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Improving Access To Medicines Doesn't Have To Mean More Patents

Luigi Palombi*

Abstract

Access to medicines presupposes that there are medicines to access, but the development of medicines, especially those needed to treat diseases that inflict the poor and the disadvantaged, are especially difficult to access because of the pharmaceutical industry's paradigm of medicines being inextricably linked to patents; meaning, without patents there is no incentive to undertake the necessary R&D to develop new medicines. This paper argues that this is a lie; told by pharmaceutical executives and spread by well meaning scientists. Uncontested by policymakers in the 1960's it has become a truth that threatens scientific progress, the development of appropriate medicines and access to medicines for all but those that can afford them.

When Ernst Chain, the newly appointed Professor of Biochemistry at the Imperial College of Science and Technology, delivered the Trueman Wood Lecture¹ in London on 19 June 1963 at the invitation of the Royal Society of Arts, he told the influential audience, 'drugs are one of the greatest blessings - perhaps the greatest blessing - of our time'.² He also spoke of how he would 'shudder at the thought'³ of undergoing surgery 'without a general anaesthetic'⁴ and how he would 'certainly hate ... [to] helplessly watch [his] wife dying from child-bed fever, or [his] friends going down with diabetes or tuberculosis, or [his] children being crippled with rickets, or - worse still - paralysed by poliomyelitis'.⁵ Undoubtedly, these sentiments left an impression on everyone present.

In May 1940 Norman Heatley made an observation while conducting an experiment that involved penicillin and mice. Heatley wrote in his diary: 'the two treated mice seemed very well'⁶, while the other four untreated mice had died. This experiment confirmed that the form of penicillin that he and his Oxford colleagues, Howard Florey and Chain, had managed to purify from the material, *Penicillium notatum*, discovered by Alexander Fleming in 1928⁷, killed the bacteria which the mice had been exposed to. The success of this experiment⁸ eventually led to the production of penicillin as an antibiotic medicine; the world's first. Not only was this new medicine to save the lives of tens of thousands of Allied soldiers during WWII, but it marked the start of a process of research and development that would lead to the development of more powerful antibiotics.

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¹ Chain, E. B. (1963), 'Academic and Industrial Contributions to Drug Research', *Nature*, 200 (4905), 441-451.

² Ibid, 441 (his emphasis)

³ Ibid, 441.

⁴ Ibid, 441.

⁵ Ibid, 441.

⁶ Wright, P. (2004), 'Norman George Heatley', *Lancet*, 363 (9407), 495.

⁷ Fleming, A. (1929), 'On the Antibacterial Action of Cultures of a *Penicillium*, with Special Reference to their Use in the Isolation of *B. influenzae*', *British Journal Ex. Pathology*, 10, 226.

⁸ Abraham, E. P., Chain, E., Fletcher C. M., Gardner, A. D., Heatley, N. G., Jennings, M. A. and Florey, H. W. (1941) 'Further Observations on Penicillin', *Lancet*, 2, 177.

Florey, as Professor of Pathology, was the leader of the research team and he was responsible for the overall direction of the research; indeed, it was he, after reading Fleming's paper in 1938, who made the decision to undertake the scientific research that would transform Fleming's almost forgotten research into a life saving medicine. The motivation for this research was not, however, anything to do with the expectation of a patent. In fact, according to Florey, not even the prospect of alleviating the 'suffering humanity ... [had] ever crossed [their] minds'.⁹ Actually, for Florey this was no more than an 'interesting scientific exercise'.¹⁰

Chain, however, did not share his colleague Florey's disinterest in the commerciality of their work and although there is nothing to suggest that Chain's primary motivation was a patent, once they had managed to experimentally prove the medicinal application of penicillin, he raised the prospect with Florey.¹¹ Florey in turn raised the subject with Sir Edward Mellanby, Secretary of the Medical Research Council, but Mellanby's reaction was predictable - the very idea that British scientists would profit by their work was repugnant; it was unethical. To Chain, a German scientist who was trained in the 'tradition of collaboration between academic research and industry'¹², the British approach was incomprehensible and it caused such a deep division between Florey and Chain, that Chain left England for the *Istituto Superiore di Sanita* in Rome at the end of WWII. When Andrew Moyer, an American government scientist with US Department of Agriculture, first patented the method of its commercial scale production in 1948¹³, not only did Chain feel vindicated, but other British scientists began to reconsider their attitude to the patenting of medicines¹⁴ as more and more American pharmaceutical companies subsequently went on to patent more potent antibiotics, such as streptomycin, aureomycin, chlormeycetin, terramycin and tetracycline, during the 1950s and 60s. The point was further sharpened by the fact that Heatley and Florey had assisted the Americans in developing the mass production method of penicillin.¹⁵

Chain, now holding an important professorial chair in England, was not about to miss the opportunity of driving the message home that it was certainly no longer true that the 'lion's share'¹⁶ in chemical and biological scientific research was being undertaken by academic laboratories. The British reluctance to commercialise research through the collaboration between academic science and pharmaceutical companies could no longer be justified and Chain stressed, to his influential audience, that only 'by the closest collaboration between academic and industrial research laboratories'¹⁷ would the British national interest be best served. The painful history over penicillin was reemphasised. He spelt out how a substance that had 'remarkable curative powers in severe bacterial infections'¹⁸ was perfected in under-funded academic laboratories which did not have the resources to turn this important discovery into a commercially available medicine. As 'dramatic'¹⁹ as their research findings were, neither they nor the British or American governments could convince

⁹ de Berg, H. (1967), 'Transcript of Taped Interview with Lord Howard Florey', 5 April 1967, National Library of Australia, Canberra, 9.

¹⁰ Ibid, 9.

¹¹ Meyers, Morton A. (2007), *Happy Accidents: Serendipity in Modern Medical Breakthroughs*, New York US: Arcade Publishing, Inc., 76.

¹² Ibid, 76.

¹³ US 2,442,141, 25 May 1948, *Method for Production of Penicillin*.

¹⁴ Liebenau, J. (1987), 'The British Success with Penicillin', *Social Studies of Science*, 17 (1), 69-86, 81.

¹⁵ Wright, op cit 6.

¹⁶ Chain, op cit 1, 441.

¹⁷ Ibid, 442

¹⁸ Ibid, 448.

¹⁹ Ibid, 449.

British pharmaceutical companies to commit to commercial scale production. According to Chain, 'though they showed polite interest in what was undoubtedly a remarkable experimental result',²⁰ the British pharmaceutical industry believed: 'the idea of developing the biological production process of penicillin to the stage where the substance could be a drug of practical value as completely unrealistic and Utopian'.²¹ Chain could see the time had come for the UK government to make it attractive for the British pharmaceutical industry to invest in the research undertaken in academic or governmental laboratories. The pharmaceutical industry, he believed, was 'essentially productive, and not parasitic, in nature',²² being, 'one of the most positive assets to our form of society'.²³ He chastised his audience, warning them: 'no pharmaceutical industry-no new drugs.'²⁴ He was not, he said, 'naïve enough to claim that everything is of a pure white within the pharmaceutical industry',²⁵ but he made it clear: '[he preferred] to have an active pharmaceutical industry and life-saving drugs, accepting in the bargain a few abuses, than to have a system in which theoretically no abuses are possible, but which produce no drugs.'²⁶

Chain's recounting of the penicillin history was deliberately designed to rub salt into British wounds. Not only was it an American who ultimately claimed to have perfected the mass production of penicillin, but it was America, a country that allowed the patenting of chemical substances, that took first prize - the patent. That a British pharmaceutical industry, even with the research presented to them on a silver platter by one of Britain's leading academic institutions, Oxford, was reluctant to manufacture penicillin in commercial quantities demonstrated, according to Chain, how much an incentive was needed before this industry would risk its capital.

What Chain's lecture failed to mention was that the new *Patents Act, 1949* (UK) repealed the prohibition on the patenting of chemical substances that had been introduced into British patent law in 1919 (s.38A(1), *Patents and Designs Act, 1907* (UK)). The repeal was in response to submissions made by the *Association of the British Pharmaceutical Industry* (ABPI), during a review of the *Patents and Designs Act, 1907* chaired by Kenneth Swan QC between 1945 and 1947.

Under s.38A(1), 'any substances prepared or produced by chemical processes or intended for food or medicine', unless they were 'prepared or produced by special methods or processes of manufacture described and claimed', were not patentable subject matter. The intent was to place the British patent system on equal footing with the German patent system, which had never permitted the patenting of chemical substances and which had only permitted the patenting of products of processes since 1891. Indeed, when s.38A(1) was introduced in 1919, Sir William Pearce, a Liberal in the House of Commons and himself a chemical manufacturer, believed that the provision was a 'great improvement' because patentability depended 'upon the process rather than the actual substance itself.'²⁷ Essentially, it was felt that by preventing German chemical manufacturers from gaining a patent monopoly in England that was unavailable to them in Germany, generic pharmaceutical production in England would be encouraged. Clearly, the shortages of essential medicines and chemicals during WWI exposed England's dependence on

²⁰ Ibid, 449.

²¹ Ibid, 449.

²² Ibid, 450.

²³ Ibid, 450.

²⁴ Ibid, 450.

²⁵ Ibid, 451.

²⁶ Ibid, 451.

²⁷ Hansard, UK House of Commons, 1919, Vol 118, Col 1, 860.

Germany for its supply of chemical and pharmaceutical products,²⁸ and the post-war government was determined to see that this never happened again.

When evidence about the impact of s.38A(1) was first gathered between 1929 and 1931 by a committee charged to advise the UK Board of Trade on whether 'amendments' to the legislation were 'desirable', its chairman, Sir Charles Henry Sargant, reported in March 1931 that the policy had indeed 'been of considerable value in encouraging the development of British chemical industry'.²⁹

Sixteen years later, in 1947, the Swan Committee did a one hundred and eighty degree turn, finding that s.38A(1) had 'proved of little value, owing to the ease with which its provisions can be evaded',³⁰ particularly noting: '[it] merely encourages the drafting of a specification to cover all conceivable methods of manufacture, so that, in effect, it is the substance itself and not the process of manufacture which is protected by the patent'.³¹ Moreover, in the intervening period since 1931, the attitude of the British chemical industry towards the patenting of new chemical substances had changed. No longer was s.38A(1) seen, as it was in 1919, to be a protective measure against German chemical manufacturers. In point of fact, the Swan Committee noted that the circumstances applying at the time of its introduction in 1919, namely 'on account of the numerous broad claims for new dyestuffs made by German inventors in British patent specifications',³² had disappeared. The Swan Committee received submissions from the ABPI suggesting: 'the real invention lies in the discovery of a new substance, with new and useful properties, and that the process of manufacture often involves little novelty in itself'³³ - a view that was more or less consistent with American patent law and practice. Importantly, the Committee concluded that the policy of s.38A(1) could be better met by strengthening compulsory licensing, noting that this would ensure: 'neither the patentee nor the public would be deprived of the full benefit of the later invention, or hindered from using it'.³⁴ In other words, it no longer mattered that patents over chemical substances were to be granted to foreigners because the social and economic protection of Britain would be achieved by the grant of compulsory licenses. Thus, it hoped to ease the tension between the demands of the British chemical industry for patents over chemical substances on the one hand and political expectation of the public's need for readily available and affordable medicines, by recommending that the Comptroller be obliged to grant compulsory licenses 'unless he sees good reason not to'.³⁵

This change in perception was, however, not something that could only be credited to the drafting skills of Britain's patent attorney profession. Partially as a result of the compulsory acquisition of enemy assets during WWII, whereby many German owned British patents, trade marks and other intellectual property became owned by American companies³⁶, and partially as result of corporate acquisitions, the

²⁸ In 1932 the Sargant Committee noted: '[d]uring the War it became apparent that Great Britain was suffering from a lack of medicine and drugs, many of which were the subject of patent rights in this country'.

²⁹ UK Board of Trade, C. H. Sargant, (1931), *Report of the Departmental Committee on the Patents and Designs Acts and Practice of the Patent Office, 1930-31* [Cmd 3829].

³⁰ UK Board of Trade, K. R. Swan, (1946), *Patents and Designs Acts, Second Interim Report of the Departmental Committee, 1945-46* [Cmd 6789], 10 (35).

³¹ UK Board of Trade, K. R. Swan, (1947), *Patents and Designs Acts, Final Report of the Departmental Committee, 1946-47* [Cmd 7206], 21 (93).

³² *Ibid*, 21 (92).

³³ *Ibid*, 21 (93).

³⁴ *Ibid*, 22 (96).

³⁵ UK Board of Trade, K. R. Swan, (1946), *op cit* 30, 13 (57).

³⁶ Steen, K. (2001), 'Patents, Patriotism, and "Skilled in the Art": USA v The Chemical Foundation., 1923-1926', *Isis*, 92, 91-122.

supply of pharmaceuticals in Britain had changed. According to data presented to Lord Sainsbury's Committee of *Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service*, conducted between June 1965 and September 1967, American pharmaceutical companies supplied 49 per cent, the Swiss 14 per cent and other European countries 10 per cent of the total value of Britain's pharmaceutical prescriptions.³⁷ Only 27 per cent was supplied by British manufacturers, the vast majority of which were generic medicines.

This data suggested that by 1965 the ABPI was representing the interests of foreign owned pharmaceutical companies - mainly Swiss and American. Motivated by the desire to reduce the patenting costs caused by differences in national patent systems and annoyed by the differing levels of patent protection afforded to pharmaceutical products across the globe, the pharmaceutical industry began to mobilise on a united front. Already able to patent pharmaceutical substances in a substantial market like the United States, American pharmaceutical companies wanted the world's patent systems to be brought into line with that of the United States. Having successfully persuaded the Swan Committee to recommend the removal of the subject matter restriction on the patenting of chemical substances, 11 years later the ABPI remained dissatisfied with the retention of compulsory licensing. It 'strongly opposed'³⁸ the continuing discriminatory treatment of pharmaceuticals brought about by the compulsory licensing regime under s.41 *Patents Act, 1949* (UK)³⁹. The Sainsbury Committee understood the ABPI's agenda, observing: 'there was almost complete agreement among its members'⁴⁰ that firstly, 'patent law should be strengthened by restraining the ability of the Government to intervene',⁴¹ and secondly, that medicines not be 'treated differently from other products'.⁴² The Committee noted the ABPI's proposed reforms of the British patent system included permitting 'the patenting of new uses for known compounds',⁴³ and the extension of the patent term to 20 years.⁴⁴ According to the ABPI, 'only by the grant of "more effective protection ... [could] the pharmaceutical industry continue its contribution to the advancement of medical science and to the national economy"'.⁴⁵

Unfortunately for the ABPI, the Sainsbury Committee was unsympathetic. Apart from having to keep the price of medicines low

³⁷ UK Committee of Inquiry, Lord Sainsbury (1967), *Relationship of the Pharmaceutical Industry with the National Health Services, 1965-1967*, [Cmd 3410], 9 (22).

³⁸ Ibid, 43 (142).

³⁹ 41(1): Without prejudice to the foregoing provisions of this Act, where a patent is in force in respect of-

(a) a substance capable of being used as food or medicine or in the production of food or medicine; or

(b) a process for producing such a substance as aforesaid; or

(c) any invention capable of being used as or as part of a surgical or curative device, the comptroller shall, on application made to him by any person interested, order the grant to the applicant of a licence under the patent on such terms as he thinks fit, unless it appears to him that there are good reasons for refusing the application.

(2) In settling the terms of licences under this section the comptroller shall endeavour to secure that food, medicines, and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights.

⁴⁰ Sainsbury Committee, op cit 37, 43 (142).

⁴¹ Ibid, 43 (142).

⁴² Ibid, 43 (142).

⁴³ Ibid, 43 (143).

⁴⁴ Ibid, 43 (143).

⁴⁵ Ibid, 44 (143).

(an economic priority for the government, especially as the National Health Service provided prescription medicines free of charge), the Committee was suspicious of an organisation that it believed was no longer British. Therefore, not only did it reject the ABPI's submission regarding the extension of the British patent term from 16 to 20 years, but expressed the view that the existing term was: 'too long, and that the position could be met by a shorter period of complete protection.'⁴⁶ With regard to the need to 'induce adequate research and development and innovation in the pharmaceutical industry',⁴⁷ the Committee preferred the idea of 'a shorter period of monopoly for the patentee followed by a right to receive royalties under a licence of right.'⁴⁸ Moreover, it rejected the ABPI's criticism that the main compulsory licensing provision, s.41, had been 'little used',⁴⁹ by explaining that this was due to the 'inefficient'⁵⁰ administration by the Comptroller of Patents, which 'seemed to have discouraged or delayed potential licensees'.⁵¹ Rather than recommending the repeal of compulsory licensing, the Committee expressed the view that through the 'considerable simplification and hastening of existing procedures'⁵², compulsory licensing applications would be encouraged.

The result was a complete rejection of the pharmaceutical-patent paradigm. The Committee believed that a system of non-exclusive patent licensing would not only provide an adequate incentive for pharmaceutical research and development, but would also mitigate against high prices for medicines. The ABPI had failed to bring a convincing case before the Sainsbury Committee; but even before its Report was presented to the British Government in September 1967, the Banks Committee's *Enquiry to Examine the Patent System and Patent Law*⁵³ had commenced, and before this committee the ABPI was determined not to fail. Seizing upon the Sainsbury Committee's concession that it was unable to deal with the patent system in general terms because its terms of reference were limited to the NHS⁵⁴, the Banks Committee, having terms of reference directly dealing with the patent system, with the encouragement of the ABPI, proceeded to sanitise any adverse comment that the Sainsbury Committee had expressed about the relationship between the pharmaceutical industry and the patent system. In its Report presented to the Government in July 1970, the Bank's Committee did three things.

Firstly, it portrayed the British patent system as being out-of-step with the rest of the world with regard to 'the treatment accorded to drugs',⁵⁵ by pointing out that the patent laws of 'the United States and most of Western European countries do not distinguish between drugs and other chemical substances.'⁵⁶ This was quite misleading, since Germany's amendment to its patent law to allow for the protection of chemical substances had only taken place in September 1967 and most other European countries continued to expressly prohibit patents over pharmaceutical products.

Next, it dismissed the Sainsbury Committee's recommendations for streamlining the administrative processes to improve the effectiveness of compulsory licensing, by arguing that whatever were the reasons behind s.41 *UK Patents Act, 1949* (as recommended by the

⁴⁶ Ibid, 45 (150).

⁴⁷ Ibid, 76 (265).

⁴⁸ Ibid, 76 (265).

⁴⁹ Ibid, 45 (150).

⁵⁰ Ibid, 45 (150).

⁵¹ Ibid, 45 (150).

⁵² Ibid, 45 (150).

⁵³ UK Committee of Inquiry, M. A. L. Banks, (1970), *The British Patent System* [1970-71 Cmd 4407].

⁵⁴ Sainsbury Committee, op cit 37, 42 (139).

⁵⁵ Banks Committee, op cit 53, 115 (401-403).

⁵⁶ Ibid, 115 (401-403).

Swan Committee in 1947), it had 'not generally worked in the way in which it was intended'.⁵⁷

Finally, it redirected attention to the Crown use provisions of s.46, a provision that enabled the Government (as opposed to third parties) to use 'any patented medicine for the services of the Crown', and to ss.40 and 32(3), which covered the Government's permission for the endorsement of patents as 'licenses of right' and the Government's ability to revoke a patent on the grounds that the patentee has failed to make the patented invention available for Government service upon reasonable terms. It suggested that instead of using s.41 the NHS, as a Government service, could counter the price impact of a patented medicine by using s.46 to create a 'license of right', thereby permitting generic medicines to be legally supplied to the NHS at a lower price.⁵⁸

However, while it was true that the Sainsbury Committee had found s.41 underutilised, it also believed that it was beneficial to retain non-government compulsory licensing because it was important for generic drug producers or suppliers to be able to use the threat of an application to seek commercial licenses to manufacture and supply generic patented medicines on reasonable commercial terms. Generic manufacturers, which made up the bulk of British-owned pharmaceutical companies, had successfully applied for 21 compulsory licenses for medicines between 1960 and 1965.⁵⁹ Hence, s.41 had not only encouraged 'extensive cross-licensing',⁶⁰ but had produced 'noticeable [downward] effects on certain price levels.'⁶¹ The Committee found, that while prescription medicines were a matter between the doctor and the NHS, many over-the-counter medicines were purchased directly by the public and these medicines could not be brought within s.46.⁶² Therefore, the repeal of s.41 would have raised the price of trade marked over-the-counter medicines.

Another danger which the Sainsbury Committee was alive to, but which the Banks Committee ignored, was that once the ABPI had succeeded in destroying non-government compulsory licensing there would be nothing to stop the pharmaceutical industry neutralising the competitive effects of generic competition in the UK market place.⁶³

By the time of the Banks Committee's Report in 1970, British politicians were ripe for manipulation by the ABPI. The steps towards patent law harmonisation that had taken place in Europe during the 1960s, starting with the Strasbourg Convention in 1963 and continuing with the Draft European Patent Convention⁶⁴ circulated later that year by Kurt Haertel, President of the German Patent Office, required the complete obliteration of nationalistic-protectionist agendas. Furthermore, the ABPI believed that once the British Government had joined the EEC, it would only be a matter of time before it could, through the patent law harmonisation process, seek to constrain the conditions upon which EEC members could employ government compulsory licensing. This, as it turned out, is precisely what was to transpire.

Ultimately, having laid the groundwork for change, the Banks Committee made recommendations that suited both the ABPI and a thankful British Government - a government that was at pains to join the EEC⁶⁵. These were that s.41 be repealed⁶⁶; 'pharmaceutical

⁵⁷ Ibid, 114 (398).

⁵⁸ Ibid, 114 (399-400).

⁵⁹ Sainsbury Committee, op cit 37, 36 (118).

⁶⁰ Ibid, 35 (118).

⁶¹ Ibid, 36 (118).

⁶² Ibid, 33 (105) - 35 (113).

⁶³ Ibid, 44 (146).

⁶⁴ Oudemans, G. (1963), *The Draft European Patent Convention*, London, UK: Stevens & Sons Ltd; New York, US: Mathew Bender & Co. Inc.

⁶⁵ In fact had it not been for the veto exercised by French President Charles

substances ... continue to be patentable'⁶⁷; and the term of a British patent be extended from 16 to 20 years.⁶⁸ In what was indeed a remarkable turnaround in fortunes for the ABPI, within three years the Sainsbury Committee Report had been thrown into the Parliamentary dustbin.

This was a remarkable achievement by Banks (who was then knighted for his services), especially as Judy Slinn⁶⁹ had observed: 'the total cost of running the NHS [between 1948 and 1967] was considerably higher than had been anticipated and proved to be something of a shock to ministers and civil servants.'⁷⁰ According to her, while '6.8 million prescriptions were dispensed by chemists' in June 1948, the month before the start of the NHS, 'by September ... the monthly figure had doubled to 13.6 million'.⁷¹ In fact, the Sainsbury Committee's enquiry was one of a number that had been commissioned by successive British governments since the NHS had started operation, all desperate to find ways of slowing the growth in prescriptions. So, in spite of the fact that the Banks Committee's recommendations roughly translated into higher prices for medicines, the British government was ultimately persuaded to adopt a patent model that was consistent with 'the dominant paradigm of the pharmaceutical industry',⁷² one that ensured, according to Slinn: '[c]ompetition in the industry ... depended on innovation rather than on price'.⁷³

The Banks Committee in turn facilitated the British government's pro-EEC agenda - an agenda that required it to officially accept the pharmaceutical-patent paradigm that stipulated that without a patent system that was strong, broad and effectively enforced, the necessary investment in capital needed to deliver new and better drugs would not be possible. In a remarkable about-face, it was now official government policy to say that the patent system was only about encouraging innovation; and forgotten were the words written some fifty years earlier by David Fulton, in his 1910 book about the *Patents & Designs Act, 1907*⁷⁴, in which he opined: 'It is indisputable that, under the Statute of Monopolies patents were not granted to inventors as a reward for being ingenious, but for the purpose of introducing new manufactures into the country and to create increased employment for the working classes.'⁷⁵ So now the patent system was about encouraging innovation, not about creating employment.

David Fulton was not the only person to have held this opinion. Lloyd George MP⁷⁶ (who was the British Prime Minister between 1916-1922) introduced the Bill (that became the *Patents & Designs Act, 1907*) into Parliament while he was President of the Board of Trade, in order to 'combat the evil'⁷⁷ created by the 'abuse'⁷⁸ of the British patent system. In giving the Comptroller of Patents the power to revoke patents (previously only courts could revoke), the British Parliament had strengthened compulsory licensing by making the petition for revocation (the ultimate penalty for uncooperative

de Gaulle, the British application to join the EEC would have been successful in 1961.

⁶⁶ Banks Committee, op cit 53, 118 (410).

⁶⁷ Ibid, 119 (410).

⁶⁸ Ibid, 99 (348).

⁶⁹ Slinn, J. (2005), 'Prescription Pharmaceuticals in the UK,' *Business History*, 47 (3), 352-366.

⁷⁰ Ibid, 353.

⁷¹ Ibid, 353.

⁷² Ibid, 355.

⁷³ Ibid, 355.

⁷⁴ Fulton, David (1910), *The Law and Practice Relating To Patents, Trade Marks and Designs*, Fourth Edition, London UK: Jordan & Sons, Limited.

⁷⁵ Ibid, 10.

⁷⁶ 1863-1945; MP, 1905-1945; British Prime Minister, 1916-22.

⁷⁷ Schuster, G. (1909), 'The Patents and Designs Act, 1907', *The Economic Journal*, 19 (76), 538-551, 538.

⁷⁸ Ibid, 538.

patentees) more administrative, less formal and less expensive than proceedings before a court. It was a measure clearly aimed at encouraging local industry to seek relief against the German dyestuffs, chemical and pharmaceutical industries which, according to George, had 'practically a monopoly' in the UK.⁷⁹ Describing them as 'powerful foreign syndicates'⁸⁰ that had been awarded 'wide patents covering all possible combinations'⁸¹ of chemical inventions 'that had not been tried in practice at all'⁸², George believed that they discouraged 'the ingenuity of the poor British inventor'.⁸³ Fulton added: 'the commercial working of the invention within the realm had fallen into abeyance during the latter half of the eighteenth century',⁸⁴ with the result, 'foreigners could obtain patents in this country with no intention of working them here, but merely for the purpose of preventing competition by tying the hands of British manufacturers and enabling the patentees to manufacture abroad and import to England at prices which were often exorbitant.'⁸⁵

The concerns expressed by George, a politician, and Fulton, a patent lawyer, were by no means isolated. They repeated a view which then had echoed through the halls of the British business community as well as the British legal community. Another patent lawyer, Kenneth R. Swan (who as already discussed would eventually chair a UK Parliamentary Select Committee into the British patent system conducted between 1945-1947), had warned in his 1908 treatise on British patent law:

"Latter-day commercial methods have ... shown that in the hands of unscrupulous [patent] proprietors a British patent can be turned to great profit for the patentee without a corresponding benefit to the public ...[and that] patents have occasionally be acquired not for the purpose of establishing a new manufacture 'within the realm', but ... as a means of suppressing the manufacture in this country, whilst the invention is being worked abroad and the patented article imported into England and sold at exorbitant prices."⁸⁶

Swan was particularly incisive and accurately foresaw another danger posed to the British economy by allowing a patent system to operate without adequate safeguards against what he described as 'unscrupulous tactics'.⁸⁷ Swan noted:

"Taking advantage of their monopoly simply to prevent manufacture in this country, powerful foreign companies built up their businesses on that Continent and in America on such a gigantic scale that *even after the expiration of the British patents, they continued to monopolise our markets*, owing to the impossibility of creating and fostering these industries at home in the face of such formidable competition from well-established industries abroad."⁸⁸ (emphasis added).

Swan's point is as true today as it was in 1908 - the patent systems of the world are being carefully manipulated by the pharmaceutical and biotech industries in order to suppress the production of generic medicines after the original patents have expired and, to use a

⁷⁹ Ibid, 551.

⁸⁰ Ibid, 538.

⁸¹ Ibid, 538.

⁸² Ibid, 538.

⁸³ Ibid, 538.

⁸⁴ Fulton, op cit 73, 10.

⁸⁵ Ibid, 10.

⁸⁶ Swan, Kenneth R. (1908), *The Law and Commercial Usage of Patents, Designs and Trade Marks*, London UK: Archibald Constable & Co Ltd.

⁸⁷ Ibid, 4.

⁸⁸ Ibid, 4.

modern term, by their ability to 'evergreen' their patent monopolies so that they extend well beyond twenty years.

As a politician, George was focused on his constituency and on his re-election. In a speech made at the Manchester Corn Exchange on 22 April 1908 he predicted, to the warm cheers of British workers: 'in the course of the next few years [the *Patents & Designs Act, 1907*] would [result in] employment to thousands, and in the course of the next ten years it would bring employment to scores of thousands of people in this country.'⁸⁹ Unfortunately, WWI was to intervene and so his prediction remained unfulfilled.

When Haertel, some fifty years later, managed to persuade the West German government to abolish the ban on the patenting of chemical substances in 1967, it demonstrated that the government of Kurt Kiesinger⁹⁰ had also succumbed to the pressure to accept the pharmaceutical-patent paradigm. Haertel was part of a movement in Europe that wanted the EEC to become an economic and political equal to America. The development of policies that would unite Europe, by opening borders to trade and European populations, was key to achieving this goal; and, for Haertel, a single European patent was fundamental. Indeed, his original draft of the European Patent Convention provided for just that, but by the time policymakers and politicians had been allowed to tinker with it, their vision of an expanded Europe resulted in something different. Instead of a single European-wide patent that would be administered and enforced through two European-wide patent organisations (patent office and patent court), a bundle of European patents would be granted by the European Patent Office (to be located in Munich) under the banner of a 'European patent'. The resulting jurisdictional patchwork of European patents would then be enforced by national courts. This compromise, as unpalatable as it was to Haertel, was finally accepted in 1973.

What did not disappear from Haertel's original draft, however, was the prohibition on the technological discrimination of patentable inventions. This was one of the fundamental changes that the European Patent Convention would now impose on all members and, naturally, this suited the Swiss pharmaceutical industry, which had joined with US pharmaceutical companies in calling for a level technological playing field. After all, they argued, how could they be expected to provide new medicines when they were discriminated in terms of other industries by antiquated patent laws? Consequently, article 52(1) of the *European Patent Convention, 1973* expressly provides that patents must be granted for inventions, 'in all fields of technology'.

Employment, however, was not the only issue that the patent system was originally designed to protect. In point of fact, the patent system ensured that industrialisation was not hindered by foreign competition - a concern of Ernst Siemens.⁹¹ Siemens, an inventor and industrialist, founded *Telegraphen-Bauanstalt von Siemens & Halske* in 1847 (becoming Siemens & Halske AG in 1902 and Siemens AG in 1966) and was a very influential businessman in Bismarck's newly unified Germany. He strenuously opposed any move that would reduce protection for German industry; and rather than repealing patents (still operating at a provincial level within Germany), Siemens wanted a single national German patent system. So by the time Bismarck had completed the drafting of a Constitution for the proposed unified Germany in 1867, it too made provision for a national German patent law.

In 1947 Heinrich Kronstein and Irene Till denounced Bismarck as 'the

⁸⁹ Schuster, op cit 77, 67.

⁹⁰ 1904-1988; Chancellor of West Germany, 1966-69.

⁹¹ 1816-1892; knighted (Germany), 1888.

leader of the anti-patent movement';⁹² but their criticism was misplaced. Simply because he had delayed establishing a national patent law until 1877 was no proof that he disapproved of patents, rather it reflected his want to have the right patent system for Germany. They ignored two points: firstly, patents were continuing to be granted by the provinces of the former German Confederation and so there was no immediate imperative for a national system and secondly, it was clear to Bismarck that German industrialists, like Siemens and Bayer, were concerned to ensure that the national patent system did not inadvertently suppress Germany industrialisation, a concern which he shared and a result that he wished to avoid.

In 1874 the *Deutsche Chemische Gessellschaft* (The German Chemical Organisation), representing the German chemical industry, collaborated with the representative organisations of other technologies, such as the electrical industry, to form the *Deutsche Patentschutz-Verein* (The German Patent Protection Association), whose sole purpose was to guide Bismarck on how to draft the proposed national German patent law.⁹³ Along with Bismarck, Siemens, as its president, was in favour of a national patent system, but he was not in favour of one that could be used by the British Empire and the United States to suppress German industrialisation. To an expert committee, established in 1876 by Bismarck to enquire into the establishment of a national patent system, Siemens made his case:

"Today [German] industry is developing rapidly; and as a result monopolization of inventions and abuse of rights will inevitably expose large segments of industry to serious injury. The government must protect industry against these dangers. From abroad another danger may arise. Inventive work is far more developed in England, United States and France than in Germany. Up to the present the number of patents taken out in Germany by foreigners has been small because of the scope of protection given to the inventor has been insufficient. New legislation will lead to a substantial increase of foreign patentees. We shall experience a wave of foreign - particularly American - patent applications. These patents will not be taken out in order to protect industrial plants established or to be established in Germany; they will be taken out to monopolize production abroad. These articles will be imported into this country. Such a danger must be met. It is not enough to provide that foreign patentees be required to submit evidence that they have established a plant in Germany. Such evidence may be mere shadow; they can merely keep a small domestic production going to maintain their patents." ⁹⁴

The chemical industry was equally concerned to ensure that any new patent law did not protect chemical products per se, just the processes of their manufacture. Their strategy was to encourage new and more efficient chemical processes - a field in which Germany had a comparative advantage over its international competitors. Accordingly, it was felt that a patent system like that of the US and England, that allowed product patents on chemical substances, would act only as a disincentive to that advantage, because if the product was subject to patent protection, then no matter how innovative the processes for their manufacture, the end product would still be subject to that monopoly.

⁹² Kronstein, H. and Till, I. (1947), 'A Reevaluation of the International Patent Convention', *Law and Contemporary Problems*, 12 (4), 765-781.

⁹³ Seckelmann, M. (2001), 'The Quest for Legal Stability: Patent Protection within the German Empire, 1871-1903', *EBHA Conference 2001: Business and Knowledge: E2: Patents and Knowledge*. [http://web.bi.no/forskning/ebha2001.nsf/23e5e39594c064ee852564ae004fa010/a6cb7066ea59eda6c12567f30056ef4d/\\$FILE/E2%20-%20Seckelmann%20ii.PDF](http://web.bi.no/forskning/ebha2001.nsf/23e5e39594c064ee852564ae004fa010/a6cb7066ea59eda6c12567f30056ef4d/$FILE/E2%20-%20Seckelmann%20ii.PDF)

⁹⁴ Kronstein & Till, op cit 92, 773.

Bismarck subsequently satisfied each of these concerns. Under the *German Patents Act, 1877*, or *Reichspatentgesetz*, enacted on 25 May 1877, the law stated:

“Patents are granted for new inventions which permit of an industrial realisation. The exceptions are ... inventions of articles of food, drinks and medicines as well as of substances manufactured by a chemical process in so far as the inventions do not relate to a certain process for manufacturing such articles.” (s.1)⁹⁵

Furthermore, a German patent would be unenforceable if, after three years: ‘the patentee neglect[ed] to work his invention in the Country to an adequate extent or to do all that was requisite for securing the said working’.⁹⁶ Moreover, as Siemens was on the patent law drafting committee, the economic protections which Siemens desired included a compulsory license power that applied: ‘when it appear[ed] conducive to the public interest that permission to use the invention be granted to others and the patentee refuse[d] to grant such permission for a suitable compensation and on good security’ (s.11).

The German patent law also refused to allow patents to be granted to an individual, unless he was the sole inventor. In fact, nowhere in the German patent application was there any reference to the inventor as such, only to the patent applicant. This was a deliberate departure from the past and signified a shift in thinking away from the individual and towards the team approach to technical innovation. Siemens believed in the importance and power of collaborative science and engineering. This Germanic approach to innovation, as Ernst Chain was to emphasize to his London audience in 1963, involved a combination of both academic and industrial institutions and, for Siemens, it was difficult, if not impossible, in that situation to magnify the inventive contribution of one person over another. Accordingly, under German patent law, it was the institution that would normally be the patent applicant because it was, by collective effort, also the inventor.

However, by 1978, when the *European Patent Convention* came into effect, this history and the reasoning behind it had been erased and replaced by a pharmaceutical-patent paradigm that was now entrenched into the very fabric of the European patent system. No longer concerned about the petty squabbles over European trade, European politicians accepted that national patent laws that excluded pharmaceutical products as inventions were unnecessary. The Italians, unfortunately, seemed not to have understood the impact that the *EPC* would have on their country’s vibrant and competitive generic pharmaceutical industry. In 1977 American pharmaceutical companies challenged the validity of the Italian patent law that continued to prohibit the patenting of chemical substances for use in medicines, and these proceedings reached the Italian Court of Cassation, Italy’s constitutional court. It ruled in 1978 that prohibition on the patenting of pharmaceutical products and their processes of manufacture was unconstitutional, and ordered Italy to comply with the *EPC*. According to F. M. Scherer,⁹⁷ there were a number of immediate consequences:

‘(1) no significant increase in Italian drug R&D expenditures relative to world trends; (2) no significant increase in the number of new drug entities introduced by Italian firms; and (3) a sharp deterioration of the Italian trade balance in drugs into the negative realm as export

⁹⁵ Dutfield, Graham (2003), *Intellectual property rights and the life sciences*, Hampstead UK: Ashgate Publishing Limited; Burlington US: Ashgate Publishing Company, 78

⁹⁶ Ibid, 78.

⁹⁷ Scherer, F. M. (2000), ‘The Pharmaceutical Industry and World Intellectual Property Standards’, *Vanderbilt Law Review*, 53, 2245-2254.

sales faltered and multinational firms imported many of their products into Italy from elsewhere in Europe.’⁹⁸

This was only the beginning of a wider and more aggressive offensive by the pharmaceutical industry⁹⁹ (which would soon include the fledgling biotechnology industry) to ensure that the pharmaceutical-patent paradigm became a feature of the patent laws of all countries. This was to include India, a country that in the meantime had passed a new *Patents Act* in 1970¹⁰⁰. Under this law the patenting of chemicals and medicines was prohibited – a particularly unpalatable development in the eyes of American and European pharmaceutical executives who saw this as a backward step for the industry.

Indian policymakers had well understood that India needed to continue to industrialise. Moreover, it was a matter of national security that India provide medicines at prices that Indians could afford and that provided treatment for diseases and illnesses that were specific to the Indian subcontinent. Under these circumstances, the Indian government rejected the pharmaceutical-patent paradigm; and, given the precedent provided by English politicians such as George and patent law commentators such as Fulton, they used patent law to do for India what it had done for Britain and Germany. But according to Kalpana Chaturvedi and Joanna Chataway, the new Indian patent law ‘propelled Indian firms on [a] reverse engineering path’¹⁰¹; however, this description ignores the fact that process patents were still permitted. For all intents and purposes the policy behind the law was no different to the policy that applied in West Germany until 1968.

Facilitating access to medicines in India was not only a matter of a new patent law. A regime of price control on drugs was already in place, and this policy continued. Under the Drugs (Display of Prices) Order of 1970, not only were prices of 18 key medicines regulated but a profit ceiling was also imposed by the Ministry of Chemicals and Fertilisers on all pharmaceutical production. By 1978 the Indian government had also implemented a policy that was biased in favour of Indian pharmaceutical producers and that encouraged them to produce ‘bulk drugs’.¹⁰² Under this policy, apart from not being given this allowance, non-Indian pharmaceutical producers and their Indian subsidiaries had to manufacture medicines in India within 2 years of commencing foreign sales, and those producers with turnovers above R50 million were required to maintain a research and development capacity in India having budgets equal to at least 4 per cent of sales. In 1979 a new Drugs (Display of Prices) Order was issued. This was much more complex than the previous order and it now applied to 347 drugs – about 90 per cent of Indian production. Medicines were classified as either: lifesaving; essential; less essential; or non essential; all of which, with the exception of those classified as ‘non-essential’, were subjected to both price and

⁹⁸ Ibid, 2250.

⁹⁹ It was the beginning of a world industry that was unconnected to any particular country, achieved through a series of mergers and acquisitions that occurred from the mid-1970s onward. In 1972 the British firm Beecham made a takeover bid for Glaxo and, although it failed at that time, by 1988 these two firms had merged to become Glaxo SmithKline. In 1973 the Swiss firms Ciba and Geigy merged into Ciba-Geigy, which in 1994 merged with Swiss firm Sandoz to become Novartis. In the US, in 1970 Warner-Lambert acquired Parke-Davis and in 1989 Bristol Myers and Squibb merged to become Bristol Myers Squibb. Pfizer acquired Warner-Lambert in 2000. In the meantime, Novartis, Hoffman La Roche, Glaxo SmithKline, Pfizer, and some others have acquired interests in biotechnology companies such as Genentech and Chiron (both US).

¹⁰⁰ It came into effect in 1972.

¹⁰¹ Chaturvedi, K. and Chataway, J. (2003), ‘Policy and Technology Co-evolution in the Indian Pharmaceutical Industry’ (available as a web download).

¹⁰² Ibid.

profit controls. Also exempted from these regulations were Indian producers.

This mix of policies successfully made India self sufficient in pharmaceutical production¹⁰³ and a net exporter of reliable, safe and cheap generic medicines. This achievement, clearly, was not simply the result of 'reverse-engineering', but involved a considerable innovative capacity that developed over time, with the support of policies designed to encourage pharmaceutical research and development within India. The result saw key Indian producers such as Cipla, Ranbaxy, Dr Reddy's, Lupin, Sun, Torrent, Cadila, Dabur and Zydus expanding their repertoire of drugs, and some, like Dr Reddy's and Ranbaxy, even establishing offices in the US to supply generic off-patent medicines to the North American market.¹⁰⁴ Consequently, once the Italian generic pharmaceutical industry was put out of business as a result of the EPC, the Indian pharmaceutical industry replaced it.

The experience of India demonstrates the inherent flaw in the pharmaceutical-patent paradigm. Even with the leg-up that local Indian producers undoubtedly received as a result of the new patent law, what history shows is that within twenty years India's pharmaceutical industry had matured from copiers into innovators. What was initially needed was a capacity for production, but once that capacity was reached inevitably Indian pharmaceutical companies progressed to develop innovative drugs at prices that were affordable to Indians as well as peoples in developing countries. An example of this kind of innovation was Cipla's release in 2001 of the HIV drug *Triomune*, the world's first fixed-dose antiretroviral drug that combined the antiretroviral drugs *Stavudine*, *Lamivudine* and *Nevirapine* (all patented drugs except in India). Cipla sold *Triomune* at US\$600 per year, reduced to US\$1 per day to *Medecins San Frontieres* - a price much less than US\$10,000 per year that it cost to acquire a combination of three drugs separately in the US and Europe (and not produced as a single drug). In addition, Cipla also developed *Duovir-N*, *Duovir*, *Viraday* and *Efavir*, each of them drugs useful in the treatment of AIDS; and while it is true that these used otherwise patented ingredients, Cipla's innovation came in developing a drug that combined two or more of these ingredients into one, simplifying the dosage regime and improving AIDS treatment. Indeed, *Viraday* not only contains ingredients that treat HIV, but because of the way it has been formulated (which is less toxic than if the ingredients are taken separately) it can be taken together with tuberculosis medicine, something that was not possible before then.

Apart from the innovation that Cipla demonstrated with its combined HIV antiretroviral drugs, its aggressive pricing encouraged Merck, a US pharmaceutical company, to reduce the price of *Crixivan*, a protease inhibitor, to about the same price, which in turn caused Bristol Myers Squibb and Glaxo SmithKline to follow suit. Moreover, Abbott Laboratories, holder of patents over *Kaletra*, another HIV drug, came to an agreement with the Brazilian government reducing the price by 30 per cent - a saving of US\$10 million per year. Cipla also took the initiative of making its drugs available to miners in South Africa, a country where about 11 per cent of its entire population is HIV positive, by using Anglo American, a major mining company, to distribute its drugs free-of-charge to its workers.

Unfortunately, during the time that Cipla was making these new drugs available it was also facing the prospect that India would soon become compliant with the *Agreement on Trade Related Aspects of Intellectual Property* (TRIPS), as required under the *World Trade Agreement* which came into effect in January 1995. The end of the ten year TRIPS moratorium required countries like India to allow for patents over chemical substances from 2005. Article 27(1) TRIPS,

¹⁰³ Today it meets 95 per cent of domestic demand (Ibid).

¹⁰⁴ In 2004 the US was India's biggest export market.

modelled on art.52(1) EPC, made it clear that technological discrimination was also prohibited - indeed the language of art.27.1 bears a marked similarity to the language of art.52(1) in its totality.

TRIPS, therefore, became the multilateral mechanism through which the pharmaceutical-patent paradigm became a universal requirement of patent law in all WTO member countries; and this explains why, according to Peter Drahos,¹⁰⁵ Pfizer, the largest US pharmaceutical company, played a major behind-the-scenes role leading up to and during the TRIPS negotiations. Pfizer's call to arms had been answered. The story that was being told to US policymakers by Pfizer during the 1970s was that the profitability of US corporations was being eroded by 'copycat' products made in low cost manufacturing countries and that this was undermining the price advantage that patents provided. When the TRIPS negotiations opened in March 1987, the chief US negotiator naturally blamed the 'deficiencies in protection of intellectual property rights'¹⁰⁶ as the cause of a distortion of the 'trade in goods',¹⁰⁷ transforming the pharmaceutical-patent paradigm into a multilateral trade issue. It was the firm view of the US TRIPS negotiator, 'the entire trading system as a whole will benefit from eliminating trade distortions resulting from lack of adequate and effective protection of intellectual property rights'¹⁰⁸; and with in-principle support coming from the EEC, Japan and most developed countries, that transformation was made complete by article 27(1) TRIPS.

There were, of course, other developments that had converged to facilitate its transformation from a pharmaceutical-patent paradigm into a technology-patent paradigm. By the mid-1970s biotechnology provided pharmaceutical companies with the promise of patents over a whole range of biological materials, many of which would obviously have pharmacological application by replacing existing drugs with recombinant versions. Human insulin and erythropoietin were two of these, but there were countless others. The potential to once again create patented versions of these materials in low cost fermentation processes made it even more imperative that patents over chemical substances be universally granted and enforced, particularly as the patenting of chemical substances established a precedent for arguing that 'isolated' versions of these natural materials were patentable, just as 'new' chemicals were.¹⁰⁹

Indian academics, such as Surendra Pattel¹¹⁰, were critical, and he noted: 'seeds, plants and biogenetic substances and innovations will have to be patented or given patent-like protection'¹¹¹ as a result of TRIPS and this, for countries like India, had ramifications for 'agricultural development'.¹¹² Biotechnology brought pharmaceuticals and food together and made the patenting of these products, either as recombinant versions or as genetically modified versions, enticing enough for pharmaceutical companies to diversify into seed and plant

¹⁰⁵ Drahos, Peter with Braithwaite, John (2002), *Information Feudalism*, London UK: Earthscan Publications Ltd, particularly Chapter 4, 'Stealing from the Mind'.

¹⁰⁶ Statement By United States At Meeting of 25 March 1987. [MTN.GNG/NG11/W/2 3 April 1987].

¹⁰⁷ Ibid.

¹⁰⁸ Ibid.

¹⁰⁹ Palombi, L. (2004) *The Patenting of Biological Materials in the Context of TRIPS*, PhD thesis, University of New South Wales, Sydney, Australia.

¹¹⁰ A Director of UNCTAD (1969-1984) and a member of the Institute of Economic and Social Research, Ahmedabad, India.

¹¹¹ Pattel, S. (1992), 'Statement to the Group of Ministers on Arthur Dunkel's Draft of the Final Act on Uruguay round of GATT Negotiations', *Social Scientist*, 20 (1/2), 99-107.

¹¹² Ibid.

production.¹¹³

Unfortunately, even with the uniform patent protection and enforcement provided by TRIPS and the WTO, there is now a growing body of evidence that both the rate of drug innovation and pharmaceutical company profits are falling.¹¹⁴ According to one industry analyst, although Pfizer had 'spent \$7.6 billion on R&D [in 2004]... [it had not] launched a blockbuster from its own labs since 1998.'¹¹⁵ More to the point, the kinds of drugs that are in the development pipeline are not necessarily those that will save lives or alleviate human suffering or illness, especially in the developing world. Rather, many of these drugs are cosmetic, such as the penile erection drug *Viagra*,¹¹⁶ and anti-obesity drugs, such as *Orlistat*, *Sibutramine*, *Metformin*, *Byetta*, *Symlyn* and *Rimonabant* – not the kinds of drugs that Chain had in mind in 1963 when he spoke of the life saving miracles that modern drugs could provide. At the same time, the classic pharmaceutical business model that traditionally associated patent protection with huge profits and blockbuster drugs, such as *Lipitor* (for reducing Cholesterol), *Nexium* (for alleviating stomach ulcers) and *Zoloft* (for alleviating anxiety and depression), seems to have changed. The reasons for this change have less to do with the patent system and more to do with the need for pharmaceutical companies to 'protect themselves from [product] recalls'¹¹⁷ and class actions¹¹⁸ in wealthy and developed countries. Consequently, the R&D focus now appears to be on drugs that are much more specific and have much smaller (but wealthier) markets, and not on the kind of drugs or vaccines that are needed by people who are malnourished, suffer from tuberculosis or live in parts of the world in which malaria¹¹⁹ and other diseases (such as leprosy¹²⁰ or trachoma¹²¹) are endemic. Arguably, if the patent system truly encourages innovation in medicines, one would think that the prospect of eradicating 515 million cases of malaria a year alone would provide sufficient incentive for the necessary R&D into diseases that

¹¹³ Sygenta, a Swiss agribusiness company, was spun off by Novartis and AstraZeneca; and Monsanto, a US agribusiness, is a product of Pharmacia and UpJohn.

¹¹⁴ See 'Pfizer profits fall' (19 January 2006), MedicalSales.co.uk: http://allaboutmedicalsales.com/news/0106/Pfizer_20.html;

'Pfizer to cut 10,000 jobs, shut 5 plants', (22 January 2007) CNNMoney.com: <http://money.cnn.com/2007/01/22/news/companies/pfizer/index.htm?postversion=2007012216>;

'Schering-Plough sees quarterly profits falling 48% on merger costs' (23 April 2008), BloggingStocks: <http://www.bloggingstocks.com/2008/04/23/schering-plough-sgp-sees-quarterly-profit-falling-48-on-merge/>.

¹¹⁵ See 'The Waning Of The Blockbuster Drug', (18 October 2004) BusinessWeek.com:

http://www.businessweek.com/magazine/content/04_42/b3904034_mz011.htm

¹¹⁶ ABC TV Four Corners (2 November 1998), 'Viva Viagra': Reporter Liz Jackson. It posed the question: Is *Viagra* a medical or marketing miracle? <http://www.abc.net.au/4corners/stories/s22482.htm>

¹¹⁷ Ibid.

¹¹⁸ The Australian law firm Slater & Gordon has brought a class action in the Australian Federal Court for Australians that have been effected by Vioxx, manufactured by Merck. See

http://www.slatergordon.com.au/pages/class_actions_vioxx.aspx

¹¹⁹ For the WHO summary: <http://www.who.int/topics/malaria/en/>

¹²⁰ For the WHO summary: <http://www.who.int/lep/en/>

¹²¹ "Chronic eye infection, resembling severe conjunctivitis. The conjunctiva becomes inflamed, with scarring and formation of pus, and there may be damage to the cornea. It is caused by a bacterium (chlamydia), and is a disease of dry tropical regions. Although it responds well to antibiotics, numerically it remains the biggest single cause of blindness worldwide. In 2001 alone, 6 million people worldwide went blind through trachoma and a further 540 million were at risk. A 2004 study estimated that 18-24% of global blindness (7-9 million people) is caused by trachoma." The Free Dictionary: <http://encyclopedia.farlex.com/Tracoma>

afflict the developing world. Yet, there is still no anti-malarial vaccine.

The example of Cipla and India aside, history shows that patents are not the promoters of innovation that the pharmaceutical industry would like us to believe. Not until November 1888 did Switzerland enact a national patent law and even then, according to Eric Schiff,¹²² it was 'probably ... the most incomplete and selective patent law ever enacted in modern times'.¹²³ In fact, not until 1907 did Switzerland finally repeal the requirement to lodge a 'model' of the invention, and then, it was only in response to pressure from Germany (which had threatened to impose draconian import duties of its manufactured goods) and the United States (which had suggested that the Paris Convention be amended so that patent protection be extended only to members that provided mutual recognition of patented inventions). The Swiss firm Ciba (now Novartis) actually prospered, by manufacturing and supplying chemicals and dyes to Germany while using manufacturing processes that were not patentable in Switzerland as a result of the 'model' requirement. Moreover, the Netherlands, which repealed its patent law in 1869 only to reintroduce it in 1912, provided Philips, today the world's largest patent filing company,¹²⁴ with a patent free environment within which to commence operations and prosper with its own innovations to the electric light bulb.¹²⁵

Instead, the overwhelming evidence appears to confirm that, rather than improving access to medicines, the patent system actually encourages research and investment into medicines that produce the greatest profit for the least cost - not necessarily medicines that will alleviate human suffering, especially in developing countries. While some argue that by increasing the costs of medicines in developing countries (by paying for patented medicines at higher prices) research into treatments for common diseases that are endemic will be encouraged, others point out that this will be of little consolation to the poor who will be unable to afford them in the first place. In fact, strengthening patent laws has not improved access to affordable medicines. Rather, as Mattias Ganslandt, Keith Maskus and Eina Wong¹²⁶ explain: 'these problems point squarely to the need for further public involvement in encouraging new drugs and in procuring and distributing medicines.'¹²⁷ By this they mean some publicly funded scheme that is subsidised by developed countries to provide pharmaceutical companies with 'a long-term guarantee for new innovations'¹²⁸ in medicines at affordable prices, 'but [with] tight controls to prevent the low-cost drugs from escaping those areas'.¹²⁹ Whether their proposal is viable is not something that this paper is able to assess, but the fact that it has been mooted suggests that the implementation of stronger and uniform patent laws has not resulted in new medicines that alleviate human suffering in the developing world. They conclude: 'the prevailing system of [intellectual property rights has] fail[ed] to provide sufficient incentives to develop new treatments and distribute them at low

¹²² Schiff, Eric (1971), *Industrialization without National Patents: The Netherlands, 1869-1912, Switzerland, 1850-1907*, Princeton, New Jersey, US: Princeton University Press.

¹²³ Ibid, 93.

¹²⁴ WIPO 2007 Patent Statistics. WIPO/PR/2007/476: Record Year for International Patent Filings with Significant Growth from Northeast Asia.

¹²⁵ Schiff, op cit, 121; Verspagen B. (1999), 'Large Firms and Knowledge Flows in the Dutch R&D System: A Case Study of Philips Electronics', *Technology Analysis & Strategic Management*, 11 (2), 211-233.

¹²⁶ Ganslandt, M., Maskus, K., and Wong, E. (2001), 'Developing And Distributing Essential Medicines To Poor Countries: The *Defend* Proposal', *The Research Institute of Industrial Economics*, Working Paper No. 552, 2001. <http://www.naringslivsforskning.se/Wfiles/wp/WP552.pdf>

¹²⁷ Ibid, 5.

¹²⁸ Ibid, 17.

¹²⁹ Ibid, 18.

cost.¹³⁰

What seems to have been either forgotten or ignored by western policymakers is that until 1970 most industrially developed countries were extremely careful to ensure that the patents were not allowed to be used to undermine the local production and supply of medicines. Even the UK, if only between 1919 and 1949, followed Germany's example by refusing to permit the patenting of chemical substances. Most other European countries, including France and Italy, expressly prohibited the patenting of pharmaceuticals and did so until 1978. Moreover, in their study of invention in Victorian England, Christine MacLeod and Alessandro Nuvolari¹³¹ observed that those that made significant technological, scientific and medical contributions, such as William George Armstrong¹³², William Thomson¹³³ and Joseph Lister¹³⁴, were rewarded through 'unprecedented elevations to the peerage ...[and] the erection of statues in city centres'.¹³⁵ Whether their ingenuity was motivated by the grant of patents or by their personal ambitions is a matter of speculation, but according to MacLeod and Nuvolari about forty per cent of such people never obtained a British patent and, of these, 'the majority ... had elected not to'.¹³⁶ Was this an act of public philanthropy or was it simply that patents were not, in Victorian England, the only motivators of technological innovation?

Chain was probably right in 1963 to ask his British audience to accept his argument that collaborative science between academic research laboratories and commercial laboratories was good for innovative drug development, and, perhaps, the success that Stanford University achieved with the licensing of Stanley Cohen and Herbert Boyer's bacterial factory invention¹³⁷ in 1976 to Genentech¹³⁸ is a good example of this, but, unfortunately, this particular success which encouraged US Senator Birch Bayh to co-sponsor the *Bayh-Dole Act* in 1980 in the US Congress was not easily replicated by other American universities. Twenty five years later, as Clifton Leaf in his retrospective piece¹³⁹ on the effects of the *Bayh-Dole Act* explained, only a handful of American universities had actually made any substantial money from their collaborations with the commercial world; and, worst still, some of these, such as Columbia,¹⁴⁰ had attempted to extend their patent royalty income streams well beyond the original patent term by exploiting a loop-hole in US patent law. Despite the fact that the loop-hole was subsequently closed in 1995, it demonstrated how universities could behave unethically.

¹³⁰ Ibid, 21.

¹³¹ MacLeod, C. and Nuvolari A. (2006), 'The Pitfalls of Prosopography: Inventors in the Dictionary of National Biography', *Technology and Culture*, 47, 757-776.

¹³² 1810-1900, an engineer who developed the hydraulic accumulator.

¹³³ 1824-1907, a mathematical physicist and engineer who developed, among other things, 'a complete system to operate a submarine telegraph.'

¹³⁴ 1827-1912, a surgeon who discovered that 'carbolic acid could be used to sterilise surgical instruments and clean wounds.'

¹³⁵ MacLeod, C. and Nuvolari A., op cit 131.

¹³⁶ Ibid, 776

¹³⁷ US 4,237,224 (2 December 1980), 'Process for producing biologically functional molecular chimeras'.

¹³⁸ Hughes S. S. (2001), 'Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980', *Isis*, 92 (3), 541-575.

¹³⁹ Leaf, C. (2005), *The Law of Unintended Consequences*, Fortune, 19 September 2005, http://money.cnn.com/magazines/fortune/fortune_archive/2005/09/19/8272884/index.htm

¹⁴⁰ Clifton provides the example of the Axel patents that Columbia had licensed to 11 biotechnology and pharmaceutical companies, permitting them to manufacture 19 different drugs including Genentech's Herceptin. Clifton writes: 'But when the patent life ran out, Columbia announced that--surprise--it had secured a new patent, issued in 2002, that won't expire until 2019.'

Consequently, American universities have paid the ultimate price - the loss of their academic independence and the research privileges that once enabled the common law to easily provide universities with an exemption to patent infringement. The decision of the Court of Appeals for the Federal Circuit (CAFC) in *Madey v Duke University*¹⁴¹ confirmed that any activity, including research, that is engaged for 'commercial gain' and in 'furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry', is not capable of coming within the 'very narrow and strictly limited experimental use defense.' Thus, the CAFC held, that as part of Duke's legitimate business involved recruiting students and that excellence in research was an element of its promotion as an attractive university, Duke fell outside of the exemption.

This has had an impact on the way scientists collaborate across universities and disciplines. The secrecy demanded by the patent system, prior to the filing of a patent application, has meant that the type of collaboration that was once open between science and medicine is not possible. Commonplace these days are contractual conditions that impose upon research scientists duties to protect the patentability of their research. Confidentiality agreements and technology transfer agreements are now part of the everyday administrative paper shuffle that research scientists labour over, regardless of the 'profit or non-profit status'¹⁴² of their organisation or their research. Universities now demand that their scientists assign over any and all intellectual property, resulting in litigation as some scientists, understandably, leave their universities to commercialise their inventions.¹⁴³

One famous example of a scientist that commercialised university research came from a meeting between Robert Swanson, a Silicon Valley venture capitalist, and Herbert Boyer. Their meeting resulted in the incorporation of Genentech, Inc on 7 April 1976. On 14 October 1980, when Genentech's shares became open to the public, the share price soared to US\$89 and Boyer, who then owned nearly one million shares, become an instant multi-millionaire. By 1981 Genentech employed 40 PhDs and 65 researchers; and with Boyer in charge of its research, he went from earning US\$10,500 per year as a university researcher to US\$50,000 per year at Genentech. Predictably, in an article published by *Time Magazine* in March 1981, Boyer was quoted as saying: 'You'll never get rich in a university'.

As honourable as Chain's intentions were and despite his claim of not being 'naïve enough to claim that everything is of a pure white within the pharmaceutical industry',¹⁴⁴ the truth is, he was naïve. The pharmaceutical industry is in the business of making money. That it makes money by producing drugs that may be life-saving does not absolve regulators or politicians or policymakers for failing to be more circumspect with respect to their commercial activities. Admittedly, the anti-trust law suits against pharmaceutical cartels over antibiotics in the 1970s and vitamins in the 1990s indicate that they are sometimes scrutinised and occasionally punished for price fixing. Regrettable as this kind of activity is, it is the kind of activity that is easy for politicians to deplore on the one hand while accepting political donations with the other. Beyond price fixing there are other kinds of activity that are just as criminal. John Braithwaite, in his study on the pharmaceutical industry in the 1970s, exposes the collective mentality that makes this kind of criminality possible.¹⁴⁵ He explains:

¹⁴¹ *John M. J. Madey v Duke University*, 01-1567.

¹⁴² *Ibid.*

¹⁴³ A recent example of this type of litigation is *University of Western Australia v Gray* [2008] FCA 498.

¹⁴⁴ Chain, *op cit* 1.

¹⁴⁵ Braithwaite, John (1984), *Corporate Crime in the pharmaceutical industry*,

"In hastening to point out that not all pharmaceutical executives are nice guys, I am reminded of one gentleman who had a sign, 'Go for the jugular', on the wall behind his desk. Another respondent, arguably one of the most powerful half-dozen men in the Australian pharmaceutical industry, excused his own ruthlessness with: 'In business you can come up against a dirty stinking bunch of crooks. Then you have to behave like a crook yourself, otherwise you get done like a dinner.'" ¹⁴⁶

Braithwaite's 1970s study should be a reminder that corporate collectivism hides a multitude of sins. In late 2006 and early 2007, when the Thai government made the legitimate decision to issue compulsory licenses over a number of HIV drugs, the reaction of the pharmaceutical industry was ferocious. In spite of acting in accordance with Thai law and within the parameters of TRIPS, the Thai government's decision was described by *Managing Intellectual Property*, a leading intellectual property publication read by patent lawyers around the world, as having 'broken three drug patents within the past four months'.¹⁴⁷ Rather than understanding the humanitarianism behind its decision, the patent attorney profession and the pharmaceutical industry portrayed the Thai government as acting duplicitously, by 'playing an elaborate game of bluff, using compulsory licensing as a negotiating tactic to lower the cost of its highly successful, but increasingly expensive, health programme'.¹⁴⁸ Even Peter Mandleson, the EU's trade commissioner, wrote to the Thai Health Minister expressing his concerns 'that the Thai government may be taking a new approach to access to medicines', taking the opportunity to remind him that his ministry's policy of compulsory licensing 'would be detrimental to the patent system and so to innovation and the development of new medicines'.¹⁴⁹ Ignoring the fact that under the Thai license these companies would be paid a royalty of 5 per cent on all sales, what Mandleson seemed to have rejected is that the Thais were facing an enormous health catastrophe that required them to have access to HIV medicines at prices that were affordable. Unrelenting, Abbott Laboratories retaliated by withdrawing seven pending drugs¹⁵⁰ from the Thai drug regulatory approval process.¹⁵¹ The reason given by Abbott's Director of Public Affairs was, unsurprisingly: 'the Thai government's decision not to support innovation by breaking the patents of numerous medicines.'¹⁵²

Since WWII the pharmaceutical industry has pushed the line - if you want more drugs then we need patents! The truth is that it is an elaborate lie devised by the pharmaceutical industry and implemented by policymakers and politicians who felt so comfortable that world war (or any disaster) would never reoccur in Europe that they no longer needed to guarantee access to medicines. Despite compulsory licensing being the last safety valve, today even this is in danger of being eradicated. However, the evidence overwhelmingly shows that despite having the strongest and most uniform patent laws in history, the level of innovation in medicines is actually falling. Moreover, if one accepts that the patent system was never designed to encourage innovation, but was actually an economic tool that protected domestic

London UK: Routledge & Kegan Paul.

¹⁴⁶ Ibid, 2.

¹⁴⁷ 'Why Thailand is at the centre of a patent storm', *Managing intellectual Property*, March 2007 (my emphasis).

¹⁴⁸ Ibid.

¹⁴⁹ 'More drugs under threat in Thailand', *Managing Intellectual Property*, 24 September 2007 (my emphasis).

¹⁵⁰ These are Kaletra (HIV); Brufen (pain killer); Abbotic (antibiotic); Clivarine (blood clotting); Humira (arthritis); Tarka (blood pressure); Zemplar (kidney disease).

¹⁵¹ 'Drug maker hits back in Thai patent row', *Managing Intellectual Property*, 1 March 2007.

¹⁵² Ibid (my emphasis).

economies from foreign competition, the continued emphasis on patents to encourage the development of new and needed medicines is misplaced. Not only does the patent system not encourage the development of new and better medicines, but if it does, it encourages the development of medicines that maximise the profits of companies that demand the benefit of powerful economic protections that are otherwise unavailable - technological monopolies that enable them to control access, price and the quality of pharmaceuticals. Furthermore, patents distort research priorities by encouraging scientists to focus their applied research towards meeting the profit objectives of an industry that is inefficient (because of the economic protections provided by the patent system), unethical (because its primary motivation is money) and predatory (because it focuses on treating diseases prevalent in the developed world), rather than encouraging those whose pure research is meeting an ethical and humanitarian duty aimed at truly alleviating the human suffering of those that are poor, hungry and ill.

True it may be that Louis Pasteur patented a process that improved the quality of beer in 1873¹⁵³, but he never patented the vaccine for rabies. Indeed Pasteur courageously developed this vaccine while powerful men of medicine in Paris scoffed at his theories of infection and immunity. Pasteur laboured on with his research, even risking prosecution¹⁵⁴, because ultimately he believed that his research would help to end human suffering; and, although Lord Florey modestly repudiated any suggestion that he was motivated to develop penicillin as an antibiotic medicine in order to alleviate human suffering¹⁵⁵, the fact remains that his work was unmotivated by the promise of a patent.

¹⁵³ US 135,245 (28 January 1973), 'Improvement in Brewing Beer and Ale'.

¹⁵⁴ Geison, G. L. (1978), 'Pasteur's Work on Rabies: Reexamining the Ethical Issues', *The Hastings Center Report*, 8 (2), 26-33.

¹⁵⁵ de Berg, op cit 9.