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Sir Austin Bide Chairman

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I write in the hope that you will be able to find time to peruse the enclosed document. It's purpose is to emphasise to you a problem that is very real and menacing for firms and industries such as mine, whose present and future depends essentially upon high-technological invention and application.

Because it concerns international patents and other intellectual property, it has both technical and legal elements that you will understand more readily than most and it is, in part, for this reason that I have presumed to make claims upon your time.

Apart from that, however, I consider the matter of sufficient importance to justify seeking to ensure that you are acquainted with what is afoot.

I am, incidentally, informed that kindred interests in the United States are getting up a very big 'head of steam' on the subject and there is, in my opinion, considerable trouble brewing about attacks upon the Paris Convention on Patents.

If you or your advisers should require further material to support or elaborate matters raised in the paper, my colleagues and I will be glad to assist.

Sir Austin Bide

The Rt. Hon. Margaret Thatcher, MP, 10 Downing Street, London SW1

Enc:

# Intellectual Property Rights and Innovative Industry with particular reference to pharmaceuticals

The primary aim of this paper is to emphasise the vital importance of certain "intellectual property rights" (see page 2), to industries that must be able to earn and invest large sums of money in research each year in order to remain innovative and successful.

Much has been written in recent times on this subject because of legislative and other trends around the world that are diminishing the value of these intellectual property rights, often selectively to the detriment of the pharmaceutical industry.

It is impossible to overstress the importance of this erosion to an inventive nation whose survival as a politico/economic power depends substantially upon exports and for which increased productivity is essential in order to enhance or maintain its ability to compete in world markets. Innovation, which is an essential part of this total process, will not be maintained, still less increased, if the necessary protection of the relevant intellectual property is not provided in export as well as home markets.

Although it is the developing nations that are seeking most assiduously to erode intellectual property rights, the greater beneficiaries in the nearer term may well be a few of the more advanced countries perceiving opportunity to improve their position at the expense of others. There have, indeed, been a number of disturbing developments in some of the industrialised nations.

Innovative industry has continually expressed great concern that these trends continue and that its voice appears to be unheard or ignored at diplomatic conferences and the like where such matters are debated and decided.

#### I Intellectual Property Rights

For the purposes of this paper "Intellectual Property Rights" means Patents, Trade Secrets and Trade Marks, some introductory observations on which are as follows:

#### (1) Patents

An effective patent system which affords a statutory monopoly for a reasonable period of time after first marketing a new product, or after the introduction of a new and patented manufacturing process, is considered by research-based companies to be an essential to the continuance of a large annual investment in Research and Development. As the majority of research-based companies need to operate internationally in order to generate the necessary funds for research, it is equally important for a continuation of their research for this kind of patent protection to be available not only in the country where they are based, but also in the overseas markets in which they operate. This applies particularly to those industries - of which pharmaceuticals is an outstanding example - that are heavily dependent on the biosciences and on the use of organic chemical synthesis. The multi-stage nature of some syntheses where any or all stages may be highly inventive and patentable emphasises the importance of patent protection. This is especially so in the pharmaceutical industry where, though rewards can be very great, the risks of failure are at least commensurate.

#### (2) Trade Secrets (sometimes called "Know-how")

Technical research inevitably leads to the acquisition of some scientific information - highly relevant to industrial processes - which is not patentable or, which, for some reason, is not patented. This is as much a product of the total research process as a patented invention and is frequently no less valuable in practice. For so long as it remains the secret property of its owner, it should be regarded as the owner's asset to deal with as he may wish, and should not be available for acquisition or use by any third party save at the wish of the owner and on his terms.

### (3) Trade Marks

Most industries, particularly those involved in the manufacture of "consumer" products, regard trade marks as essential to their business. The pharmaceutical industry views this particular intellectual property right as especially important because it provides the doctor and the consumer (the patient) with an immediate identification that can be related to assurance of the source, nature, integrity and quality of the product.

There have been numerous attempts around the world by legislative, juridical and other methods to diminish the protection afforded by trade marks, again often selectively against the pharmaceutical industry. But, damaging though these activities are to British Industry, it is not proposed to deal with them in detail in this paper, since trade marks are not so directly involved in the process of innovation as patents and trade secrets.

### II Erosion of Patent Rights by the Developing Countries

### (1) General

In many developing countries there is a belief that one effect of patent systems is to deny them the use of the technology of the industrialised countries, notwithstanding that the products of that technology may be available to them by importation of the patented products. In consequence of this view, there has been an organised diminution of the local patent protection available to the foreign patentee or would-be patentee. Examples of the nature and extent of this erosion are provided below.

(a) The Indirect Attack on Patent Rights - Proposed Amendment of

"The Paris Convention" - thereby diminishing the rights available
under its provisions.

One very disturbing example of the attempts by the developing countries to erode protection for patents inventions (and trade secrets - see Section III below) is their strong attack over several years upon the provisions of the Paris Convention of 1883 which had as its aim the protection of intellectual property broadly. The signatories to the Convention who, of course, undertook to be

bound by its terms, include some developing nations and together form the membership of the Paris Union. The most important feature of the Convention is that each member state is required to afford the same protection to the intellectual property of the nationals of other member states as it affords to its own nationals, i.e. a non-discriminatory approach.

The Convention is also the basis of the crucially important concept of the "Convention Date" whereby the date of application for protection in one member state is accepted as the "priority date" in other member states from which, for the life of the patent, the property right is enforceable at law.

A vital characteristic of the Paris Union as originally formed was that revision of the Convention required a unanimous vote of all members at a Revision Conference convened in accordance with the Rules of the Convention.

There have been three Diplomatic Revision Conferences in the past few years. The first, at Geneva, purported to change the unanimity requirement to one whereby a revision proposed could be adopted by a two-thirds majority of expressed votes, provided not more than twelve votes were cast against the proposal. There are proposals for repeating the voting procedure in the absence of a positive result on the first vote. How this was constitutionally achieved when the United States of America voted consistently against it, is, to say the least, obscure.

The second conference - now lacking the unanimity safeguard - granted recognition to Inventors' Certificates as the equivalent of patents in the matter of Convention "priority date". These Certificates which theretofore had no status as intellectual property do not confer any right to exclude others, but may provide the owner with a basis for imposing a royalty obligation. There may be a proviso (e.g. Mexico) that all information "necessary for the exploitation" of the invention is furnished to the licensee. This proviso obliges the handing over of Trade Secrets (see Section III below).

Finally, in Nairobi at the end of 1981 there was a further Diplomatic Revision Conference which, inter alia, sought to amend Article 5A of the Convention in a way which for the first time created two classes of members 1) the developing nations, 2) the industrialised nations. The former would be permitted to legislate so that non- or insufficient- use of a patent (and importation into the country concerned would not be regarded as sufficient use) could result in the grant of an exclusive compulsory licence to a local national or forfeiture of the patent. The reader will understand that the effect of such a licence would be thereafter, within the life of the patent, to exclude the patent owner himself from operation under the patent in the country concerned. It could even prohibit importation of the patent owner's patented goods.

At the end of the Nairobi Conference an "agreed text" of a modified Article 5A was published but apparently it was not submitted to any voting procedure, not even the "qualified majority" system which emerged from the Geneva Conference (see above). However, the only clear dissentient, once again, appears to have been the USA.

After approval of the "agreed text" a number of Group B countries (Australia, New Zealand, Canada, Portugal, Spain and Turkey) indicated that they wished to be included among the "privileged" members of the Paris Union which would be permitted to grant exclusive compulsory licences or to render patents forfeit for non-working.

The aggregate effect of these changes bodes ill. From reports of the Nairobi Conference it appears, astonishingly, that the Governments of the EEC countries, including the UK, supported the demands of the developing countries. The outcome is clearly against the interests of British industry, particularly innovative industry. Organisations representing industry in this country and elsewhere have indicated, both before and after the Nairobi Conference, the deepest apprehension about all these moves,

- 6 particularly the latest, which they regard as a deliberate process of destroying the value of the Paris Convention to the industrialised nations, whilst exploiting the eviscerated form to the advantage of others. One wonders how far this clearly organised and co-ordinated erosion can reasonably or wisely be supported or allowed to persist. The extent of the concern of industry in this matter is reflected in the fact that in April 1982 a two-day inter-industry conference took place in Brussels and was attended by representatives of USA and Japanese industry as well as a UNICE delegation from France,

Germany, Italy and the United Kingdom.

#### (b) The Direct Local Attack on Patent Rights The following are a few examples of ways in which erosion of

patent rights is being directly attempted or has been accomplished locally by some developing countries.

- (i) By total statutory abrogation of patent protection selectively against pharmaceuticals, e.g. Brazil
- By de facto abrogation of patent protection: (ii)
  - By reducing the length of patent protection to such a short period that it has little practical value, e.g. India, Costa Rica
  - By compelling the owners of pharmaceutical patents B. to grant licences upon demand to all applicants at derisory royalty rates, e.g. India, Canada
  - By the substitution of patent rights by the right of C. Certificate of Invention, e.g. Mexico (The background to such Certificates is set out in Section II (1)(a) above)
  - D. By a combination of A and B above, e.g. India, Andean Pact countries

#### III Erosion of Owners' Rights in Trade Secrets (Know-how)

Over a period of years a large number of developing countries by local legislation and by the activities of the World Industrial Property Organisation (WIPO) and the United Nations Conference on Trade and Development The Agency which is concerned with the attack on the Paris Convention, which is dealt with at length in Section II (1)(a) above is, of course, the World Intellectual Property Organisation (WIPO). The United Nations Conference on Trade and Development (UNCTAD) leads an attack against the industrialised nations and multinational corporations in its efforts to gain free access to Trade Secrets.

One understands why the opportunity arises only rarely for industry to be directly represented in any of these bodies; but where it can happen it most certainly should. But where it cannot occur, then it is essential on so vitally important a matter, to canvass fully and continuously the reactions of potentially affected industry and to give full weight at all stages to the views thus revealed. Government representatives, who speak for us on these matters, must be made aware of the effect of these trends on the wealth and future of this country, and should seek to resist them (alone or, better still; in concert with like-minded countries, such as the U.S.A.).

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Thank you for your letter of 19 July and attacked and and

Thank you for your letter of 19 July and attached paper on intellectual property which I have read with interest.

I know that your industry, more than most, relies on patent No. 10 and trade mark rights in order to finance its intensive research programmes. At the same time, of course, many of the third world countries to which you export feel that the international patent is not serving their interests. They argue that where a patent is not worked in their country the system is doing no more than maintain a high level of prices there without giving any comparable benefit from the point of view of development of their own industry. Whatever the merit of their case, we must take their views seriously because, as you make clear in your letter, it is very much in our interest to maintain the patent system worldwide. It would be disastrous if they lost faith in the system and either closed down their national systems or sought to form a new Convention under different auspices, say UNCTAD, which might come nearer to meeting their wishes. Were they to form such a Convention, it could easily receive support from certain Western countries and the total result would be a serious weakening worldwide of patent and trade mark protection. This threat is one of the major reasons for the revision of the Paris Convention.

The particular concern of this revision has been to see if the developing countries could be helped to ensure working of inventions in their territories. At the same time we saw it as vital to avoid

any erosion of patent rights among developed countries, and so we have come down strongly in favour of a system of preferential treatment for the developing countries. The text which achieved substantial agreement last year does in fact make more of an apparent concession for developing countries than a real one. Much of the correspondence that we have received from British industry acknowledges this, but is concerned about conferring "respectability" on the idea of exclusive licences. It is difficult to assess the importance of this factor, but we do realise that industry is worried by it and, of course, the United States maintains its hostility. It seemed to us therefore that the best thing was to support a recent United States initiative for a cooling-off period during which a discussion on a widely acceptable compromise could be initiated informally. This is the present policy of all countries of the Western group.

You also remarked on the direct local attack on patent rights which I recognise as a particularly important problem for United Kingdom exporters. Broadly, we are always ready to make representations to try to persuade the country in question to be more accommodating and we are often able to base our arguments on the advantages to the country itself of a good patent system. But, we are in a very much stronger position when we are seeking to enforce one of the requirements of the Paris Convention. And there is no doubt that our ability to maintain patent systems in various countries, which from our point of view are useful, rests very much on the integrity of the Paris Convention: so in negotiation, we inevitably have to balance our view of particular changes against the acknowledged wider general advantage of keeping the developing countries attached to the Convention. i' does to see much will pely-

I am grateful for your offer to let me have further material; may I suggest that you make this available in the first instance to senior officials at the Department of Trade and that in due course you discuss the matter with them.

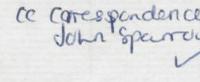
9 August 1982

The Prime Minister has asked me to thank you for your letter of 19 July which she found extremely thought provoking. She would like to take up your kind invitation to submit further material: perhaps you could let me know if you wish to do so. The Prime Minister has asked the Department of Trade to give careful consideration to your paper and any further material and will be replying as soon as possible.

Tim Flesher

Sir Austin Bide

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Glaxo Holdings p.l.c. Clarges House 6-12 Clarges Street London W1Y 8DH



Sir Austin Bide Chairman

Telephone 01-493 4060 Telex 25456 Cables Glaxogroup London W1

CC Tuesting Roes (Kricle) 11th August 1982

Downtrotether,

Thank you for your letter of 9th August referring to mine of 19th July to the Prime Minister.

We have quite a lot of material on the subject and rather than fire it out willy-nilly I have suggested that one or other of my colleagues who is very close to the subject will contact you to see whether we can be helpfully selective.

The persons most likely to do this will be Mr. M.R. Camp, who is the Group Solicitor, and Mr. H.W. Martin, who is our Intellectual Property Consultant. He was, indeed, the Head of our Intellectual Property Department up to the time of his retirement.

Succention Bride

Sir Austin Bide

Tim Flesher, Esq., Private Secretary to The Prime Minister, 10 Downing Street, London SW1

I replied by share to day

Glaxo

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Telephone 01-493 4060 Telex 25456 Cables Glaxogroup London W1

Glaxo Holdings p.l.c. Clarges House 6-12 Clarges Street London W1Y 8DH

September 21st 1982

Dear Mr Flesher

I am taking the liberty of writing to you as I have been unsuccessful in contacting you by telephone - maybe you have been away on holiday.

May I refer to your letter dated 9th August addressed to our Chairman Sir Austin Bide which acknowledged his letter of the 19th July enclosing a paper that was produced for the Prime Minister. In Sir Austin's reply to you of the 11th August he mentioned that there may well be further information that you judge could be of use to those charged with considering the whole topic of the Nairobi Convention proposals (particularly Article 5A). Perhaps a word with you personally could clarify more easily exactly what might be of relevance having in mind that it is not so much quantum of paper but quality of subject matter that you are concerned to have.

Please therefore do not hesitate to let me know (my day time private phone number is 493 - 3769 and of course, Mr Martin and I would gladly step round to see you. We are conscious of the fact that the Geneva Conference is (I think) scheduled for October 4th so should you wish to have additional information against that time scale don't hesitate to say so - we can distil the information very quickly from our almost inexhaustable supply!

Sincerely

Maurice R. Camp.
Tim Flesher, Esq.,

Private Secretary to The Prime Minister, 10, Downing Street, LONDON SW1. Trade theor of intellectual process · OMBLE) 7 56 982 

Sir Ausvin Bide

9 August 1982

On 3 August you sent me a draft reply for the Prime Minister to send to Sir Austin Bide, the Chairman of Glaxo, about intellectual property. The Prime Minister does not feel that the draft meets Sir Austin's case with which she has a good deal of sympathy. She has asked, therefore, that Sir Austin be invited to submit the further additional material promised in his letter and I have written to him accordinkly. When he has done so, I should be grateful if your Secretary of State could arrange for further consideration with a view to a fresh submission to the Prime Minister. The Prime Minister has indicated she would be willing, if necessary, to discuss the matter with Sir Austin and Lord Cockfield.

T. FLESHER





From the Secretary of State

Timothy Flesher Esq Private Secretary to the Prime Minister 10 Downing Street London SW1 E Sidney

3-d August 1982

Dear Tim,

As requested in your letter of 23 July, I attach a draft reply for the Prime Minister to send to Sir Austin Bide, Chairman of Glaxo.

Yours ever, Forallan Rees

JONATHAN REES Private Secretary

#### DRAFT LETTER FOR THE PRIME MINISTER TO SEND TO:

Sir Austin Bide Chairman Glaxo Holdings plc Clarges House 6-12 Clarges Street London W1Y 8DH

Thank you for your letter of 19 July and attached paper on intellectual property which I have read with interest.

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I am grateful for your offer to let me have further material; may I suggest that you make this available in the first instance to senior officials at the Department of Trade and that in due course you discuss the matter with them.

## Si Austri BIDE

6/8

23 July 1982

I enclose a copy of a letter the Prime Minister has received from Sir Austin Bide, Chairman of Glaxo.

I should be grateful if you could let me have a draft reply for the Prime Minister's signature by Friday 6 August.

Tim Flesher

Jonathan Rees, Esq., Department of Trade.



23 July 1982

I am writing on behalf of the Prime Minister to acknowledge your letter of 19 July. This is receiving attention and a reply will be sent to you as soon as possible.

Tim Flesher

Sir Austin Bide

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