INTELLECTUAL PROPERTY, CORPORATE STRATEGY, GLOBALISATION: TRIPS IN CONTEXT

PETER DRAHOS* AND JOHN BRAITHWAITE**

The Agreement on-Trade-Related Aspects of Intellectual Property Rights (TRIPS) is probably the most important international intellectual agreement that was signed in the 20th century. It has also become the most controversial. There are three broad lines of criticism aimed at it. First is that it was the product of duress by powerful states against weak states rather than a bargain struck by sovereign equals.[1] The second line of criticism is that it is part of a hard bargain in which developing states received very few reciprocal gains.[2] A third category of criticism focuses on the adverse consequences for developing countries of implementing the agreement.[3] The debate over the impact of TRIPS standards on access to vital medicines is one example of this type of criticism.[4]

In each of these cases of criticism, certain business organisations and multinational companies are implicated. For example, the use by the U.S. of its trade enforcement mechanisms (section 301 of its Trade Act of 1974 and the Generalized System of Preferences under Title V of that Act) against developing countries was triggered in many cases by petitions by U.S. companies or business organisations.[5] Similarly, the economic gains of the standards contained in TRIPS are most likely to be captured by companies committed to radical innovation and with large economies of scale.[6] Not many countries in the world have robust valleys of innovation like Silicon Valley and so the benefits of TRIPS remain something of a

* Professor, RegNet, Law Program, Research School of Social Sciences, Australian National University, Canberra, ACT 0200, Australia.

** Professor, RegNet, Law Program, Research School of Social Sciences, Australian National University, Canberra, ACT 0200, Australia.

1 This is described by Peter Gerhart as the "coercion story". *See* Peter M. Gerhart, *Reflections: Beyond Compliance Theory – TRIPS as a Substantive Issue*, 32 CASE W. RES. J. INT'L L. 357, 368-370 (2000).

2 Indian commentators have developed this line of criticism especially. *See* VR Krishna Iyer et al., *Peoples' Commission On GATT*, Centre for Study of Global Trade System and Development (New Delhi, 1996).

3 For a general discussion of costs and benefits, see *The TRIPS Agreement and Developing Countries*, UNCTAD, United Nations, New York and Geneva, 1996.

4 NGO Actors such as the James Love of the Consumer Project on Technology, MSF and Oxfam have done the most to gather the evidence and develop this line of criticism.

5 By way of example, the section 301 action initiated by the USTR against Brazil in 1987 was in response to a petition brought by the Pharmaceutical Manufacturers Association (PMA). The PMA also filed a petition in 1988 against Argentina on the issue of patent protection that triggered an USTR investigation. The details of these and other petitions are available from the USTR website, *at* http://www.ustr.gov.

6 *See* Table 1, Estimates of Impacts of TRIPS Patent Changes on International Flows of Economic Activity for Selected Countries (millions of 1995 dollars), *in* Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 32 CASE W. RES. J.INT'L L. 471, 503 (2000).

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distant promise to them. There is also a growing body of literature that documents the role of private sector actors in shaping TRIPS.[7]

The purpose of this paper is not to trace the genesis of TRIPS, but rather to locate it within the context of strategic firm behaviour and the evolution of institutions. One advantage of doing this, it will be seen, is that the problems of access to medicines raised by the patent system are part of a deeper historical pattern of behaviour by firms that have been and remain heavy repeat players in the patent system. The patent system has delivered massive rewards to these firms. As a result they have had incentive, as well as the power, to reshape that system in their own interests. If public policy makers do not address this pattern of firm behaviour, international crises of access to technology will continue to repeat themselves. As we will see, the present crisis of access to AIDS drugs is not the first time that the patent system has been causally implicated in creating problems of international access to essential medicines.

The paper is divided in the following way: Part I describes the emergence of global knowledge firms in the chemical and pharmaceutical industry and the way in which their strategic use of the patent system evolved. Part II describes the role of the patent profession in the development of this strategy. Part III draws attention to the historical problems of cartels in the chemical and pharmaceutical industries. Part IV shows how the progressive transformation of the patent system by private actors has seen it become more and more isolated as a social institution. Part V argues that the reform of national patent regulation is vital and suggests some lines of reform.

I. GLOBAL KNOWLEDGE FIRMS

Many of the companies on Fortune magazine's leaderboard of the world's largest industrial enterprises have a history stretching back to the

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[7] *See, eg.*, Peter Drahos, *Global Property Rights in Information: The Story of TRIPS at the GATT*, 13 PROMETHEUS 6 (1995); Susan K. Sell, *Intellectual property protection and antitrust in the developing world: crisis, coercion, and choice*, 49 INT'L ORG. 315 (1995); MICHAEL RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY (The Brookings Institution, Washington, 1998). There is a growing body of literature on the negotiations themselves. *See, eg.*, Julie. C Ross & Jessica A. Wasserman, *Trade-Related Aspects of Intellectual Property Rights, in* TERENCE P. STEWART (ED.), 2 THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY (1986-1992) 2241 (1993); DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (1998); JACQUES J. GORLIN, AN ANALYSIS OF THE PHARMACEUTICAL-RELATED PROVISIONS OF THE WTO TRIPS (INTELLECTUAL PROPERTY AGREEMENT) (INTELLECTUAL PROPERTY INSTITUTE, 1999); JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES, OUP (NEW DELHI, 2001).

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beginning of the 20th century and in some cases further. When in 1905 three cousins of the DuPont family consolidated the US explosives industry under the Executive Committee of the E.I. DuPont de Nemours Powder Company, the DuPont company had already been in existence as a family firm for one hundred years.[8] The Computing Tabulating and Recording Company (CTR), which was renamed International Business Machines (IBM) in 1924 by its Chairman Thomas Watson had been founded in 1896 by Herman Hollerith, an engineer and inventor of a system of punch cards for the taking of census data.[9] Hollerith had called the company the Tabulating Machine Company and sold it in 1911 to Charles Flint, a financier who renamed it CTR.

Some of these companies became what in modern parlance is called a 'knowledge creating company.'[10] This referred to not the creation of knowledge for its own sake, but rather for the purpose of developing new products or improving existing ones. Research was seen as a vital way of protecting or expanding a company. These early corporations organized themselves to create knowledge by means of industrial research laboratories. The laboratories were large-scale affairs. It was the inventor Thomas Edison who provided the model that the corporate giants of the 20th century were to follow. In 1876, Edison built a laboratory at Menlo Park in New Jersey, staffing it with large numbers of scientists and tradesmen to work on a multitude of projects. Far from being the lone inventor, Edison in fact managed an 'invention factory.'[11] Its production goal was to produce "a minor invention every ten days, and a big one every six months or so."[12] It was the best-equipped facility of its kind in the U.S. There were other examples of the importance of research laboratories to industrial supremacy. The domination by Germany of the international chemical industry in the 19th century and into the 20th was built on an infrastructure of highly organized industrial research. The Germans had realized that nature would only give up its chemical secrets under a collective systematic assault by large groups of scientists. The sheer number of tests required, for example, to find a successful dye meant the lone inventor had little chance of making discoveries of industrial interest. Once the knowledge had been discovered,

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[8] DAVID A. HOUNSHELL & JOHN KENLY SMITH, JR., SCIENCE AND CORPORATE STRATEGY: DUPONT R&D, 1902-1980 11 (1988).

[9] DAVID MERCER, IBM: HOW THE WORLD'S MOST SUCCESSFUL CORPORATION IS MANAGED 24-26 (1987).

[10] IKUJIRO NONAKA & HIROTAKA TAKEUCHI, THE KNOWLEDGE-CREATING COMPANY (1995) (for the origin of the term).

[11] HOUNSHELL & SMITH, *supra* note 8, at 2.

[12] DAVID F. NOBLE, AMERICA BY DESIGN 8 (Alfred A. Knopf ed., 1979) (quote by Thomas Edison).

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it had to be turned into a product and this required more interaction between scientists and those responsible for production. Large industrial laboratories linked to equally organized production and sales facilities, all coordinated by one management structure, became a fundamental pattern of corporate organization.

DuPont early on integrated scientific labour into processes of industrial production and market competition. In 1902, the company established the Eastern Laboratory. This was followed by a second research facility known as the Experimental Station in 1903. Amongst other things, its laboratories delivered cellophane, Rayon, Teflon, neoprene, nylon, Dacron, lycra and Kevlar to the company. By 1958, DuPont dominated the U.S. chemical industry. Knowledge continued to be its focus. It employed roughly 4% of the industrial chemists in the U.S., and so many PhDs that it equalled about a third of the number in the U.S. academic system. Moreover, on average it spent about double the amount of its competitors on basic research.[13]

DuPont was not the only company whose business strategies pivoted around investment in research. Other companies also entered the knowledge game. General Electric's laboratory was established in 1900, AT&T set one up in 1907, and Westinghouse did so in 1903.[14] The more companies that went down the path of large-scale industrial research, the more that followed. By the end of the first decade of the 20th century, Western Electric, Electric Storage Battery, International Harvester, Corn Products, General Chemical, Goodrich Rubber, Corning Glass, National Carbon, Parke Davis and E.R. Squibb all had large scale research departments.[15] It was a pattern to be found in all industries. American Cotton Oil and National Lead had established labs to research their products in the 1890s. Between 1921 and 1941, the number of industrial research laboratories went from 300 to 2,200. These laboratories employed over 70,000 research staff. In 20 years the U.S. had built an industrial research structure that towered over that of other nations (with Germany perhaps the exception). Like a vortex, this structure drew in much of the best and brightest scientific talent in the country, as well as talent from abroad. GE's lab went from a staff of 102 in 1906, to 555 in 1929, and Bell Labs by 1925 employed 3,600 with the physicist C.J. Davisson being the first Nobel Prize winner to come out of Bell Labs.[16] Graduates working for these large

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[13] HOUNSHELL & SMITH, *supra* note 8, at 366.
[14] NOBLE, *supra* note 12, at 112-113.
[15] ALFRED D. CHANDLER, JR., THE VISIBLE HAND: THE MANAGERIAL REVOLUTION IN AMERICAN BUSINESS 375 (1977).
[16] NOBLE, *supra* note 12, at 116.

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companies were given some of the best-equipped laboratories in the country and salaries exceeding anything they were likely to earn in the university system. Universities themselves became more and more dependent upon funding from large corporations like DuPont. These companies understood that their needs for highly skilled scientific labour could only be met through healthy science faculties. Corporate funds flowed to universities.

Knowledge as the basic economic resource of economic production arrived before the great industrial production run of the 20th century. In essence, it laid the foundation for that run. Large, sophisticated laboratories, staffed by thousands of researchers, enabled the strategy of product diversification that characterized the chemical, electrical, automobile and machine industries. Chemical companies like Monsanto and DuPont started from a narrow technological base, the chemistry of saccharin in the case of the former and nitro-cellulose in the case of the latter. Research turned that base into many different product lines. Nitro-cellulose technology, for instance, gave DuPont, "artificial leather, rayon and other textiles, paints, varnishes and dyes, cellulose, and plastic products ...."[17] This knowledge-based strategy of diversification brought with it a new form of corporate organization, the 'integrated, multidepartmental enterprise'.[18] Its basic form was that of autonomous divisions strategically coordinated by a general office. This structure was widely adopted by American companies as they set about the task of expanding into overseas markets after the Second World War.

The entrepreneurs of the great companies of the early 20th century understood the importance of knowledge better than most. The financier J. P. Morgan was a long time supporter of Edison, investing heavily in his electric light companies and serving on the board of General Electric until he died in 1913.[19] Henry Ford also saw the importance of Edison's industrial laboratory to the industrial age: "It is the fashion to call this the age of industry ... Rather, we should call it the age of Edison. For he is the founder of modern industry in this country."[20] Edison's laboratory was a footbridge between the world of scientific research and competitive advantage in the business world. In the hands of the corporate giants of the 20th century that footbridge became a multi-lane highway. Most of the traffic would come to travel in the direction of the business world.

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[17] ALFRED D. CHANDLER JR., STRATEGY AND STRUCTURE: CHAPTERS IN THE HISTORY OF THE INDUSTRIAL ENTERPRISE 375 (1962).

[18] *Id.* at 24.

[19] NOBLE, *supra* note 12, at 9.

[20] Henry Ford, *quoted in* NOBLE, *supra* note 12, at 113.

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II. PATENT LOCKSMITHS – THE PATENT PROFESSION

It was the patent profession rather than the corporations themselves that saw the potential benefits of the patent system to the corporate sector. In England this profession had been born of the need by inventors for technical advice on the drafting of patent petitions and other documents.[21] This technical knowledge along with the procedural intricacies of obtaining patents allowed the profession over time to acquire enormous technocratic power.

One example of a highly influential figure in the development of a corporatized U.S. patent law system was Edwin J. Prindle. Like his father, he entered the patent bar, working in the U.S. Patent Office until 1899. In 1905, he moved to New York, where he established a successful patent practice. Prindle was a great lover of the patent system. He once observed in an address:

> our Patent System has been *the* primary factor in making the United States foremost among the nations in agriculture, inventing and manufacturing. While, of course there were other factors, the Patent System was by far the most potent one.[22]

Prindle was not, however, simply a starry-eyed patent enthusiast. As the Secretary of the Patent Committee of the National Research Council, Prindle became the key player in shaping changes in patent procedure:

> He selected those who appeared before the various Congressional Committees in their hearings held in advance of and to guide their actions, and took charge of the witnesses so appearing. He assisted in preparing the provisions which eventuated in the Nolan and Lampert bills and he directed the operations in great part which led the technical and scientific organizations to take pronounced action on these bills.[23]

Aside from his position on the National Research Council, Prindle was, amongst other things, the President of the New York Patent Law

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[21] *See* the address by R. B. Ransford, President of the Chartered Institute of Patent Agents, *The Profession Of Patent Agency, in* THE CHARTERED INSTITUTE OF PATENT AGENTS: TRANSACTIONS 15-35, 20 (1919-1920) (vol. XXXVIII).

[22] Edwin J. Pringle, *The Marvellous Performance of the American Patent System*, 10 J. PAT.OFF. SOC. 255, 258 (1927-28).

[23] *Comments – The Secretary of the Patent Committee of the National Research Council,* 4 J. PAT. OFF. SOC. 361, 362 (1922).

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Association, and the Chairman of the Patent Committee of the American Chemical Society.

Perhaps more importantly, it was through his writing that Prindle began to alert those in business to the full potential of the patent system. He wrote a highly influential set of articles on 'Patents in Manufacturing Business' that were subsequently turned into book form. His main message was that corporations had to see the patent system as a fundamental tool of business:

> Patents are the best and most effective means of controlling competition. They occasionally give absolute command of the market, enabling their owner to name the price without regard to cost of production. ... The power which a patentee has to dictate the conditions under which his monopoly may be exercised has been used to form trade agreements throughout practically entire industries, and if the purpose of the combination is primarily to secure benefit from the patent monopoly, the combination is legitimate. Under such combinations there can be effective agreements as to prices maintained ....[24]

Much the same conclusion was being reached in Germany. The German writer, Hermann Isay observed in 1923 that "no other industries have at their disposal for cartellizing purposes as effective a device as the manufacturing industries have. This auxiliary device is the patent."[25]

Knowledge about patents became as crucial to corporations as knowledge about inventions. Having made scientific labour part of their internal structure via the mechanism of the industrial laboratory, corporations made patent knowledge part of their internal structure by forming patent departments. Establishing patent departments was a natural extension of the multi-department structure that corporations were in any case developing. Patent departments were amongst the earliest departments created, at least in the U.S. In England there were also some early examples of corporate patent departments, with British Westinghouse Electrical setting up a patent department in 1897.[26] Where parent U.S. companies had set up patent departments, British subsidiaries would often follow suit. Patent litigation between companies was also sometimes a trigger for the

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[24] Edwin Prindle, *quoted in* NOBLE, *supra* note 12, at 89.

[25] Dr Hermann Isay, *Die Patentgemeinschaft im Dienst des Kartellgedankens* (1923), *quoted in* ERVIN HEXNER, INTERNATIONAL CARTELS 72 (1946).

[26] Norman Waddleton, *The British Patent Agent in the Last 100 Years*, Presidential Address to the Chartered Institute of Patent Agents (Dec. 17, 1980).

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establishment of a patent department. Here again, Edison had pointed the way, for he had appointed a patent draftsman at his Menlo laboratories.

Corporate patent departments and legal divisions became the overseers of a corporation's most important assets - its intellectual property rights, especially its trademarks, trade secrets and patents. Intellectual property lawyers in these departments had several important functions. First, they functioned as patent police, keeping a watchful eye on the publishing behaviour of the scientists in the laboratory. For scientists, the path to scientific immortality did not lie in having one's name on a lot of patent applications; rather, it lay in publication in publicly accessible journals. Publication, however, spelt death for a patent application. If even a hint of an invention was thrown out in a paper which was published before a patent application had been filed, that publication could be used to attack the patent. A publication by a DuPont employee in 1931 relating to the making of nylon allowed I.G. Farben in 1938 to develop nylon 6, somewhat undermining the patent position DuPont had developed in relation to its own nylon patents.[27] After that experience, DuPont tightened its previously liberal policy on the publication of scientific papers by employees. Tough internal procedures were set up to scrutinize any proposed publication by a DuPont scientist.

All companies went down the path of setting up procedures for the surveillance of scientific publishing by research employees. Each company knew that it had to have a strong portfolio of patents so it could negotiate licensing deals for the use of technology with other companies from a position of strength. Each company in this game knew that it was unlikely to have all the technology it needed to manufacture a given product. This meant that it would have to licence in the technology. It could only be sure of getting the licence if it had something to offer in return. Cross-licensing, in other words, was really only a game for equals. Even more importantly, each company knew that there was another calculation running silently in the background. In the biggest product markets, large companies would cross-licence provided they did not sense any weakness in the patent position of the other players. If they detected a weakness and the market share they would gain by overturning the patent was large enough, it made sense to go after the patent in the courts. In this world it was dangerous for even the biggest shark to bleed in the water. Thus, all companies carefully policed the publishing activities of their scientists.

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[27] HOUNSHELL & SMITH, *supra* note 8, at 302.

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Aside from vetting publication proposals from their own scientists, patent departments would watch the publishing and patenting activity of other companies. One of their main jobs was to neutralize the effects of patents belonging to other corporations. Legal departments would carefully scrutinize the patents and patent applications of competitors, assessing them for strength and weakness. This information would be used in the bargaining and litigation games that corporations played with each other in their struggles to obtain or preserve 'turf' in some domain of technological knowledge. Sometimes the patent knowledge would be used to overturn another company's patent and sometimes it would be used to counter the threat of litigation. A company might react to the threat of litigation from an opponent by saying "you claim that we are infringing your patent x, but we think you are infringing our patent y." The threat of mutually assured litigation costs saw many possible patent disputes quietly settled. In order to be successful in these negotiations, it was vital for each company to acquire as much knowledge as possible about the other side's patent strengths, as well as maintaining a strong patent portfolio itself. Companies became systematic in the way they acquired patents, with companies like IBM setting themselves patent quotas in particular fields of technology.

The most important function of patent departments was, of course, to file for and obtain patents. It was the task of a patent department to weave a web of patents around a particular technology, a web so thick no one could steer through it, or even think to try. DuPont did this with cellophane, warning Union Carbide "that any other company that tried to manufacture cellophane would be in difficulty with many patents in view of the long time we have been working on cellophane and the amount of work which has been done not only to strengthen the position with regard to cellophane but to build up a defensive patent situation as well."[28] Weaving patent webs around knowledge was not a strategy that DuPont or other U.S. corporations dreamt up for themselves. They had learnt it from the German chemical industry. The German chemical industry employed thousands of chemists and their output was measured by thousands of patents. Companies like Bayer and Badische Anilin Fabrik held hundreds of patents in America. German industry held in total approximately 4,500 U.S. patents, creating a "colossal obstacle to the development of the American dyestuff industry."[29]

Drafting patent applications developed into a special kind of art. Since knowledge was the basis of competitive advantage, it followed for all companies that they should disclose as little of their knowledge as possible.

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[28] *Id.* at 177 (quote by The Director of DuPont's Chemical Department, Elmer Bolton).

[29] Abraham S. Greenberg, *The Lesson of the German-Owned U.S. Chemical Patents*, 9 J. PAT. OFF. SOC. 19, 19-35, 20 (1926-27).

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But the patent system required the disclosure of the invention to the public. Over time, the patent attorney profession developed two kinds of solutions to this problem. Some of the core knowledge related to the invention was kept back from the patent system as private 'know-how.' Know-how was usually the subject of a separate licensing arrangement between commercial parties. Without the know-how, a patent licence was worth less and sometimes not much at all. The second solution to the problem of public disclosure was a drafting one. Patents were drafted in ways that satisfied the patent office, but were virtually useless to public readers of the documents. The best patent attorneys took the art of the 'empty' but valid patent specification to spectacular heights. During World War I, the Western allies confiscated patents belonging to German companies, but to little avail. These companies had kept careful control of the know-how. The German patents did very little to help the U.S., British, and French chemical industries, and in fact, after the war these industries went back to forming cartels with these German companies (especially I.G. Farben), such was their dominance in the chemical industry.[30]

The shift toward the use of patents by U.S. business was swift. Two things happened: first, the number of patents being granted in the U.S. went up. At the end of 1870, 120,573 patents in total had been issued. By 1911, that number had jumped to 1,002,478.[31] Second, the nature of patent ownership underwent a change. In the 19th century, most patents were owned by individuals. Surprisingly early in the 20th century, the bulk of patents came to be owned by big business. By 1930, for example, it was clear that of the patents being assigned before they were actually issued, most were going into the hands of U.S. corporations.[32] Individuals continued to troop through the patent system, complaining no doubt about its procedures and costs in the way that 'Old John' had in Dickens' *A Poor Man's Tale Of A Patent.* The patent system was society's enticing promise of a just reward for an inventor's contribution to the public good. The promise of a golden patent continued to suck individual inventors into the patent system. The patent attorney profession, which had swollen in number to service the demands of big business, played the role of mythmaker portraying the system as the servant of the heroic inventor. Underneath the promises the patent system was becoming the sophisticated bureaucratic arm of big business, a system which big players used to outmaneuver opponents

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[30] GEORGE W. STOCKING & MYRON W. WATKINS, CARTELS IN ACTION 467 (1947).

[31] Felix Frankfurter, *The Business of the Supreme Court: A Study in the Federal Judicial System*, 9 J. PAT. OFF. SOC. 8, 8-18, 10 (1926-27).

[32] *See*, 12 J. PAT. OFF. SOC. 225-230 (1930) (for a letter originally written to the New York Times by Joseph J. O'Brien on Feb. 2, 1930).

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or, where this was not possible, to unite with them. Intellectual property rights and their globalization in the 20th century allowed business to echo an old medieval form of organization - the guild.

III. GLOBAL KNOWLEDGE GUILDS – CARTELISM AND INTELLECTUAL PROPERTY

Cartels of all kinds were simply a fact of international economic life in the first part of the twentieth century.[33] They were present in most commodity markets including cocoa, coffee, corn, sugar, and tea. There were cartels in strategically important metal industries such as steel, aluminum, beryllium, cobalt, copper, lead, magnesium, mercury, tin and zinc. Generally speaking, the more technologically sophisticated the process of production, the more use was made of patent and know-how agreements amongst competitors. Other forms of intellectual property such as trademarks were also involved. Through these agreements members of the cartel 'networked' their territorially based patents in order to co-ordinate their actions in world markets. The details of these arrangements varied as did their legality in different jurisdictions. The patent monopoly by its nature gave its owner strong rights over the making of the invention including the terms upon which it could be licenced. An arrangement between two producers dividing territories and setting limits on production that would have been illegal in the absence of a patent monopoly could be legal as a patent licensing arrangement. For international producers, the national monopoly privilege of patents became the privilege of international cartelism. Two or more international players would come together and negotiate an agreement on the intellectual property rights relating to the products and technologies in the industries in which the players were involved. Typically, the agreement would divide the world into areas (e.g. the British Empire, the United States, and Central America, with each of these being more precisely defined, sometimes in terms of latitude). The agreement might specify that some areas were to be the exclusive territory of Party A and others the exclusive territory of Party B. Some territories might be shared. Party A would agree to grant Party B 'sole and exclusive licences' to patents and trade secrets owned by Party A and of interest to Party B in its exclusive markets. Party B would return the favour. There would also be obligations on the sharing of information relating to the patents and know-how. Once this framework of co-operation on intellectual property rights and technology was in place, all sorts of games could be

[33] For a survey, see generally ERVIN HEXNER, INTERNATIONAL CARTELS (1946).

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hidden by a dense cloud of licensing arrangements. Party A might, for example, licence a patent to Party B in order to help Party B fight off a competitor threatening Party B's market. The contractual 'networking' of intellectual property portfolios belonging to two large players gave those players legal tools with which to explore the possibilities of fixing price, production and markets. Not every agreement on patents hid a cartel, but many did.

Patent-based cartels were most strongly present in the chemical and pharmaceutical fields. Some of the most complex were to be found in the coal tar industry (important in dyes, explosives, and medicines). Over two or three decades, the cartels involved German companies (IG Farben, Bayer, Badische, Kalle, and Höchst), Swiss companies (Ciba, Sandoz and Geigy), the British company ICI and the American companies Du Pont and the National Aniline Chemical company.

For some chemical companies the move into pharmaceuticals made sense. Drugs could be synthesized through chemical processes and chemicals were a source of raw materials in the pharmaceutical sector. IG Farben was a prominent player in the pharmaceutical cartels of the 1930s, forming agreements with other European companies such as Ciba and Hoffmann La Roche, as well as U.S. companies such as Sterling Products. Perhaps it was because cartels brought peace from competition for their members that they occasionally bore the word 'treaty' in their title. Merck, then the largest pharmaceutical manufacturer in the U.S., signed a 'Treaty Agreement' in 1932 with the German company E. Merck of Darmstadt in which the parties agreed to co-operate on more or less everything, thereby earning itself an anti-trust action in 1943.[34]

Co-operation amongst chemical companies was not always the rule. National industries would sometimes push states into a protectionist use of patents. A good example was the UK's change to its patent law in 1919, preventing the patentability of chemical compounds. Chemical processes remained patentable. Fearing the might of IG Farben, British industry pursued a strategy of freeriding by concentrating on inventing better processes that duplicated German dyestuffs. This was to be precisely the strategy that the Indian Government adopted in its Patent Act of 1970 for its pharmaceutical manufacturers: grant process patents for pharmaceuticals, but not product patents, thereby providing an incentive for national producers to patent cheaper processes for making pharmaceutical products.

[34] *Id.* at 334.

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The changes in the U.S. pharmaceutical sector were especially dramatic.[35] Prior to World War II, the U.S. pharmaceutical industry was similar to other manufacturing industries. The number of drugs of high therapeutic value under patent were few. There was also a competitive generics industry. Companies wishing to protect their proprietary medicines found that trade marks and advertising were in fact more important than patents, which in any case were hard to obtain when it came to chemical compounds. In most European states, including Germany, it was not possible to get a patent on a chemical compound (but it was possible to obtain protection for chemical processes, which was enough for companies like IG Farben to be able to run their cartels). The discovery of penicillin prior to World War II and sulfanilamide led to an era of wonder drugs after World War II. Companies like Pfizer, Bristol, Parke Davis and Merck rushed towards patents over antibiotics. Obtaining patent protection was absolutely vital. These companies had seen what a competitive market could do to the price of a drug like penicillin. Penicillin, which had not been patented, had gone from costing $3,955 per pound in 1945 to $282 per pound in 1950.[36]

One obstacle stood in the way of companies obtaining a patent hold on antibiotics. The development of new antibiotics like streptomycin depended on the discovery of naturally occurring substances in soil samples that killed harmful micro-organisms. An obvious objection to patentability was that these substances occurred in nature and so they were really unpatentable discoveries. Here the patent profession rode to the rescue. For decades the profession had been successfully pushing the principle that substances which occurred in nature, but had been isolated and purified by the discoverer, were in fact patentable. Technically, they no longer existed in nature. Progressively, the principle of purification/isolation came to have a wider and wider application in the case of chemical patents.[37] In the case of the patents for broad spectrum antibiotics, the U.S. Patent and Trademark Office (PTO) accepted the application of the principle and granted the patents. In fact, it granted too many of them. Companies found that each one of them could make life difficult for the other. Rather than live in a world of mutually assured patent litigation these companies swapped patents in order to form a producers' cartel. The prices of antibiotics like tetracycline were held constant by Pfizer, Cyanamid, Bristol, Upjohn and

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[35] For an excellent account, see Peter Temin, *Technology, Regulation, and Market Structure*, 10 BELL J. ECON. 429 (1979).

[36] *Id.* at 435.

[37] The law begins to develop early in this field. *See* Kuehmsted v. Farbenfabriken of Elberfeld, 179 F. 701 (7th Cir. 1910) (dealing with purified acetyl salicyclic acid (aspirin)).

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Squibb between 1951 to 1961. The U.S. government brought an antirust action against the companies based on the remarkable price uniformity of tetracycline. Aside from the criminal cases, there were also civil cases based on evidence of patent fraud. It was not only U.S. citizens that bore the cost of this cartel. A U.S. Senate Subcommittee on Antitrust and Monopoly led by Senator Kefauver in the 1960s uncovered what seemed to be a classic international cartel with the price of tetracycline being identical in the 13 countries for which price data was available.[38] Neither for the first time nor the last have patents kept a vital medicine out of the hands of the poor in developing countries.

During this time these companies experienced a period of enormous expansion based on the supra-normal profits they obtained by means of the patent system. However, the profits of each individual company tended to come from only one or two drugs. For example, in 1960 terramycin and tetracyn accounted for 33% of Pfizer's sales; chloramphenicol accounted for 45% of Parke Davis' sales and Merck saw Divril account for 39% of its sales.[39] When these patents ran out, the companies would be cast back into competitive markets. For these companies there was now a massive incentive to strengthen the patent system. The patent system had played a crucial role in globalising these firms and now they had an overwhelming interest in globalising the patent system. They would need longer and stronger patents to protect the blockbuster drugs upon which they had become financially dependent. They would need every country in the world to recognise product and process patents[40] for pharmaceuticals so that it would be possible to become a monopoly supplier in every market of their choice. They would need standards of patent protection that would make it difficult for the generics industry to compete with them in these national markets. They would need stronger trademark law to protect their global marketing strategies, trademark laws that could not be tampered with by developing countries. They would need something like TRIPS.

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[38] JOHN BRAITHWAITE, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY 181 (1984).

[39] Temin, *supra* note 35, at 429, 442.

[40] Obtaining protection for both chemical products and processes was vital for US companies since it would increase the range of options they had at their disposal for protecting knowledge. Many countries did not recognize patents for pharmaceutical products, meaning that in those countries US companies had to rely on process protection. If a US company wanted strong protection in that country for its product, it would have to patent as many processes as it could in order to protect the product. In the US, a company could rely on product protection and keep the process secret or disclose only one process (not the cheapest one). TRIPs, by requiring states to recognize both product and process protection, provides multinationals with more options as to how they will protect their products. They may well choose to rely more on product protection than process protection. One effect of the patent part of TRIPs may well be that it will lower the number of processes that end up in the public domain via the patent system.

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The need for TRIPS by a few global pharmaceutical firms can be seen through the eyes of one of the principal players in its creation, Pfizer.[41] Like most players in the knowledge game, Pfizer had a long history.[42] It was incorporated in 1942 as Charles Pfizer & Company, but had earlier beginnings in a partnership between two cousins, Charles Pfizer and Charles Erhart. They had come to New York in the 1840s from Luwigsburg in Germany, lured from their well-to-do background by the potential of the New World. The company's main product became citric acid. During the 1920s, two of the company's chemists developed a fermentation process for using sugar and then molasses to obtain citric acid in large quantities. The deep-tank fermentation methods that the company developed for citric acid became the basis of the mass production of penicillin during World War II. Pfizer became the single biggest supplier of penicillin to the Allies during the war. During the war years, Pfizer had been required to share its penicillin production techniques with other U.S. manufacturers in order to meet the demand of the Allies. (The U.S. government in fact resorted to compulsory licensing because American pharmaceutical firms were reluctant to share their knowledge of the processes for making penecillin.[43]) Facing strong domestic competition in the production of penicillin after the end of World War II, in the 1950s, the company began a program of expansion into developing country markets. Pfizer's move into overseas markets was the idea of John "Jack" Powers Jr., who in effect globalised Pfizer as a firm. Out of his initiative was born Pfizer International. Manufacturing plants and distribution networks were established "in countries ranging from Argentina to Australia and Belgium to Brazil."[44] By 1957, Pfizer International had achieved more than its target of $60 million overseas sales. More importantly, it had decided that developing country markets were worth persisting with. The pharmaceutical markets of populous, less-developed countries like India and China became long-term bets.

The long-term prospects of these markets, however, became clouded as countries like India began to develop technologically. Industrialization started slowly in these countries because they were preoccupied with throwing off colonialism and achieving political sovereignty. The overseas sales figures that Pfizer International achieved in the 1950s were in a sense a post-colonial legacy. Technological

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[41] *See* PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM ch. 4 (forthcoming 2002) (for a detailed description of the role of Pfizer). *See also* Oxfam Company Briefing Paper, Pfizer, *available at* www.oxfam.org.uk/cutthecost.

[42] A good account of the company's early history is *available at* http://www.pfizer.com.

[43] *See* BRAITHWAITE, *supra* note 38, at 164.

[44] *See* the Pfizer website, *available at* http://www.pfizer.com/150/1951.htm.

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development could hardly take place in countries struggling to win their independence and create stable political institutions. But the citizens of such countries still got sick. This meant that drugs had to be imported. National pharmaceutical industries either did not exist or were only in their infancy. In fact, many people in Africa, India, and South America relied on a variety of indigenous knowledge systems for their health care needs.

The problem with importing drugs lay in their expense. In the 1960s, India, despite having one of the poorest populations in the world, had some of the world's highest drug prices. There was price discrimination but not in favour of India's many poor. Pharmaceutical companies were instead aiming at the small but growing class of Indians who could afford western prices. Achieving more affordable drugs became a priority in India and other developing countries. Political stability brought a measure of technological development and a capacity to produce drugs locally. Governments of developing countries asked themselves a simple question: how might we use the patent system to help the production of cheap drugs in our country? India had had a patent law before many European countries, having acquired one in 1856 while under British colonial rule. From that time on, British manufacturers used the patent system to obtain the best possible prices in the Indian market. After India's independence in 1948, two expert committees conducted a review of the Indian patent system. They concluded that the Indian patent system had failed "to stimulate inventions among Indians and to encourage the development and exploitation of new inventions."[45]

This led India down the path of designing a patent system that helped to meet the demand by its population for cheap drugs. During the 1950s when Pfizer had ventured into developing country markets, patent protection was less important to it because countries like India did not have the technology or know-how to copy its products. Patents, as with all intellectual property rights, only matter when competitors acquire the capacity to copy and distribute to markets. As India and other developing states began to acquire technological capabilities, Pfizer's bet on these markets began to look shaky. It began to look especially shaky as India and others passed patent laws aimed at fostering a local pharmaceutical industry. The patent law in countries like India did not allow for patents on pharmaceutical products and would only permit patents on pharmaceutical processes for five to seven years. Developing countries also made use of compulsory licensing regimes to bring down the price of essential drugs.

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[45] S. Verman, *The New Indian Patents Law*, 3 INT'L REV. INDUS. PROP. COPYRIGHT L. 39, 43 (1972).

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As these policies began to bite, Pfizer was faced with unprofitable operations in these countries. In the words of Edmund Pratt, the CEO of Pfizer from 1972 to 1991, "[w]e were beginning to notice that we were losing market share dramatically [in developing countries] because our intellectual property rights were not being respected in these countries."[46] The loss of market share in developing countries did not really impact on Pfizer's overall profitability. Pratt again: "fortunately, we were doing well in our other operations so it didn't affect our overall performance dramatically."[47] The world's biggest pharmaceutical markets remained the U.S., Japan and Europe. Pfizer's own sales in developing markets were never much more than 10-12% of its total sales.[48] Nevertheless, these less developed countries were nibbling at the edges of the global knowledge game. Amongst other things, they were providing pharmaceutical products to their populations at very cheap prices. Not only that, but some countries like India were also supplying neighbours like Nepal. Pharmaceuticals from India were also finding their way into African states. The presence of these cheaper manufacturers in the world also had the potential to raise embarrassing questions within Western markets about the nature of the connections between patents and the price of drugs. Witness the following statement from a Western doctor who had worked in Nepal:[49]

Having just returned from medical work in Nepal, I am intrigued by the Association of the British Pharmaceutical Industry's statement that "the pharmaceutical industry in the UK is highly competitive especially in terms of prices." Most of the drugs available in Nepal are manufactured in India and their efficacy in clinical practice I have found to be the same as their UK equivalents but the price is about one-tenth to one-twentieth of the UK price. Any argument about research and development costs can hardly apply to such humble drugs as paracetamol.

IV. PATENT ENGINEERING

Once the breakthroughs in molecular biology had occurred, the multinational companies with markets in areas affected by the breakthroughs began to plan how to exploit the new opportunities of the technology. The experience with penicillin and stryptomycin was highly instructive in this respect. If a company allowed research to remain in the public sector, or

[46] *See* L.S. PAINE & M.A. SANTORO, PFIZER: PROTECTING INTELLECTUAL PROPERTY IN A GLOBAL MARKETPLACE 6 (Harvard Business School 1992).
[47] *See id.* at 7.
[48] *See id.* at 2, 4.
[49] *See* Letters to the Editor, Dr David J Hill, INDEPENDENT, Dec. 17, 1998, at 10.

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alternatively licenced the technology widely, its rates of return would be comparatively low.[50] Patents, on the other hand, could deliver a very high rate of return to the company. Their planning took into account the need to change the patent system. They wanted the patent system to deliver the kind of returns in biotechnology that it had in chemical technology. The changes to the patent system that occurred in relation to biotechnology patenting were not the causes of the bio-industrial revolution, but rather an outcome. The patent system was there to be used and use it the companies did. Plants, animals, micro-organisms, genes as well as the tools and processes for the production of these things became targets of patenting. By the late 1980s, the use of the patent system in the fields of genetic engineering, and molecular biology was well underway. For genetic engineering the number of patents granted by the U.S. PTO had risen from below 20 in 1978 to almost 200 in 1987.[51] For molecular biology and microbiology, the number of patents granted in 1978 went from approximately 400 to over 1000 in 1987. The bulk of patents went to U.S. corporations.

Patenting in biotechnology faced some problems of principle and application. The foundations of patent law had been laid in an era of mechanical invention. Drawing a distinction between invention and discovery and applying it in the case of a steam engine was comparatively easy. As companies moved into the patenting of chemical compounds, the invention-discovery distinction started to get fuzzier. Drawing on the metaphor of engineering one could liken the synthesis of new compounds to invention in mechanical engineering. The use of the metaphor became more problematic in the case of organic chemistry where the chemist was finding molecules which existed in nature and had useful properties. In the case of patent claims over DNA instructions and their corresponding proteins the metaphor seemed even weaker. It was hard to claim an entitlement to the DNA code on the basis that it had been engineered. It, after all, had been in existence for thousands of years before the genetic engineer and corporate laboratories. It had been uncovered or found rather than designed and built.

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[50] Licensing can limit the profitability of the patentee. For example, streptomycin was patented, but licenced widely with the result that its price went from $160 (10 grams) in 1946 to 36 cents in 1960. *See* GARY GEREFFI, THE PHARMACEUTICAL INDUSTRY AND DEPENDENCY IN THE THIRD WORLD 107 n. 10 (1983). The lesson for the drug companies was that the real profits lay in not licensing the product. Compulsory licensing is an anathema to pharmaceutical multinationals.

[51] Figures from the US PTO, reproduced in US Congress, Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life - Special Report* 63-64 (Washington, D.C., US Government Printing Office 1989).

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Chemical companies in particular had been rehearsing technical arguments about the patentability of chemical inventions before patent offices and courts for almost a hundred years. These companies also had experience with biotechnology going back that far. They knew how to overcome problems of patentability in order to make patent principle serve their strategic needs. As we mentioned earlier, the problem of patenting products had been met by the principle that one could, through an act of isolation and purification, transform a naturally existing product into an invention. For the principle to apply the invented product had to be different in kind to the naturally existing product.[52] By the 1990s, this rider to the principle was being largely ignored by patentees and patent offices. Patent offices continued to grant patents on DNA codes purified by the removal of redundant segments of code even though the purified DNA coded for the same protein as the naturally occurring sequence.

Naturally, to begin with the companies did not have it all their own way. The U.S. PTO was from time to time criticised by the patent profession for not being sufficiently co-operative in the grant of patents. The courts also proved less than helpful at times. The U.S. Supreme Court in particular was a source of irritation to the patent faithful. In 1930, an editorial of the Journal of the Patent Office Society complained that the "permissible monopoly under a patent has been shorn to the extent that it is subject to the existing anti-trust laws and it cannot be used for restraining commerce".[53] Other courts would on occasions also remind the profession and the U.S. PTO that the patent system was there to serve the public rather than industry. The District Court of Columbia, for instance, observed in 1957 that "the Patent Office should be very careful and perhaps even reluctant to grant a patent on a new medical formula until it has been thoroughly tested and successfully tried by more than one physician."[54] After the evidence of price fixing by the pharmaceutical industry that emerged during the course of the Senate committee led by Senator Kefauver in the early 1960s, Kefauver almost managed to push through a proposal for the three year patent term on drugs. At the end of that time, a regime of compulsory licensing and a royalty rate of up to 8% was to apply.[55] In truth, however, the history of chemical patenting turned into one of relentless expansion. Whatever judicial reservations were expressed from time to time about this became as pebbles against a rising king tide.

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[52] Merck & Co. Inc. v. Olin Mathieson Chemical Corp., 253 F.2d 156 (4th Cir. 1958).
[53] Editor's Page, *Is the Patent Monopoly Waning?*, 13 J. PAT. OFF. SOC. 363, 364 (1931).
[54] Isenstead v. Watson Comr. Pats., 157 F.Supp. 7, 8 (D.D.C. 1957).
[55] BRAITHWAITE, *supra* note 38, at 163.

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There were other fundamental problems of patentability in the case of DNA. Before an invention can be patented it must be shown to be useful. The idea behind the requirement is to force the inventor to move beyond discovering information which might or might not be useful and into products and processes that are part of the 'useful arts'. If applied strictly in the case of DNA code the requirement of utility might defeat many patent applications since often the applicant has little idea as to what the function of the DNA is and what it might be useful for in product terms. The utility requirement had also been the subject of analysis in the chemical field. In the mid 1960s, the U.S. Supreme Court reversed a trend towards a weakening of the utility requirement for chemical patents, pointing out that the "basic *quid pro quo*" for the grant of the patent monopoly was an invention possessing a specific and defined benefit to the public.[56] If an inventor could not specify a concrete and practical use for the invention and a patent was granted, the effect of the patent might be "to confer power to block off whole areas of scientific development."[57] The Supreme Court's approach, however, did not stick. During the 1990s utility turned out not to be a high hurdle in biotech filings with the U.S. PTO: "you get utility if you can spell it" (U.S. patent attorney, 1999[58]). Patents were granted on DNA sequences, the practical utility of which the patent office, the inventor, and the public had very little idea. Patents had become hunting licences, the very thing the Supreme Court had said 30 or so years earlier they were not.[59]

The patenting of genes, which through the 1990s increasingly drew more public attention, was the culmination of a business approach that had been evolving in the chemical, agricultural, seed and pharmaceutical sectors for all of the twentieth century. Genetic engineering was only a part of biotechnology, albeit a significant one. As biotechnological production had become more and more industrialised so had the patent system's shadow over it lengthened. Of course, this dynamic was different in each country, but in general developments in U.S. patent law have turned out to be the most influential, even if they were not always the first. The conclusion of the U.S. Supreme Court in *Diamond v. Chakrabarty* in 1980 made it clear that a micro-organism that had been modified by the application of genetic engineering techniques could be the subject of patent. The fact that it was living was not a bar to patentability. Similar decisions had already been reached in 1969 by the Supreme Court of the Federal Republic of Germany

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[56] Brenner v. Manson, 383 U.S. 519, 534, 86 S.Ct. 1033, 1042, 16 L.Ed. 2d 69 (1966).
[57] *Id.*
[58] DRAHOS & BRAITHWAITE, *supra* note 41.
[59] Brenner v. Manson, 383 U.S. at 534.

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and by the Australian Patent Office in 1969.[60] Nevertheless, the *Chakrabarty* decision had a catalysing and global effect on biotech patenting simply because of the sheer size of the U.S. market. For all its totemic status, well before *Diamond v. Chakrabarty* U.S. patent attorneys were claiming micro-organisms, but claiming them in a solution or inert matter so as to minimise objections based on discovery of living matter. These claims were being let through by the U.S. PTO. Not for the first time the reach of the patent system was being extended through some clever drafting of patent claims.

In many ways beyond the scope of this paper to detail, the patent system in the U.S. and other countries was adapted to meet the needs of those in the biotech business. Living systems like plants and micro-organisms posed fundamental problems for patent law and its administration. There was the problem of how to describe a 'plant invention' satisfactorily so that others could reproduce it. Plants and micro-organisms could not be described as easily as mechanical inventions, nor did they necessarily follow the dictates of a patent description when they reproduced. This made it hard for inventors to disclose their invention to the public (sufficient disclosure being a basic requirement of patentability) and hard for others to repeat the invention. In truth, those applying for patents over living systems, unlike the inventor of a mechanical device, had only a partial understanding of how their 'inventions' worked. The response to these kinds of problems was the evolution of a patent system of ever deepening complexity that became increasingly disconnected from its duty of serving the public welfare. The Plant Patent Act of 1930, for instance, relaxed the description requirement for plants. Systems of deposit for micro-organisms evolved in both the U.S. and Europe, but they were mired in complexity making it difficult for others to gain access to the invention.

Lying at the heart of the re-engineering of patent law has been the large chemical and pharmaceutical companies, the biggest users of the patent system. Together they have formed a transnational medium pushing a common message: increasing patent protection will increase the supply of biotech products to the marketplace. As lobbyists and litigators, they have been active in all the key patent jurisdictions (U.S., Europe, and Japan). TRIPS, we have seen, provided them with the experience of lobbying for global standards. Making sure that Congressional representatives stay focused on the need to protect their patents is so vital to the pharmaceutical

[60] For a survey of the important liberalizing decisions, see F.K. BEIER ET AL., BIOTECHNOLOGY AND PATENT PROTECTION: AN INTERNATIONAL REVIEW, ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT annex C (OECD) (Paris 1985).

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industry that it has 297 lobbyists working for it.[61] Whether it is in the U.S. or Europe the large players in this industry will have an ease of regular high level access to senior politicians and bureaucrats unmatched by even the best organised NGOs when it comes to discussing issues like the price of patented AIDS drugs.

The large companies have been prepared to absorb the cost of appeals against patent office decisions. Patent offices with their more limited budgets have not been in a position to keep up with these kinds of strategic litigation games. Courts too, have noted that companies have persisted in very expensive litigation when the patents have expired and one might have expected a settlement.[62] The deeper game in these kinds of cases has been the pursuit of a precedent. The complexity of chemical science combined with the complexity of patent law has seen companies apply for patents on chemical inventions that are the same as inventions on which the patents have expired. Eli Lilly and Co. tried this with their blockbuster drug Prozac. Sometimes this has been picked up by the courts and sometimes not.[63] Patent offices are even less likely to pick up instances of double patenting.

Patent offices over time have undergone a cultural change in which their motto has become one of keeping their multinational customers happy. The motto makes good economic sense because increasingly, patent offices have to fund their operations from the patent fees they collect from patentees. The larger patent offices lead the smaller ones in a process of quiet harmonisation. When the Australian patent office (IP Australia) wants to know what to do about the patentability of mathematical algorithms it takes its lead from the U.S. PTO. The three large patent office players (the U.S. PTO, the European Patent Office and the Japanese Patent Office) have a programme of trilateral co-operation.

The policy committees that are tucked away in major patent offices invariably have heavy private sector representation with no or little representation from consumers, environmentalists, or the health and food security movements. Consumers for patent offices are the multinationals which make use of their services. Outsiders critical of the patent system's commodification of basic information are instructed that a patent does not

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[61] *See* Julian Borger, *Industry that Stalks the US Corridors of Power*, GUARDIAN, Feb. 13, 2001, at 3.

[62] *See, eg.*, Beecham Group Ltd v. Bristol Laboratories Ltd and Bristol-Myers Co. [1977] FSR 217 (comments of Lord Diplock's the expired patents).

[63] *See* Eli Lilly and Co. v. Barr Laboratories Inc., 222 F.3d 973 (Fed. Cir. 2000) (Nos. 99-1262, 99-1263, 99-1264 and 99-1301). In the case of the Prozac patents, the US Court of Appeals for the Federal Circuit held invalid a patent claim claiming the active ingredient in Prozac because an earlier expired patent had already claimed it.

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confer the right to commercial exploitation, merely the right to exclude. The causality of patents in other words is denied. When critics question the patent system's expansion they are told that patent rights are needed to encourage the commercialisation of socially valuable technologies. The causality of the patent system in other words is invoked. For the purposes of classifying a living system as an invention, its 'engineered' nature is emphasized, but for the purpose of relaxing the disclosure standard the 'living' nature of the invention is emphasized. The technical density of patent law obscures its basic contradictions.[64] The capacity of patent thinking to accommodate contrary positions allows it to answer any criticism.

A central player in the re-interpretation of patent law principle to serve commercial rather than public interest is the U.S. Court of Appeals for the Federal Circuit (CAFC). Patent appeals from the Court of Federal Claims, the International Trade Commission and the U.S. PTO and the U.S. district courts (in most cases) are all funnelled to the CAFC, giving it centralized power over patent law principle. Created in 1982, when the U.S. Court of Customs and Patent Appeals and the U.S. Court of Claims were merged, the CAFC was charged with the task of increasing the doctrinal stability and unity of patent law. Whether it has done this is open to question. Analysts have pointed to the large number of times the court has flatly contradicted itself, as well as its distortion of patent law in the context of biotech patenting in order to better serve the private sector.[65] What it has done is to increase the chances of a patent holder succeeding in litigation. During the 1940s and 1950s, getting a court to find a patent valid was tough. So, for example, one study of patent decisions of circuit courts of appeals found that for the period 1940-1944, the number of patents held valid was 17.6% and for 1945-1949 it was 22.25%.[66] When the CAFC arrived on the scene in 1982, the odds changed dramatically in favour of the patent holder. In 1988 in Harmon's first edition of his book dealing with the CAFC's decisions, he observed that an "accused infringer who loses below has less than 1 chance in 15 of turning things around on appeal."[67] By the fourth

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[64] *See* Gerd Winter, *Patent Law Policy in Bioechnology*, 4 J. ENVTL L.167-87 (1992) (for a discussion of these problems).

[65] *See* Tom Arnold, *Using ADR Instead of Litigation, in* PATENT LITIGATION STRATEGIES HANDBOOK 25, 26 (Barry Grossman & Gary Hoffman eds.); PHILIPPE G. DUCOUR, PATENTING THE RECOMBINANT PRODUCTS OF BIOTECHNOLOGY AND OTHER MOLECULES 3 (1998).

[66] E.H. Lang & B.K. Thomas, *Disposition of Patent Cases by Courts During the Period 1939 to 1949*, 32 J. PAT. OFF. SOC. 803-807 (1950).

[67] ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 382 (The Bureau of National Affairs Inc., Washington, D.C. 1988).

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edition (1998), those odds had reduced to 1 in 7.[68] They remained nevertheless pretty good odds for the patent holder.

It is not just the CAFC that has been active in creating a patent jurisprudence that pays diminishing regard to the patent as a social bargain that is meant to serve the public. Over the decades, the courts in most western states have coded into the law the assumption that exceptions to patentability are to be narrowly construed.[69] At the same time, this jurisprudence has read down tests of morality or suggested that issues of morality and patenting are not to be decided within the patent system. The result is a patent system that operates more and more as a regulatory island at a time when property rights in information have greater and greater effects in fundamental areas such as food, health and agriculture.[70]

V. REFORMING PATENT OFFICE REGULATION

This paper has shown how the institution of patent law has been profoundly shaped by the strategic behaviour of firms. TRIPS is an outcome of a long tradition of strategic behaviour by firms in the chemical, pharmaceutical and biotechnology sectors, which see TRIPS standards as those which are best suited to their own innovation and marketing needs. The current problems that TRIPS is creating in the field of access to medicines is itself an example of a recurring problem of the institutional development of patents responding more to the strategic behaviour of firms than to the welfare needs of given populations.

One important difference between the present access to medicines issues and other patent-related problems of access to technology is the presence of members of civil society. They have taken a sustained interest in the impact of the patent system on the price of and access to medical technologies and have drawn attention to the problems of TRIPS. The focus of civil society actors has been on the immediate and practical problem of achieving decreases in the price of patent-related drugs for the poor in developing countries. Beyond this, there is a longer term issue of what do about the institution of patents in a world where the rights of the patent holder affect other rights such as the right to health and the right to development, rights which will almost certainly require the provision of

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[68] ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 980 (4th ed.) (The Bureau of National Affairs Inc., Washington, D.C. 1998).

[69] For a discussion of the trends, see Peter Drahos, *Biotechnology Patents, Markets and Morality*, 21 EUR. INTELL. PROP. L. REV. 441-49 (1999).

[70] *See* PETER DRAHOS & MICHAEL BLAKENEY (EDS), IP IN BIODIVERSITY AND AGRICULTURE: REGULATING THE BIOSPHERE (2001).

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more international public goods than was previously thought.[71] This issue is distinct from what to do about TRIPS. National patent systems were expanding to take in developments in, for example, biotechnology and software prior to TRIPS. National patent systems and the strategic behaviour of global firms were creating problems of access to technologies prior to TRIPS. The tetracycline patent cartel of the 1950s mentioned earlier shows how patents in the past have been used to deny poor populations access to life-saving medicines. These problems of access were not just being faced by developing countries. For example, attempts by the New Zealand government to use the Crown use provisions of its patents law to obtain cheaper drugs in the 1960s and its attempts to use parallel importation in the 1980s to bring in cheaper drugs from Australia failed due to a combination of litigation pressure from the subsidiaries of global pharmaceutical firms based in New Zealand as well as trade pressure from the United States Trade Representative.[72] Even if TRIPS were to vanish tomorrow, one would be left with other international agreements such as the Paris Convention for the Protection of Industrial Property, a complex web of bilateral trade agreements that include patent standards[73] and expanding national systems of patent law. The issue which lies beyond TRIPS is how to reshape and reform patents as national institutions for a world in which access to technology by poorer countries remains a problem and a world in which more rather than less knowledge will have to be provided as a public good.

This paper concludes by suggesting two paths of reform. The first draws on the theory of varieties of capitalism developed by Peter Hall and David Soskice.[74] The implication of the theory is that national models of patent regulation are most likely to be successful if they match and complement the broader type of institutional infrastructure of the nation in which they are located. The second path of reform claims that national patent systems will be more efficient if patent regulation is opened up to a greater variety of actors.

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[71] On the issue of public goods, see Marco Ferroni, *Reforming Foreign Aid: The Role of International Public Goods*, OECD Working Paper Series, No. 4 (2000).

[72] *See* Astrid Baker, *Setting the Rules: Pharmaceuticals Benefits and the Welfare State, in* FOR HEALTH OR PROFIT? MEDICINE, THE PHARMACEUTICAL INDUSTRY, AND THE STATE IN NEW ZEALAND 18-35 (Peter Davis ed., 1992).

[73] *See* Peter Drahos, *BITS and BIPS: Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791-808 (2001) (for a survey).

[74] *See* VARIETIES OF CAPITALISM: THE INSTITUTIONAL FOUNDATIONS OF COMPARATIVE ADVANTAGE (Peter A. Hall & David Soskice eds., 2001).

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A recent study by Deepak Somaya does reveal real differences in the way patents are administered in different countries.[75] U.S. and Japanese patent administrations were found to differ, with U.S. administration being more supportive of the exclusive property rights of patentees. In contrast, Japanese patent administration was more demanding of explanations on how inventions worked, giving more priority to facilitating the sharing of new knowledge and to rapid dissemination of innovation: "[T]he Japanese view inventions more as a public and less as a private, good," patents "more as a means to reward inventions and less a right to exclude others from use than in the United States." Somaya found European patent administration to lie between the United States and Japan, with Germany closer to Japan and the UK closer to the U.S.. This is exactly as one would expect from David Soskice's theory of comparative capitalisms.[76] According to Soskice, both German/Japanese and U.S./UK capitalism are successful models. The German/Japanese model, which they share loosely with Sweden, Switzerland and South Korea among others, involves substantial intercompany cooperation including sharing of innovation, with the state playing a framework-setting role on matters ranging from labour markets to training to innovation policy. Under the Anglo-Saxon model, the state plays an arms-length role and competition and intellectual property law discourages intercompany collaboration. This Anglo-Saxon model, according to Soskice, is better for the development of service industries, such as the superior finance sector we see in London and New York, and for tightly coupled production systems (airlines, large software houses, large entertainment systems). The German model is superior for relatively complex production processes and after-sales service, such as sophisticated engineering products from motor vehicles to washing machines. What follows from the Soskice analysis is that societies must choose their system for regulating intellectual property with an eye to how it will fit other crucial legal and industry policy institutions from competition policy to labour market policy. Institutional mismatch, falling between the coherent institutional packages for engendering different kinds of flourishing capitalisms, is the worst choice to make. Put another way, every society must choose how to regulate property rights in the context of the niche in which it seeks to excel in the world system. Again, this is a prescription for

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[75] D. Somoya, *Obtaining and Protecting Patents in the United States, Europe and Japan, in* REGULATORY ENCOUNTERS: MULTILATERAL CORPORATIONS AND AMERICAN ADVERSARIAL LEGALISM 279-309 (R.A. Kagan & L. Axelrad eds., 2000).

[76] D. Soskice, *Divergent Production Regimes: Coordinated and Uncoordinated Market Economies in the 1980s and 1990s, in* CONTINUITY AND CHANGE IN CONTEMPORARY CAPITALISM 101-134 (H. Kitschelt et al. eds., 1999).

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rich local democratic deliberation on how to enforce property rights. It is a prescription against buying any WIPO Anglo-German hybrid regime as "best practice" in getting the best of both worlds.

As previous sections of this paper have shown, the evolution of the institution of patents has been deeply shaped by the strategic behaviour of those firms that have been the patent system's most regular users. Essentially, the courts and executive governments in the Western world (though perhaps not yet in India and some other sophisticated developing countries) have rubber stamped the capture of patent offices by multinationals. The economics of this is straightforward. Under the "new public management," patent offices increasingly have to fund their operations from the fees they collect from patentees. For patent offices everywhere most patentees are U.S. and European companies or their local agents. The other financial fact of life is that as intellectual property rights have become more economically crucial to big business they have bankrolled patent offices out of contesting their strategic litigation games. Multinationals appeal patent office decisions in the courts mainly with an eye to securing precedents that turn the body of law to their structural advantage. Patent offices have had neither the legal resources nor the will to adequately contest these strategic litigation games.

What is to be done then about the progressive capture of the patent offices and courts by multinational corporations? Just as regulatory scholars have neglected the practices of patent offices as an object of study, so have non-governmental organisations (NGOs) neglected them as objects of lobbying. The consumer movement, development NGOs and to a lesser extent trade unions have now heard the TRIPS wake-up call. The realisation that they were deceived and excluded on the TRIPS debates is one of the things that had them out on the streets in Seattle and active on the internet resisting a Millenium round of the WTO. The not insignificant political clout that these NGOs now have, their capability to join arms with developing countries to gain outcomes such as the Declaration on the TRIPS Agreement and Public Health, give them the capability to intervene with demands for the reform of patent office administration. At the moment, the anti-TRIPS NGOs see reforming patent office policies as a rather less romantic activity than street marches in Seattle. It is time to shift this perception.

Consumer groups in many countries today do have the clout to demand seats on the policy and consultative committees of patent offices, copyright offices and trade mark offices, seats that are currently occupied almost exclusively by business, copyright, patent and trade mark attorney interests. It is not enough for NGOs to make submissions to these

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committees or to have a token representation. Submissions without advocates on decision-taking committees tend to become part of filing history rather than committee action. NGOs can set themselves the objective of campaigning in a classic "good-cop-bad-cop" fashion for reform of patent or other intellectual property offices. The "good cop" NGOs can take their seats on policy committees within the walls of the patent office seeking to persuade changes in patent administration: (1) that demand resistance to the strategic litigation games of the multinationals; (2) that demand effective application of the tests of patentability in the public interest; (3) that demand that human rights, such as rights to health and Indigenous rights, be taken seriously in patent determinations; (4) that insist on denial of patents to companies which do not adequately document the know-how needed to work the invention properly once the patent has expired. The fourth point is important so others can exploit the information in the patent that society has received in exchange for the grant of the patent privilege and so new generations of innovators can stand on their shoulders. The "bad cop" NGOs can attack the patent office (and indeed the "good cop" NGOs) from outside the walls, accusing them of regulatory capture. Experience in other domains with combating regulatory capture by big business, for example with environmental regulation, suggests that persistence over a long period with this strategy of bad cop and good cop NGOs competing for political influence is what produces public-regarding reform.

The objective of such an NGO strategy needs to be much more than demands for critical reforms to patent office regulatory administration on matters such as utility and strategic litigation games. Political lobbying also needs to be directed at regulating intellectual property offices with a new jurisprudence of intellectual property. Pre-eminent here is the need for Indigenous rights groups to lead demands for intellectual property rights law and administration to be constrained by fundamental international human rights obligations. Human rights law must be clarified, made more explicit in its application, to ensure that it precludes actions by intellectual property offices to leave Indigenous people trespassers on their own culture. Patentable inventions should be required to not only pass meaningful standards of patentability and patents linked to a full disclosure of know-how test, but also the test that the issuance of the patent will not threaten any fundamental human right as defined by the international human rights instruments the state has ratified. The structural reform of patent administration needed to enforce these three tests is a shift from state administration captured by big business to tripartite administration where patent examiners are monitored on one side by business and on the other by NGOs, particularly consumer groups with links to Indigenous rights, human

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rights and development NGOs. Tripartism has been demonstrated in other regulatory arenas to be the key reform for deterring regulatory capture and corruption[77].

There is a fourth test that must be added to the patent, disclosure and human rights tests. This is the competition policy test. Again, NGOs have the key role of blowing the whistle to the national competition regulator when their monitoring of the decisions of patent examiners reveals that competition law has been breached. In short, the competition regulator needs to be positioned as a check and balance on the decisions of intellectual property regulators and NGOs, the whistle blowers who alert competition regulators to matters of concern. For the reasons outlined in Soskice's theory of comparative capitalisms, it is vital that intellectual property and competition institutions are mutually responsive so as to support an intercompany system that is fertile soil for investment. Furthermore, NGOs in most countries will need to lobby for a more aggressive use of competition law principles in relation to the exercise of intellectual property rights. The hands-off-intellectual-property policy of the Reagan Administration meant that competition principles stood silently by as intellectual property monopolies like Microsoft inflicted heavy losses on consumers and the process of innovation around the world. NGOs could also lend their strength to the cause of globalising competition policy rules aimed at defeating global knowledge cartels which are beyond the reach of any one national competition authority. Finally, globally networked NGOs could campaign/lobby for the transplant of good regulatory initiatives aimed at improving tools of competition law for dealing with the ill effects of intellectual property monopolies on innovation. The concept of a dependency licence in French law, for example, is aimed at giving rights of access to those who are in a position to improve on the patent holders original invention.[78] Such licences recognise the sequential nature of innovation and prevent intellectual property from being used to turn innovation into a winner take all game based on legal stratagems.

There is also a need to reform the deliberative quality of intellectual property regulatory administration. This need has become greater as the patent system expands to cover technologies that raise moral issues. As argued above, getting an efficient balance in intellectual property rights requires representation, transparency and non-domination combined with

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[77] *See* I. AYRES & J. BRAITHWAITE, RESPONSIVE REGULATION: TRANSFORMING THE DEREGULATION DEBATE, OXFORD UNIVERSITY PRESS ch. 3 (1992).

[78] For a discussion of dependency licenses and how the balance between patents and competition rules might be struck, see John H. Barton, *Patents and Antitrust: A Rethinking In Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449 (1997).

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institutionalised opportunities for thoughtful deliberation. Tripartism which gives a plurality of NGOs a voice alongside government officials, business and representatives of patent attorneys would be a big step along this path. But the deliberative process also needs attention. Before decisions of patent examiners become final and the subject of formal appeal those decisions should be tabled for discussion by these parties. Patent examiners may actually find this helpful. Under the European Patent Convention, for example, inventions that are contrary to morality are not patentable.[79] At the moment there is no deliberative process that a patent examiner can participate in to work out what this might mean in relation to a specific invention. A deliberative process might also help patent examiners to contend with senior patent attorneys representing large corporate clients who threaten to litigate whenever a patent examiner questions one of their patent applications. Patent examiners are expected to push through patent applications and not ask too many questions. Around the table most draft decisions would be straightforward and go through with minimal discussion. The greatest value of such a deliberative process is contestability, patent examiners knowing they might be called upon to defend their draft decisions not only by business critics but by NGOs of various kinds as well. This pressure would improve the quality of reasons given by patent examiners in their written decisions and this in turn would put pressure on patentees to improve the clarity of their patent applications and the care with which they explain its utility, inventiveness and the descriptions of the invention needed to make it work. For intellectual property to be an integral part of a comparative capitalism that buzzes with efficiency and administrative competence, deliberative competence is needed.

[79] Convention on the Grant of European Patents, Oct. 5, 1973, art. 53(a), 1065 U.N.T.S. 255, 272.

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