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Hungry Corporations:

Transnational Biotech Companies Colonise the Food Chain

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Chapter 2:

Corporations: from Royal Charters to Biotech Gold Rush

2.1 A brief history of the corporation

> *By becoming a corporation, a business is given a distinct legal identity separate from the people that run it. The effect of this arrangement is to shield those who actually run the business from responsibility for their actions.*
>
> Dan Bennett, Helena Paul and Bill Bachle, *Who's in Charge?*[1]

The rise of the modern corporation, with its increasing freedom to operate and its lack of obligations, except to make profits, has helped to shape modern technology in general, and the development of genetic engineering in particular. Corporations were first created in Europe for charitable activities such as establishing hospitals during the medieval period of European history (eleventh–fifteenth centuries). They were meant to advance the public good and were non-profit making. However, the commercial corporation has become a very different entity.

During the medieval period in Europe, businesses typically operated as groups of people in partnership who shared the risks of an enterprise, which did not have a separate legal identity. During this period the restrictions on usury, or lending at interest, gradually broke down and the use of money was replacing payment in kind or barter of goods. Thus the conditions for the accumulation of capital were created. At the same time, the voyages of 'discovery' meant that new trade routes were being opened up, offering possibilities for the investment of capital for commercial enterprise. Towards the end of the sixteenth century, certain trade associations were granted royal charters of incorporation by the British Crown to act as not-for-profit corporations with a monopoly over a certain area of business.

The British East India Company was granted its royal charter by Queen Elizabeth I on 31 December 1600. Its members gradually put all their assets together until they became a single partnership, which owned the goods and assets (stock) jointly. This partnership then sold its stock to the East India Company itself and received in return a share in the Company. The Company traded their stock in its own name and the profits were distributed amongst the members, so creating the first for-profit corporation. This action was illegal but was not challenged at the time. The East India Company made immense profits and its 'vast expansion in India meant that it not only had a monopoly on trade but was also in charge of the army, the roads, food supply, in fact all the domestic and foreign powers of a government'.[2]

During the early eighteenth century, many new corporations were created which sought public investment to profit from the opening up of the British colonies around the world. One of these companies, the South Sea Company, attracted vast amounts of investment until confidence collapsed, and the stock market, which had been over-inflated by this 'South Sea Bubble', crashed. The UK government then passed the 1720 'Bubble Act' ostensibly designed to prevent the speculative buying and selling of shares and curb

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Benefiting the colonial powers

> By the East India Act of 1784 the [British] government assumed more direct responsibility for British activities in India, setting up a board of control for India. The company continued to control commercial policy and lesser administration, but the British government became increasingly the effective ruler of India. Parliamentary acts of 1813 and 1833 ended the company's trade monopoly. Finally, after the Indian Mutiny of 1857–58 the government assumed direct control, and the East India Company was dissolved.[3]

Colonial powers in general benefited from the activities of their trading companies and corporations by adding to their empire many of the territories formerly controlled by these companies. Examples for Britain are the East India Company, the Hudson Bay Company and the Africa Company.

fraudulent corporate activity. However, the government continued to borrow at interest from the East India and the South Sea companies for wars and other adventures, further fuelling the process of empire building and assisting the expansion of the national debt. During the nineteenth century, restrictions on corporate activities and rights were gradually lifted by the courts and by government, and corporations began to take on their current shape. They consolidated their legal status as individual persons, gradually assuming most of an actual human being's rights. However, unlike people, these corporate persons are potentially immortal, can merge with another corporate person, divide themselves into several persons, cannot be imprisoned, and have no feelings. During this same period, the liability of shareholders was gradually limited and they became the most privileged of all stakeholders. The Bubble Act was repealed in 1825. Previously limited by the charter under which they were created, the powers of corporations were gradually extended with the collusion of the courts, until the board of directors acquired total freedom to decide and to change the activities and objectives of the corporation without any public consultation. The creation of subsidiary companies also shields corporations from the consequences of their actions. This is achieved by ensuring that the subsidiaries carry out the activities of greatest risk but have no assets, while the parent corporation is merely a shareholder in the subsidiary and thus is not liable for its acts. In the event of any problem, the subsidiary simply folds and the parent is left unscathed because of 'the corporate veil' between parent and subsidiary. 'The consequences of granting freedoms to fictitious persons who existed only to make profits were never discussed.'[4] Finally, the Companies Act of 1989 abolished the right of 'anyone who isn't the corporation to challenge the right of the corporation to take various courses of action'.[5]

Although the American Revolution began as a rebellion against the British monarch and his corporations, with a number of corporate charters being revoked, a similar path was followed in the US, with judges steadily increasing corporate powers through landmark decisions in the courts.[6]

From colonial empire to corporate recolonisation

Since the Second World War, corporations have used events in the international political arena to further globalise their reach. These include the Cold War, and the dismantling of the colonial empires established by the British, French, Dutch, Portuguese, Spanish, Germans and other nations in the previous few centuries. They have also used the Bretton Woods institutions – the World Bank, the International Monetary Fund (IMF) and the General Agreement on Tariffs and Trade (GATT) – and the speculative financial markets. The World Trade Organisation (WTO), created out of the GATT in 1994, is a perfect vehicle for extending corporate rights. Unlike other international instruments, it has legislative and judicial powers that can be enforced against states through its complaints mechanism. Governments can use this procedure to force other governments to change laws and lower environmental and social standards in the interests of 'free trade'. Yet it does nothing to limit the ability of the transnationals to 'use their economic power to drive competitors out of the market by unfair means; absorb competitors through mergers and acquisitions; or form strategic alliances with competitors to share technology, production facilities, and markets'.[7]

Besides the WTO itself, free trade agreements are strongly promoted by the corporations. The North American Free Trade Agreement (NAFTA) was the first regional treaty, linking Mexico, Canada and the US. Bitterly opposed by indigenous and small-farmer communities in Mexico, it is seen by the corporate fraternity as a model to be replicated wherever possible, even though the impacts of NAFTA on jobs and the environment have already proved detrimental to ordinary people.

Recently, representatives from 34 countries have been working to expand NAFTA to Central America, South America and the Caribbean, in order to create the Free Trade Area of the Americas (FTAA).[8] Some have called this a smaller version of the Multilateral Agreement on Investment (MAI), which was defeated but nevertheless enunciated a principle too important to corporations to be dropped: the freedom to invest. There are other possible free trade configurations being discussed for the Americas. The African Growth and

Opportunity Act, passed in 2000 in the US, provides the basis for constructing free trade agreements within Africa, and the US is targeting the Southern African Customs Union of five countries as a first step (see Chapter 8). Agreements were signed in November 2002 regarding future free trade between the countries of the Association of South-East Asian Nations (ASEAN), China and Japan.[9] Following war in Iraq in 2003, President Bush announced proposals to create a free trade zone in the Middle East by 2013. There are also a number of bilateral free trade agreements, the majority of them between the US and other countries. These are but some of the initiatives being discussed or put into effect.

- **Getting intellectual property into the trade arena**

As we shall see later, the US administration decided to move the intellectual property debate out of the World Intellectual Property Organisation and into the trade arena, specifically the Uruguay Round of trade negotiations, which ended in 1994. The impact of this was enormous, especially since it made patent protection of microorganisms mandatory, without defining them, so providing the first international framework for patents on living organisms.

2.2 Factors in the growth of the biotechnology industry

> *What you are seeing is not just a consolidation of seed companies, it's really a consolidation of the entire food chain.*
>
> Robert Fraley, Executive Vice-President, Monsanto, 1996[10]

Just as the green revolution had its enabling context, so also does the gene revolution. The freeing up of the financial markets has played a vital role.

The tide of investment has ebbed and flowed massively in response to the promises of biotechnology and the tension between the need for quick returns as against the long period of time required to bring products to market. The extension of patents to living organisms and their parts was a crucial part of the gene revolution, assiduously lobbied for by the corporations in every available arena. Rapidly developing capacity in genomics led to a race between public and private domains to sequence the human genome and those of other organisms, including oilseed rape (canola) and rice.

The corporations involved have a number of different requirements, including the following:

- compliant financial markets, open to rapid movements of capital and speculative investment;
- access to cheap raw materials;
- methods of protecting intellectual capital and new products from competition, through intellectual property rights, especially patents;
- access to research through universities and independent research companies;
- infrastructure, such as roads, ports, airports, etc.;
- favourable regulations that do not impede the commercialisation of their products.

While they have been working on all these, corporations have continued to develop new technologies with great potential for opening up yet more new territories for corporate colonisation. When the interface with other emerging technologies is added, these territories expand as the elements involved become smaller and move into molecular and atomic levels of investigation. Nanotechnology involves the manipulation of matter at the quantum level – a nanometer is one billionth of a metre. The issues involved are beyond the scope of this book. However, there are two points to be made briefly here: the first is that as biotechnology meets with nanotechnology, informatics and the cognitive sciences, and combines with them, its own development will be profoundly influenced. The second is that development itself will increasingly be driven by these synergies. Development always has been driven by technology, although it is sometimes forgotten that this is the case. The accelerating emergence of new technologies means that human society is less and less able to internalise the implications and respond appropriately. The marketplace can respond without the impediment of ethics or precaution to dreams of vast profits and progress, and no-one wants to be left behind. In the end the key driving force for such development may simply be the technological change itself.

The financial markets – biotech bubbles

The financial markets were liberated from most constraints during the 1980s and 1990s. Capital, freed from all relation to locality, tends to flow to the area of least regulation, and moves at the speed of light. All the major corporations, bar Cargill, are publicly listed, which means they are financed by shareholders as well as bank loans. Winning investor confidence is fundamental to corporate strategy because their market value is determined not only by their assets, but also by the value of their shares.

At the moment, the biotech industry is largely based on a futures market. Investment is absorbed in R&D (research and development), public relations and advertising, and spectacular results are promised in the future. Currently there are more promises than products. This has caused enormous volatility in the market, with share prices soaring and crashing on the basis of rumours. There is also a strong incentive to 'talk up' the potential of products in development, so as to increase the share price. The story of British Biotech and Dr Andrew Millar is a case in point (see p. 27: 'British Biotech misleads investors').

Dr Alan Williams, a British Member of Parliament, said on behalf of the House of Commons Science and Technology Committee in August 1998:

> In an environment, such as the biotechnology industry, where subjective judgements and sentiment are so important in determining share price and company value, and where investors are to a large degree dependent upon the company to inform those judgements, accurate provision of information by the company is essential.[11]

Beyond all borders

Between the late 1970s and early 1997, 'investors have pumped approximately £40,000 million (US$60 billion) into biotechnology enterprises [not just genetic engineering] according to figures from international accounting firm, Ernst & Young'.[12] In 1996, then a record year for biotech investment, only 50 or so of these companies actually made a profit, and few generated significant revenues.[13] By 1997, there were 1,800 biotech research companies registered worldwide. In 2000, biotechnology as a whole raised $38 billion according to the BioIndustry Organisation (BIO, see Chapter 3) – a figure that dropped again to an estimated $11 billion in 2001.[14]

In 2000, with optimism at its height, one commentator wrote:

> This year, for the first time, the biotechnology industry became truly borderless. The trend has been building for several years, but it's reached major proportions by now. And it's far more than going global implies, for companies are not just setting up foreign subsidiaries to manage their clinical trials or market their products. They're also creating entirely new companies that are a synthesis of skills and expertise from many different areas of the world. Thanks in large part to the Internet and other high-tech means of communication and data exchange, these borderless firms have come close to transcending both time and distance.[15]

This faith in the power of new technologies and the buoyancy of the market in general meant that biotech shares rose above the level of the rest:

> In 2000, high-risk biotechnology stocks outperformed the overall market, fuelled by the promise of the mapping of the human genome. Now that the milestone has been reached, the sector has lost some of its spark since it became all too clear that it would be years before health care felt the impact of the research.[16]

British Biotech misleads investors

British Biotech was founded in 1986 and floated in 1992, becoming the first UK biotech company to be fully listed on the stock market. In May 1996 its shares exceeded 300 pence and the company was valued at £2 billion when two drugs in development – the cancer drug Marimastat and the pancreatitis drug Zacutex – were presented as potential multi-billion-dollar blockbuster drugs. To keep the investors interested, the company substantially overstated the performance of the drugs in its trials. In Spring 1998 this was disclosed to investors by British Biotech's head of clinical research, Dr Andrew Millar, which led to his dismissal. It came further to light that the US Securities and Exchange Commission was investigating British Biotech over allegations that it had issued misleading press releases in 1995 and 1996 about its new cancer drug.

> On 10 June 1999, the American Securities and Exchange Commission (SEC) found that it was in the public interest to impose a Cease and Desist Order on British Biotech and its ex-CEO Dr McCullagh, having found them guilty of violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1 and 13a-16 thereunder on no less than seven occasions by making false representations in Press Releases.[17]

With these events in the open, investors rapidly lost faith, shares plummeted and by July 1998 the company was worth less than £330 million.

In June 1999 the London Stock Exchange 'publicly censured British Biotech for a "most serious" case of misleading investors…. Lacking the power to fine British Biotech, an exchange spokesman said it was taking the strongest action it could short of delisting the shares.'[18]

And in the same month British Biotech announced that the dispute was settled with its former director of clinical research. It was stated in a press release that 'British Biotech have withdrawn their claims and allegations of improper behaviour and Dr Millar has agreed not to continue with his proceedings against British Biotech.'[19]

According to the Ernst and Young report 'Beyond Borders 2002', the global biotech industry in 2001 was

> comprised of 4,284 companies (622 public; 3,662 private) in 25 nations. The 622 public companies generated revenues of $35 billion, spent $16 billion in R&D and employed more than 188,000 people…. 72 per cent of the public company revenues were generated by companies in the US….[20]

The UK has developed a strong biotech research base – outperforming other European countries – due to a greater availability of risk capital in the City of London than in the rest of Europe. As John Hodgson explains,

> In 1992, with encouragement from British Biotech and other parts of the UK industry, the London Stock Exchange threw UK biotechnology a lifeline. It altered its listing rules in a way that allowed research-driven small companies to raise money through a public offering even though they had no history of revenues or profits.[21]

The largest shareholders in big corporations are almost always other companies. These might be other blue-chip corporations or financial institutions such as insurance companies, unit trusts or pension funds. Others are simply 'asset managers', whose job is to make as much profit as possible for the real owners of the money (frequently occupational pension schemes or local authorities) by investing it wherever it can generate the highest returns. This means that investment is increasingly removed from local knowledge and local control. It is not reinvested where it was generated, but flies through speculative virtual markets with no responsibilities attached. There are increasing calls for the localisation of production and investment and for ways to make it harder to externalise or transfer production and consumption costs, dumping them on others who did not generate them. There have also been calls for a tax on purely speculative activities in financial markets (one such proposal is known as the Tobin Tax) and for controls on transnational trade and investment, as well as for regulation to prevent global TNC monopolies.[22] None of these have yet been enacted.

2.3 The extension of patents to genes, cells and organisms

> *The most important publications for our researchers are not chemistry journals, but patent office journals around the world.*
>
> from the Hoechst website[23]

> *Today, the strength of a nation is measured not by the weapons it wields, but by the patents it produces.*
>
> Canadian Finance Minister Paul Martin, Budget speech, 2000

Patent law is typically explained as 'a compromise between preserving the incentive to create knowledge and the desirability of disseminating knowledge at little or no cost'.[24] The industrial revolution demonstrated the value of technology or innovation to national competitiveness, and, while not wanting to jeopardise access to new knowledge, states and industrial capital were interested in developing ways to profit from and control technological developments. Patents were a logical choice. They give inventors exclusive rights to their inventions for a limited period of time (usually 20 years) and, in exchange, patent holders must disclose their inventions to the public. In this way, innovation expands, knowledge is diffused and, so the argument goes, the public good is maximised.

Since the late nineteenth century, patents have been an integral part of industrial capitalist economies. But there is no inherent connection between Western industrial development and patent protection. Indeed, there is a basic contradiction between monopoly rights and the free market and, at a practical level, there is little evidence that patents increase investment in R&D.[25] Not that patents are a neutral force. Patents play a major role in determining the context through which innovation occurs and the forms that innovation takes. Patents are based on a narrow, romantic interpretation of innovation, as carried out by author-entrepreneurs – people like Thomas Edison, working in isolation to develop original ideas for profit.[26] In reality, innovation is most often a collective, incremental process, where people build on the knowledge and work of others for a wide range of motivations. This is particularly true of crop development. Any 'new' plant variety is merely a variant of its parents, which were typically developed through careful selection by generations of farmers. Patents are inappropriate in this context, and efforts to bring crop development under patent law have much more to do with the interests of certain actors than with increasing overall innovation.

The corporate push for patents on plants

For practical reasons, plants and animals were not considered for inclusion when the international patent regime was consolidated at the end of the nineteenth century. Even as capital investment in the seed industry increased in the first half of the twentieth century, patent lawyers and officials refused to open most Patent Acts up to living organisms, fearing that it might dilute the entire patent system.[27] The seed industry had other, biological options.

In the 1920s and 1930s the American seed industry began a programme to develop hybrid maize. While the agronomic advantages of hybrids are debatable, the advantage to the seed industry is clear: to produce hybrid seeds (F1) two specific and distinct parental lines are needed. Thus hybrids can only be reproduced by the breeder; replanting saved seeds (F2) is of little use as they will not grow into a crop resembling the previous hybrid plants but rather perform in an irregular and unpredictable way.[28] Hybrids thus force farmers to buy seed every year and prevent other breeders from using the varieties in their own breeding programmes. This built-in 'patent' protection attracted enormous interest from the seed industry, which had the full-fledged support of the Secretary of the US Department of Agriculture, who also happened to be the president of Pioneer, one of the leading maize (corn) seed companies in the US. Hybrids brought big rewards for business, generating revenues of $60–$70 million by 1944, but the gains for the overall public good were less clear: yields for wheat, a crop with no biological patent protection and with little investment from the private sector, increased twice as much as yields for maize in the US between 1920 and 1945.[29]

As it was too expensive and difficult to develop hybrids for most major agricultural crops, the seed industry continued to pursue legal intellectual property protection for plant varieties. Frustrated in its attempts to enter the patent system, it put forward a separate system of legal protection. In 1961, several European countries agreed to a minimum set of standards for the protection of plant varieties that they would implement in their own countries. This convention, known as the international Union for the Protection of New Varieties of Plants (UPOV), led to the establishment of separate legal systems for the property rights of plant breeders.

The criteria for plant breeders' rights (PBRs) are less demanding than those for patents, but the scope of protection is also narrower. 'Patents protect the inventor against all unauthorised commercial use of the invention; a PBR certificate entitles the breeder only to prevent unauthorised commercial propagation of plant varieties.'[30] Similar legislation was introduced in the US in 1970 and 51 countries are now party to UPOV.

The seed industry has never abandoned its objective of full-scale patent rights, and UPOV itself has moved closer and closer to such rights. Under the latest version of UPOV, drawn up in 1991, farmers are prohibited from saving seeds except under highly restricted conditions. And, in the US, new plant varieties can now be patented. Moreover, even in countries where patents are not issued for plant varieties, the seed industry has taken out patents on genes that establish patent-like rights over genetically engineered varieties.

The patent trap

Under the Trade-related Intellectual Property Rights (TRIPS) agreement of the WTO, member countries must provide for patent rights on microorganisms. The term 'micro-organism' is not defined and many patent offices have determined this provision to include patents on genes and DNA sequences. In Canada, for example, Monsanto owns the patent rights to the gene construct genetically engineered into canola (oilseed rape) to give it resistance to the herbicide glyphosate. Monsanto claims that this gives it patent rights over any plant variety containing this patented gene construct, even if the genes arrive in a farmer's canola fields through cross-pollination. In March 2001, the Federal Court of Canada ruled that Saskatchewan farmer Percy Schmeiser had violated Monsanto's patent by growing canola containing the patented genes, even if it was true that the gene had arrived in his crop through cross-pollination, as he alleged, making him in effect guilty of violation through being contaminated.[31] Such contamination is now becoming widespread. Lyle Friesen, a researcher at the University of Manitoba who studied seed lot samples of canola, claims that 'you would have a RoundUp-resistant plant every couple of square yards' in canola crops not planted with RoundUp Ready canola.[32] US farmers have the same problem and face similar legal sanctions, as would any farmer in a country that implements US-style patent law.

Such patents have generated a climate of fear among farmers. Plant breeders' rights, patents, and the notorious growers' contracts are forcing farmers to abandon their age-old practices of seed saving, sharing and selling. No farmer wants to risk a major lawsuit by attracting the attention of the private detectives that now police the countryside for the seed companies. For many farmers, the only way out is to grow the patented genetically engineered crops and abide by the contracts.

Patents have obvious repercussions for farmer seed selection and breeding practices, which still constitute the most important sources of plant varieties in the world, especially in the South. But the push for patents on plants and their DNA is also causing havoc among public breeders. Three-quarters of the patents on agricultural biotechnology in the world are controlled

by six companies. Often these patents are broad patents that have a crippling effect on any research in closely related areas. In 1994 the company Agracetus was awarded a European patent (EP 301749) (American patent in 1991 – US 5015580) which covered all GM soybeans using a specific method of gene transfer. Rival companies, including Monsanto, were outraged, saying that it would result in just one company having an effective monopoly over all transgenic soybeans. Monsanto's solution was to buy the company and drop the complaint. Monsanto also holds a patent in both Europe and the US on all genetically engineered cotton (EP 270355 and US 5,159,135). PGS – a biotech company now owned by Bayer CropScience – has been granted a broad patent in the US for genetically engineered plants containing an insecticidal Bt toxin (US-5,460,963 for Bt4 and Bt18, for example, or US-5,633,446 for any Bt toxin modified in a specific way).

Researchers seeking to develop crops through biotechnology encounter labyrinths of interconnected patents blocking their way. The public researchers who developed Golden Rice claimed that the 70-odd patents involved in the GM rice forced them to sell the rights for it to Syngenta. Even research on non-transgenic crops can be derailed by intellectual property rights. In 1999 Steven Price, a plant breeder with the University of Wisconsin, sent out a survey to 187 public breeders in the US asking them about difficulties they might be having in obtaining genetic stocks from private companies. Forty-eight percent of those who responded said that they had had difficulties obtaining genetic stock from companies; 45 per cent said it interfered with their research; and 28 per cent said that it interfered with their ability to release new varieties.[33] Public researchers are beginning to realise that such restrictions are about to get much worse.

Most breeding programmes, public or private, now routinely use molecular marker techniques to speed up the breeding process. These markers allow breeders to identify whether the traits that they seek have been incorporated into their crosses, thereby speeding up the breeding process. However, many of the most important markers that are discovered are patented and the traits that they identify are also being patented. On 30 September 1999 Monsanto filed a patent in 81 countries on soybeans with enhanced yield (WO-0018963). That patent has already been issued in Australia (AU6277599). It covers any cultivated soybean containing certain genes or segments of DNA from 'wild' or 'exotic' soybeans identified through molecular marker techniques. The group of genes, which is only vaguely defined, is said to be responsible for enhanced yield. Not only does the patent claim an important trait in soybean breeding, but it also gives Monsanto monopoly rights on *Glycine soja* (wild soybean), particularly PI407305 from southern China and all its progeny. Further, the patent extends to any soybean carrying the yield genes.

The push for patents on plants and their parts is extending corporate control over agricultural R&D. It is also linked to the decline of cooperative and collaborative work between different research groups and a breakdown in open communication in the scientific community. Jonathan King, Professor of Biology at the MIT, USA, in oral evidence to the Royal Commission in New Zealand in 2001, stated:

> I'd like to clarify two further points. Patent lawyers often speak about how patents require the revealing of the information. In the area of modern biological research this profoundly misrepresents the actual use of patents. In the normal course of modern biological research, scientists are striving to publish and reveal their results; this is their stock and trade in currency. The intervention of the patent system reverses that.
>
> Patent law requires that the subject of the patent, if it's been previously revealed, that is it becomes prior art, then the patent would be disallowed. Thus oral reports, abstracts, grant proposals, public papers all constitute prior art. As a result individuals or groups planning to file for a patent have to avoid public disclosure of their work prior to the filing of a patent claim. Patent attorneys regularly advise researchers to restrict their presentations to colleagues, don't show your work, don't show your notebook, don't give that talk, so as not to jeopardise the planned patent submissions.
>
> This has reversed the half-century culture of free and open communication in the scientific communities.[34]

Unfortunately, few public researchers are raising objections, deciding instead to jump aboard the corporate bandwagon, especially since funding may depend on whether a 'result' might be patentable. There are already instances of researchers developing complicated techniques in genetic engineering to give plants certain traits, when such plants could be produced through conventional means.[35] Areas of research that cannot be controlled through patents are neglected by the private sector and many public institutions that are now pursuing partnerships with private companies. For example, in October 2002 the Consultative Group for International Agricultural Research (CGIAR), perhaps the most influential noncommercial research organisation operating in the South, announced that the Syngenta Foundation was now an official member, joining 46 member countries and three other member foundations.

Essential conditions for countries to profit from patents

Commentators agree that certain conditions are essential for operating a successful patent system. These include facilities for high technology research, active investors, an efficient patent office, trained patent examiners and lawyers, and an effective judicial system. Many Southern countries can satisfy none of these conditions. Operating in the patent world can be extremely expensive. Some have unkindly said that the legal complexities are even more formidable than the scientific complexities. Many countries of the South are faced with trying to bridge a wide gap in time and capacity before they have established the conditions that would enable them to benefit from patents. Meanwhile they will experience a huge outflow of resources in the form of royalty payments and the patenting of their natural and intellectual resources and knowledge by developed countries and their corporations.[36]

Trade-related Intellectual Property Rights (TRIPs) agreement

The pharmaceutical lobby has close connections with the US government. In 1981 US President Reagan appointed Ed Pratt, the chief executive of pharmaceutical giant Pfizer Inc., to head the United States' top private sector trade advisory panel.[37] Gerald Mossinghoff was Reagan's Assistant Secretary of Commerce and Commissioner of Patents and Trademarks until 1985 when he became President of the Pharmaceutical Manufacturers Association, the world's most important pharmaceutical lobby.[38] According to Mossinghoff

> There was a lot of frustration during negotiations about intellectual property matters. As the US ambassador to the diplomatic conference of the World Intellectual Property Office, I personally felt this frustration because I was representing the United States of America – the wealthiest, most powerful, biggest free market in the world – and I had just one vote. As a result, the Reagan administration decided to move these intellectual property negotiations out of WIPO [the World Intellectual Property Organisation] and into the trade world.[39]

Results came swiftly, as Tony Clarke explains:

> It is well known that the Intellectual Property Rights Committee, composed of 13 leading US corporations (for example, Bristol Myers Squibb, DuPont, Pfizer, Monsanto, and General Motors) effectively wrote, word for word, the TRIPS agreement that was adopted at the Uruguay Round of the GATT negotiations and subsequently became part of the WTO body of rules.[40]

Compulsory for all WTO member countries, TRIPS was a big victory for the biotech industry. It consolidated corporate power over information and extended intellectual property rights (IPRs/patents) to cover genetic material, including seeds, plants, animals and the genes and cells of all species, including humans. In agricultural biotechnology, the top six corporations control 74 per cent of all agricultural biotechnology patents, and five corporations control 70 per cent of all patents on genes for wheat and 47 per cent of all patents on genes for sorghum.[41] Patent protection and the move to genetic engineering give the biotech corporations unprecedented control over research and development, which has traditionally been the domain of farmers and public scientists. Together patents and genetic engineering provide the instruments for transnational corporations to gain control over agriculture and the food chain.

A response from Africa – the Africa position on TRIPs

In 1999, the part of the TRIPs agreement that explicitly extended patents to cover living organisms – Article 27.3(b), Protection Of Plant Varieties –was meant to be reviewed, as mandated during the original negotiations. There were arguments over the scope of such a review process and some countries were afraid of emerging with a worse situation than before. A group of African countries produced a strong statement setting out their fundamental difficulties with the article. After calling for developing countries to be given more time to consider the implications of implementing TRIPs, they made a number of recommendations.[42]

The African group insisted that countries should be allowed to meet their obligations under other international treaties, especially the Convention on Biological Diversity (see Chapter 6), which gives a country the right to prior informed consent about access to and use of its genetic resources (including benefit sharing), and the International Undertaking, now the Treaty on Plant Genetic Resources (see Chapter 5). They called for the wording of TRIPs to be changed to recognise explicitly the right of countries to 'satisfy their need to protect the knowledge and innovations in farming, agriculture and health and medical care of indigenous people and local communities'. They also called for food sovereignty, plus the right of farmers to save and exchange their seed and sell their harvest, to be enshrined in a revised TRIPs agreement. They pointed out serious inconsistencies in the agreement arising from the fact that, while plants and animals could be excluded from patenting, micro-organisms could not. And they demanded that

> The review process should clarify that plants and animals as well as microorganisms and all other living organisms and their parts cannot be patented, and that natural processes that produce

plants, animals and other living organisms should also not be patentable.

The Africa statement still represents the core position of the South in the face of the onslaught from the North for IPR/patent protection to be extended to living organisms. Neither Article 27.3b nor the agreement as a whole have been revised. However, the US has led the push for bilateral agreements that go beyond TRIPs and the fight may be shifting away from the trade arena to WIPO.

Pushing for a world patent system

The TRIPs agreement set a basic framework for intellectual property protection. However, protection worldwide remains a mosaic, with different rules and frameworks in each country and wide differences between the levels of protection in North and South. There is also an increasing backlog of patent applications awaiting examination, increasing the length of time it takes to process a patent. Industry would prefer a simplified system, set at the highest level of property rights protection (the US level) that would cover all countries, speed up the granting of patent rights and remove the need to make separate applications in different jurisdictions. The dream scenario for the biotech industry would be a uniform set of procedures across the globe, with a single patent application giving global cover. WIPO is mandated to promote intellectual property protection. As we saw above, the Reagan administration moved negotiations away from WIPO to the trade arena, but it could become the focus once more, this time for attempts at 'harmonisation' of patent law.

The Patent Cooperation Treaty (PCT) came into force in 1970 and is currently being reformed. Besides being an important source of revenue for WIPO, it provides a common international facility for the preliminary examination of an application, to establish whether or not it is valid, before proceeding to make national applications. Reform of the PCT could involve pressure for the grant of world patents.

In 2000, WIPO members adopted the Patent Law Treaty, which has yet to come into force. It is designed to harmonise procedures for patent applications. Countries then moved on to consider a Substantive Patent Law Treaty (SPLT), which would further harmonise and tighten patent law. The US is prepared to give up its principle of 'first to invent' and adopt the more general 'first to file' principle if the SPLT follows US patent law in other important ways, such as allowing the patenting of 'business methods'. The US and industry also want to ensure that, under the SPLT, countries would not be allowed to exempt plants and animals from patenting, while Europe and the countries of South oppose this. Some countries (Brazil, Peru) have also indicated their refusal to cooperate with SPLT unless prior informed consent and disclosure of the country of origin of the material to be patented are made part of the regime. This has been rejected by the North and by industry.

If SPLT were adopted, it could perhaps supersede TRIPs itself. Certainly, a harmonised global patent system would remove the ability of countries to use patent regimes as a tool for development. It would totally undercut Southern country attempts to build capacity in this field, reducing many of them to mere observers rather than players in the increasingly important intellectual property (IP) arena.[43]

2.4 'Independent' research companies

In the late 1970s only a few biotech companies existed in the USA. By 1997 there were around 1,800 worldwide. The excitement about biotechnology from the mid-1990s onwards led to a proliferation of companies. These new ventures could not operate in isolation, as they needed to attract both public and private investment for expensive research. This was one reason why many independent research companies were bought up by the corporations:

> Biotechnology research was initially conducted by small specialised industry 'boutiques', hatched out of the basement labs of moonlighting university scientists with supplementary cash from the big corporations who were unwilling to invest their own research programmes … in what was undoubtedly a high-risk endeavour. As the science has developed and the risk receded, however, the big players have moved in, picked up their options, and now dominate the high-tech field.[44]

Genentech, founded in 1976 by Stanford University geneticist Herbert Boyer and the entrepreneur Robert Swanson, was the first biotech company to go public. It raised $39 million in its initial public offering in 1980. More significantly, perhaps, on its first day of trading Genentech's share price climbed from $35 a share to a high of $89. This raised not only money for one company, but investor and public awareness of biotechnology in general. After successfully bringing two new drugs to market, Genentech shocked the biotech world in 1990 by allowing Swiss multinational, Hoffman–La Roche to acquire a controlling stake. Whilst it was spending vast sums on R&D, its products were not raising enough revenue and it had no new products coming through. The Roche buy-out left many people asking: 'If Genentech can't make it on its own,

who can?'[45] The same fate befell successful independent agribiotech research companies such as Calgene and Mycogen, now owned by Monsanto and Dow respectively.

In general, it suited the big corporations for initial research to be carried out in universities, research institutes and independent companies. If they liked what they saw, they could always take over, once the groundwork had been done. This way they limited their own risk and could reap the benefits. With universities becoming more dependent on corporate funding, as research became more expensive, they could more easily be persuaded to respond to corporate priorities. Increasingly, they have been willing to underwrite contracts that either allow the corporations ownership of resulting IPRs/patents, or make them sole licence holders. In addition, universities themselves are becoming active pursuers of patents in the hope of increasing their incomes.

Many of the small private biotech firms found it difficult to survive.[46] Often the only way to do so was by licensing their patented technologies to bigger corporations. The university spin-off companies had more stability, as they often benefited from direct public subsidies and access to the resources and students of the universities. One way to remain independent was to focus on specific areas of genetic research, such as bioprospecting, writing software or carrying out genomics research, or on a particular technology such as vaccine-producing crops. According to Roger Wyse, a venture capitalist at Burrill and Co., agricultural biotechnology firms have had to deal with the same problems over patent rights and product development as their counterparts in pharmaceuticals, but with far less investor interest. In 2000, according to Burrill and Co, the number of medical biotech firms rose by 58 per cent, compared with a fall of 11 per cent for agbiotech firms.[47]

2.5 A new gold rush: the run on genes and genomes

Genomics is the study of genes and their functions within an organism, and includes the sequencing of whole genomes (the complete genetic information of one species). Such knowledge is valued for its potential to enhance conventional practices of crop and livestock breeding. However, if the function of a gene has a potential application, a company will file a patent. Ownership and profit from identifying specific genes has over the years been determined at least partly by access to gene sequencing equipment, largely owned by corporations and specialist research companies.

Five pesticide companies – DuPont, Syngenta, Aventis (now Bayer CropScience), Monsanto and Dow – controlled 71 per cent of all patents on agricultural biotechnology by 2000.[48] Through patenting genes, these corporations are privatising valuable information and plant varieties that have been developed through generations of farmer selection. This they justify on the grounds of recouping R&D costs when products developed from these patents finally come to market. However, it also helps them control the direction of plant breeding, develop new products that suit their commercial aims and prevent others from using the genes.

The race for the rice genome

Whilst most of the public interest around genomics research has focused on mapping the human genome, there has been a race for the genes and the genomes of major crops such as rice.

Ed Kaleikau, director of the plants division at the US Department of Agriculture, stated in 2002:

> Rice is a model for all cereal plants … [Its sequencing] will lead to the identification of genes important not only in rice but in other cereals. Eventually it will lead to a better understanding of rice and all cereal crops including wheat, barley, and corn – for ag[riculturally]-important plants, this could be compared to the [sequencing of the] human genome….[49]

Concerning this sequencing of the rice genome the National Center for Biotechnology Information (NCBI) stated on its website in 2002:

> There is a publicly funded effort and there is a commercially funded effort. The first commercial effort, by Monsanto, resulted in a database[50] of genomic sequence and SSR [simple sequence repeat] objects. The genomic sequence has been shared with the International Rice Genome Sequencing Project members. The second commercial effort, a collaboration between Myriad Genetics[51] and Syngenta,[52] has allegedly completed the genomic sequence. This effort has entered no sequence into the public domain.[53]

When Syngenta AG and Myriad Genetics Inc. announced the mapping of the rice genome in February 2001, the FAO declared that 'this was a breakthrough to increasing the productivity and nutritional value of rice, a staple for more than half the world's people'.[54] This statement reflects once again a narrowly focused faith in genes to improve food security and diets.

Furthermore, it avoids drawing attention to the fact that the completed genome map is being held in the private and corporate domain and that IPRs will allow Syngenta to benefit from any applications derived from the sequencing information.

The publicly funded International Rice Sequencing Group (IRGSP) announced in December 2001 that it intended to complete the high-quality draft of the rice genome by December 2002.[55] On 18 December 2002 a press release announced the completion of this draft for the *japonica* subspecies of rice that is cultivated in Japan, South Korea and the United States. The final, 'finished' genome sequence is now expected to be completed by 2005.

The focus so far has been on the *japonica* strain of rice (*Oryza sativa japonica)*. Chinese researchers announced in early 2002 that they had sequenced the *indica* rice strain, the one most commonly used in China, India and other countries. It is said that the information, once finalised, will be made completely available with no strings attached.[56]

The Monsanto rice genome sequence site ceased operations on 30 December 2002. Monsanto stated that owing to accelerated progress of the public sequencing project, 'the unique role that the Monsanto rice genome site played in support of public research is no longer needed'.[57] Monsanto claims further that 'more than 90 per cent of the sequences contained in the Monsanto draft rice genome sequence data can now also be found in public databases'.

Myriad, Syngenta and the rice genome

In 2002, Myriad stated on its website:

Myriad and Syngenta make the rice genome publicly available through collaboration agreements. Application information is available on the Syngenta website, www.nadii.com. Collaboration proposals are evaluated bimonthly. Criteria for evaluation include scientific significance and potential for social benefit.

Myriad and TMRI [Torrey Mesa Research Institute – a subsidiary of Syngenta] will seek patent protection for inventions relating to specific gene uses that result from this project. In some cases, these inventions will include the composition of a gene.

The sequence generated by this project will be made available to researchers via a genome technology access agreement.[58]

Other genomes

The first genome of a higher organism (eukaryote) to be sequenced was that of the yeast *Saccharomyces cerevisiae* (1997), followed by the nematode worm *Caenorhabditis elegans* (December 1998), the fruitfly *Drosophila melanogaster* (2000) and the Thale cress *Arabidopsis thaliana* (December 2000). The sequencing of the human genome was announced in 2001 and that of the mouse genome in November 2002. There are still very few complete genome sequences available. Translation of the sequence data into profitable applications is still seen to be a long way off.

Knowing the sequence of a gene is one thing, but knowing how this gene functions and interacts as an integral part of an organism is quite another. It is the product of a gene, a protein, that is usually of interest, yet little is known of how most proteins interact. Thus a new branch of science is developing, termed *proteomics*, which involves studying protein–protein interactions. Its stated goal is the identification and characterisation of complete sets of proteins. The study of *proteomes*, an organism's total set of proteins, is now overtaking the race to acquire and sequence genomes, an organism's total set of genetic information.

As organisers for a proteomics conference stated: 'There is growing recognition that one of the key ways in which companies are going to obtain maximum return on their investment in genomics is to include strong capabilities in the field of proteomics.'[59]

The human genome

In 2000 the exuberance that surrounded the race to complete the human genome led to a rapid rise in biotech stocks. This was mainly fuelled by the belief of investors that exciting new drugs, crops and other products were only a few years away. In a year in which the NASDAQ index posted its worst performance ever, with Internet and hi-tech stocks plummeting, the biotech index rose 15 per cent. In 2001, however, the biotech index began the year by losing 25 per cent of its value, prompting fears of a bursting bubble in the sector. Investors feared that genomics would not speed up the discovery and development of drugs or bring products to the market as quickly as expected. Genentech's chief executive Arthur Levinson warned investors that the sequencing would not translate into shorter development time for new drugs.[60] No matter how promising, potential drugs still must be tested in laboratories and human clinical trials; regulatory procedures continue to be burdensome. This market anxiety was reflected in the response to announcements by Celera Genomics in 2000 and 2001. In February 2000 Celera announced that it was entering the final phase of its genome sequencing. In response the market soared by 30 per

cent. However, when in February 2001 Celera announced that it had published the map of the human genome, the market rose by only 17 per cent.

The publication of the human genome was not the great triumph that the life science industry had expected. Instead – as pointed out in a recent article by Barry Commoner, a senior scientist at the Center for the Biology of Natural Systems at Queens College, New York – the publication of the complete human genome put to rest the 'central dogma' of molecular biology and the biotech enterprise: the assumption 'that an organism's genome (its total complement of DNA genes) should fully account for its characteristic assemblage of inherited traits'.[61] To the astonishment of the genomics industry and scientists, there were far fewer genes than would be necessary to account for the entirety of human proteins and traits.[62] Out of at least 100,000 genes predicted the actual gene count was only about 30,000. The assumed correlation between genes and traits appears to be spurious, bringing the foundations of genetic engineering and the biotech industry into doubt.

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