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The Business and Industry Advisory Committee (BIAC) to the OECD is pleased to submit the attached paper: "Competition and Regulation Issues in the Pharmaceutical Industry: Comments on the OECD Secretariat's Analysis", for consideration by the OECD Working Party 2 on Competition and Regulation at the June 7, 2000 Roundtable Meeting on Competition and Regulation Issues in the Pharmaceutical Industry.
COMPETITION AND REGULATION ISSUES IN THE PHARMACEUTICAL INDUSTRY

Comments on the OECD Secretariat’s Analysis

A Report

by

Europe Economics

Europe Economics
Chancery House
53-64 Chancery Lane
London WC2A 1QU
Tel: 020 7831 4717
Fax: 020 7831 4515
E-mail: info@eer.co.uk
www.eer.co.uk

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Introduction

Europe Economics was commissioned to provide a critique of the OECD paper “Competition and Regulation Issues in the Pharmaceutical Industry” (DAFFE/CLP/WP2(2000)4).

The OECD paper was prepared by the OECD Secretariat ahead of a roundtable meeting on the pharmaceutical industry on 7 June 2000. Participants at the meeting included the Secretariat, representatives from OECD Member States, and industry representatives from the Business and Advisory Committee to the OECD.

The OECD paper is wide-ranging. It emphasises the extent to which the pharmaceuticals market is subject to regulation. On the demand side, regulation includes widespread social insurance; the control of product availability through doctors and pharmacists; and the regulation of prices and reimbursement conditions. On the supply side, it includes licensing controls for safety and efficacy; and the award of patents to protect the rewards to innovative effort.

But the core of the paper is an analysis of the effectiveness of competition in the pharmaceuticals sector. Section 2 of this paper focuses on what we consider to be the central economic issue raised by that analysis: the nature of competition in pharmaceuticals, including whether patents generate a degree of market power that is not balanced by corresponding market power of the purchasers.

We take the view that in crucial respects the argument of the OECD paper is unbalanced. While the Secretariat’s paper recognises that some form of intellectual property protection is necessary to reward the substantial and risky investment that goes into new products, its argument emphasises the risk that patents may give pharmaceutical companies excessive market power in particular therapeutic classes. Their proposals offered for discussion focus on solutions to this perceived “problem”. This analysis by Europe Economics therefore focuses on the nature and vigour of competition in the pharmaceuticals sector. It includes comment on:

- the evidence on whether the pharmaceutical sector has been able to earn super-normal profit (as suggested in paragraphs 28-29); and
- the suggestion (paragraphs 42-47, 53-55, and elsewhere) that patents allow anti-competitive behaviour.

Two suggestions for institutional reform set out in the OECD paper that relate directly to the rewards of pharmaceutical R&D are analysed in Section 3 below. These are:

- that for many OECD countries the private sector may be able to better manage the procurement and use of pharmaceuticals than the current public sector agencies (paragraph 71, and emphasised in the conclusions in paragraphs 168-169); and
- that patents might usefully be replaced by a system of compulsory licensing and royalties (paragraphs 48, 114-116).

Competition in Pharmaceuticals

The Dynamic Nature of Competition in Pharmaceuticals

The conclusions of the OECD paper underplay the importance of innovation to the competitive process in pharmaceuticals. The fortunes of the major pharmaceutical companies turn on new products, particularly on the small minority of products that are major sellers. These breakthroughs typically offer improved health care and reduce other medical costs associated with illness such as, for example, the way pharmaceutical treatment for stomach ulcers largely eliminated the need for expensive and dangerous surgery. These points are recognised in the OECD paper (paragraphs 19-23 on risk and 9 on the contribution to health care), but are not reflected in the paper’s recommendations.

Analysis by IMS Health of sales profiles for 670 molecules launched since 1983 (reported in the IMS Health Strategic Management Review for 1998) suggests that revenues peak about ten years after product launch and then tend to decline until patents expire, when revenues fall more sharply. The biggest-selling drugs in any year are unlikely to be amongst the world’s biggest selling drugs ten years later. Companies’ relative sales and profitability 10 years from now will depend on drugs that have recently been launched and those in the late stages of development. In this

1 From the IMS Health analysis, only four of the top 15 selling drugs in 1987 were in the top 15 in 1997.
context, static analyses of the shares of leading brands in particular therapeutic categories (as reported in paragraphs 30-33) are a poor basis for making policy recommendations. Those responsible for competition policy in both the EU and US have emphasised the importance of competition in innovation, more than of price competition between the current generation of products, when assessing proposed mergers between pharmaceutical companies. In the words of John Lang, a Director in the European Commission’s Competition Directorate General: “In [high-technology] markets price is often less important than the technical or other advantages of the product. These advantages are usually due to an innovation, which is likely to be a recent innovation because all or almost all the features of these products are changing”.

Relevant measures of competition in innovation would include:

- measures of inter-class competition, such as change over time in the rate at which classes of therapeutic products are superseded and the revenue declines;
- measures of intra-class competition, such as change over time in the rate at which further branded products enter a new therapeutic category and change over time in the rate at which market share and revenue fall away on the entry of competitor brands; and
- measures of the vigour of generic competition, such as change over time in the rate at which market share and revenue fall away on generic entry.

The OECD paper does not provide any such analysis, and therefore cannot be seen as providing a fully rounded analysis of the nature of competition in pharmaceuticals.

**Market Power from Patents**

The second serious imbalance in the OECD Secretariat’s argument is over market power. The market power arising from patents is overstated, while the degree of monopsony (sole buyer) power of purchasers is understated. The Secretariat’s paper expresses concern that the temporary exclusivity provided by patents may give a degree of market power to pharmaceutical companies that is undesirable in terms of society more widely. Several sources or forms of distortion are cited:

- treatment choices being distorted or denied by having price above marginal cost (paragraph 46);
- weak competition in R&D, such that the patent protection given by legislation is more generous than required (paragraph 44); and
- companies being able to devise secondary patents to prolong an underlying patent for longer than legislators intended (paragraphs 44-45).

Studies of the importance of patents have consistently found that patents are more important to innovation in pharmaceuticals than in other industrial sectors. With almost universal agreement on the need for effective intellectual property protection to encourage the development of new medicines, the first point requires an alternative method of providing such protection if prices are to be reduced to marginal costs of production. The Secretariat’s proposals here are considered in Section 3.2 below.

The key evidence on the second of these points consists of evidence of change over time in the effective degree of patent protection and the market power it confers; and evidence on the underlying rate of return on capital invested in the pharmaceutical sector compared to that in other industries. As noted above, there is no evidence in the report on change in competition over time. The key point that remains – the evidence on whether the pharmaceutical sector has consistently earned supernormal profits – is considered in Section 2.5 below.

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2 For US policy, see for example, “Antitrust Guidelines for the Licensing of Intellectual Property”, US Department of Justice and Federal Trade Commission, April 1995, with the emphasis on future-generation products: here the market definition refers to goods and services which ultimately flow from R&D.
5 H. Grabowski and J. Vernon found that 11 branded drugs whose US patents expired between 1988 and 1992 had an average generic market share of 50 per cent in the first year after patent expiry, compared to 38 per cent for a sample whose patents expired in 1986-7. (Longer Patents for Increased Generic Competition in the US: the Hatch-Waxman Act after One Decade.” Pharmaceconomics 1996.
6 A 1986 study by Edwin Mansfield, through a survey of firms from 12 industries, found that only 14 per cent of innovations overall (in a period from 1981-83) would not have been developed without patent protection. However, this figure was 30 per cent for chemical inventions and as high as 65 per cent for pharmaceutical inventions: most of the pharmaceutical innovations in his study would not have taken place without patent protection.
Optimal Patent Length and Patent Renewal

The third point, the question of whether innovators should be able to extend the protection of intellectual property by secondary patents, remains unresolved from the economic literature. A long patent life increases the inventor’s appropriability at the cost of a longer period of monopoly pricing. Likewise, a shorter life reduces appropriability but brings about efficient pricing sooner. The natural implication is that an optimal patent life lies somewhere in between the two extremes.

Even though all countries impose a uniform statutory patent life, most patent systems require that patentees pay annual renewal fees in order to maintain patent protection up to a statutory patent life. Even if these fees (variable across countries and usually rising with patent age) are relatively low, they have effectively created a degree of differentiation in patent lives.

Patent renewal fees are currently often used simply as a fiscal device to fund patent offices, but some economists argue that patent renewal fees can be designed strategically by the government in order to improve economic efficiency. The disadvantage of a uniform patent life is that it may provide ex ante excessive incentives to carry out R&D to the low productivity firm and insufficient incentives to high productivity firms. For this reason it may be welfare-increasing to differentiate patent life across inventions. The differentiated scheme is implementable through renewal fees that endogenously determine an optimal pattern of patent life. The optimal pattern of patent life spans depends on the degree of heterogeneity in R&D productivity across firms, the ability of patentees to appropriate the potential rents generated by R&D and the learning process about the value of innovation.

A related debate has focused on the conditions under which other companies should be able to patent products that rely on the basic innovation, typically concluding that the ability to do so should be restricted. This has focused on the conditions under which innovators of incremental improvements should be able to obtain patent protection. It is possible that some national health insurers are sufficiently large to have sizeable bargaining power with respect to certain manufacturers (paragraph 118).

This is an obvious understatement of the current situation. The real position is that within most OECD Member States, the main purchasing authority is in the public sector and has a high degree of monopsony (single buyer) power backed by statutory control over price levels and reimbursement schedules.

Many EU Member States countries, including Belgium, France, Greece, Italy and Portugal, impose legal controls on manufacturers’ maximum selling prices of drugs, either individually or by therapeutic category. Various criteria are used for determining prices such as allowable costs, the prices of existing drugs with comparable therapeutic effects, or the prices charged in other countries. Health insurers in OECD countries, whether private or, as in most cases, public, then set reimbursement prices for particular products. Reimbursement prices may be directly related to the manufacturer’s selling price ceiling or they may be separately determined by other characteristics, such as perceived therapeutic benefit.

This is because the distribution of returns across products is highly skewed, with most returns coming from a small proportion of products – Grabowski and Vernon’s analysis showed 70 per cent of returns coming from a fifth of products, and most products not breaking even.

Market Power of Purchasers

The understating of the market power of purchasers is a third serious imbalance in the OECD paper. The most the Secretariat acknowledges is that:

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The free movement of goods within the EU means that a low price set by purchasing authorities in one Member State affects the value of patents in all Member States. This is particularly important given that individual Member States have strong incentives to set low prices and free-ride on the willingness of others to fund R&D investment. Such parallel trade can prevent the efficient recovery of sunk costs
and lead to reduced access to important medicines for patients in countries with lower per-capita incomes.\(^{12}\) Some forms of price control encourage the introduction of “new” products that are marginal improvements or line extensions merely to gain approval for a higher price. Hence the evidence cited by the OECD that most new products in Germany in the 1980s did not represent significant therapeutic advance (footnote 35 to paragraph 43) is as likely to be a result of price and reimbursement controls as it is to constitute an argument for them.

### Does the Pharmaceutical Industry Earn Super-Normal Profits?

The OECD paper reports that inter-industry comparisons show the pharmaceutical industry to have consistently earned higher profits than an average of other industries, and that this result is robust to the necessary accounting adjustments. If this conclusion were shown to be sound, this would be a powerful result suggesting either an excessive degree of intellectual property protection for pharmaceuticals or some other source of continuing market power. As reported by the OECD, comparisons using simple versions of standard accounting ratios usually suggest that the profitability of the pharmaceutical sector over time has been higher than that of other sectors.\(^{13}\) For instance, Scherer (1996) notes that over a 32 years period, the return on equity averaged 18.4 per cent for pharmaceuticals and 11.9 per cent for 500 largest industrial companies. This study is cited by the OECD report, but not Scherer’s comment that accounting profits are likely to overstate actual profits in the drug industry. The issue of the appropriate accounting adjustments is central to the debate.

Research-based pharmaceutical companies invest substantial sums in R&D. These sums are investment in intangible capital, creating valuable assets, such as patents, trademarks, know how, brand loyalty and skilled workforce that may generate cash flows for many years. Such investments, in accounting statements, are usually treated as an expense rather than as a capital investment. As a consequence, for the pharmaceutical industry, as for any other industry with significant intangible investments, accounting measures of capital are downward-biased and estimates of returns on capital (usually calculated as ratios of income to assets) are upward biased. This bias fuels the perception that the pharmaceutical industry earns abnormally high profits, which in turn leads to pressure for lower prices.

In analysing more precisely the expected effects of switching from expensing research to capitalising and depreciating it, two different cases should be considered:

- **A steady-state**: in this case annual research expenditure should equal the annual depreciation of the research assets, so as to maintain the stock of those assets. Removing research expenditure from costs and adding research depreciation should leave annual costs, and hence annual profits, unchanged. Capitalising research expenses will add a new element to assets without reducing anything else. Hence a switch from expensing to capitalising research must reduce the return on assets.

- **Growth**: in this case current research expenditure will exceed the depreciation on past expenditure. Hence capitalising research will reduce costs and so increase profits. Since assets will also increase, the effect on the rate of return will be indeterminate, depending on the actual magnitudes involved.

Clarkson conducted an analysis of Merck & Company accounting records to correct accounting rates of return in order to remove some of the differential effects of unrecorded intangible capital.\(^{14}\) He found that the accounting return on book equity over the period 1980-1993 dropped from 27.5 per cent to 14.3 per cent after correcting for the investment outlay and correcting equity for the omission of intangible assets.

In a comparison across US industries for 1980-93, Clarkson found an unadjusted “accounting” rate of return for pharmaceuticals to be 24.4 per cent, highest of 14 sectors and twice the 14-industry average of 12.3 per cent. Under his corrected rates of return, the comparative figures were 13.5 per cent and 10.3 per cent, and the rate of return in pharmaceutical industry was fourth of the 14 sectors.

\(^{12}\) The economic analysis that shows that for products with high sunk costs (such as research and development costs) and consumers with different willingness to pay, allowing parallel trade is likely to reduce, rather than increase, economic welfare, is set out in an article published earlier this year by staff at Europe Economics: Tim Booer, Peter Edmonds, Dermot Glynn and Claudia Oglialoro, Economic Aspects of the Single Market in Pharmaceuticals, European Competition Law Review, Volume 20 Issue 5, May 1999.

\(^{13}\) The most common indicators of profitability are ROE (return on equity) and ROI (return on investment). The former is the ratio between earnings and average equity, while the latter is the ratio of after tax operating income to the net (depreciated) book value of assets.

These are not the “small” reductions suggested by the OECD. Clarkson’s analysis suggests that once accounting rates of return are adjusted for intangible capital, the pharmaceutical industry no longer stands out as having particularly high returns on capital that other industries. Scherer also reported that there may be downward pressures on the rate of return in pharmaceuticals, a view supported by more recent evidence. For example, the US Congressional Budget Office concluded that the net effect of the rise in generic competition since 1984 and the patent life extensions under the Hatch-Waxman Act has been a fall in the average returns from a branded medicine in the US of about 12 per cent.[15]

A full analysis of relative profitability of different industries also needs to take account of risk. Myers and Shyam-Sunder explain why the cost of capital for pharmaceutical R&D is higher than the cost of capital for producing and selling established drugs. Differences in the underlying riskiness of returns across industries may also provide part of the explanation for the higher average rates of return observed in pharmaceuticals.

Other measures also cast doubt on the view that pharmaceutical companies earn super-normal profits. Zweifel and Breyer cite studies that calculated the internal rates of return of pharmaceutical innovations in the United States to be an average of 6.1 per cent.[16] In addition, they estimate that half of the innovations that were introduced in the United States during the period 1962-1977 would not have paid back their development costs even after 36 years.

The Secretariat’s Main Recommendations

As noted in the Introduction, the Secretariat follows through its analysis of competition and market power with two main recommendations.

Privatising the Regulation of Pharmaceutical Pricing and Reimbursement

The OECD paper suggests that in many OECD countries the private sector may be better able to manage the procurement and use of pharmaceuticals than the current public sector agencies (paragraph 71, and emphasised in the conclusions (paragraphs 168-169)). “The tendering process would be designed to keep pharmaceutical costs down to a minimum and to innovate in techniques for monitoring and controlling pharmaceutical expenditure.” (paragraph 71). This proposal builds on what is viewed by the Secretariat as the successful development of new models of health care management in the US. The US economic literature shows that over the last 15 years, the pricing and other competitive strategies of pharmaceutical companies have been altered by developments in information technology, new state drug substitution laws, federal legislation and the emergence of market institutions that include health maintenance organisations (“HMOs”) and pharmacy benefit managers (“PBMs”). The industry has also undergone significant structural changes that include growth of the generic drug segment and substantial horizontal and vertical consolidation such as acquisitions of PBMs by drug companies.

Whether the market power of US health plans with monopsony powers as purchasers of health care services and market power as health insurers may lead to socially unattractive outcomes has long been the subject of debate in the US. The evidence is that such power may well have been used to reduce the cost of health care, but it remains much less clear whether this has been accompanied by reductions in the quality of care.

There are several respects in which the direction of reform outlined by the Secretariat may be less promising than it first appears. These include the following:

- The Secretariat’s paper does not explain what would happen to the statutory powers most OECD member state governments have taken to set prices and reimbursement rates. Would this market power simply be delegated? One study that found no evidence of abuse of market power in the US from the development of HMOs and PBMs (such as reducing services, shifting costs or forcing consumers to take over-specified plans) suggested that this result may reflect the threat of competitive entry. If so, it cannot be relied on as a precedent for the behaviour of European firms given a statutory monopsony.

- Reductions in pharmaceutical expenditure can lead to higher costs elsewhere in the health care system, or in later years. It needs to be made clearer how contracts could be drawn up requiring private firms to reduce pharmaceutical costs without generating such undesirable side-effects.

- If private sector companies with strong monopsony positions were charged with keeping down pharmaceutical expenditures over a certain time period, what steps would be taken to ensure they recognised in their behaviour that the sunk costs of R&D expenditures need to be recovered through pharmaceutical prices? The long lags in the development of new products would mean that even in the extreme case of refusing to recognise any need for

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15 CBO “How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry” July 1998.
18 HMOs provide health care coverage and services for roughly 11 per cent of the US population. They generally offer relatively extensive coverage for prescription pharmaceuticals.
intellectual property protection and forcing prices down to marginal production costs, it would be several years before the supply of new medicines dried up.

- Companies charged with minimising pharmaceutical expenditures could be expected to seek to exclude expensive categories of treatments from what was provided, even where the benefits of the treatment could be shown to outweigh the costs. They could also be expected to seek to exclude from benefits, patients who were likely to be expensive eg the elderly or those with expensive-to-treat medical conditions. How would governments write contracts that prevented such exclusions?

**Replacing Patents with other forms of Intellectual Property Protection**

It is common ground that R&D investments in the pharmaceutical industry need to be protected through intellectual property rights. Without this protection, the expectation would be that the price of a product, once developed, would be bid down to marginal production cost. Under such conditions, investment in the development of new medicines would simply stop. As noted in Section 2, empirical evidence shows that the pharmaceutical sector relies more on patent protection than most other sectors.

Section 2 above reviewed the Secretariat’s argument that patents grant an excessive degree of market power, and found it unconvincing. However, the point remains valid that by allowing prices to be set above marginal cost, patent protection introduces an economic distortion. The effects of this distortion could be significant. For instance, if the price of a pharmaceutical is above the cost of certain alternatives, patients may be forced to incur in the cost of surgery, even if the cost of a pharmaceutical, based on its marginal cost, is higher than the cost effectiveness of these alternative treatments.

Besides patents there are other techniques for protecting intellectual property rights such as awards (eg for scientific achievements), contracts (eg for defence research), or copyright. The Secretariat notes other possible mechanisms but emphasises compulsory licensing (paragraph 48 and the subsequent box).

The main proposal put forward for discussion by the Secretariat is to control the purchasing contracts between manufacturers and national health insurers, replacing patent rights by a royalty paid under a compulsory licensing system. Insurers would offer to pay a fixed annual fee in exchange for purchasing a brand-name drug at its marginal cost. The level of the fee should be chosen so that it would compensate the manufacturer for the loss of market revenue (therefore its R&D expenditures), while eliminating at the same time the distortionary effect of pricing above the marginal cost. Presumably, a government agency would also take over the role of informing medical professionals about the availability and characteristics of the new product.

Such a compulsory licensing system would presumably have to be introduced for all products simultaneously, otherwise the value of patents in products competing with those subject to compulsory licensing would be destroyed. Within the EU, they would also have to be introduced in all countries simultaneously if parallel trade was not to undermine the value of patents in countries where they were still valid.

To encourage efficiency in production, the Secretariat suggests that several companies might also compete for the right to produce the licensed product, (see especially paragraphs 113-117) but that is a secondary issue to that of the effects of compulsory licensing on the development of new medicines.

The technical economics literature does not establish that patents dominate prizes or research contracts as a form of reward. Wright (1983) shows how different forms of information asymmetry between firm and government make different forms of intellectual property rights socially optimal. In his model, the key difference of patents from prizes or research contracts is that they allow information held by researchers but not by government about the potential value of successful inventions to be incorporated into the allocative process.

The primary advantages of patent protection are its efficient use of information and the fact that the patent process makes new innovation public information. The economic and social value of a new innovation is extremely difficult to assess in advance. The Secretariat does not explain how, even at the point at which a product was ready for market, governments would estimate its likely potential commercial value to determine the royalty. Indeed, in a world of compulsory licensing there would be no such concept as the potential commercial value of a new medicine. Instead, the royalty would in practice have to be determined by what governments could measure: their estimate of the degree of therapeutic advance, or their estimate of the savings in health care costs.

As noted by Grabowski and Vernon (see reference above), the value of patents in pharmaceuticals is skewed. Most of the returns come from a small minority of patents. Suppose that with the samples of patents studied in these references, governments following the OECD Secretariat’s recommendations had placed caps on the maximum royalty payable at the level of the 25th percentile of the distribution ie the upper quartile. Such a move would have greatly reduced the total returns.

The expected value of a patent on a new medicine, and changes in this value over time, provide an important indicator and guide during the development of new products. What would take its place in that role if patents were abolished? Under compulsory licensing, products already well advanced in the pipeline would be brought to marketable stage. But for the longer term, a critical question would be the following:

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“At the time it first synthesised a new product and developed a notion of its therapeutic potential, would the returns a company expected to make on developing the product and undertaking clinical trials make that investment worthwhile?”

If not, then governments may need to plan and carry out trials themselves, paying companies royalties simply in respect of initial innovations rather than of marketable products. This suggestion by the Secretariat is incomplete, as it does not specify any solution to the central issue of the information the royalty decision would be based on and how that information would be used.

### Conclusions

This paper has provided a brief review of the OECD paper on regulation and competition in pharmaceuticals. Our main conclusions on the Secretariat’s analysis are as follows:

- The Secretariat’s conclusions on competition in pharmaceuticals do not give enough weight to the central role of innovation in competition. The readily available evidence suggests that competitive pressures may be reducing the value of pharmaceutical patents over time.

- The Secretariat’s paper significantly understates the extent of monopsony (single buyer) power held by national health authorities.

- The argument on whether companies seeking to extend patents is an abuse or not, is not as clear-cut as the Secretariat’s paper suggests.

- The evidence we have seen does not suggest that rates of return in the pharmaceutical industry, once measured correctly, are significantly out of line with those in other industries.

The Secretariat’s argument that patents give an excessive degree of market power in pharmaceuticals is therefore less than wholly convincing. Its weakness is made more serious by the minimal treatment in the OECD paper of market power on the demand side of the pharmaceuticals market.

The two main proposals put forward by the Secretariat do not seem to have been adequately considered:

- the proposal to privatise the management of the procurement and use of pharmaceuticals does not take into account the market power of health insurers or the difficulties of contracting to avoid short-termist or otherwise opportunist behaviour by private companies charged with reducing the drugs bill; and

- the proposal to replace patents for pharmaceuticals with compulsory licences fails to spell out the information and processes that would be used to determine the value of these compulsory licences, and does not consider what the longer-term consequences of such a move might be for the development of new medicines.