7, 17 August 2000.
[10] McNeil, D. "Oxfam Joins Campaign to Cut Drug Prices for Poor Nations," *New York Times*, 13 February 2001.
[11] Pollack, Andrew, "Bristol-Myers and Athersys Make Deal on Gene Patents", *New Yor*k *Times*, January 8, 2001

[12] Hord, Bill, "Food Industry Hungry for Biotech Tests Companies look for ways to quickly and accurately identify genetically altered crops", Omaha World-Herald, February 11, 2001,, Pg. 1m
[13] Reuters, "Argentina Uses Sputnik To Cut Farm Fraud ",1/9
[14] "GeneScan Europe AG And Motorola Establish Technical Collaboration To Detect Genetically Modified Crops" (SRC:PR Newswire -- ATH:)
[15] Meek, James ,"Genetic chickens get DNA copyright tag: Biotech firm plans to create strain with extra large breasts for more meat", The Guardian (London), July 31, 2000 Pg. 4

[16] "GENE BARRIER IN CORN MAY BOOST TRADE, ENVIRONMENT "
[17] *New Scientist*, 9 December, 2000, p.7.
[18] Dorris, Eva Ann. "Monsanto Contracts: To Sign or Not to Sign," *Mississippi Farmer*, December 1, 2000. The article can be found on the internet at: http://www.biotech-info.net/to_sign_or_not.html.
[19] Corrigan, Tracy, 'Cross-border M&A deals at record levels', *Financial Times*, April 5, 1999, p. 16. Actually, the article sets the figure for the first three months of 1999 at $855 billion – just under the global 2996 record but there is reason to believe that final adjustments will raise this figure slightly. The same article places the global M&A total in 1998 at $2.5 trillion. Both the *Financial Times* article and RAFI use, as a major source, the Securities Data website.
[20] *Our Creative Diversity* – Report of the World Commission on Culture and Development, UNESCO, 1995, p. 138.
[21] For a more complete discussion of the US and global merger environment in the 1974–97 time period, please see *Development Dialogue*, the journal of the Dag Hammarskjöld Foundation, Special Issue, 1998, '*The Parts of Life*', Chapter 7, 'Private Parts', pp. 134–7, by Pat Mooney of RAFI.
[22] *The Economist*, 'Business this week', July 8th 2000, p. 5.
[23] *Human Development Report,* UNDP, 1999, p. 67.
[24] *The Economist*, 'Business this week', July 8th 2000, p. 5.
[25] Pilling, David, and Michael, Adrian, 'Pfizer seals Warner-Lambert deal', *Financial Times*, February 8, 2000, (ft. com website feature business story).
[26] *The Economist*, 'Business this week', July 8th 2000, p. 5.
[27] 'Mergers and Alliances Hold My Hand', *The Economist*, 15 May 1999 (from the *Economist* website library).
[2828] Robert Paarlberg, "The Global Food Fight" *Foreign Affairs*, May/June, 2000, Vol. 79, No. 3, p. 35.
[29] . Robert Paarlberg, "The Global Food Fight" *Foreign Affairs*, May/June, 2000, Vol. 79, No. 3, p. 36
[30] Prof. Michael Lipton, Sussex, personal communication, June 23, 2000.

[31] Human Development Report 2000, *Human Rights and Human Development*, UNDP, New York, page 33, Figure 2.3.
[32] According to the Global Plan of Action for Plant Genetic Resources adopted in Leipzig in 1996, 1.4 billion people obtain their food from farmers who save seed.
[33] Alston, J.M., P.G. Pardey, and J. Roseboom, 1998. "Financing Agricultural Research: International Investment Patterns and Policy Perspectives". World Development Vol. 26, No. 6: 1057-1071.
[34] Alston, J.M., P.G. Pardey, and J. Roseboom, 1998.
[35] Alston, J.M., P.G. Pardey, and J. Roseboom, 1998, p. 1066.
[36] Personal communication from Meridiam Vonsultants, Washington DC.
[37] Torres, Fileman, Martin Pineiro, Eduardo Trigo, and Roberto Martinez Nogueira, *Agriculture in the Early XXI Century: Agrodiversity and Pluralism as a Contribution to Address Issues on Food Security, Poverty, and Natural Resource Conservation,* DRAFT, GFAR, Rome, April 2000, p.14.
[38] Eyal Press and Jennifer Washburn, "The Kept University," Atlantic Monthly, March, 2000, pp. 39-54.
[39] Mullaney, Timothy J. and Spencer E. Ante, "Info Wars", *Business Week*, June 5 2000, p.12.
[40] Human Development Report, UNDP, 1999, pp. 67 and 57 respectively.
[41] Human Development Report, UNDP, 1999, p. 68.
[42] Human Development Report 2000, *Human Rights and Human Development*, UNDP, 2000, Box 49, p. 84.
[43] Rivette, Kevin G. and David Kline, *Rembrandts in the Attic*, Garvard Business School Press, Boston, 2000, pp. 8–10.