The European Commission Pharma Sector Inquiry

A Paper by the Rt. Hon. Sir Robin Jacob
For the Fordham Conference, March 2009

Sector Inquiries are investigations that the European Commission may decide to carry out. The test for launching an investigation is whether the economic sector does not seem to be working as well as it should or whenever there are indications of anti-competitive practices. Such an Inquiry is being carried out now about the pharma industry. A bystander might well say, how come the Commission picked on this industry rather than others.? Was not the banking industry a better target? Did the Commission not notice that? What about the insurance industry or any other?

So what material did the Commission have to justify this inquiry – for justification I suggest it really needed. After all the Commission has devoted considerable resources – I don't know how many man-hours and it would important as well as interesting to know the answer. Moreover the Commission's expense is only a fraction of what was involved. The industry must have spent at least 50 million euros – possibly 100 million, dealing with the host of inquiries.

I also have to say that to many a human rights lawyer the way the Commission went about the inquiry was oppressive and wholly unjustified. For it commenced by unnannounced dawn raids of a number of major international research based companies. As if this were a police matter and the companies concerned were criminals who, but for a dawn raid, would be likely to destroy or hide documents. No regard was paid to due process, no regard to any documents which might be covered by privilege. I seriously question whether this was a correct approach – true it is that the companies have not complained or at least not enough to go to court. There are likely to be reasons for that – not least fear of antagonising the Commission – whose attitude throughout has been hostile to the industry.

The justification offered – the face that launched dawn raids and constant succession of questionnaires of considerable complexity with demands for answers in very short order – is stated in the preliminary report thus:

> … there were signs that competition in the pharmaceutical sector might be distorted. The number of new chemical entities coming to the market seemed to be in decline. Moreover, generic manufacturers might not be able to enter the markets as quickly as one would expect. The Commission therefore concluded that the pharmaceutical sector required an in-depth investigation.

What is there to show for all this? In my view nothing. Here is q quick, no exhaustive list.

1. Absolutely no useful insight as to why less chemical entities coming on the market. Is that because, like a gold-mine the seams of possible new medicines are running thin, or because the regulatory requirements have become so stringent that it is much harder to pass them, or because in the US

the fear of class actions by a few patients who suffer side effects has made the industry more defensive.

2. Certainly it is wholly improbable that the industry has given up looking for new important drugs – preferably blockbusters.
3. An indication that minor improvements should not be patentable – does that mean that patent offices should employ competition lawyers. Does the Competition Directorate think that there should be no patent incentive except for big inventions
4. A serious revelation that the Competition Directorate does not really understand how the patent system works and has always – complaints about clusters, using patents to restrain competitors are in truth complaints about the system itself – there is nothing special about the pharma sector here.
5. A conclusion that big pharma has tried, largely unsuccessfully, to use patents to delay generic entry. Even the 4 months for big products is not shown to be caused by pharma companies as opposed to the failure of governments to settle prices or regulatory delays.
6. A complete failure to appreciate that all the players concerned are big and well able to look after themselves. This is not an industry which sells to the public or to small purchasers.
7. A complete failure to understand that we are talking about a global industry – R&D is for the world, not for Europe alone. To do the job seriously the whole world position would need to be looked at.
8. A dangerous tendency to want to interfere in the settlement of actions.
9. Another dangerous tendency to equate a failed legal action as somehow abusive or anti-competitive – there was no attempt to identify actions which were so bad as to amount to an abuse of process.

So what positives do I get from the report. Just a few, all of which were well-known before:

1. The need for a single European Patent Court
2. The need for being able to deal with bad patents quickly;
3. The need for something to be done about the EPO opposition process;
4. The need for tidying up the EPO application procedure – for instance by stopping or reducing voluntary divisional applications which make it harder for third parties to work out what they can do.

As many of you will know I was asked by the Commission to comment on the inquiry when the preliminary results were launched. For convenience I attach my paper (also now published). I stand by everything I said in it.

Patents and Pharmaceuticals – a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry

The Rt. Hon. Sir Robin Jacob[1]

I begin by qualifying myself to speak. From the late 60s a significant part of my work has involved the pharmaceutical industry: first when I was a barrister and from 1993 as a Judge. I have been in, and presided over many battles about pharmaceutical patents. Those battles have not only been about validity and infringement but other, economic matters too. Thus until 1977 under the UK law[2] allowed anyone to apply for a compulsory licence under a patent for a medicine. And until then a patentee who had not got adequate remuneration from his patent before the normal date of expiry (16 years from application) could apply to the court for an extension of term – a much more sophisticated equivalent of a supplementary protection certificate. It was more sophisticated because it involved a deep inquiry into how much money the patentee had made in capacity as a patentee. And after 1977, when the term of patent went up to 20 years, pre-1977 patents got 4 more years but subject to a licence of right. Both sorts of licence involved deep inquiries into costs and profits in order to set the royalty rate.

Over the years I have seen bad behaviour by both big pharma companies and generic companies. I am neither pro nor against either of them. I am a judge. My job is decide who is right in fact and law.

I begin with two quotations. The first is from the Pied Piper of Hamelin:

> "If I can rid your town of rats
> Will you give me a thousand guilders?"
> ``One? fifty thousand!" -- was the exclamation
> Of the astonished Mayor and Corporation.

Later, when the rats had all been drowned, the Mayor said:

[1] A Judge of the Court of Appeal of England and Wales, in charge of the Intellectual Property List. A judge since 1993, before that a barrister in practice at the Patent Bar from 1997.
[2] s.41 of the Patents Act 1949

``So, friend, we're not the folks to shrink
``From the duty of giving you something to drink,
``And a matter of money to put in your poke;
``But as for the guilders, what we spoke
``Of them, as you very well know, was in joke.
``Beside, our losses have made us thrifty.
``A thousand guilders! Come, take fifty!"

So it is with pharmaceuticals. Before the invention of a new drug we would willingly pay for it. After the risking and investment have produced a new medicine there is a great temptation to say the price is too high.

My second quotation is from a 1947 small booklet[3] by T.A, Blanco White:[4]

> There is … a way in which a monopoly in an important invention may be kept alive after the patent has come to an end, and that is by patenting large numbers of minor improvements to the original invention. … Provided the patented improvements represent genuine development over the period during which the original patent is in force, and provided they are patented with determination and persistence, by the time the original patent expires a would-be imitator should be faced with this situation: that the article described in the original specification is too inferior to contemporary designs to be commercially saleable, while he cannot imitate the newer models without risking an action for infringement of so many of the improvement patents, that he would almost certainly lose in respect of some patent or other. Even if he were to win the action on enough of the patents to let him go on manufacturing without any fundamental change in his design, the cost of fighting and losing the action as a whole would still take much of the profit out of his venture. For this reason the existence of a mass of improvement patents is often a sufficient deterrent to would-be imitators. The original manufacturer's position need not deteriorate with further lapse of time: he should always be some years ahead in design so far as patentable improvements are concerned, while the loner he keeps the field to himself the greater the advantage he has in manufacturing experience. His monopoly will last until some competitor comes along with the skill needed to 'design round' the more dangerous patents and the courage to fight a patent action if necessary; how long this will be will depend as usual on the importance of the market covered by the monopoly, as well as on the rate at which he continues to devise new patentable improvements. In the past, such monopolies have sometimes lasted a long time.

This passage demonstrates that there is nothing new about what the Commission calls "patent clusters". Nor that they are confined to pharma patents. On the contrary any experienced patent lawyer will tell you that clusters of improvement patents are a

[3] Patents and Registered Designs, Stevens.
[4] Later QC one of the most influential writers thinkers about IP law in the post-war era.

feature of nearly all industries. It is a bit worrying that the Commission seems to think that it has discovered something new and special to the pharma industy.

I now proceed to some sure foundations, essential for understanding this industry. The following matters are really beyond any reasonable argument:

1. Most pharmaceuticals cost very little to make. All you need per dose is a very small amount (typically, say, 10 mg) of a chemical itself fairly easy to make. A kilogram of active material will be enough for 100,000 doses. Putting it in picturesque terms: drugs cost tuppence a bucket and a bucket is enough for a nation.

2. So the selling price of a patented medicine is way, way, above its manufacturing cost. Unlike for instance an engineering product, a patented medicine cannot be and simply is not priced on the basis of cost of manufacture plus a mark up.

3. Patented medicines are priced taking into account the current cost of research and development. To that is added overheads, marketing costs, the small amount of manufacturing costs and a profit. On a more sophisticated analysis one adds in the cost of capital employed The key thing for the purposes of the present debate is this: the income produced by the sales of today's patented medicines pays for the ongoing R&D which may lead to new and better medicines.

The Commission in some places talks about "recouping" investment. That can be misunderstood. No one can or could run a research based pharmaceutical company on the basis of trying to work out how much it cost to invent and develop a drug and get a return on that. The pharma industry is the same as most of us: current income must pay for current research and all the other things a company does (promotion, cost of capital employed, cost of overheads, dividends, etc etc.).

The most important figure in the Preliminary Report is that current R&D costs are 17% of turnover. That is much higher than most if not all other industries. I am sorry that the interim report somewhat belittles the figure by added that only 1.5% is "basic research". I am not sure I know what is meant here, but it does not matter. It is no good finding a potential suitable molecule. Unless you spend the money and

time to find out if it really works and is safe, it is no use. Assuming the figure is indeed 1.5% it would come to nothing without the remaining 155%.

4. It is the patent system, which has made the advances in medicines possible. Although economists sometimes debate whether the patent system is useful generally, no one has ever seriously challenged its place for medicines. And that is because it is so obvious that without a reliable patent monopoly there is simply no incentive to invest. The entire period of the command economy of the Soviet Union did not produce, so far as I know, any major pharmaceutical product. And in the West, even in those rare cases of an important invention being made at a University (e.g. the cephalosporin antibiotics) or by a small inventor or company (e.g. the anti-epilepsy drug sodium valproate), it has been the pharmaceutical industry which has undertaken the risk of the considerable costs of development.

5. Promotional expenditure is indeed higher than R&D at 23% of turnover. There is perhaps an innuendo that it is too high – and for the whole industry. Such an inference should be rejected. Firstly such promotion should not be thought of as analogous to promotion to the public, of a cosmetic, for instance ("Because you're worth it"). Promotion aimed at consumers, is typically a greater proportion of turnover. But more significantly we are here concerned with promotion to the medical profession. It essential that the benefits and side effects are well-communicated. Experience over the years shows that this is not easy. The profession is conservative and it takes a lot to persuade a doctor to prescribe a new medicine. Of course there have been glaring examples of overelaborate promotion. For instance I can remember an article in the early 1970s, by Bernard Levin in The Times attacking the promotion of a new drug called "Nobrium" But merely stating the average figure is miles from suggesting any breach of competition law rules. It is not for the Commission to tell drug companies how to promote their products, any more than it is for the Commission to tell companies in other sectors how to do so.

6. Moreover the nature of the investment is risky. Most research leads nowhere. The few winners must pay for all the losers. And in recent years the number of really important drugs coming forward seems to be diminishing. It is in the nature of

investors – human that they are - that the higher the risk the more reward is needed to persuade them to put their money up.

7. The time of true monopoly is likely to be very limited. Although the term of all patents is the same – 20 years from application, in reality a new drug is unlikely to get more than 10 or 11 years even with the supplementary protection system. Personally I do not think that is enough time to encourage the risk and expense involved in seeking further medicines, but that is beside the point. The short period may help explain some of the conduct by way of "evergreening" the subject of the Commission's inquiry, but it is more likely that it would happen whatever the period of full protection.

8. Generally speaking, in Europe, drug prices are the subject of high-level negotiation between powerful players. In my country and Spain for example it is essentially a matter between the companies and the Government. Governments have traditionally shied away from attacking patents or getting involved in disputes about validity of bad pharma patents. I do not know why, they are, after all, the customers.

9. The generic companies have no or very limited research costs. Nor do they undertake anything like the risk involved in original research. Nor do they promote their product save to the limited extent of trying to persuade doctors to promote generically – something which is much more powerfully pressed by governments.

10. That is not to say that generic companies do not perform a useful function. On the contrary once a patent has expired these companies will enter the market and cause prices to fall. The more companies enter the market the faster the prices fall. And when a product comes off patent it is right that prices should fall.

11. Generic companies are not actually in favour of low prices. Just as in the case of the big research based companies, they are in business for a profit. The lower the prices the less the profit. It is human nature for a generic company to want to be close to a high price. That is why, for instance, we often receive evidence from generic companies about how important it is that they should be first in the market. This can happen, for instance, where a generic company believe for one reason or another that

it is ahead of all the others. If it can be first it can and very likely will set its initial price at something like 10% below the patentee's. That will very likely take a substantial portion of the market and with a very large profit margin.

Generic companies have traditionally, and not surprisingly, waved the flag of "lower prices" – the position has been so throughout my entire career. They never talk about the profits they themselves make. The Commission has not inquired into how many multi-millionaires have made their money by selling "me-too" pharmaceuticals with no corresponding research benefit.

12. There can be little doubt that a number of drug companies have sought to protect their market monopolies beyond the life of their basic patent by spurious or near spurious patents – a process generally called evergreening. And there is no doubt that, as the Canadian Supreme Court recently observed[5] "Evergreening is a legitimate concern."

13. Legal questions in the pharma industry are nearly always about the validity of patents rather than their scope. This is because there is seldom a real argument about the extent of protection. The claims are clear – normally to a class of chemical compounds or often to a particular compound. This has important consequences as regards the question of how these questions are to be resolved

14. Finally the whole subject of patents and medicines and medical treatments is fraught with emotion and, dare I say it, irrational prejudices. Some say: "how can big pharma charge the ill for medicines that are so cheap to produce? Down with these greedy companies." We even have in the European Patent Convention a specific exclusion from patentability of methods of medical treatment which has led to a lot of convoluted quasi-nonsensical reasoning by way of trying to get round the rule as far as possible. Personally I think the rule should go. If you want better methods of medical treatment, the patent system is the way to encourage it.

I turn to some of the subjects raised by the inquiry:

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[5] *Apotex v Sanofi* 6th November 2008, *per* Rothstein J at [96]

1. "Raising the bar." The idea here is that patent offices should do better – that they should get closer to the ideal of granting all good patents and refusing all bad ones. How that is to be achieved given the ever-rising flood of applications and the ever-increasing importance of Chinese prior art, I have no real idea. Pharmaceutical patents are only a minor proportion of the total numbers of applications. Patent offices have limited resources: they have no mandate and should have no mandate to examine pharma patents by different standards from those for other subject matters.

Here I should point out that the phenomenon of patents for trivial or non-inventions is by no means confined to those for pharmaceuticals. Far from it. Anyone with experience of other fields, for instance, telecom or computer related inventions, would be familiar with abundant examples. No doubt if there were more co-operation between patent offices around the world on things like searches some savings and perhaps improvements could be made. But I think it is unrealistic to suppose that we can go back to the pre-EPC days when passing the German or Dutch Offices (and their examination procedures were very slow) was a kind of hallmark of a good patent.

Moreover I am wholly unconvinced that even giving more time for an examiner to consider an application would make much a difference in the pharma field. Let me explain why by reference to a recent case in our courts. Simplifying a little, a pharma company had a patent taken out in 1980 over a basic valuable new compound. It got the product onto the market very quickly – in 1987. In 2000 it took out a new patent covering what it said was a new crystalline form said to be particularly useful for formulation. You could not tell from reading the old patent anything about the crystalline form. So you could not tell that the later patent was in fact for the old product. It is not surprising the patent was granted. The Office had no choice. In England the patent was knocked out by the High Court in fairly short order and my court, the Court of appeal, upheld the result soon after.

This is important. Fiddling with the law will not make any difference to the reality: it is this that one cannot ever expect the grant of a patent by a Patent Office to be also a certificate of validity. It never has been and never will be. In truth a Patent

Office is a kind of coarse filter – rejecting clearly bad cases but having to allow those which may be good.

One should not feel too depressed by this major truth – particularly in the pharma industry where the legal costs of both innovating companies and generic companies are only a minor proportion of what is stake.

2. I wish to emphasise that the phenomenon of evergreening is not confined to the pharma field. Nor is it new. Far from it. Every patentee of a major invention is likely to come up with improvements and alleged improvements to his invention. By the time his main patent has expired there will be a thicket of patents intended to extend his monopoly. Some will be good, others bad. It is in the nature of the patent system itself that this should happen and it has always happened. There is nothing new about "evergreening", only the name and the implication which flows from the word, that there is something sinister going on and that it has only recently been discovered. My quotation from Blanco White shows this.
I would add that the particular figure of "up to 1,300" patents for a cluster needs more detail. I do not believe it to be typical. In any event one one needs to divide the figure by 27 (for the membership of the EU). But whether the patents are good or bad is not mentioned. For all we know they are for perfectly good inventions, perhaps only incremental. It has never been the law that patents are refused for incremental non-obvious improvements. Nor should it be.

3. I have mentioned that some have proposed changes to patent law. Let me examine those proposals in more detail:

(a) It is suggested there should be an obligation upon the patentee to disclose all information known to it material to patentability.

This has never been the law. Moreover it is impossible to see how it can work satisfactorily or at a reasonable cost. Must there be disclosure of all the patentee's documents and legal advice? Is there to be cross-examination of the patent agent? What is the cost of the proposal – every case could involve complicated question of what the patentee knew, when he knew and what he should have known.

They have some of that in the US – something which contributes to the extreme cost of litigation there.

Nor is the proposal necessary – if there is material which is a clear knock-out it will normally emerge in the course of a proper and ordinary search. So far as pharma is concerned I know of no case where material prior art was hard to find.

(b) It is suggested that better third party participation should be available at the pre-grant stage. Already third parties can submit prior art to the Office at that stage – and make observations. But, unless you beef up the whole process – in effect introduce pre-grant opposition – it just will be of little use. And a long time ago the founders of the EPC rejected – rightly in my view – pre-grant opposition. We had it in my country and the grant of patent rights would be held up for years.

Moreover the proposal is unlikely to be used by generic companies. Currently they do not or seldom oppose a patent at a time where there is no product on the market protected by it, The reason is simple. You have to oppose (i.e. apply for revocation) within one year of grant. Grant, even if delayed, is likely to be within at the worst about 8 years from application. At that stage the basic product will probably not be one the market. And if it is – because the patent is a late evergreener – the generic companies (and governments) have another remedy – attack it in the courts. Of course if the evergreening patent is applied for when a financially attractive product is on the market, generic companies may oppose. If they do they have a fair point that the period of opposition is likely to be long.

(c) It is suggested current opposition proceedings should be faster. With that I wholeheartedly agree. I have said so for years. But the problem is quite general, and far from being confined to pharmaceuticals. I would favour an in depth study of the practice and procedures of the EPO – along with education of the profession as to – as to how such speeding up could be achieved.

(d) There is complaint that courts are willing to grant interim injunctions. So they are: I have little sympathy with the complaint for two reasons. First generic

companies can attack validity earlier than they do– "clear the way" as I put it in one of judgments. There can be no interim injunction if they take that elementary course. Second I have long wondered why perhaps the most affected party – the paying ultimate customer, normally a government, does not intervene when the injunction is sought: to say it wants to be compensated if it turns out that the patent is no good and there never should have been an injunction.

5. There is a suggestion that pharma companies have used litigation against regulatory authorities in order to hold up authorisation. Again this is nothing new. Similar actions were taken in the 1970s[6]. Sometimes the companies are right, even if they are more often than not, wrong. To say they should not go to court on a weak case would be a serious threat to access to justice.

6. Generally the Commission appears to take a censorious attitude to big pharma companies resorting to litigation to attempt to delay generic competition. The old French proverb comes to mind: "Ce chien et très mèchant. Quand on l'attaque, il se défend." There is nothing new in any of this. It was suggested that the Commission has discovered conduct which is "shocking". On the contrary it has "discovered" conduct which is normal and has been an inevitable feature of the industry for many many years. All that is new are the numbers – none of which are particularly surprising.

7. One thing is clear – and again this is by no means confined to the pharma sector - the need for a strong and fast Central Patents Court for Europe sticks out a mile. And in this connection it should be noted that proposals for "bifurcation" – for a court splitting the issue of validity and infringement in the current proposals will not help that speed. Under the proposal if a patentee starts a case in a regional court and the defendant raises invalidity the question of validity can be transferred to a central court. All that will take time. And the longer a patentee can keep uncertainty going even for a patent ultimately shown to be invalid, the worse.

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[6] E.g. *Hoffman-La Roche v Secretary of State for Trade and Industry* [1975] AC 295 – a failed attempt at attacking a price control order by an interim injunction to restrain its coming into force

8. Do Competition Authorities have a part to play where a patent is obviously invalid? Should a company be punished for applying for (or if not that at least attempting to enforce) such a patent? I do not know, and even if I did, as a judge I could not comment, but the question is worth asking. I can say this: it would be seriously dangerous to have a rule that applying for or seeking to enforce a patent of doubtful validity was a violation of competition law: most companies in the world would be guilty on that basis. Courts are the basic places for deciding on the validity of rights – to punish someone for going to court may involve conflict with Art. 6 of the European Convention on Human Rights. And besides the true remedy for really bad patents is their swift demise in speedy revocation proceedings brought before the patent can do any damage.

9. So therefore I suggest that what needs doing is (a) forgetting about all changes to the law of grant, (b) a serious look at current opposition procedures within the EPO and (c) above all the creation of a respected, fast, and reliable European Patent Court. That is as true in the pharma sector as in any other. It is particularly that last proposal which matters for European industry as a whole. Evergreening by bad patents can in the end only be dealt with by courts knocking them out swiftly. That has always been true.

10 Finally although there have been bad patents in pharma sector, it is important to keep things in perspective. As a whole patents for pharmaceuticals have greatly benefitted and continue to benefit mankind greatly. Changes to the system should be viewed with great care – on the whole it works very very well. One should be very careful to avoid panic-driven or emotion-led changes which could damage an important and beneficial part of industry. The Commission repeatedly says that it does not want to damage the pharmaceutical industry and that it recognises how important patents are to it – it sounds to me a bit like Mark Anthony emphasising that Brutus was an honourable man. The big truth is that if you damage the income stream of research companies, you are going to imperil future research at the expense of European – indeed World - citizens. Yes, you will save money now, but at the cost of fewer future medicines.