

The Role of Patent Law in Regulating Access to Medicines

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In May 1940 Norman Heatley observed the effect of an experimental substance on some laboratory mice. He recorded in his diary: ‘the two treated mice seemed very well’.¹ Next he observed that the four untreated mice were dead. In reporting these observations to his Oxford colleagues, Howard Florey and Ernst Chain, the experiment confirmed what they had all hoped for: that *Penicillium notatum*, a naturally occurring substance, first discovered by Alexander Fleming in 1928², arrested the spread of systemic bacterial infection. The experiment’s success³ was a crucial step in the development of the world’s first antibiotic, a medicine which saved the lives of tens of thousands of Allied soldiers and the forerunner to more powerful antibiotics.

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’.⁴ For Florey this was no more than an ‘interesting scientific exercise’.⁵

Chain, however, did not share his colleague’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 demonstrate the medicinal application of penicillin in humans, he raised the prospect with Florey⁶, who in turn raised the subject with Sir Edward Mellenby, Secretary of the Medical Research Council. Mellenby’s rebuke was predictable - the very idea that British scientists would profit by their work was repugnant; it was unethical.

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¹ Wright, P. (2004), ‘Norman George Heatley’, *Lancet*, 363 (9407), 495.

² 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.

³ 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.

⁴ de Berg, H. (1967), ‘Transcript of Taped Interview with Lord Howard Florey’, 5 April 1967, National Library of Australia, Canberra.

⁵ Ibid, 4.

⁶ Meyers, Morton A. (2007), *Happy Accidents: Serendipity in Modern Medical Breakthroughs*, New York US: Arcade Publishing, Inc., 76.

To Chain, a scientist who was trained in the German ‘tradition of collaboration between academic research and industry’⁷, 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. Then when Andrew Moyer, an American government scientist with US Department of Agriculture, first patented the method of its commercial scale production in 1948⁸, not only did Chain feel vindicated, but other British scientists began to reconsider their attitude to the patenting of medicines⁹ 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.¹⁰

Fifteen years later, Chain was enticed back to England with the offer of the prestigious chair of biochemistry at the Imperial College of Science and Technology in London. He was invited by the Royal Society of Arts to deliver the Trueman Wood Lecture¹¹ on 19 June 1963, and he used the opportunity to exact revenge on a philosophy that had deprived him of access to research funds that were not ‘wholly dependent ... on political largesse’.¹²

Chain was not about to miss the opportunity of driving the message home that it was certainly no longer true that the ‘lion’s share’¹³ of 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 that only ‘by the closest collaboration between academic and industrial research laboratories’¹⁴ would the British national interest be best served.

Chain also knew that if he was to sap British stoicism he had to personalise his argument. Thus, he spoke of how he would ‘[s]hudder at the thought’¹⁵ of undergoing surgery ‘without a general anaesthetic’¹⁶ and ‘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’.¹⁷ Deliberately playing on their worst fears, he made his pitch to this

⁷ Ibid.

⁸ US 2,442,141, 25 May 1948, *Method for Production of Penicillin*.

⁹ Liebenau, J. (1987), ‘The British Success with Penicillin’, *Social Studies of Science*, 17 (1), 69-86, 81.

¹⁰ Wright, op cit 1.

¹¹ Chain, E. B. (1963), ‘Academic and Industrial Contributions to Drug Research’, *Nature*, 200 (4905), 441-451.

¹² Mansford, K. R. L. (1979) ‘Sir Ernst Chain, 1906-1979’, *Nature*, 281 (5733), 715-717, 715.

¹³ Chain, op cit 11, 441.

¹⁴ Ibid, 442

¹⁵ Ibid, 441.

¹⁶ Ibid.

¹⁷ Ibid.

influential audience: ‘drugs are one of the greatest blessings – perhaps *the* greatest blessing – of our time’ (emphasis in original)¹⁸.

Chain’s assault on this uniquely British philosophy was not without precedent. Already steps towards patent law harmonisation, starting with the Draft European Patent Convention¹⁹ and reinforced a few months later by the Strasbourg Convention signed by Belgium, Denmark, France, Ireland, Italy, Luxembourg, the Netherlands, Norway, Sweden and the United Kingdom, were preparing British policymakers and politicians to accept that full patent protection for the pharmaceutical industry was essential.²⁰

Leaving no stone unturned, Chain recalled how neither the ‘dramatic’²¹ evidence that demonstrated penicillin’s ‘remarkable curative powers in severe bacterial infections’²² nor the British or American governments could convince British pharmaceutical companies to commit to commercial scale production of this miracle drug during wartime. ‘Though they showed polite interest in what was undoubtedly a remarkable experimental result’,²³ said Chain, ‘the idea of developing the biological production process of penicillin to the stage where the substance could be a drug of practical value’ was thought to be ‘completely unrealistic and Utopian’.²⁴

What was needed, according to Chain, was the guarantee of money that could only come through the grant of patents over pharmaceuticals - substances which in 1941 were not patentable subject matter under British patent law.²⁵ And even though that was change²⁶ when the new patent law came into effect in 1949, he believed that more

¹⁸ Ibid.

¹⁹ Oudemans, G. (1963), *The Draft European Patent Convention*, London, UK: Stevens & Sons Ltd; New York, US: Mathew Bender & Co. Inc.

²⁰ At that time most European countries prohibited patents on chemical substances and medicines, although chemical processes were patentable.

²¹ Chain, op cit 11, 449.

²² Ibid, 448.

²³ Ibid, 449.

²⁴ Ibid.

²⁵ 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’. Hansard, UK House of Commons, 1919, Vol 118, Col 1, 860. 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’. 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 that the policy had indeed ‘been of considerable value in encouraging the development of British chemical industry’. 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].

²⁶ Sixteen years later, in 1947, the Swan Committee did a one hundred and eighty degree turn, finding

was needed to be done by the British government if it was to act in the best interests of the country.

The UK's ballooning National Health Service budget

By 1963 there was a significant degree of tension between the UK's National Health Service (NHS), established in 1948 and which provided prescription medicines free of charge to patients, and the Association of the British Pharmaceutical Industry (ABPI). During the 1950s successive British governments had conducted inquiries²⁷ to attempt to halt the massive blow out in the NHS's budget and to find ways of reducing the ballooning cost of patented medicines.²⁸ The upshot of these inquiries, unfortunately, had done little to change the status quo.

While acknowledging that he was not 'naïve enough to claim that everything is of a pure white within the pharmaceutical industry',²⁹ Chain made it clear that 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.'³⁰ Indeed, rather than portraying the pharmaceutical industry as the villain, Chain described it as 'one of the most positive assets to our form of society'³¹, warning his attentive and, by this stage, concerned

that s.38A(1) had 'proved of little value, owing to the ease with which its provisions can be evaded' [10 (35)]. 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' [21 (93)] - a view that was more or less consistent with American patent law and practice. UK Board of Trade, K. R. Swan, (1946), *Patents and Designs Acts, Second Interim Report of the Departmental Committee, 1945-46* [Cmd 6789].

²⁷ On April 1, 1953 the UK Minister for Health appointed Prof C. W. Guillebaud to chair a Committee of Enquiry, '[t]o review the present and prospective cost of the National Health Service; to suggest means, whether by modifications in organisation or otherwise, of ensuring the most effective control and efficient use of such Exchequer funds as may be made available; to advise how, in view of the burdens on the Exchequer, a rising charge upon it can be avoided while providing for the maintenance of an adequate Service; and to make recommendation.' Chester, T. E. (1956) 'The Guillebaud Report', *Public Administration*, 34 (2), 199-210.

In 1959 the Committee of Inquiry chaired by Sir Henry Hinchcliffe submitted its final report on the 'Cost of Prescribing' to the UK Minister for Health. Hinchcliffe's report was the subject of some debate in Parliament, mainly because there was some suggestion that the cause of the rise in the cost of prescription medicines was due to the relationship between doctors and pharmaceutical companies. Dr Edith Summerskill MP, for instance, stated: 'The joke among doctors' wives today is that when they want to do shopping in town they leave their husbands to have lunch with a drug firm. The following invitation came to my notice last week. It says: "Bayer Products Ltd. have pleasure in inviting Dr.—to the showing of a new film-strip on rheumatoid arthritis. Any medical colleagues will also be welcome. At the Green Dragon, N.21, on Wednesday and Thursday, 8th July and 9th July. Cocktails, 12.45; Film. 1 p.m., lunch, 1.20 p.m." A doctor whom I know, who went to one of these shows—rather a cynical man—said, "We were expecting some pep pills at cocktail time." But no, there was an adequate supply of gin. The film was not a film at all, but a few cheap lantern slides. The lunchers were well supplied with wine, and another cynical doctor said, "The most important things given out were leaflets telling us what drugs to prescribe"—all made by the firm, to recompense it for the lunch.' HC Deb, 15 July 1959, Vol 609, 419-548, 421.

²⁸ By 1959 the cost to the NHS of prescribed medicines was over £70 million. HC Deb, 15 July 1959, Vol 609, 419-548, 420.

²⁹ Chain, op cit 11, 451.

³⁰ Ibid.

³¹ Ibid, 450.

audience: ‘no pharmaceutical industry-no new drugs.’³²

Chain’s recounting of the penicillin story 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, which took the prize – the patent. Even when the research was done by a prestigious university, that the British pharmaceutical industry was reluctant to manufacture penicillin in commercial quantities demonstrated, according to Chain, just how much of an incentive was needed before it would risk its capital in the development of a new pharmaceutical.

Still, with the continuing escalation in the cost of prescription medicines, shortly after the government of Harold Wilson took office in 1965, the UK Minister of Health commissioned a further enquiry appointing Lord Sainsbury to chair a *Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service*.³³ Once again, tensions between the ABPI and the National Health Service were raised, only this time the ABPI not only had the public support of eminent scientists, such as Chain, it was also supported by events in Europe.

Encouraged by the developments towards patent harmonisation that had taken place in 1963 and which were continuing, the ABPI, which now represented an association controlled by American and Swiss pharmaceutical companies³⁴ and had already successfully persuaded the Swan Committee in 1947 to recommend the removal of the ban on the patenting of chemical substances as applied in 1919, now ‘strongly opposed’³⁵ what it considered to be the discriminatory treatment of its industry brought about by non-governmental compulsory licensing.³⁶

Observing that ‘there was almost complete agreement’³⁷ among the members of the ABPI, it argued first, that ‘patent law should be strengthened by restraining the ability of the Government to intervene’,³⁸ and secondly, that medicines not be ‘treated

³² Ibid.

³³ Lord Sainsbury (1967), *Relationship of the Pharmaceutical Industry with the National Health Services, 1965-1967*, [Cmd 3410].

³⁴ The Sainsbury Committee found that 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. Ibid, 9 (22).

³⁵ Ibid, 43 (142).

³⁶ s 41(1), *Patents Act, 1949 UK*: 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.

³⁷ Sainsbury Committee, 43 (142).

³⁸ Ibid, 43 (142).

differently from other products’.³⁹

Furthermore, dovetailing with the Draft European Patent Convention and the Strasbourg Convention, the ABPI proposed ‘the patenting of new uses for known compounds’,⁴⁰ and the extension of the patent term to 20 years.⁴¹ Latching onto the words of Chain spoken only two years earlier, the ABPI argued that ‘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”’.⁴²

Thus the scene was set. On the one side was the ABPI which, with the aid of its European and American counterparts and with the support of eminent scientists, was striving to strengthen patent protection for the pharmaceutical industry in the UK. On the other side was the Sainsbury Committee which was determined to find a way to halt the runaway cost of the NHS.

Understandably, the Sainsbury Committee was unsympathetic towards the ABPI’s position. Apart from having to keep the price of medicines low (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 not only was the existing term ‘too long’ but ‘that the position could be met by a shorter period of complete protection.’⁴³ With regard to the need to ‘induce adequate research and development and innovation in the pharmaceutical industry’,⁴⁴ the Committee believed that ‘a shorter period of monopoly for the patentee followed by a right to receive royalties under a licence of right’⁴⁵ would suffice. Not only that, it rejected the ABPI’s criticism that compulsory licensing had been ‘little used’⁴⁶ by blaming the Comptroller of Patents for its ‘inefficient’⁴⁷ administration, which ‘seemed to have discouraged or delayed potential licensees’.⁴⁸ Rather than recommending the repeal of non-governmental compulsory licensing, the Committee was in favour of simplifying and expediting its administration⁴⁹ so that British generic drug makers would be more likely to apply.

The result, in effect, also amounted to a complete rejection of the Draft European Patent Convention and the Strasbourg Convention. In fact, the Committee went even further, recommending that a system of non-exclusive patent licensing be developed.

³⁹ Ibid, 43 (142).

⁴⁰ Ibid, 43 (143).

⁴¹ Ibid.

⁴² Ibid, 44 (143).

⁴³ Ibid, 45 (150).

⁴⁴ Ibid, 76 (265).

⁴⁵ Ibid, 76 (265).

⁴⁶ Ibid, 45 (150).

⁴⁷ Ibid.

⁴⁸ Ibid.

⁴⁹ Ibid.

In its view, a system of non-exclusive licensing would not only provide an adequate incentive for pharmaceutical research and development, but would also mitigate against the effect of high prices for patented medicines.

The UK's decision to enter the EEC

The ABPI, therefore, failed miserably before the Sainsbury Committee. However, 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*⁵⁰ had commenced, and before this Committee the ABPI was determined not to fail.

What had changed during those two years was the acceptance by the Wilson government that the UK needed to be part of the European Economic Community (EEC). Despite that fact that Wilson was committed to pursuing a Labour agenda that was sympathetic towards the NHS and while it was concerned to find ways of reducing the escalating cost of healthcare, it was even more concerned that it not be left out of the EEC.⁵¹ Thus, it needed a way to neutralise the Sainsbury Report.

This the Banks Committee did by seizing upon the Sainsbury Committee's concession that it was unable to deal with the patent system in general terms.⁵² Proceeding to sanitise any adverse comment that the Sainsbury Committee had expressed about the relationship between the pharmaceutical industry and the patent system, its Report presented to the newly elected government of Edward Heath in July 1970 did three things.

First, 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',⁵³ 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.'⁵⁴ This was quite misleading, of course, since Germany only allowed the patenting of chemical substances from 1968 and most other European countries still 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 compulsory licensing in 1947, it had 'not generally worked in the way in which it was intended'.⁵⁵

⁵⁰ UK Committee of Inquiry, M. A. L. Banks, (1970), *The British Patent System* [1970-71 Cmd 4407].

⁵¹ Young, J. W. (2002) 'Technological Cooperation in Wilson's Strategy for EEC Entry' in Oliver J. Daddow (Ed) *Harold Wilson and European integration: Britain's second application to join the EEC*, Frank Cass Publishers: London.

⁵² Sainsbury Committee, op cit 33, 42 (139).

⁵³ Banks Committee, op cit 50, 115 (401-403).

⁵⁴ *Ibid*, 115 (401-403).

⁵⁵ *Ibid*, 114 (398). However, while it was true that the Sainsbury Committee had found compulsory licensing 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 [Sainsbury Committee, 36 (118)]. Hence, the Sainsbury Committee found that compulsory licensing had not only encouraged 'extensive cross-licensing', but had produced

Finally, it argued that the Government had the ability to control the price of patented medicines by, first, invoking Crown Use powers that enabled it to use ‘any patented medicine for the services of the Crown’, secondly, imposing ‘licenses of right’ on patents and, thirdly, revoking patents on the ground that the patentee has failed to make the patented invention available for Government service upon reasonable terms.⁵⁶

What the Banks Committee ignored, however, 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.⁵⁷ That, of course, was the price that had to be paid if Britain was to join the EEC; thus, having laid the groundwork for a different approach, the Banks Committee made recommendations that suited both the ABPI and a thankful British Government. They were first, that non-government compulsory licensing be abolished⁵⁸, secondly, that ‘pharmaceutical substances ... continue to be patentable’⁵⁹; and thirdly, that the term of a British patent be extended from 16 to 20 years.⁶⁰ 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.

Accordingly, it now suited the UK government to adopt the pharmaceutical-patent paradigm. From now on the British patent system was about encouraging innovation and not about ‘introducing new manufactures into the country and to create increased employment for the working classes.’⁶¹ Clearly, the UK government was not alone. Haertel, the President of the German Patent Office, had managed to persuade the West German government of Kurt Kiesinger to accept the pharmaceutical-patent paradigm – one that was seen to be essential if the EEC was to be an economic and political equal to America and it is important to recognise that the development of policies to unite Europe, by opening borders to trade and labour, were seen to be the key to achieving this goal; and, for Haertel, a single European patent was also part of meeting that objective.

‘noticeable [downward] effects on certain price levels’ [36 (118)].

⁵⁶ Ibid, 114 (399-400).

⁵⁷ Ibid, 44 (146).

⁵⁸ Banks Committee, op cit 50, 118 (410).

⁵⁹ Ibid, 119 (410).

⁶⁰ Ibid, 99 (348).

⁶¹ Fulton, David (1910), *The Law and Practice Relating To Patents, Trade Marks and Designs*, Fourth Edition, London UK: Jordan & Sons, Limited, 10. David Fulton was not the only person to have held this opinion. Lloyd George MP (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’ created by the ‘abuse’ 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 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. See also Schuster, G. (1909), ‘The Patents and Designs Act, 1907’, *The Economic Journal*, 19 (76), 538-551.

Indeed, his original draft of the European Patent Convention in 1963 provided for just that, but after ten years of international consultation and with a pressing need to meet the political compromises involved in expanding the EEC to include the UK, Ireland, Denmark and Norway, Haertel's vision of a single European-wide patent that would be administered and enforced through two European-wide patent organisations (patent office and patent court) was turned into a patchwork of European patents to be granted by the European Patent Office (located in Munich) under the banner of a 'European patent', with national courts retaining the right to revoke that part of the European patent that applied in their country. 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 American and Swiss pharmaceutical companies demand 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'.

By 1978, when the *European Patent Convention* came into effect, the pharmaceutical-patent paradigm was 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. This was only the beginning of a wider and more aggressive offensive by the pharmaceutical industry⁶² (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.

India

This was to include India, a country that had passed a new *Patents Act* in 1970.⁶³ Under this law, and in contrast to developments in Europe, the patenting of chemicals and medicines was prohibited.

Of course, India was not as economically developed as the United States, Europe and the UK. Indian policymakers appreciated that India needed to continue to industrialise, especially if it was to provide employment to its people. Moreover, it was a matter of national security that India provide medicines at prices its people could afford and treatment for diseases and illnesses that were specific to the Indian subcontinent. Under these circumstances, the Indian government rejected the

⁶² It was the beginning of a world industry that was unconnected to any particular country and 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).

⁶³ It came into effect in 1972.

pharmaceutical-patent paradigm; and, given the precedent provided by English politicians such as Lloyd George and patent law commentators such as David Fulton, they used patent law to do for India what it had done for Britain and Germany.

According to Kalpana Chaturvedi and Joanna Chataway this approach ‘propelled Indian firms on [a] reverse engineering path’,⁶⁴ but their criticism ignores the fact that process patents were still permitted, thus innovation was directed towards new processes rather than to the end product of those processes. For all intents and purposes the policy behind the Indian law was no different to the policy that applied in West Germany until 1968.

To facilitate 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. This mix of policies successfully made India self sufficient in pharmaceutical production⁶⁵ and a net exporter of reliable, safe and cheap generic medicines. Indeed it was not ‘reverse-engineering’, but a considerable innovative capacity that developed with the support of policies designed to encourage pharmaceutical research and development within India that, in time, saw key Indian producers such as Cipla, Ranbaxy, Dr Reddy’s, Lupin, Sun, Torrent, Cadila, Dabur and Zydus expanded their repertoire of drugs. Some, like Dr Reddy’s and Ranbaxy, even established offices in the US to supply generic off-patent medicines to the North American market.⁶⁶

An example of Indian drug 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 Frontitieres* – a price much less than the 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 drug 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, the holder of patents over *Kaletra*, another HIV drug, came to an agreement with the Brazilian government that reduced the price by 30 per cent – a saving of US\$10 million per year. Cipla also took the initiative to make 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

⁶⁴ Chaturvedi, K. and Chataway, J. (2003), ‘Policy and Technology Co-evolution in the Indian Pharmaceutical Industry’ (available as a web download).

⁶⁵ Today it meets 95 per cent of domestic demand (Ibid).

⁶⁶ In 2004 the US was India’s biggest export market.

company, to distribute its drugs free-of-charge to its workers.

The Impact of TRIPS

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, modelled on art.52(1) EPC, makes it clear that technological discrimination is also prohibited.

TRIPS, therefore, was 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,⁶⁷ Pfizer, the largest US pharmaceutical company, played a major behind-the-scenes role leading up to and during the TRIPS negotiations.

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. 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.⁶⁸

Patents as disincentives for the right kind of drugs

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.⁶⁹ 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.'⁷⁰ 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.

⁶⁷ Drahos, Peter with Braithwaite, John (2002), *Information Feudalism*, London UK: Earthscan Publications Ltd, particularly Chapter 4, 'Stealing from the Mind'.

⁶⁸ Palombi, L. (2004) *The Patenting of Biological Materials in the Context of TRIPS*, PhD thesis, University of New South Wales, Sydney, Australia.

⁶⁹ '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/>.

⁷⁰ 'The Waning Of The Blockbuster Drug', (18 October 2004) BusinessWeek.com:

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

Rather, many of these drugs are cosmetic, such as the penile erection drug *Viagra*⁷¹ 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’⁷² and class actions⁷³ 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 malaria⁷⁴ and other diseases (such as leprosy⁷⁵ or trachoma⁷⁶) are endemic.

Are Patents Necessary?

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,⁷⁷ it was ‘probably ... the most incomplete and selective patent law ever enacted in modern times’.⁷⁸ In fact, it was not until 1907 that Switzerland finally repealed the requirement to lodge a ‘model’ of the invention, and 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

⁷¹ 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>

⁷² Ibid.

⁷³ 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. http://www.slatergordon.com.au/pages/class_actions_vioxx.aspx

⁷⁴ For the WHO summary: <http://www.who.int/topics/malaria/en/>

⁷⁵ For the WHO summary: <http://www.who.int/lep/en/>

⁷⁶ “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>

⁷⁷ Schiff, Eric (1971), *Industrialization without National Patents: The Netherlands, 1869-1912, Switzerland, 1850-1907*, Princeton University Press, Princeton, New Jersey, US.

⁷⁸ Ibid, 93.

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,⁷⁹ with a patent-free environment within which to commence operations and prosper from its own innovations to the electric light bulb.⁸⁰

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.

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 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 Nuvolari⁸¹ observed that those that made significant technological, scientific and medical contributions, such as William George Armstrong⁸², William Thomson⁸³ and Joseph Lister⁸⁴, were rewarded through ‘unprecedented elevations to the peerage ... [and] the erection of statues in city centres’.⁸⁵ 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’.⁸⁶ Was this an act of public philanthropy or was it simply that patents were not, in Victorian England, the only motivators of technological innovation?

⁷⁹ WIPO 2007 Patent Statistics. WIPO/PR/2007/476: Record Year for International Patent Filings with Significant Growth from Northeast Asia.

⁸⁰ 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.

⁸¹ MacLeod, C. and Nuvolari A. (2006), ‘The Pitfalls of Prosopography: Inventors in the Dictionary of National Biography’, *Technology and Culture*, 47, 757-776.

⁸² 1810-1900, an engineer who developed the hydraulic accumulator.

⁸³ 1824-1907, a mathematical physicist and engineer who developed, among other things, ‘a complete system to operate a submarine telegraph.’

⁸⁴ 1827-1912, a surgeon who discovered that ‘carbolic acid could be used to sterilise surgical instruments and clean wounds.’

⁸⁵ MacLeod, C. and Nuvolari A., op cit 81, 758.

⁸⁶ *Ibid*, 766.

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 invention⁸⁷ in 1976 to Genentech⁸⁸ 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 piece⁸⁹ 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.

Unfortunately, the *Bayh-Dole Act* 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'⁹⁰ 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.⁹¹

As honourable as Chain's intentions were and despite his claim of not being 'naïve' in his defence of the pharmaceutical industry, the truth is, he was. 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. John Braithwaite, in his study on the pharmaceutical industry in the 1970s, exposes the collective mentality.⁹² He writes:

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

⁸⁷ US 4,237,224 (2 December 1980), 'Process for producing biologically functional molecular chimeras'.

⁸⁸ 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.

⁸⁹ 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

⁹⁰ *Ibid.*

⁹¹ A recent example of this type of litigation is *University of Western Australia v Gray* [2008] FCA 498.

⁹² Braithwaite, John (1984), *Corporate Crime in the pharmaceutical industry*, Routledge & Kegan Paul: London UK.

a crook yourself, otherwise you get done like a dinner.⁹³

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 was accused of having 'broken three drug patents within the past four months'.⁹⁴ Instead of sympathy, 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'.⁹⁵ 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*'.⁹⁶ 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 drugs⁹⁷ from the Thai drug regulatory approval process.⁹⁸ 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.'⁹⁹

Conclusion

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 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

⁹³ Ibid, 2.

⁹⁴ 'Why Thailand is at the centre of a patent storm', *Managing Intellectual Property*, March 2007 (my emphasis).

⁹⁵ Ibid.

⁹⁶ 'More drugs under threat in Thailand', *Managing Intellectual Property*, 24 September 2007 (my emphasis).

⁹⁷ These are Kaletra (HIV); Brufen (pain killer); Abbotic (antibiotic); Clivarine (blood clotting); Humira (arthritis); Tarka (blood pressure); Zemplar (kidney disease).

⁹⁸ 'Drug maker hits back in Thai patent row', *Managing Intellectual Property*, 1 March 2007.

⁹⁹ Ibid (my emphasis).

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 1873¹⁰⁰, 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 prosecution¹⁰¹, 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 suffering¹⁰², the fact remains that his work was unmotivated by the promise of a patent.

¹⁰⁰ US 135,245 (28 January 1973), ‘Improvement in Brewing Beer and Ale’.

¹⁰¹ Geison, G. L. (1978), ‘Pasteur’s Work on Rabies: Reexamining the Ethical Issues’, *The Hastings Center Report*, 8 (2), 26-33.

¹⁰² de Berg, op cit 9.