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Volume 6, Issue 2, August 2009

The Role of Patent Law in Regulating and Restricting Access to Medicines

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Abstract

Even with the uniform patent protection and enforcement provided by TRIPS and the WTO, there is now a growing body of evidence showing that both the rate of drug innovation and pharmaceutical company profits are falling. History shows that patents are not the promoters of innovation, unlike the pharmaceutical industry would like us to believe. 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 – but not necessarily medicines that will alleviate human suffering, especially in developing countries.

[This article was presented at the 'Unlocking IP' conference held in New South Wales on 16-17 April 2009.]

DOI: 10.2966/scrip.060209.394

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1. Introduction

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. The experiment's success was a crucial step in the development of the world's first antibiotic, penicillin.[2]

Howard Florey, as Professor of Pathology, was the leader of the Oxford research team. After reading Alexander Fleming's paper in 1938, he decided to undertake the scientific research that would transform Fleming's almost forgotten research[3] into a life saving medicine. The motivation for this research was not, however, anything to do with the expectation of a patent. According to Florey, not even the prospect of alleviating the "suffering [of] humanity … [had] ever crossed [his] mind."[4] For Florey it was no more than an "interesting scientific exercise."[5]

Ernst Chain, Florey's other partner, however, had different ideas. Although there is nothing to suggest that Chain was motivated by a patent, he raised the prospect with Florey[6], who in turn raised it with Sir Edward Mellenby, Secretary of the Medical Research Council. Mellenby, however, rejected the idea as being unethical.

To Chain, steeped in the German "tradition of collaboration between academic research and industry," this was unacceptable. He was disappointed that he left England for the *Istituto Superiore di Sanita* in Rome at the end of WWII. As it turned out, it was an American, Andrew Moyer, who first patented the method of its commercial scale production in 1948.[7] On hearing the news, Chain felt vindicated. Yet as more and more American pharmaceutical companies went on to patent more potent antibiotics during the 1950s and 60s, British resistance started to weaken – the point being further sharpened by the fact that Heatley and Florey had assisted the Americans during WWII.

Fifteen years later, in 1963, Chain was back in England holding the prestigious chair of biochemistry at the Imperial College and, in this capacity, he was invited by the Royal Society to deliver the Trueman Wood Lecture.[8] He used this opportunity to

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[1] P Wright, "Norman George Heatley" (2004) 363 (9407) *Lancet*, 495.

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

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

[4] H de Berg, "Transcript of Taped Interview with Lord Howard Florey", 5 April 1967, National Library of Australia, Canberra.

[5] *Ibid*, 4.

[6] M A Meyers, *Happy Accidents: Serendipity in Modern Medical Breakthroughs* (New York: Arcade Publishing, Inc, 2007) at 76.

[7] US 2,442,141, 25 May 1948, "Method for Production of Penicillin".

[8] E B Chain, "Academic and Industrial Contributions to Drug Research" (1963) 200 (4905) *Nature*, 441-451.

remark on a philosophy that had deprived him of access to research funds that were not "wholly dependent … on political largesse".[9]

Chain argued that it was certainly no longer true that the "lion's share"[10] of scientific research was being undertaken in academic laboratories and he stressed that only "by the closest collaboration between academic and industrial research laboratories"[11] would the British national interest be best served. Personalising the point to his British audience, he spoke of how he would "[s]hudder at the thought"[12] of undergoing surgery "without a general anaesthetic";[13] and he would:

> *[H]ate ... [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.*[14]

He made his pitch to this influential audience: "drugs are one of the greatest blessings – perhaps *the* greatest blessing – of our time" (emphasis in original).[15]

Chain's criticism of this philosophy was not without precedent. Already, steps towards patent law harmonisation – starting with the Draft European Patent Convention[16] 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.[17]

Chain recalled how neither the "dramatic"[18] evidence that demonstrated penicillin's "remarkable curative powers in severe bacterial infections,"[19] 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,"[20] said Chain, "the idea of developing the biological production process of penicillin to

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[9] K R L Mansford, "Sir Ernst Chain, 1906-1979" (1979) 281 (5733) *Nature*, 715-717 at 715.

[10] Chain, op cit 8, 441.

[11] *Ibid*, 442

[12] *Ibid*, 441.

[13] *Ibid*.

[14] *Ibid*.

[15] *Ibid*.

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

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

[18] Chain, *op cit* 8, 449.

[19] *Ibid*, 448.

[20] *Ibid*, 449.

the stage where the substance could be a drug of practical value 'was thought to be' completely unrealistic and Utopian."[21]

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.[22] And even though that was changed[23] when the new patent law came into effect in 1949, he believed that more was needed to be done by the British Government if it was to act in the best interests of the country.

2. The UK's Ballooning National Health Service Budget

The problem was that by 1959 the cost the UK's National Health Service (NHS) – established in 1948 and which provided prescription medicines free of charge to patients – had ballooned to over seventy million pounds.[24] There was considerable tension between the Ministry of Health and the Association of British Pharmaceutical Industry (ABPI).

During the time when a Committee of Inquiry[25] was being conducted into the cost of the NHS in 1959, Dr Edith Summerskill, MP, speaking in Parliament, sought to criticise drug companies. She said:

> *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*

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[21] *Ibid*.

[22] 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," Deb HC, 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 the 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].

[23] Sixteen years later, in 1947, the Swan Committee did a 180º turn, finding 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].

[24] HC Deb, 15 July 1959, Vol 609, 419-548, 420.

[25] This was the second enquiry into the NHS in the 1950s. The Committee was chaired by Sir Henry Hinchcliffe.

> *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.*[26]

This kind of anecdote meant little to Chain. While acknowledging that he was not "naïve enough to claim that everything is of a pure white within the pharmaceutical industry,"[27] he said 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."[28] He warned his audience: "no pharmaceutical industry-no new drugs."[29]

Chain's recounting of the penicillin story was particularly pertinent. 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 credit for the breakthrough in the form of the patent. Even when the research was done by a prestigious university, the fact 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.

With the continuing escalation in the cost of prescription medicines, shortly after the government of Harold Wilson took office in 1965, the Ministry of Health commissioned a further enquiry.[30] This time Lord Sainsbury chaired. Once again tensions between the ABPI and the Ministry were high, but this time the ABPI not only had the public support of Chain – a Nobel prize winning scientist – but also Kurt Haertel – a German patent lawyer and chair of a committee that was soon to release the first draft of what was to become the European Patent Convention.

Encouraged by this, the ABPI, which now represented an association controlled by American and Swiss pharmaceutical companies,[31] argued, first, that "patent law

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[26] HC Deb, 15 July 1959, Vol 609, 419-548, 421.

[27] Chain, *op cit* 8, 451.

[28] *Ibid*.

[29] *Ibid*.

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

[31] The Sainsbury Committee found that American pharmaceutical companies supplied 49 %, the Swiss 14 % and other European countries 10 % of the total value of Britain's pharmaceutical prescriptions. *Ibid*, 9 (22).

should be strengthened by restraining the ability of the Government to intervene,"[32] and secondly, that medicines not be "treated differently from other products."[33] It also proposed "the patenting of new uses for known compounds,"[34] and the extension of the patent term to twenty years.[35] Indeed, in the words of Chain only two years earlier, the ABPI advised Lord Sainsbury 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.'"[36]

The scene was thus 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 trying to find a way to halt the runaway cost of the NHS.

Understandably, the Sainsbury Committee was sceptical and suspicious of an organisation which it believed was no longer British. Not only did it reject the ABPI's submission regarding the extension of the British patent term from sixteen to twenty years, but it expressed the view that the existing term was "too long" as well as saying "that the position could be met by a shorter period of complete protection."[37] With regard to the need to "induce adequate research and development and innovation in the pharmaceutical industry," [38] the Committee believed that "a shorter period of monopoly for the patentee followed by a right to receive royalties under a licence of right"[39] would suffice. Not only that, it rejected the ABPI's criticism that compulsory licensing had been "little used"[40] by blaming the Comptroller of Patents for its "inefficient"[41] administration, which "seemed to have discouraged or delayed potential licensees."[42] Rather than recommending the repeal of non-governmental compulsory licensing, the Committee was in favour of simplifying and expediting its administration[43] so that British generic drug makers would be more likely to apply.

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[32] *Ibid*, 43 (142).

[33] *Ibid*, 43 (142).

[34] *Ibid*, 43 (143).

[35] *Ibid*.

[36] *Ibid*, 44 (143).

[37] *Ibid*, 45 (150).

[38] *Ibid*, 76 (265).

[39] *Ibid*, 76 (265).

[40] *Ibid*, 45 (150).

[41] *Ibid*.

[42] *Ibid*.

[43] *Ibid*.

3. The UK's decision to enter the EEC

However, even before its Report was presented to the UK Parliament in September 1967, the Banks Committee's *Enquiry to Examine the Patent System and Patent Law*[44] had commenced.

What had changed since 1965 was the Wilson Government's decision to have Britain join the European Economic Community (EEC).[45] This meant that it needed to find a way to go along the draft EPC, not so much because accession to the EPC was mandatory, more that it was necessary for Britain to be seen as a team player. This was particularly important, given the failure of the first attempt in 1960, for the British Government not to be perceived as politically and legally inflexible. Thus, the Wilson government needed a way to neutralise the Sainsbury Report's patent law recommendations.

The Banks Committee was established in May 1967 to "examine and report with recommendation upon the British patent system and patent law, in the light of the increasing need for international collaboration in patent matters." Its establishment coincided with the Wilson Government's announcement that Britain would make a second attempt to join the EEC, which suggests a link between the two.[46] More to the point, however, were the terms of reference, which Douglas Jay (President of the British Board of Trade) provided in July 1967. Specifically, the Banks Committee was directed to examine, report and make recommendations with respect to "the desirability of harmonising national patent laws and the degree of protection obtained by the same invention in different countries." This term was aimed squarely at the Sainsbury Report's patent law recommendations which, if implemented, would have led to a clash rather than harmonise Britain's patent laws with its neighbours. Clearly, by May 1967 the Minister for Health, if he had not received a copy of the Sainsbury Report, was aware of what to expect.

Thus the Banks Report, presented to a British Parliament controlled by 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,"[47] 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."[48] 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. That the Banks Report acknowledged

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

[45] J W Young, "Technological Cooperation in Wilson's Strategy for EEC Entry" in O J Daddow (ed) *Harold Wilson and European integration: Britain's second application to join the EEC* (London: Frank Cass Publishers, 2002).

[46] The Banks Committee was established by Mr Douglas Jay, President of the British Board of Trade, on 10 May 1967. See the Letter from Mr Maurice Banks to Mr Roy Mason MP, President of the British Board of Trade, 12 May 1970. The letter is reproduced at page v of the Banks Report, *op cit* 44 and reference is made at page xvii to its establishment.

[47] Banks Committee, *op cit* 44, 115 (401-403).

[48] *Ibid*, 115 (401-403).

that Germany had a "new" patent law permitting the patenting of chemical substances did not render it any more accurate, for the fact was that France and Italy – two principal EEC countries – had not followed Germany's example.

Next, it argued that whatever were the reasons behind compulsory licensing in 1947, it had "not generally worked in the way in which it was intended."[49]

Finally, it argued that by invoking Crown Use powers; by imposing "licenses of right"; or by revoking patents, on the ground that the patentee has failed to make the patented invention available for Government service upon reasonable terms, the Ministry should be able to encourage generic drug manufacture in Britain when needed.[50]

That was the price that had to be paid if Britain was to be seen as a cooperative new member of the EEC. Thus, having laid the groundwork for a different approach, the Banks Committee made recommendations that satisfied the ABPI and, coincidentally, both the Wilson and Heath governments. They were, first, that non-government compulsory licensing be abolished;[51] second, that "pharmaceutical substances … continue to be patentable"[52]; and thirdly, that the term of a British patent be extended from sixteen to twenty years. [53] In what was indeed a remarkable turnaround in fortunes for the ABPI, within three years the Sainsbury Report had been thrown into the Parliamentary dustbin. Accordingly, it then suited the UK Government to adopt the pharmaceutical-patent paradigm.

The UK Government, however, 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. 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. For Haertel, a single European patent was also part of meeting that objective.

His original draft of the European Patent Convention in 1963 provided for just that. After ten years of international consultation, however, 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 –

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[49] However, while it was true that the Sainsbury Committee had found compulsory licensing underutilised, it is also believed that it was beneficial to retain non-government compulsory licensing. This is 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 twenty-one 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 "noticeable [downward] effects on certain price levels" [36 (118)].

While the Banks Committee acknowledged this argument – indeed it had to given what the Sainsbury Report had stated – there is nothing in its Report to suggest that it accepted it. *Ibid*, 114 (398).

[50] *Ibid*, 114 (399-400).

[51] Banks Committee, *op cit* 43, 118 (410).

[52] *Ibid*, 119 (410).

[53] *Ibid*, 99 (348).

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.[54]

What did not disappear from Haertel's original draft was the prohibition on the technological discrimination of patentable inventions. Consequently, Article 52(1) of the *European Patent Convention, 1973* expressly provides that patents must be granted for "any inventions"[55] and that was to include chemical substances and, specifically, pharmaceuticals. 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 industry[56] (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.

4. India

This was to include India, a country that had passed a new *Patents Act* in 1970.[57] 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 provide 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

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[54] The compromises that were made during the ten year process of international negotiation is apparent when the text of the EPC, 1973 is compared with the original draft of the EPC. See Oudemans, *op cit* 16.

[55] The word "any" in the context in which it is used means that anything that is an "invention" and which is new; involves an inventive step; and is industrially applicable , is patentable subject matter. The word "any" before the word "invention" renders the words "whether products or processes, in all fields of technology," inserted into TRIPS some 20 years later, redundant at worst, or clarifying at best.

[56] 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 onwards. 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 had acquired interests in biotechnology companies such as Genentech and Chiron (both US).

[57] It came into effect in 1972.

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.

Some commentators believed that this approach "propelled Indian firms on [a] reverse engineering path"[58] – implying that India was a country of copycats. Yet such criticism ignored the fact that process patents were still permitted, just as they had been in Germany until 1968, and so innovation was directed towards new processes rather than to the end product of those processes, i.e. chemicals.

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 production[59] 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 expand 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.[60]

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 developing countries that did not provide patent protection for pharmaceutical substances). Cipla sold *Triomune* at US$600 per year, but reduced this to US$1 per day for *Medecins San Fronitieres* – 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. 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 roughly 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 were about 11 per cent

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[58] K Chaturvedi, "Policy and Technology Co-evolution in the Indian Pharmaceutical Industry" (2005) Open University DPP Working Paper No 50 available at http://www.open.ac.uk/ikd/workingpapers/workingpaper_08.pdf (accessed 17 May 2009)

[59] Today it meets 95 per cent of domestic demand (*Ibid*).

[60] In 2004 the US was India's biggest export market.

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.

5. 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.[61]

TRIPS, therefore, was the multilateral mechanism through which the pharmaceutical-patent paradigm became a universal requirement of patent law in all WTO member countries, which explains why, according to Peter Drahos[62] (of 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. This was so 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.[63]

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[61] Firstly, comparison of the language of Article 52(1) EPC, 1973 with art.27.1 TRIPS, 1995 shows a very close substantive and linguistic similarity. Art 52(1) EPC, 1973 states: "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."

Art 27(1) TRIPS, 1995 states: " … patents shall be available for any inventions, *whether products or processes, in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application. …" (emphasis added) The word "any" in the context in which it is used means that anything that is an "invention" and which is new; involves an inventive step; and is industrially applicable , is patentable subject matter. The word "any" before the word "invention" renders the words "whether products or processes, in all fields of technology," inserted into TRIPS some 20 years later, redundant at worst, or clarifying at best. When one considers that the EPC was drafted in the 1960s and early 70s and that TRIPS was drafted in the early 1990s, some 20 to 30 years later, it suggests that art. 27.1 TRIPS was indeed modelled on art 52.1 EPC, 1973. True it may be that art 52(1) EPC was amended in 2000 so that as it now applies it reads: "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application" but, for the reasons already given, the words "in all fields of technology" arguably add nothing to the meaning of the word "any."

[62] P Drahos with J Braithwaite, *Information Feudalism* (London: Earthscan Publications Ltd, 2002) particularly Chapter 4, 'Stealing from the Mind'.

[63] L Palombi "The Patenting of Biological Materials in the Context of TRIPS" PhD thesis, 2004, University of New South Wales, Sydney, Australia.

In 2005 India became TRIPS compliant. Dr Hamied, the chair of Cipla said:

> *The global pharma patent system to which India now subscribes denies the poor access to healthcare and curtails their right to life. The third world pharmaceutical industry has been chastised for making copycat drugs and condemned for engaging in so-called piracy. What is overlooked is that this industry had made affordable drugs available to the nations of the South, home to 6 billion people, most of whom are poor and battling a crippling disease burden with little or no help from their governments. But now, ... our ability to perform this social function will be reduced dramatically. We will no longer be able to produce and export cheap generic copies of patented medicines. Besides, since it takes at least ten years to bring a drug a to market from the time of filling the patent, all new drugs are going to be under monopoly and thus beyond the reach of most Indians, as well as the poor in other parts of the world. And the supply of affordable new medicines will dry up in due course.*[64]

6. Patents as disincentives for the right kind of drugs

Unfortunately, even with the extent of patent protection and enforcement provided by the minimum patentability standards in TRIPS, there is now a growing body of evidence that both the rate of drug innovation and pharmaceutical company profits are falling.[65] 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."[66] 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*[67] and anti-obesity drugs, such as *Orlistat*, *Sibutramine*, *Metformin*, *Byetta*, *Symlin* and *Rimonabant* (not the kinds of drugs that Chain had in mind in 1963 when he spoke of the life saving miracles that modern

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[64] Y K Hamied "Trading in Death", (2005) *The Pharma Review*, August, available at http://www.kppub.com/articles/pharmaceutical-publisher-india-articles-001/trading_in_death.html (accessed 17 May 2009).

[65] "Pfizer profits fall" (19 January 2006), MedicalSales.co.uk, available at http://allaboutmedicalsales.com/news/0106/Pfizer_20.html (accessed 17 May 2009).

"Pfizer to cut 10,000 jobs, shut 5 plants", (22 January 2007) CNNMoney.com, available at http://money.cnn.com/2007/01/22/news/companies/pfizer/index.htm?postversion=2007012216 (accessed 17 May 2009).

"Schering-Plough sees quarterly profits falling 48% on merger costs" (23 April 2008), BloggingStocks., available at http://www.bloggingstocks.com/2008/04/23/schering-plough-sgp-sees-quarterly-profit-falling-48-on-merge/ (accessed 17 May 2009).

[66] "The Waning Of The Blockbuster Drug", (18 October 2004) BusinessWeek.com, available on-line at http://www.businessweek.com/magazine/content/04_42/b3904034_mz011.htm (accessed 17 May 2009).

[67] ABC TV Four Corners (2 November 1998), "Viva Viagra", Reporter: Liz Jackson. It posed the question: Is *Viagra* a medical or marketing miracle? available on-line at http://www.abc.net.au/4corners/stories/s22482.htm (accessed 17 May 2009).

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"[68] and class actions[69] 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,[70] suffer from tuberculosis or live in parts of the world in which malaria[71] and other diseases (such as leprosy[72] or trachoma[73]) are endemic.

7. 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. It was not until November 1888 that Switzerland enacted a national patent law and even then, according to Eric Schiff,[74] it was 'probably … the most incomplete and selective

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[68] *Ibid*.

[69] 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. Available on: http://www.slatergordon.com.au/pages/class_actions_vioxx.aspx (accessed 17 May 2009)

[70] World Heath Organization Report on Infectious Diseases, *Removing Obstacles to Healthy Development,* 1999. Available on: http://www.who.int/infectious-disease-report/pages/textonly.html (accessed 14 July 2009). This Report states:

> Infectious diseases figure low on the global health research and development agenda. In 1992, global spending on health research was $56 billion - less than 4% of total global expenditure on health. And of that, no more than 10% was allocated to research relating to the health needs of developing countries - mainly infectious diseases. The combined investment in research and development into ARI, diarrhoeal diseases and TB - which kill over 7 million people a year - was $133 million(about 0.2% of global spending on health research and development). Yet these three diseases together account for almost one-fifth of the global disease burden. Malaria, which accounts for 3% of the disease burden globally and almost 10% in sub-Saharan Africa, fared as poorly - attracting about 0.1% of research funds.

Although since this report was published there has been a considerable attempt to address this disparity in drug development between the developed and developing world, it would seem that there is still a long way to go before a satisfactory situation is achieved. See World Health Organization Report, *Public Health Innovation and Intellectual Property Rights*, 2006. Available online at http://www.who.int/intellectualproperty/report/en/index.html (accessed 15 July 2009). See also P Chirac and E Torreele, "Global Framework on Essential Health R&D" (2006), *The Lancet*, 367 (9522), 1560-1561.

[71] For the WHO summary. Available at http://www.who.int/topics/malaria/en/ (accessed 17 May 2009).

[72] For the WHO summary. Available at http://www.who.int/lep/en/ (accessed 17 May 2009).

[73] "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." Available on-line:

The Free Dictionary: http://encyclopedia.farlex.com/Tracoma (accessed 17 May 2009)

[74] E Schiff *Industrialization without National Patents: The Netherlands, 1869-1912, Switzerland, 1850-1907* (Princeton: Princeton University Press, 1978)

patent law ever enacted in modern times'.[75] 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, whilst 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 – the world's largest patent filing company[76] today –with a patent-free environment within which to commence operations and prosper from its own innovations to the electric light bulb.[77]

The overwhelming evidence appears to confirm instead 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, but 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 Nuvolari[78] observed that those that made significant technological, scientific and medical contributions (such as William George Armstrong[79], William Thomson[80] and Joseph Lister[81]) were rewarded through "unprecedented elevations to the peerage …[and] the erection of statues in

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[75] *Ibid*, 93.

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

[77] Schiff, *op cit*, 74; B Verspagen "Large Firms and Knowledge Flows in the Dutch R&D System: A Case Study of Philips Electronics", (1999) 11 (2) *Technology Analysis & Strategic Management*, 211-233.

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

[79] 1810-1900, an engineer who developed the hydraulic accumulator.

[80] 1824-1907, a mathematical physicist and engineer who developed, among other things, "a complete system to operate a submarine telegraph."

[81] 1827-1912, a surgeon who discovered that "carbolic acid could be used to sterilise surgical instruments and clean wounds."

city centres."[82] 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."[83] Was this an act of public philanthropy or was it simply that patents were not, in Victorian England, the only motivators of technological innovation?[84]

Chain was probably right in 1963 to ask his British audience to accept the 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 invention[85] in 1976 to Genentech[86] is a good example of this. Unfortunately, however, this particular success, which encouraged US Senator Birch Bayh to co-sponsor the *Bayh-Dole Act* in 1980 in the US Congress, has not been easily replicated by other American universities. Twenty five years later, as Clifton Leaf explained in his retrospective piece[87] on the effects of the *Bayh-Dole Act*, 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"[88] of their organisation or their research. Universities now demand that their scientists assign

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[82] *op cit* 74, 758.

[83] *Ibid*, 766.

[84] Under the 1852 Patent Law Amendment Act patent administration was simplified. A single patent application would cover England, Wales, Scotland and Ireland reducing the cost and complexity of patenting significantly. Furthermore, only one fee was payable and that fee, for England, fell from £100 to £25. The fall was even more significant given that the cost, prior to 1852, of a patent application that covered Scotland and Ireland was £350. By 1883 the cost of a British patent application had fallen from £25 to £4 and while the renewal fee remained at £50, the renewal dates were extended by one year to the end of the fourth and eighth year – effectively reducing the cost of a 4 year patent from £75 to £4; and 8 year patent from £125 to £104; and a 14 year patent (then the maximum term) from £175 to £154. What this suggests is that from the mid-19th century onwards the decision not to patent could not be attributed to the cost or complexity of patenting in the UK and this was even less likely to have been a factor after 1883.

[85] US 4,237,224 (2 December 1980), "Process for Producing Biologically Functional Molecular Chimeras".

[86] S S Hughes "Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980" (2002) 92 (3) *Isis*, 541-575.

[87] C Leaf, "The Law of Unintended Consequences", *Fortune*, 19 September 2005. Available at http://money.cnn.com/magazines/fortune/fortune_archive/2005/09/19/8272884/index.htm (accessed 17 May 2009).

[88] *Ibid*.

over any and all intellectual property, resulting in litigation as some scientists, understandably, leave their universities to commercialise their inventions.[89]

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.[90] 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 a crook yourself, otherwise you get done like a dinner.'*[91]

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."[92] Instead of sympathy, the pharmaceutical industry portrayed the Thai Government as acting duplicitously, by:

> *[P]laying 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.*[93]

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."[94] 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

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

[90] J Braithwaite, *Corporate Crime in the pharmaceutical industry* (London: Routledge & Kegan Paul, 1984).

[91] *Ibid*, 2.

[92] "Why Thailand is at the Centre of a Patent Storm", *Managing Intellectual Property*, March 2007.

[93] *Ibid*.

[94] "More Grugs Under Threat in Thailand", *Managing Intellectual Property*, 24 September 2007.

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 drugs[95] from the Thai drug regulatory approval process.[96] 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."[97]

8. Conclusion

Since WWII the pharmaceutical industry has pushed the line – if you want more drugs then we need patents! This truism has suited both European policymakers and politicians who have felt so comfortable that world war (or any disaster) will never reoccur that they no longer need 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 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 which 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-making 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 1873[98], but he never patented the vaccine for rabies. Indeed, Pasteur developed this vaccine while the medical community dismissed his theories of infection and immunity. Pasteur continued with his research (even risking prosecution[99]) 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 (for the purposes of alleviating human

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

[96] "Drug-maker Hits Back in Thai Patent Row", *Managing Intellectual Property*, 1 March 2007.

[97] *Ibid*.

[98] US 135,245 (28 January 1973), "Improvement in Brewing Beer and Ale".

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

suffering[100]), the fact remains that his work was unmotivated by the promise of a patent.

[100] de Berg, *op cit* 4.