DISCUSSION PAPER SERIES

No. 675

PHARMACEUTICALS – WHO'S AFRAID OF '1992'?

Gernot Klepper

Centre for Economic Policy Research

ISSN 0265-8003

PHARMACEUTICALS – WHO'S AFRAID OF '1992'?

Gernot Klepper

Discussion Paper No. 675
March 1992

Centre for Economic Policy Research
6 Duke of York Street
London SW1Y 6LA
Tel: (44 71) 930 2963

CEPR Discussion Paper No. 675

March 1992

ABSTRACT

Pharmaceuticals – Who's Afraid of '1992'?*

This paper develops a framework within which the impact of the proposed initiatives of the European Commission for creating an internal market for pharmaceuticals can be analysed. In a model of third-degree price discrimination, arbitrage between two markets and price controls through governments in one market are introduced. The effects of easier arbitrage opportunities, i.e. lower arbitrage costs, on the prices in the two markets are analysed. Also, the impact of a reduction in price controls in the low-priced markets as well as their combined effects are characterized. The welfare effects of the Internal Market in pharmaceuticals are ambiguous, since a movement from segmented and price-controlled markets towards integrated markets does not lead to a first- or second-best solution.

JEL classification: D43, D60, F13, F15
Keywords: European integration, price controls, re-imports, pharmaceuticals

Gernot Klepper
Institut für Weltwirtschaft
Dusternbrooker Weg 120
D-2300 Kiel 1
GERMANY
Tel: (49 431) 884 485

*This paper is produced as part of a CEPR research programme on 'The Consequences of "1992" for International Trade', supported by a grant from the Commission of the European Communities under its SPES Programme (no. E89300105/RES). The research for this paper was financially supported through the SPES Internal Market Project of the EC, whose help is gratefully acknowledged. I am grateful for valuable comments by Alan Winters and numerous participants of the 'IT92' workshops.

Submitted 30 March 1992

NON-TECHNICAL SUMMARY

Completing the European Internal Market is usually thought of as consisting of the removal of all barriers to trade within the EC such that market segmentation will disappear and, ideally, equal prices will prevail. Pharmaceutical markets are still the most segmented markets exhibiting large price differences between high-priced countries like Denmark, Germany, and the Netherlands and low-priced countries like Greece, Italy, Portugal, and Spain. For the European Internal Market in 1992 and beyond, the EC Commission has introduced several initiatives aimed at reducing this market segmentation. This paper analyses the likely impact of these measures on prices in the different countries and their possible welfare effects.

The segmentation of pharmaceutical markets does not emanate from tariffs and quantitative barriers but from differences in national regulations, different demand patterns and price controls in certain markets. Consequently, no real barriers to intra-EC trade exist, but constraints on arbitrage nevertheless sustain price discrimination between markets. The European Commission's initiatives to enhance the integration of pharmaceuticals markets consist of a requirement to make the imposition of national price controls more transparent (thus increasing political pressure against discriminatory price controls), and attempts to harmonize registration procedures for new products as well as for re-imports or parallel imports by arbitrageurs, in order that price controls should become less stringent and the cost of arbitrage between EC members states will fall. (Re-imports are imports that have previously been exported from the producing firm and parallel imports are imports by arbitrageurs as well as the producing firm.)

In order to address these issues, this paper develops a model of a price discriminating firm serving two markets, one of which has price controls. These markets have different price elasticities, e.g. because of different income levels between the southern and northern part of the EC. The two markets are not completely segmented since arbitrage is possible, but this involves costs that are assumed to increase with the amount of pharmaceuticals that are re-imported or parallel imported. Market integration measures by the Commission of the EC are represented through a parametric shift in the cost function of arbitrageurs.

The model predicts that a reduction of price controls in one country, e.g. as induced by the Transparency Directive of the EC, will reduce the price differences, but this may be accompanied by rising prices in the unrestricted market, contrary to the expectation that both prices move towards a uniform price somewhere between the original prices. The specific form of the cost function of arbitrage determines which price effect will prevail. Similarly ambiguous is the effect of changes in the regulatory barriers to arbitrage. Easier arbitrage

opportunities reduce price differences between the two markets, but whether prices fall or rise in a single market depends on the shape of the demand functions. If demand is very inelastic, as is possible especially in the German market, prices may fall in the high-priced as well as the low-priced market.

The impact of market integration on profits and consumer surplus is not necessarily positive. Whereas a reduction in price controls unambiguously raises profits, it also lowers consumer surplus in the price-controlled market and possibly in the unrestricted market. Facilitating arbitrage also has ambiguous effects on the consumer surplus in both markets and on firms' profits. As the producer is no longer able to price discriminate, its profits are likely to fall. The consumer surplus in the high-priced market always rises, whereas it rises in the low-priced market only if demand in the high-priced market is very inelastic.

The overall welfare effects for the two markets cannot be uniquely predicted. The analysis is complicated by the fact that due to the high fixed costs of producing pharmaceuticals the welfare maximum with marginal cost pricing is not attainable without subsidization and a uniform price is not a second-best solution. Profit-constrained welfare maxima – for example with a zero profit constraint – would always involve price controls in both markets; they could not be achieved through price controls in only one market.

The analysis has focused on a pharmaceutical producer having a monopoly in a particular market segment, for example through patent protection. All the conclusions also hold if the monopoly situation is replaced by an oligopoly, however, which is more common for the market segments defined by the different therapeutic groups.

In summary, the reduced restrictiveness in price controls which is beginning to appear in the EC will reduce price differences. It will not eliminate market segmentation, however, which is made possible by the different national registration procedures, which allow firms to differentiate their products so that they can only be re-imported or parallel imported at high costs of relabelling, repackaging and additional registrations. Only a European registration or a mutual recognition of national registrations will integrate pharmaceutical markets.

Integrating pharmaceutical markets in the spirit of the Internal Market will redistribute consumer surplus from the low-priced countries to the high-priced countries. Whether the overall welfare effect of market integration is positive or negative cannot be answered as it depends on a complex set of supply and demand conditions.

1. INTRODUCTION

The market for pharmaceuticals is probably the most strongly segmented and highly regulated market in the EC - witness the large price differences between countries. At the same time, the pharmaceutical industry in some countries such as Germany and the UK belongs to the most successful sectors of the economy.

In studies of the internal market in 1992 the prospects for a unification of the markets for pharmaceuticals have been seen as not too bright (CEC, 1988a). The expectations about the success of the planned directives of the Commission of the EC were reserved, although some convergence of price levels was predicted, but the potential path for prices in the process of unification and the resultant welfare effects remained unexplored (CEC, 1988b). In "The Economics of 1992" a convergence of prices to a community average was assumed resulting in a fall of spending on pharmaceuticals of 720 mio. ECU or to some 3 percent in total expenditure.

This paper developes a framework within which the likely outcomes of measures taken towards an internal market can be analysed. It first introduces some features of pharmaceutical markets in terms of industry characteristics and demand regulations, and summerizes the proposed measures by the Commission of the EC. In the second part I present a simple model of a price discriminating monopoly which is exposed to price controls in one market and which faces limited arbitrage between the markets. Changes in regulations concerning arbitrage and price controls are then investigated and the impact of moves towards unified markets on welfare are discussed. The paper concludes with some speculations about

the likely process of creating an internal market for pharmaceuticals as it is laid out by the directives of the EC and further planned directives.

2. INDUSTRY AND MARKET STRUCTURE

2.1 MAIN INDUSTRY CHARACTERISTICS

The European pharmaceutical industry can best be characterized by its dual structure. On the one hand, there are small companies which do not develop new drugs, have small R&D budgets and sell mostly to local markets. They make up the bulk of the 2200 pharmaceutical companies in Europe. The European market is dominated, however, by around 60 internationally operating, large, research oriented companies of which about 30 are of European origin. They control about 70-80 percent of the market in France, Germany, Italy and the UK and account for most of the 4-5 billion spent to R&D.

These large international firms rely to a considerable extent on intra-firm trade and production in local affiliates such that trade statistics reveal only a small proportion of the internationalization of the market for pharmaceuticals. It has been estimated that while in 1984 imports into the EC amounted to about 1.2 billion ECU, sales by local affiliates of non-EC companies amounted to 7.7 billion ECU (CEC, 1988b). This emphasis on local production has two causes: It is often claimed that the national authorities which regulate pharmaceutical markets and control demand discriminate against imports, thus forcing foreign companies to establish local facilities. The other reason is based on the technology of producing pharmaceuticals.

Developing new drugs requires large investment in R&D adding up to, e.g., DM 2915 mio. (1980) in Germany, i.e. 14.6 percent of German industry turnover (BPI, 1990). This is about one third of total R&D spending in the EC (CEC, 1988b). It is estimated that the development of one new pharmaceutical entity costs about DM 250 mio. Since R&D projects have a low probability of success large companies choose to work simultaneously on 8-10 projects in order to spread the risk. In addition, research facilities require a minimum efficient scale for libraries, animal testing, laboratories, etc. such that the R&D facilities are in one centralized place, usually the headquarter of the company. Once the chemical entity has been developed, it is necessary to prepare the active ingredients and convert them into dosage form. The latter step involves few economies of scale and can be decentralized. The marketing of drugs then is a purely local activity. The production technology can therefore roughly be characterized as one which involves sizeable fixed costs but otherwise constant marginal costs.

Table 1 - Estimation of Relative Drug Prices from Different Studies, UK=100

	COOPER 1974	PROGNOS 1981	HEALTH ECON. 1982	EEC 1983	DUKES 1984	EFPIA 1985
Belgium	143	73	66	103	69	70
Denmark	n.a.	n.a.	143	154	99	n.a.
France	80	69	57	76	52	77
FRG	288	128	159	164	124	120
Greece	n.a.	n.a.	n.a.	73	n.a.	n.a.
Italy	85	65	62	57	58	72
Netherlands	n.a.	n.a.	140	145	114	113

Source: Taken from CEC (1988b), Table 4.2.

The demand for pharmaceuticals is determined by complex interactions between patients, physicians, and different health insurance systems. The choice of an ethical, i.e. by prescription only, drug - the dominating market segment - is largely made by the physician who is privileged to prescribe drugs but he does not pay for it. Patients, the consumers of pharmaceuticals, have little incentive to respond to price differences of drugs. The national and local health institutions who bear the costs have had to seek alternative ways to control the cost of pharmaceutical therapies. Except for Germany, Ireland, the Netherlands, and the UK, all EC countries use direct price controls. Other measures include controls on total expenditure, positive or negative lists, and direct negotiations between health systems and the pharmaceutical industry.

Table 1 reveals that the different approaches to cost control have resulted in drastic price differences between high price countries like Denmark, Germany, and the Netherlands - which incidently do not control prices - and low price countries like Italy and France which limit prices. Also Spain and Portugal which are not included here have low prices.

2.2 BARRIERS TO TRADE

The major regulations for pharmaceuticals concern health aspects. Every pharmaceutical has to pass a registration procedure before it can be sold in a national market. Proof of safety, efficacy and quality have to be supplied by the producer. In addition, packages, labels, patient information leaflets and dosages must be approved. These characteristics together define a pharmaceutical product in a national market. Strictly speaking this means that two products sold in two different countries with different patient information leaflets or different labels but iden-

tical chemical ingredients are treated as different products. Hence, the admission process of pharmaceuticals unintendedly produces perfect market segmentation if viewed from a legal standpoint.

In reality this view has been contested. Since the late 1970's companies have appeared which have tried to arbitrage pharmaceuticals from low priced countries to high priced countries, mostly to Germany, the Netherlands and the U.K. These companies bought, e.g., German pharmaceuticals in France or Italy and exported them to Germany or they bought Italian pharmaceuticals in Italy and they exported those parallel to the exports of the producers to Germany. These reimports and parallel imports are estimated to be rather small amounting to 150 mio. ECU in the EC in 1985 (CEC, 1988b). For Germany a market share of one percent has been quoted (Sachverständigenrat für das Gesundheitswesen, 1987) which - according to industry representatives - has remained fairly constant. Companies specializing in reimporting pharmaceuticals report that producers respond quickly to increased arbitrage by lowering prices in high priced markets. The model below also indicates that a low volume of reimports and parallel imports does not necessarily indicate low pressure on market segmentation.

In Germany, arbitrage is undertaken by approximately 5 to 6 large firms and a larger number of small firms. Since these firms are required to be registered as pharmaceutical producers and since their reimported or parallel-imported products have to go through the national registration, arbitrage activities can not be performed on a hit-and-run basis. It is impossible to assess exactly the cost structure of arbitrage firms, but there seem to be some setup costs, with marginal costs being relatively flat until the producers of the arbitrage products actively try to prevent arbitrage. Then marginal costs may become very steep.

The European Court has already ruled in 1976 that reimports and parallel imports do not need a separate admission procedure - which is time consuming and expensive - if the products are identical. If there are therapeutically relevant differences between the products, however, then a new admission is necessary. This statement is at the heart of the matter of many court rulings concerning reimports and parallel imports. National regulations differ substantially. In the Netherlands, a simplified registration procedure can be used by arbitrageurs if the pharmaceutical has the same chemical compounds and the same dosage. This procedure is frequently used (Hart/Reich (1990), pg. 250). Germany does not have a special admission procedure for reimported pharmaceuticals. It requires, however, that the reimporting firm is registered as a pharmaceutical producer with all the responsibilities for safety of the drugs which it sells. A recent court ruling in 1989 has reinforced the barriers for arbitrage since it requires that in order to be identical products, reimported pharmaceuticals need to have identical names with those sold in Germany. The federal court (Bundesverwaltungsgericht) decided that the products "Methorexat" sold in Germany and "Methorexate" sold in Italy which except for the last letter are otherwise identical cannot be treated as identical products. Arbitrage is therefore made very costly since the reimported product must go through the complete admission process which is time consuming and expensive.

Taken together these regulations in countries with high prices for pharmaceuticals, it is fair to conclude that arbitrage inside the EC is still considerably restricted. It is costly since the imported products often have to be repackaged, or since wholesalers in the exporting countries do not deliver products to exporters, or since companies have reacted to court rulings by exploiting the possibilities of product differentiation

in order to keep markets segmented as much as possible. Therefore national admission processes which undoubtedly are necessary for health and safety reasons provide the basis for market segmentation. The question is then as to whether the measures taken by the EC will attack this situation and will move pharmaceutical markets toward a unified internal market without segmentation.

This market segmentation is also a necessary condition for the sustainability of price control measures which are taken by the majority of countries. The measured price differences (see table 1) therefore represent a mixture of price discrimination imposed by profit maximizing firms and price controls imposed by national health institutions. An elimination of national price controls will therefore not necessarily lead to uniform prices within the EC. It is even an open question whether price differences would be larger with than without price controls. Whether European directives towards easier arbitrage opportunities under unchanged price control regimes will be sustainable is also unknown. The analysis below will shed some light on these issues.

2.3 INITIATIVES TOWARDS AN INTERNAL MARKET

The commission of the EC has in the past already introduced a number of measures to harmonize pharmaceutical markets. Their intended aim is to secure a safe supply of pharmaceuticals without limiting the development of the European pharmaceutical industry and the free movement of goods within Europe. Whereas in the past a producer could register a drug only with the national authority of the country in which the product was sold, a multi-country registration procedure has been introduced.

The multi-country procedure gave pharmaceutical companies the option to obtain registration of a pharmaceutical product for the entire EC by supplying first five and since 1983 only two national registrations to the European Commission for Proprietary Medicinal Products (CPMP) which then evaluates the documents supplied by the company and give a positive or negative recommendation to the member countries for accepting the national registrations in their countries without further delay.

This procedure has not been used very much. The pharmaceutical industry accused it of being too time consuming. In 1987 the CPMP has been given more power through the rule requiring that national in registration processes for high technology drugs such as drugs produced with biotechnology are also processed by the CPMP, i.e. a European wide registration is automatically prepared.

Despite these efforts to harmonize registration procedures, the final decision still remains with the national authorities. This also means that pharmaceutical firms still have the option to obtain only national admissions for their products. They can thus choose the degree of product differentiation and market segmentation through "spurious" product differentiation such as slight changes in the name of a drug, different packaging, different dosage or different patient information.

New initiatives towards a harmonized registration within the EC go in three directions (Hart/Reich, 1990): First, the establishment of the principle of mutual recognition of registration; second an expansion of the competence of the CPMP, yet without giving it registration authorities, and finally the creation of a pan-European admission agency, the "European Medicines Agency". The last proposal of the Commission of 1990 on a "Future System for the Free Movement of medicinal products within

the European Community" envisages on obligatory pan-European registration for bio-technically produced drugs and an optional one for high-technology and new drugs. A decentralized procedure with mutual recognition of admissions is planned for drugs not in the two groups just mentioned but with European dimension. National authorities are therefore responsible only for drugs with a local market.

The so called "Transparency Directive" addresses the question of price controls. The commission does not challenge price controls in general but aims at making price control measures more transparent for those involved in the process by setting time limits on procedures or giving companies more rights to challenge price controls. Under these rules price controls can still be imposed, they may however be accompanied by higher political costs if the decision processes become transparent and the alleged discrimination of foreign firms can be documented. If the initiatives and plans by the Commission of the EC toward an internal market for pharmaceuticals are accepted and implemented a first step toward a unified market will be made. Through the pan-European registration of bio-technology products market segmentation will be ruled out. For other products companies may still have the option of segmenting markets through national registration. Whether the European court will challenge some of the national rules concerning arbitrage through reimports and parallel imports is hard to predict, but some harmonization between, e.g., German and Dutch rules will probably come about resulting in lower costs of arbitrage. Price controls, on the other hand, seem to prevail.

The question then is what will be the impact such regulatory measures be on pharmaceutical markets in Europe? What will happen to price discrimination by firms? Will prices rise or fall? Will price controls per-

market with possibly uniform prices is the welfare issue. Consumer surplus will fall in countries whose prices increase, but even on a community level it is not clear whether a move from the current system which is inefficient to a unified market which is also inefficient will raise or lower welfare. In order to clarify these questions and to answer some of them, I now develop a simple model of a price discriminating firm faced with price controls in one market but not in the other.

3. A MODEL OF PRICE DISCRIMINATION, PRICE CONTROLS, AND ARBITRAGE

3.1 MARKET SEGMENTATION

Suppose a firm produces an ethical drug which is protected by patents and serves a specific therapeutical group. There may be some substitutes in that market segment, but essentially the firm will have a monopoly - especially if it supplies the most advanced pharmaceutical for curing this specific illness. The firm is assumed to produce just one pharmaceutical and to sell in two markets, 1 and 2. It has a cost function of the form

$$c(x) = F + c \cdot x \qquad (1)$$

where F is Fixed cost (R&D, etc.)

c is marginal cost, and

x is the volume of production;

hence there are constant marginal costs and increasing returns to scale.

The firm's profit if it can price discriminate between markets will then be given by

$$\pi(p_1,p_2) = x_1(p_1)p_1 + x_2(p_2)p_2 - c(x_1(p_1)+x_2(p_2)) \qquad (2)$$

where $x_1(p_1)$ and $x_2(p_2)$ are the demand functions in market 1 and 2. Profit maximization yields the following first order conditions

$$\frac{p_2}{p_1} = \frac{1 + \frac{1}{\epsilon_1}}{1 + \frac{1}{\epsilon_2}}, \tag{3}$$

where ϵ_1 and ϵ_2 (≤ -1) are the respective demand elasticities in the two markets. Equation (3) shows that prices in the market with lower demand elasticities (in absolute terms) will be higher. For the following it is assumed without a loss of generality that $|\epsilon_2| > |\epsilon_1|$, hence $p_1 > p_2$.

Under a regime without market segmentation, the firm will set a uniform price p_o such that its marginal revenue in both markets together will equal its marginal cost, i.e.

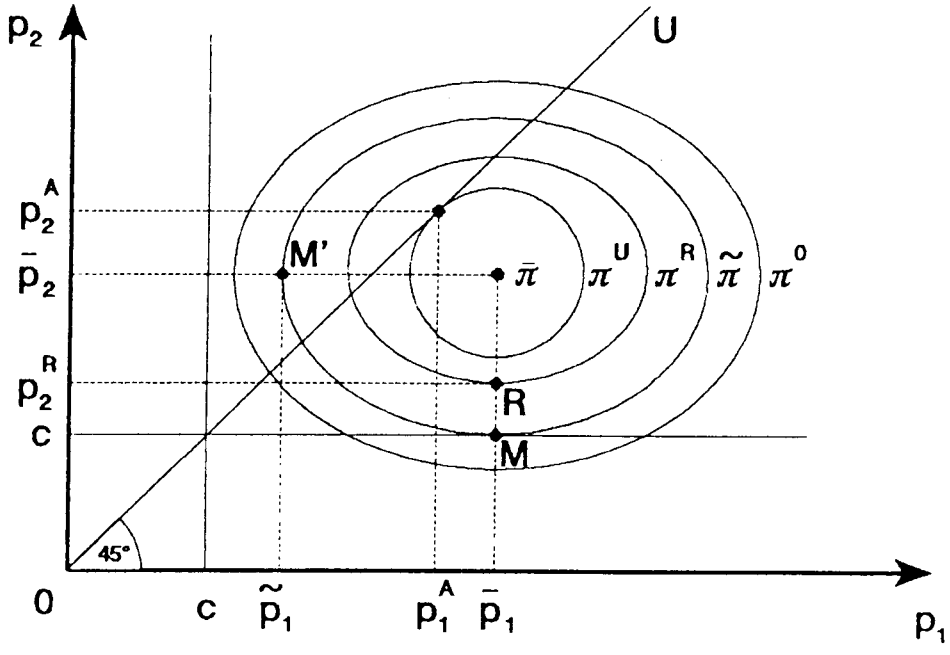
$$p_U \left(1 + \frac{1}{\epsilon_U}\right) = c \tag{4}$$

where ϵ_U is the price elasticity in the combined market.

Suppose now that prices are controlled by a regulatory agency in country 2 which fixes p_2 at p_2^R. Since the pharmaceutical producer faces constant marginal costs and the demand functions are independent, the price in market 1 will remain at p_1 whereas $p_2 = p_2^R$. This result is illustrated in Figure 1.

$\bar{\pi}$ represents the profit maximizing price combination $(\bar{p}_1, \bar{p}_2)$ under third degree price discrimination. The isoprofit line labled π^R goes through the price pair $(\bar{p}_1, p_2^R)$ when prices are controlled in market 2. The tangency point of the isoprofit line π^U with the 45°-line, represents the equilibrium without market segmentation. π^0 denotes price combinations

Figure 1 Third Degree Price Discrimination with Price Controls



where profits of the firm are zero. Under the demand constellation of the model prices in market 2 can be lowered to c through controls. Then the firm will cease to supply that market but will still make profits in market 1.

3.2 Arbitrage

Suppose now that markets are only imperfectly segmented. Goods can be arbitraged between markets at some costs. There are arbitrageurs who supply parallel imports or reimports by buying in the low price market and selling in the high price market. In order to perform this activity they have additional costs of repackaging, of distribution, of sourcing, etc. which may parametrically depend on the institutional structure of the markets. The profit function of an arbitrageur would be

$$\pi^A(x_A,\alpha) = (p_1-p_2)x_A - c(x_A,\alpha) \tag{5}$$

where x_A denotes the quantity which is bought, resp. sold, in the two markets and $c_A(\cdot)$ is the cost function of arbitrage parameterized with α. It is assumed that the cost function is convex, i.e. $c' = \delta c/\delta x_A > 0$, $c'' > 0$ and $\delta c/\delta\alpha > 0$.

Under the assumption that the arbitrageurs do not believe that they can influence prices the profit maximizing arbitrage x_A will be given by

$$p_1-p_2 = c'(x_A,\alpha). \tag{6}$$

The supply function of the arbitrageur in market 1 will then be given as the inverse of (6),

$$x_A = x_A(p_1-p_2,\alpha) \tag{7}$$

with $x'_{A1} > 0$, $x'_{A2} < 0$, $x'_A > 0$, where x'_{Ai} denotes the partial differential of the supply function with respect to p_i, and $x'_A = \delta x_A/\delta(p_1-p_2)$. The signs follow from the strict convexity of the cost function.

The pharmaceutical firm will now recognize the behaviour of arbitrageurs which itself depends on the extent of the firm's own price discrimination among the two markets. Profits of the pharmaceutical firm then become

$$\begin{aligned}\pi(p_1,p_2,\alpha) = {} & p_1\,[x_1(p_1) - x_A(p_1-p_2,\alpha)] \\ & + p_2\,[x_2(p_2) + x_A(p_1-p_2,\alpha)] \\ & - c\,[x_1(p_1) + x_2(p_2)] - F.\end{aligned} \tag{8}$$

Maximization with respect to p_1 and p_2 then yields first order conditions

$$0 = p_1 \left[1 - \frac{1}{|\epsilon_1|} \left[1- \frac{x_A}{x_1} (1+\epsilon_A) \right]\right] - c \tag{9}$$

$$0 = p_2 \left[1 - \frac{1}{|\epsilon_2|} \left[1+ \frac{x_A}{x_2} (1+\epsilon_A) \right]\right] - c. \tag{10}$$

$|\epsilon_1|$ and $|\epsilon_2|$ are defined as the market demand elasticities net of arbitrage. ϵ_A denotes the reaction elasticity of arbitrage with respect to the price dispersion, i.e.

$$\epsilon_A(\alpha) = \frac{\delta x_A(p_1-p_2,\alpha)\cdot(p_1-p_2)}{\delta(p_1-p_2)\cdot x_A(p_1-p_2,\alpha)} . \tag{11}$$

The familiar condition on third degree price discrimination given in (3) is then transformed into

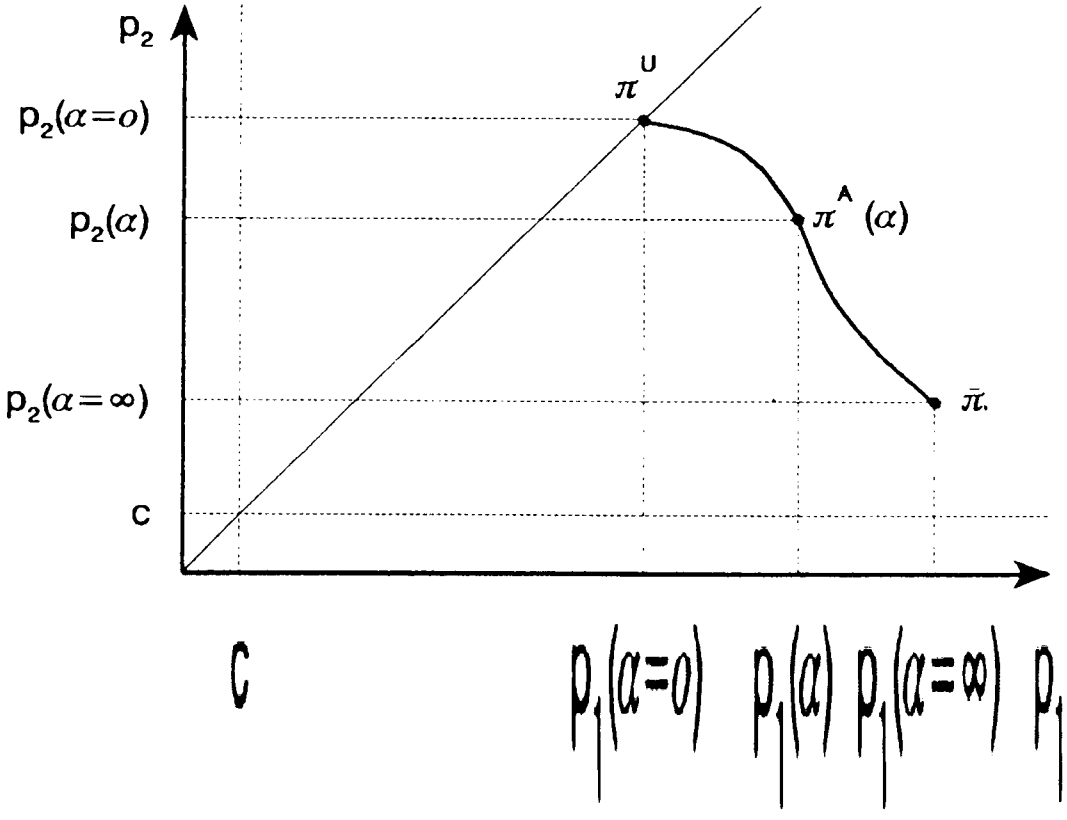
$$\frac{p_1}{p_2} = \frac{1 - \frac{1}{|\epsilon_2|} \left[1 + \frac{x_A}{x_2} (1+\epsilon_A(\alpha))\right]}{1 - \frac{1}{|\epsilon_1|} \left[1 - \frac{x_A}{x_1} (1+\epsilon_A(\alpha))\right]} \tag{12}$$

A comparison of the first order conditions under price discrimination without arbitrage (equation 3) and with arbitrage (equation 11) shows that arbitrage reduces the wedge between the two prices. The degree of reduction then is determined by the two brackets on the right-hand side of equation (12).

The degree of price discrimination by the pharmaceutical firm depends on the extent to which arbitrage is made costly by the regulation for the marketing drugs in a country and by the barriers to reimports or paral-

lel imports. It is thus implicitly assumed that the producer has exhausted his ability to impose costs to the arbitrageurs. This effect is captured by the parameter α. Suppose a high α represents strict regulations such that the cost of arbitrage increase. Then the extent of arbitrage will fall as α increases, $\delta x_A/\delta\alpha < 0$ and consequently $\delta\epsilon_A/\delta\alpha < 0$. Hence, with falling α, i.e. low cost of arbitrage, the bracket in the numerator of equation (11) increases and it falls in the denominator. In other words, the perceived price elasticity of the pharmaceutical firm in market 2 falls and it rises in market 1. Since $|\epsilon_2| > |\epsilon_1|$, the perceived elasticities will eventually equalize as α falls and price discrimination will cease to exist. Conversely, as α increases the perceived elasticities will deviate and price discrimination will increase.

Figure 2 Third Degree Price Discrimination with Arbitrage



In Figure 2 the line $\pi^{U}\bar{\pi}$ indicates the optimal price discrimination under alternative costs of arbitrage. The comparative static results for alternative costs of arbitrage are

$$\frac{dp_1}{d\alpha} \begin{cases} \geq 0 & \text{if } 2x_2' + (p_2-c)x_2'' \leq 0 \\ < 0 & \text{if } 2x_2' + (p_2-c)x_2'' > 0 \end{cases} \tag{13}$$

and

$$\frac{dp_2}{d\alpha} \begin{cases} \leq 0 & \text{if } 2x_1' + (p_1-c)x''_1 \leq 0 \\ > 0 & \text{if } 2x_1' + (p_1-c)x_1'' > 0 \end{cases} \tag{14}$$

The path of profit maximizing allocations under different arbitrage opportunities has a negative slope like in Figure 2 if both demand functions are not too convex. The curve $\pi^{U}\bar{\pi}$ could have a positive slope, i.e. with relaxed arbitrage opportunities prices in both markets fall, if the demand in market 1 is very inelastic. It is also apparent that the sign of the slope of the path $\pi^{U}\bar{\pi}$ is independent of the cost structure of arbitrage.

3.3 Price Controls with Arbitrage

The introduction of price controls in a model with perfectly segmented markets leads to lower prices in the market in which the controls are imposed but prices in the unconstrained market are not affected. This follows immediately from the first order conditions of profit maximization and is illustrated in Figure 1. Under arbitrage this independence disappears since price controls increase the price dispersion between the two markets such that arbitrage will increase in order to exploit the new profit opportunities. Consequently, producers will adjust prices

in the market without price controls such that their profits are maximized given the behaviour of the arbitrageurs.

If prices in market 2 are controlled by the authorities of that country, the pharmaceutical producer will adjust p_1 such that

$$\frac{dp_1}{dp_2^R} = - \frac{(p_1-p_2)x_A'' + 2x_A'}{2x_1' + (p_1-c)x_1'' - 2x_A' - (p_1-p_2)x_A''} \qquad (15)$$

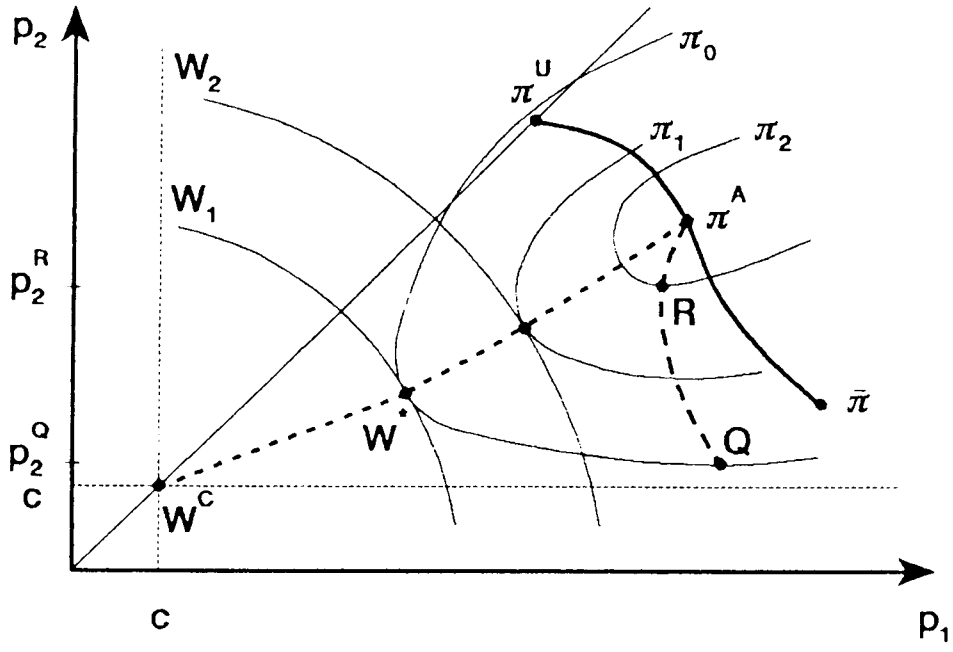
The denominator is identical to the first diagonal term of the second-order condition and is negative. The sign of the numerator potentially depends on the sign of x_A'' which is ambivalent and which represents the shape of the marginal cost curve of arbitrage.

If the arbitrage supply function, i.e. the marginal cost curve is concave, then the sign of equation (15) is uniquely positive, hence a reduction of the price in market 2 through administered price ceilings will be accompanied by a reduction in the price in the uncontrolled market. If however $x_A'' < 0$ and $(p_1-p_2)x_A'' < -2x_A'$ then prices may be raised in market 1 as a response to lower prices in market 2. This could happen, if the marginal cost curves of the arbitrageurs is sufficiently convex.

In Figure 3 an example is given where price controls at p_2^R initially induce a reduction of the price p_1 in market 1 such that R is the optimal allocation. If the price in market 2 is further reduced to p_2^Q, then the optimal decision by the producer will be to raise the price of good 1 in order to compensate for the losses in market 2. The reason for such a result comes from the fact that as p_2 falls arbitrage will increase ceteris paribus resulting in a lower p_1. If, however, the marginal cost

curves of the arbitrageurs are sufficiently steep then it becomes profi-

Figure 3 Price Discrimination with Arbitrage and Price Controls



The introduction of arbitrage and price controls could therefore lead to either a rise or a fall in prices in the uncontrolled market. Which occurs is essentially an empirical issue which is determined by the shape of the marginal cost curve of arbitrage. Since arbitrage involves buying large amounts of the commodity in the low price market, it will not go unnoticed by the producer if the market share of reimported goods or parallel imports increase. Companies specializing in the reimport of pharmaceuticals report increasing difficulties in buying large quantities from one wholesaler and have often to rely on a large number of

smaller suppliers. Such evidence suggests that a convex marginal cost curve for arbitrage is more likely than a concave one. This, in turn, would indicate that increasing arbitrage going hand in hand with stricter price controls could be accompanied by rising prices in market 1.

3.4 OLIGOPOLISTIC MARKETS

Pharmaceutical companies usually supply many different products in several market segments, i.e. different therapeutic groups. Sometimes there is only one producer supplying a dominating drug, in other cases there are very few; very rarely, however, here is a larger number of suppliers. The question is therefore whether the result which has been derived for a monopoly in a market segment also holds for an oligopolistic market structure. One can show that the same results can also be derived in a Cournot-Nash framework.

Suppose there are two producers, K and L, which both sell in the two markets, 1 and 2, having the same characteristics as before. The supply of the two oligopolists is (x_{K1}, x_{K2}) and (x_{L1}, x_{L2}). Under Cournotbehaviour each producer will choose those quantities which maximize his profits given the output of the other producer and given the arbitrage which takes place between the two markets.

The profit of producer K is

$$p_1(x_{K1}+x_{L1}+x_A)x_{K1} + p_2 (x_{K2}+x_{L2}-x_A)x_{K2} - c(x_{K1}+x_{K2}) \qquad (16)$$

and correspondingly for producer L. Arbitrage is determined correspon-

ding to (6) by

Under Cournot-behaviour each producer maximizes profits subject to the constraint of the arbitrage between the two markets. The resulting reaction functions are illustrated in Figures 4 and 5. Figure 4 represents the market with the high prices. Without arbitrage the Nash-equilibrium is $\bar{\pi}_1$ where the reaction functions K_1K_1' and $L_1'L_1$ intersect. In the presence of arbitrage, the reaction functions can not uniquely relate, say, x_{L1} to x_{K1}, but instead one must work in terms of the total market supply, i.e. $x_{K1}+x_A$ in market 1 and $x_{K2}-x_A$ in market 2. For a specific

Figure 4 Reaction Functions Under Different Arbitrage Opportunities in Market 1

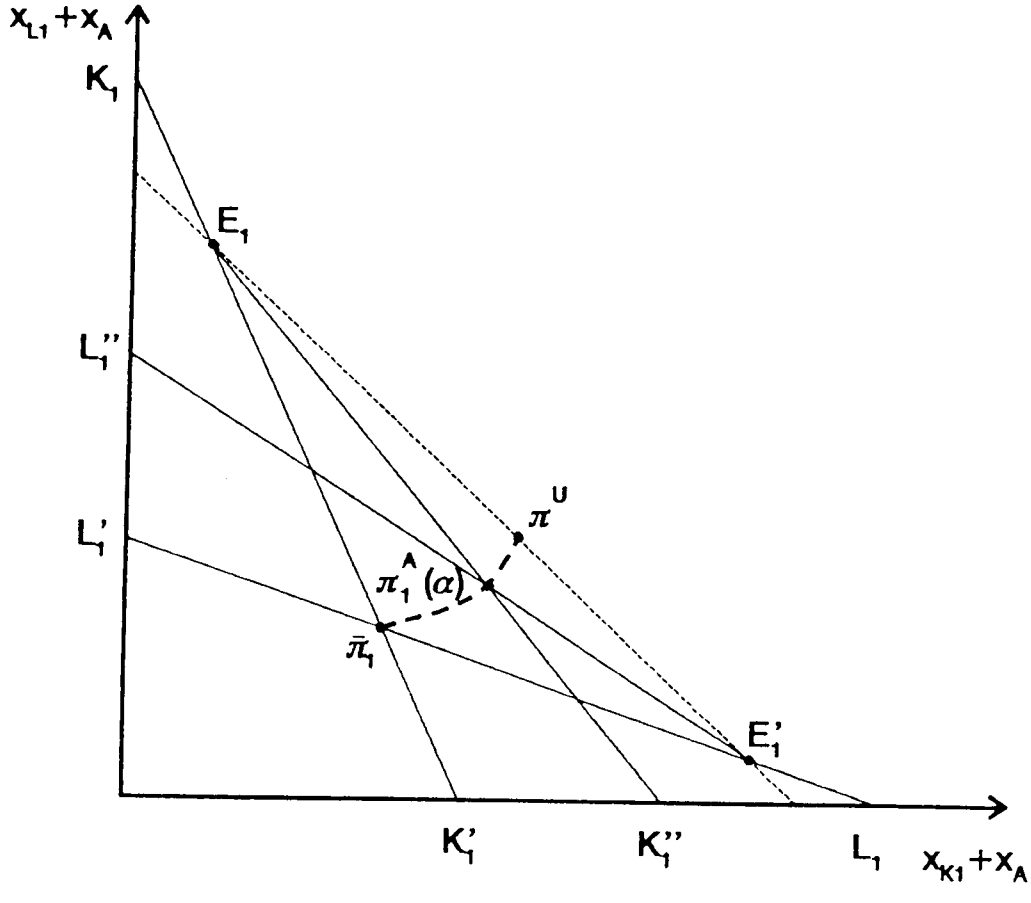
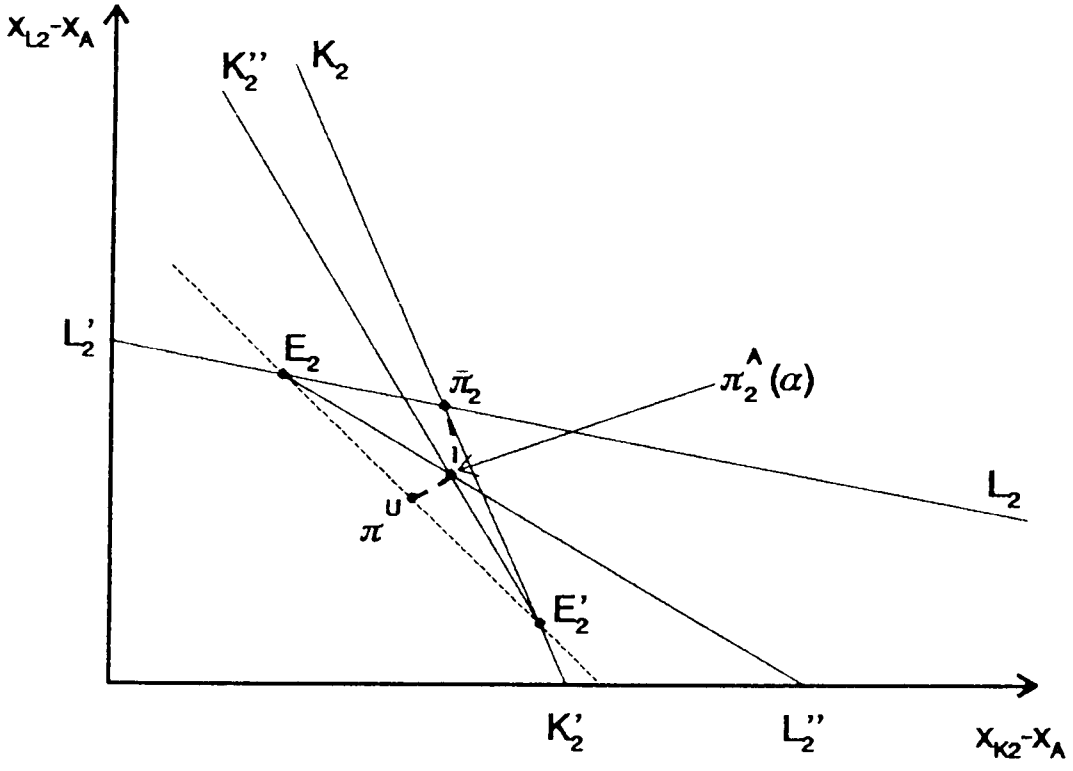


Figure 5 Reaction Functions Under Different Arbitrage Opportunities in Market 2



arbitrage opportunity parameterized by α, the resulting equilibrium market supplies are represented by $\pi_1^A(\alpha)$ in Figure 4 and the corresponding supply in market 2 is $\pi_2^A(\alpha)$ in Figure 5.

The comparative static results are the same as in the monopoly. If arbitrage becomes more costly, i.e. $d\alpha>0$, then

$$\frac{dx_A}{d\alpha} = \frac{-\pi_{11}\,\lambda p_2'^2}{\Delta} \cdot \frac{\delta c''(x_A, \alpha)}{\delta \alpha} < 0 \qquad (18)$$

where π_{11} is the second derivatives of the constraint maximization (16) and (17), Δ is the determinant, and λ is the Lagrangian multiplier.

For each producer the response of the sum of arbitrage supply and his own supply is also negative, i.e.

$$\frac{dx_A}{d\alpha} + \frac{dx_{K1}}{d\alpha} = \frac{p_1'}{\Delta}\left[\frac{\delta c''(x_A, \alpha)}{\delta \alpha}\ \lambda p_2'^2 + \Pi^2_{2A} p_1' \frac{\delta c'(x_A,\alpha)}{\delta \alpha}\right] < 0 \qquad (19)$$

where p_1' is the first derivative of the demand function in market 1.

From equation (19) one can immediately see that with increased costs of arbitrage the price in market 1 rises. Whether the price in market 2 rises or falls depends on how the demand of the arbitrageurs changes relative to the change in the supply of the producers. As in the monopoly case this is not uniquely determined. Hence, the price discrimination equilibria as illustrated in Figure 2 carry over to the oligopoly.

In the case of price controls the profit maximization of each firm as given by equation (16) and the constraint (17) has the additional constraint that the price in market 2 must remain below p_2^R:

$$p_2(x_{K2}+x_{L2}-x_A) \leq p_2^R. \qquad (20)$$

The comparative static results of this maximization also reveal that as the price controls are loosened, i.e. $dp_2^R > 0$, the price difference will be reduced. Whether the price in market 1 falls or rises, again depends on the slopes of the demand functions in the two markets.

4. WELFARE EFFECTS

The welfare effect of third-degree price discrimination has been investigated by SCHMALENSEE (1981) and VARIAN (1985). Varian derives bounds on the welfare change of different degrees of price discrimination and on the difference in welfare between uniform pricing and profit-maximi-

zing price discrimination. The basic necessary condition for an increase in welfare when a firm is moving from uniform pricing to price discrimination is that the sum of outputs in both markets must increase. This result depends on profits of the firm as well as on consumer surplus. In analyzing the welfare effects of price controls at some given regulation of arbitrage the results of Schmalensee and Varian can be used. One has only to employ the additional assumption that arbitrage takes place in a perfectly competitive environment with zero profits. Then the welfare of the overall region - assuming quasi-linear utility - is given by

$$W(p_1,p_2,\alpha) = \int_{p_1}^{\infty} x_1(v)dv + \int_{p_2}^{\infty} x_2(v)dv + \pi(p_1,p_2,\alpha) \qquad (21)$$

where $\pi(p_1,p_2,\alpha)$ is defined by (8).

Figure 3 illustrates the results. W^C represents the welfare maximum although at negative profits. W^* is the welfare optimum under a zero profit restriction illustrated by the iso-profit contour π_0. The dotted line $\overline{W^*\pi^A}$ contains the welfare optima under alternative profit constraints and given arbitrage opportunities α. These optima all involve some degree of price discrimination. They do not, however, correspond to equilibria given by price controls in either one market. The line $\overline{\pi^A RQ}$ corresponds to equilibria under alternative price control measures in market 2. One can show that the iso-welfare contours W_1 and W_2 have negative slope for prices above marginal costs and therefore the tangency points with the iso-profit contours have a negative slope as well. The points along $\overline{\pi^A RQ}$, however, are defined by zero slopes of the iso-profit contours; consequently the price-control equilibria $\overline{\pi^A RQ}$ always involve a loss of profits relative to the profit constrained welfare

ceutical market - with increasing price controls overall welfare will first increase as long as prices in both markets fall, i.e. consumer surplus rises faster than profits fall. But after equation (15) has turned negative, i.e. after the producer reacts to price controls with higher prices in market 1 because of high costs of arbitrage, then welfare can fall as price controls become tighter. From the arguments about the likely slope of the line $\overline{{}^{A}_{\pi}\ RQ}$ above one can conclude that "small" price controls increase welfare but "large" price controls probably lower welfare.

The welfare analysis of changes in the regulatory framework which determines the costs of arbitrage as represented by the parameter α are more difficult to analyse. Changes in α without price controls move profits along the line $\pi^{U}\bar{\pi}$. Such movements are accompanied by new iso-profit contours and by new iso-welfare contours which contain the profits of the producing firm. It is therefore impossible to compare the welfare of two equilibria determined by alternative α, i.e. alternative regulatory regimes. One can, however, illustrate the impact of α on consumer surplus alone.

In a situation without price controls anything can happen to consumer surplus for both countries together when α is varied. The shape of the line $\pi^{U}\bar{\pi}$ determines the welfare effect. In Figure 6 easier arbitrage first goes hand in hand with an increase in consumer surplus, but beyond π_2^A consumer surplus begins to fall. Uniform prices then may or may not yield higher consumer surplus then perfect price discrimination for which the bounds on welfare are given by VARIAN (1985).

The sign of consumer surplus changes can be predicted when price controls are imposed. If the price in market 2 is restricted to p_2^R (see Fi-

gure 6) and this control is not lifted as arbitrage becomes liberalized, then price and welfare in market 2 is fixed while consumers in market 2 benefit from increased arbitrage. Total differentiation of the first order condition for profit maximization with respect to p_1 yields

$$\frac{dp_1}{d\alpha} = \left[\frac{\delta F_1(p_1, p_2^R, \alpha)}{\delta p_1} \right]^{-1} \left[\frac{\delta x_A}{\delta \alpha} + (p_1 - p_2) \frac{\delta^2 x_A}{\delta (p_1 - p_2) \delta \alpha} \right] > 0 \qquad (22)$$

with

$$F_1(p_1, p_2^R, \alpha) = x_1(p_1) + (p_1 - c) \frac{\delta x_1}{\delta p_1} - x_A - (p_1 - p_2^R) \frac{\delta x_A}{\delta (p_1 - p_2^R)} = 0$$

being the first order condition $\delta\pi/\delta p_1$.

Figure 6 Changes in Arbitrage Under Price Controls

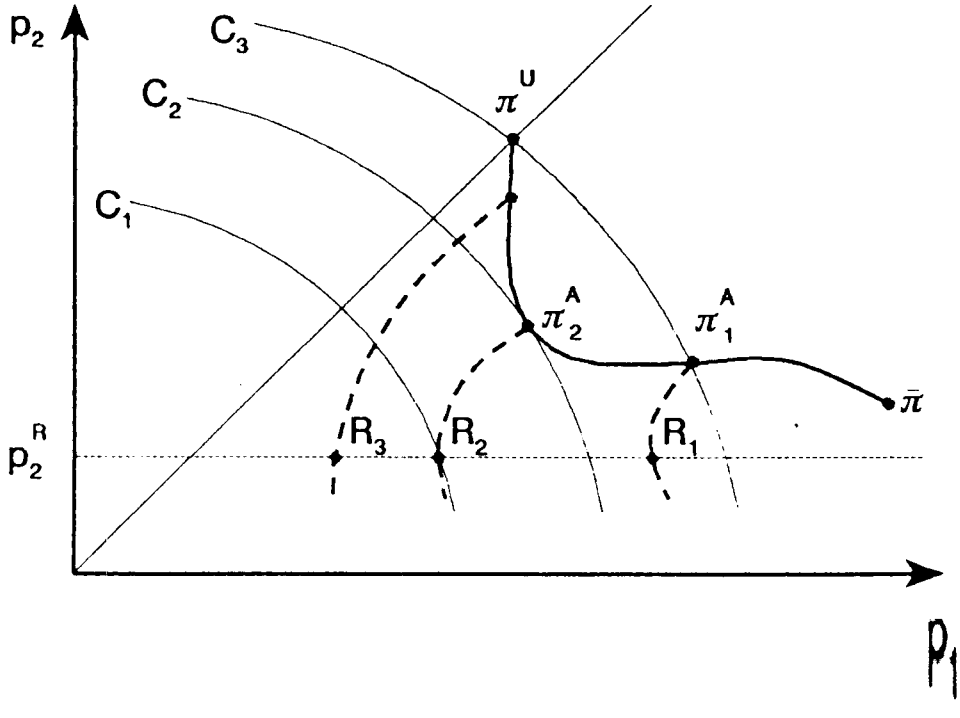


Figure 6 illustrates this case. Without price controls easier arbitrage would move the price discriminating prices from π_1^A to π_2^A and finally to π^U. Whereas these movements are accompanied first by a rise in consumer surplus and later by a fall, the equilibria under prices controlled at p_2^R which are represented by the intersection of the p_2^R-line with the dotted lines yield increasing consumer surplus throughout. It should be mentioned, however, that the profits of the pharmaceutical firm fall and eventually it will make negative profits. Before such a situation arises the firm may also stop supplying market 2 and set the price in market 1 as in the unconstrained case. This situation occurred recently when a German pharmaceutical company stopped supplying the Greek market because the price controls and the induced arbitrage opportunities were unacceptable for that firm.

5. THE LIKELY IMPACT OF HARMONIZATION

The commission of the EC has addressed the two preeminent issues, namely market segmentation and price controls in directives on market transparency and on the authorization of medicinal products. The directives in both issues will surely not create an internal market for pharmaceuticals; they will rather induce some slight moves towards an unified European market. Two immediate questions then arise: What will happen to prices in the national markets and what might be the likely welfare effects of moves towards unification?

The transparency directive requires national authorities to lay open their procedures and guidelines in controlling and authorizing prices of pharmaceuticals. Although it is not a ban on price controls, it is hoped that the new regulations will pressure national authorities to end discriminatory practices and will therefore lead to less restrictive price

setting for products from foreign countries. According to market insiders, companies already get more freedom to price their newly introduced products according to their interests. Arbitrageurs also report that new products now exhibit lower price differences than in the past.

The model presented here does not uniquely predict the outcome of an easing of price controls. One can, however, expect that in cases where price differences are large and the arbitrage cost function is strongly convex, allowing prices to rise in the controlled market is accompanied by falling prices in the unrestricted market as is commonly expected. If, on the other hand, arbitrage can be expanded relatively easy then it is more likely that the optimal response of pharmaceutical companies to rising controlled prices will be to raise prices in the unrestricted market. The outcome of the transparency directive would then be falling consumption accompanied by rising prices in both markets.

The welfare impact of the transparency directive depends on price responses as well. The welfare of the EC overall may slightly increase through movements from, e.g., Q to R in Figure 3 if the path π^{A}_{RQ} has a sufficiently negative slope between R and Q. It is more likely, however, that welfare declines because the losses of consumer surplus in the price controlled market and possibly the unrestricted market will not be outweighed by increasing profits of the pharmaceutical companies.

The existing procedures for the authorization of pharmaceuticals and the proposed procedures leave open alternative ways for pharmaceutical companies to introduce new products. With the exception of biotechnology products they can still choose national authorization thus allowing to segment markets by obtaining different national admissions for the same

that as long as price discrimination is sufficiently profitable - e.g. because of price controls or because of different demand elasticities - community procedures such as the multistate registration will not be used extensively. Still, arbitrage will become alleviated somewhat in the future.

It has been shown that institutional changes which facilitate arbitrage represent movements along the path between perfect price discrimination and uniform pricing such as $\pi^{U}\bar{\pi}$ in Figure 6. Since the present situation also entails price controls the starting point would be an allocation like R_1 (Figure 6). If price controls remain in place the new admission procedures will move prices from R_1 to R_2, i.e. only prices in unrestricted markets fall. In that case profits will fall and consumer surplus will increase. If, on the other hand, price controls are partially lifted as well this would be represented by a move from R_1 towards some point along the line $R_2\pi_2^A$. The impact on consumer surplus would be ambivalent and would among other things depend on the shape of the line $\pi^{U}\bar{\pi}$.

If the goal is to reach uniform pricing in European markets it is clear that facilitating arbitrage is the most powerful policy since it moves pharmaceutical firms at unchanged price controls quickly towards their zero profit contour. This puts pressure on national authorities to lift price controls or to risk having their market not supplied by the company in question. Lifting price controls alone could not eliminate market segmentation since, given the existing income differences within the EC and different demand structures, it would still be profitable to exploit the different price elasticities.

A welfare analysis in segmented markets raises the general question to which situation one wants to compare the current situation. Since the welfare maximum with marginal cost pricing is not achievable one could use a constrained welfare maximum, e.g. with a zero profit constraint as shown by W* in Figure 3. Yet, this second best optimum also leads to some degree of price discrimination, hence the equilibrium with uniform prices π^U is not even second best. The problem then is that the publicly announced goal of creating an internal market by eliminating market segmentation does not lead to a second best situation as described by points along $W^*\pi^A$ in Figure 3, not to speak of the first best W^C which includes subsidies to firms. It is therefore not surprising that the policy initiatives of the European Commission which were discussed here lead to welfare losses or at best to ambivalent results.

Literature

Bundesverband der Pharmazeutischen Industrie (1990): "Pharma Daten 1989", Frankfurt.

Commission of the European Communities (1988a): "The Economics of 1992". European Economy, No. 35.

Commission of the European Communities (1988b): "The Cost of Non-Europe in the Pharmaceutical Industry". Research on the Cost of Non-Europe, Basic Findings, Vol. 15, Brussels.

Eurim-Pharm Arzneimittel GmbH (1985): "Arzneimittel-Parallel- und Reimport", Piding.

Hart, D. und Reich, N. (1990): "Integration und Recht des Arzneimittelmarktes und in der EG", Bd. 13, Nomos Verlagsgesellschaft, BadenBaden.

Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen (1987): "Jahresgutachten 1987: Medizinische und ökonomische Orientierung", Nomos Verlagsgesellschaft, Baden-Baden.

Schmalensee, R., "Ouput and Welfare Implications of Monopolistic Third-Degree Price Discrimination". In: The American Economic Review, Vol. 71, 1981.

Thier, U. (1990): "Das Recht des EG-Arzneimittelmarktes und des freien Warenverkehrs", Europäische Hochschulschriften, Reihe II, Bd. 951, Frankfurt/M.

Varian, H.R., "Price Discrimination and Social Welfare". In: The American Economic Review, Vol. 75, 1985.