

Parallel imports of pharmaceutical products into Switzerland

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Parallel Imports of Pharmaceutical Products into Switzerland

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***Parallel Imports of
Pharmaceutical
Products into
Switzerland***

Diploma Thesis

MAS ETH in IP

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Chapter 1

Introduction

In their concerns and with the responsibility against their population to ensure a constant supply of affordable medicine, governments do not leave the pharmaceutical market sovereign. As a consequence of governmental regulation according to the marketing of drugs, the worldwide market with pharmaceuticals is fractured along national frontiers. Intellectual property rights further complicate the situation as they often differ among countries or regions. Regarding an ordinary medicament, cross-border trade can conflict with a patent on a compound or a production process, with the trademark under which the drug is sold and even with copyrights in the text on the patient information leaflet. Apart from these IP rights many countries have strict requirements to pharmaceutical compounds for getting market authorization. All these trade restrictive measures have in the first place the purpose to grant domestic drug consumers high quality medicine for an affordable price, which itself is able to generate enough income for drug manufacturers to continue and improve their business.

In contrast with the practiced market foreclosure for pharmaceuticals there is dynamic competition, which is said to be the elixir of an economy and which ensures long-term economic growth and social welfare. For favoring competition, it is essential that markets are open to everybody and that trade barriers are disestablished. Allowing parallel imports would be a competition supporting measure, which is often proclaimed as the panacea to bring the high prices in Switzerland to their knees. On the other side of the same coin there are again the intellectual property rights, which are supposed to stimulate competition by encouraging investments as well.

1.1 The Pharmaceutical Industry in Switzerland

In the pharmaceutical sector innovation is certainly the most important parameter. The biggest part of the investment flows in the creation of know-how through intensive research and development and its testing upon the practical applicability. The realization of gained knowledge by large-scale production of a pharmaceutical compound that is ready to market is comparably simple.

Due to this high degree of dependence of the pharmaceutical industry on research based innovation, it is not surprising that patents constitute an absolutely essential tool to protect the advantage against competitors and finally to turn the investments into financial rewards. The pharmaceutical industry is a very patent intensive industry sector and 60 percent of the turnover with medicinal products in Switzerland is realized with patent protected compounds.¹

Ironically, the missing or incomplete patent protection was one important reason that attracted copyists of chemical compounds, particularly dyestuffs, from France and the UK to Switzerland.² Nowadays the companies that emerged of these forerunners became staunch supporters of a strong Patent Law and by all means use their size and their power to influence political processes in order to carry their point to several subjects.

1.2 Why Parallel Imports of Pharmaceuticals?

Pharmaceutical products effectively lend themselves for parallel trade. Hardly any other products on the market seem to be as convenient therefore and that has several reasons. The first and most obvious one is that although pharmaceuticals are globally almost perfectly standardized, there is still a significant price difference for pharmaceuticals from county to country. Even within an industrial area as the European Economic Area, prices can massively differ and wholesalers of medicaments in low-price countries can raise a substantial profit from exporting the drugs to high-price countries. Further on, there is almost no country which is not faced with continually increasing expenses in the health sector and every possibility to stop or reverse this development is seen as chance for a countries economy.

Another reason for the suitability of pharmaceutical products for parallel trade is the relation between price and volume. Drugs are easy to transport and can be very expensive in relation to the size of their packages. A high profit can therefore be achieved with relatively low efforts.

¹ Humanarzneimittelstudie (2002)

² Kilchenmann (2004)

1.3 Hurdles to Parallel Trade

Generally, there are two barriers that are able to block parallel imports. These are first of all intellectual property rights that have the purpose to give its owner a certain exclusivity to use a product commercially. Secondly there are some legitimate restrictions to free movement of goods regulated under Competition Law. For pharmaceutical products there is however a third hurdle in the way to parallel imports imposed by sectoral regulation.

1.3.1 Intellectual Property Rights

As far as parallel imports of patented products are concerned, Switzerland applies the principle of national exhaustion. Since provisions regulating the issue of exhaustion are missing in national legislation as well as in international treaties, the practice was alleged by case law. Following international legal positions and cantonal case law, the Federal Supreme Court of Switzerland decided to apply the principle of national exhaustion in the *Kodak-Case*.³ The decision of the lower instance court, the Commercial Court of Zurich, which had followed the liberal position of the Supreme Court in copyright⁴ and trademark⁵ cases and argued in favor of international exhaustion based on the “implied license doctrine” as it is known from the UK,⁶ was revised in the last instance.

However, the Federal Supreme Court also mentioned that the restriction on parallel imports of patented goods shall not apply in case of abusive behavior of the import monopolist in Switzerland. In such a case, the provisions of the Cartel Act shall be enforced.

The decision of the Supreme Court partially met with heavy criticism,⁷ nevertheless it evolved its legislative function and it was to expect that it would influence future revisions of laws in Switzerland. This was already the case in the revision of the Cartel Act⁸ where the new formulation in Article 3 paragraph 2 clarifies the application of the Cartel Act in cases of import restrictions based on intellectual property laws and goes on in the revision of the Patent Law.

³ BGE 126 III 129

⁴ BGE 124 III 321

⁵ BGE 122 III 469

⁶ ZR 97 (1998) Nr. 112

⁷ Hilty (2000)

⁸ The new Federal Act on Cartels and Other Restraints of Competition is in force since April 1, 2004.

1.3.2 *Restrictions to Free Movement of Goods*

The Swiss Cartel Act aims at preventing “harmful economic or social effects of cartels and other restraints of competition”. As it is evident, competition usually does not end at frontiers and therefore this law is applicable to “effects [that] are felt in Switzerland, even if they originate in another country”. That means that import restrictions having negative effects as the prevention of parallel imports generally fall under the Cartel Act.

Except for so called hardcore restrictions⁹ where competition law applies in all cases, there are some restrictions to free movement of goods that are legitimate and not considered to be harmful. In the trade with pharmaceutical products, particularly concerning parallel imports, there is a possibility to limit free trade by entering vertical agreements such as distribution agreements. The question that must be assessed before determining the permissibility of these kinds of restrictions is whether a company has market power¹⁰ or not.

Basically the principle of freedom of contract applies and a company is free to choose its trading partners. Also in a position of market power, “agreements granting exclusive rights to deal in certain goods or services” and “agreements granting exclusive licenses for intellectual property rights“ deemed to be justified under Article 6 paragraph 1 lit. c and d of the Cartel Act.

In practice there are two main types of distribution agreements through which the producer of goods can restrict the territories of sale. The first is exclusive distribution, where there are no further requirements than exclusivity. Thus one single distributor can be prevented from selling its product actively outside his territory. Passive sales however are impossible to cut off. The second is selective distribution which is non-exclusive, but where the producer imposes certain quality requirements on the vendor of the product, as for instance special training for salespersons or special furnishing of the location. Suppliers that have entered a selective distribution agreement are allowed to sell the products actively everywhere, but they can be restricted not to resell the relevant goods to unauthorized distributors.¹¹

In addition to these legitimate restrictions on free trade of goods, restrictions might go a step further for several pharmaceutical companies if they do not reach an absolute market share of 10 percent within a the relevant market. The relevant market is not necessarily defined as the

⁹ Hardcore restrictions are practices that, by their very nature, have the intent to prevent or restrict competition (e.g. resale price maintenance).

¹⁰ Market power is defined as the ability of a company to set prices profitably above the competitive level for the foreseeable future or the ability to exclude competitors from the market.

¹¹ Notice of the Competition Commission of 18 February 2002 on the Competition Law Treatment of Vertical Agreements available at <http://www.weko.admin.ch/imperia/md/images/weko/43.pdf>

entire market that is supplied by a company, but rather as the market for one special compound or product group. With regards to vertical agreements a market share of all enterprises involved of below 10 percent is considered a de minimis case and restrictions are regarded as non-material.

1.3.3 Regulatory Affairs

Pharmaceutical products underlie a substantial market authorization procedure where the applicant has to submit a complete documentation about the identity, the cleanness and the potency of a new compound to Swissmedic, the Swiss Agency for Therapeutic Products. The examination of the request for authorization is extensive and takes about 10 month of time.¹²

Swissmedic is an institute of the Federation, governed by public law and affiliated to the Federal Department of Home Affairs. The legal basis of the institute is the Swiss Law on Drugs,¹³ which acts as a protection for humans and animals by granting that only high-quality, safe and effective medicine is put into circulation.

The threshold for market authorization is high and the authorization through Swissmedic serves as a basis for the authorization in 70 other countries.¹⁴ On the other hand, the Law on Drugs provides in Article 14 paragraph 2, a simplified authorization procedure for pharmaceuticals that already have market authorization in countries with equivalent authorization procedures and quality standards like Switzerland. Although this measure shall particularly apply to pharmaceutical products whose patent term had expired, it clearly takes a step towards market liberalization in the pharmaceutical sector. However, almost five years after the introduction of this provision, it is not only a single generic product that has been parallel imported into Switzerland. The press often speaks of bureaucratic bullying¹⁵ of Swissmedic and remedy should be found with the revision of the “regulation of the Swiss Agency for therapeutic products about the simplified authorization and notification requirement of medicines”¹⁶ which should come into force in October 2006.

¹² Interpharma

¹³ The Law on Drugs (Heilmittelgesetz) is in force since January 1, 2002.

¹⁴ Cueni (2005)

¹⁵ NZZ of November 30, 2005

¹⁶ *German*: Verordnung der Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung und die Meldepflicht von Arzneimitteln (VAZV)

1.4 Drug Market v Market with other Patented Products

Compared to the market with any other products, the market with pharmaceuticals takes a special position. Regarding the European Union there is even the Directive 2001/83 of which Article 83 provides for appropriate and continued supplies of medicinal products “so that the needs of patients in the Member State in question are covered”.¹⁷ This legal obligation is furthermore enhanced by a moral obligation towards patients. A retraction of a pharmaceutical company from a market that does not generate enough income, as it is done in other industrial branches, is almost unthinkable in the pharmaceutical sector and would possibly lead to an irreparable loss of reputation.

Essentially, a well functioning pharmaceutical industry is in the end not least to the advantage of consumers and therefore, this industry has certain relevance for society.

1.4.1 Complexity and Peculiarity of the Pharmaceutical Market

The product class of medical compounds is very heterogeneous and complex. This complexity may have its origin in social relevance and price regulation but the latter also complicates the drug market itself again. The consequence is a vicious circle that leads upwards a spiral to more regulation and even less transparency.

For purposes of interconnection of the pharmaceutical market with governmental or official authorities, there are several classifications that must be taken into consideration. A first step divides the products in original compounds available on prescription and original compounds available over the counter of which both can be patent protected or not. The costs of these compounds can be fully, partly or not at all covered by the health insurances, which of course, is a criterion for many consumers or doctors to decide on the products. Original compounds, whose patent term has expired, can be copied identically and can get market authorization. These are called generic drugs and are dealt with separately. Generic drugs though are important to be distinguished from so called “me-too” or “follow-on” compounds.¹⁸ “Me-too” compounds are designed slightly different from the original compounds but are supposed to have the same function. The idea behind “me-too” compounds is on one hand for a competitor

¹⁷ Directive 2001/83 EC

¹⁸ In a news article from 09.03.2006 of an organization called “eyeforpharma” it is said that 65 percent of the new drugs approved in the last decade were in fact such modified mimics of existing medications called “me-too” drugs (available at <http://www.eyeforpharma.com/index.asp?news=50078>).

to get patent protection for a competitive product or for a patent owner, on the other hand, to extend the patent term of an original product.

Apart from this complex structure of the pharmaceutical market, there is another peculiarity that distinguishes it from the market with other goods. Within the drug market, and especially within the prescription drugs segment, it is mostly the case that the person, who orders or prescribes the medicament, the doctor, is different from the person who uses it, the patient, which again is different from the “person” who pays it, which is the health insurance. This certainly is still a reason for the missing cost-consciousness of many consumers with regard to pharmaceuticals.

These whole arrangements and circumstances within the pharmaceutical market and its relation to national authorities is just an extract of the real situation. However, the complexity of this market and the mentioned consumers’ indifference towards drug prices facilitates the manipulation of the market by those involved actively in any case and irregularities are very difficult to be detected.

1.4.2 Price Regulation

Another point, why pharmaceuticals have to be looked at from a different perspective is that prices for many pharmaceutical products are regulated by the Federal Office of Public Health. In a normal open market, apart from manufacturing and marketing costs, it is typically the balance between supply and demand of a good that determines its price. Competition within this market is supposed to ensure that neither the consumer nor the supplier will be able to capitalize their price interests excessively. However, it is in the nature of a patent to give its owner a monopoly on the patented invention and thereby to reward his investment or his inventive talent. Although monopolies are unpopular in free and competitive markets, they inevitably constitute the tradeoff of the patentee for early making the invention available to the public. This kind of “market restriction” is the core part of the whole patent system and justified by having beneficial effects on the economy as a whole.

Due to the public relevance and peculiarity of the pharmaceutical market, this side effect of patent protection could lead to an unfavorable price development or to abusive behavior of drug suppliers. If it was just supply and demand that would determine the price, much-needed medicine could become unaffordable in case of missing substitutability. The worst case scenario of such a development could be the collapse of the whole market segment so that the

supply of the population with indispensable medication could be endangered. To avoid this, the government takes action by regulating the prices for pharmaceuticals.

The policy of the Swiss government or governments in general to regulate prices and influence markets is very typical the more important the market segment is to society and the worse the effects of a market failure would be for the population. However, a trend to market liberalization and a stepwise, but constant withdrawal of the Swiss government from the market is in progress since the last couple of years. Some examples of market fields that already have or that are changing at the moment are the telecommunication industry, the Swiss Post or the electricity market.¹⁹

The pharmaceutical market is commonly regulated by a method called the Ceiling Price Regulation,²⁰ where the government sets the maximum monopoly price that covers the company's R&D costs and allows them a reasonable profit.²¹ To estimate this maximum price, the regulator takes into consideration prices for the same product in other European countries²² as well as prices for similar products from the same therapeutic group within Switzerland. The first problem that should be mentioned concerning this price determination is that the foreign maximum prices are determined in similar procedures, so that the result is a complex and hardly traceable interdependency of regulated prices. Another problem which is much more relevant for the discussion of the Swiss drug market is that authorization authorities for pharmaceutical products tend to work faster in Switzerland than in the European Union.²³ As for the signaling effect of the first country to authorize a medicament on the neighboring countries, this could be problematic and increase the ceiling price. The reason therefore is, that the producer of the pharmaceutical compound is going to consider the expected ceiling price while planning his expenses for R&D on this compound.²⁴ This basically results in the possibility of the pharmaceutical industry to influence the maximum price set by the authorities for their own compounds not just for the Swiss market, but to some degree also for the neighboring markets.

¹⁹ Saurer (1999)

²⁰ *German* Höchstpreisregulierung

²¹ Weder (2006)

²² Germany, Denmark, Great Britain and the Netherlands; subsidiary also France, Austria and Italy, available at <http://www.interpharma.ch>

²³ Pharmamarkt Schweiz (2006)

²⁴ Weder (2006)

Chapter 2

Situation in Europe

2.1 Policy in Europe

The European Union applies the principle of regional exhaustion within its territory.²⁵ Accordingly the right of the intellectual property holder is exhausted within the whole Community after the first sale in a member state by him or with his consent. The territory of regional exhaustion was extended to the European Economic Area in the mid-nineties, so that by now, the principle of regional exhaustion of intellectual property rights is applicable to all 28 EEA member states.²⁶

2.1.1 The Internal Market

The creation of the internal market was one of the biggest targets of the EU over the past 20 years and became the core of today's Union. Among many other barriers to free trade and free movement of goods as technical, bureaucratic and cultural ones, national protectionist measures related to intellectual property rights were to be eliminated through drafting and adopting new directives by EU institutions and member states.

The relevant provision that serves as a basis for free trade and movement of goods supporting the regional exhaustion principle is Article 28 of the EC-Treaty,²⁷ which states that “[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States”. However, several limitations to this provision can be found in Article 30 EC, whereas one of these limitations says, that Article 28 shall not apply to “preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of (...) the protection of industrial and commercial property”.

²⁵ Snell (2003)

²⁶ Stothers (2005)

²⁷ The Treaty establishing the European Community (EC-Treaty)

The balance between Article 28 and Article 30 EC was developed by the European Court of Justice in the two *Centrapharm* decisions of 1974²⁸ and resulted in regional exhaustion in Europe.

Pharmaceuticals however, used to be dealt with in a different way since pharmaceutical products were exempted from patentability in several European countries at the time this issued was developed. The ECJ decided in *Merck v. Stephar*²⁹ that the right of the patent owner was also exhausted by placing a product on the market in a country with no patent protection. Although this decision was expected to be overruled in the case *Merck v. Primecrown*,³⁰ the court refused to change course and explained that pharmaceutical companies themselves have to draw the consequences from placing products in countries with no patent protection for pharmaceutical compounds. The only option for pharmaceutical companies to completely avoid parallel imports of their own products from countries that did not grant patent protection to this class of goods, was not to place these products on the market in these countries.³¹

This is a major distinctive feature between the general consumer goods industry and the pharmaceutical industry, since it is a justified question, whether pharmaceutical companies have the freedom to decline to market a medicament in a certain country. Should this not be the case due to the ethical responsibility of pharmaceutical companies to provide drugs for everybody, parallel imports of drugs should perhaps be restricted under Article 30 EC. This article allows restrictions on imports justified by reasons of protection of public health, but whether it is the public health of the restricting state or of another member state's population is not specified.

2.1.2 Provisions for New Member States

On May 1, 2004 the EU admitted ten new member states³² to the Union, which led to an extension of the internal market and of course, also enlarged the territory of exhaustion of intellectual property rights. According to the case law mentioned above, a patentee in one of the old member states would not have been able to prevent parallel imports from the new member states, irrespective of whether protection for pharmaceutical compounds was

²⁸ Case 15/74 and Case 16/74

²⁹ Case 187/80

³⁰ Joined Cases C-267-268/95

³¹ Snell (2003)

³² Czech Republic, Cyprus, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia

available in the exporting country or not. However, due to the special situation and effective lobbying of the pharmaceutical industry, a special provision was introduced in the Act Concerning the Condition of Accession of the New Member States.

Thus with regard to the new member states, except Cyprus and Malta, “(...) the holder or beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the (...) new Member states for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent”.³³ As there is no time limitation mentioned in this provision, the patent holder is able to bar parallel imports from the new member states for the whole lifetime of the patent plus the maximum of five years in the case of a supplementary protection certificate.

The reason for such a provision and for Cyprus and Malta not being affected by it lies in the history of the new members. All the eight member states that fall under the scope of the temporary provision were members of the Communist Block up to 1990 and limited the protection of pharmaceuticals to the production processes. During the Cold War, pharmaceutical companies of Eastern Europe were dependent on imitating products from the West, irrespective of whether they were patent protected or not.³⁴ Even though all the eight new members introduced patent protection for pharmaceutical compounds between 1991 and 1994,³⁵ there are still many pharmaceuticals, which have been developed in the early 90’s or before, that do not enjoy patent protection.

Due to the history of Cyprus and Malta, which have both been colonies of the United Kingdom in the past, the intellectual property laws were considered sufficiently close to the laws of the EU, so that they were not subject to the trade restrictions for pharmaceuticals. The fact that the pharmaceutical industry of Cyprus and Malta did not constitute a threat to the influential western pharmaceutical companies due to its diminutiveness has certainly been taken into consideration as well, yet it remained unspoken.³⁶

Although this specific mechanism is often criticized, because of its content and especially because of its diverging wording in different translations leading to interpretive problems,³⁷ it

³³ Act Concerning the Condition of Accession of the New Member States

³⁴ Clark (2004)

³⁵ Heath (2004)

³⁶ Clark (2004)

³⁷ Heath (2004)

inevitably strengthens the position of the pharmaceutical industry by restricting free trade and free movement of goods within the EU.

Due to the fact that the assessment of patent rights under these conditions remains difficult, patent holders host other strategies to prevent or at least to limit parallel trade and thereby often conflict with the EC competition provisions.

2.1.3 Competition Provisions of the EC-Treaty

The basic legal framework of the Competition Law for member states of the European Community is laid down in Article 81 and 82 EC, whereas the two articles cover different aspects of competition. Article 81 paragraph 1 prohibits agreements between undertakings and likewise practices, which aim at preventing, restricting or distorting competition within the common market. Article 82 sets provisions against abusive behavior of undertakings in dominant positions affecting trade between member states. As for the discussion of the issue of parallel trade in general, attempts of enterprises to prevent parallel imports directly fall under the provisions of Article 81 if they include any kind of agreements or concerted practices between companies, respectively are to be examined under Article 82 in cases where the restricting company has a dominant position on the market.³⁸

Regarding Article 81, there is a provision in paragraph 3 that sets some exemptions for the applicability of paragraph 1 and states that agreements between undertakings shall be allowed, if they contribute “to improving the production and distribution of goods or to promoting technical or economic progress”,³⁹ as long as competition is not eliminated. A further requirement for the applicability of Article 81 paragraph 3 that has been developed in case law⁴⁰ is, that in the end, there must be consumers that benefit from the restrictions to a reasonable degree.

A specification of the exemption to Article 81 paragraph 1 for vertical agreements is given in the Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81 paragraph 3 of the Treaty to categories of vertical agreements and concerted practices.⁴¹ This Block Exemption Regulation applies to almost all vertical agreements concerning the sale of goods and services as long as the sum of the market share of the

³⁸ Stothers (2005)

³⁹ The Treaty establishing the European Community (EC-Treaty)

⁴⁰ Case 42/84 and Case T-17/93

⁴¹ Commission Regulation (EC) No 2790/1999

contracting parties is below 30 percent in the relevant market. Serious restraints on competition, so-called hardcore restrictions, remain prohibited irrespective of the market share of any involved party. Equal to the situation in Switzerland (see section 1.3.2), the hardcore clauses of territorial restriction are qualified in Article 4 lit. b of the Block Exemption Regulation in that exclusive and selective distribution channels are not considered anti-competitive if they fulfill certain requirements.

Concerning the market share in the relevant market it is to say, that it is difficult for nearly all big pharmaceutical companies not to reach and exceed the 30 percent threshold in the course of trade with a patent protected drug. The crucial point therefore is the “relevant market” which is not only understood as the geographical market, but also includes the relevant product.⁴² Regarding the pharmaceutical market, the products are often very specialized and just a few companies are competing with a product containing similar active compounds so that a high market share is achieved easily with blockbuster products.

Although for instance, Novartis has a global market share of 5 percent for prescription drugs,⁴³ the market share of its blockbuster drug⁴⁴ Diovan within the angiotensin-receptor blocker class of anti-hypertensive agents is 30 percent.⁴⁵ Another example, which is even more demonstrative, appears in the market of agents for treatment of male erectile dysfunction. After its launch in 1998, Pfizer’s Viagra was the absolute market leader with a market share of more than 90 percent. Today’s market share is in the range of 68 percent,⁴⁶ even though Pfizer has an overall market share for medicaments of 8.4 percent.⁴⁷

In the case where current and forecast market shares are established to be high in the relevant market, competition authorities generally pay more attention to the companies’ behavior. However, relevant market power is only the starting point to determine an infringement of EC Competition Law provisions. Several other factors like consumer’s buying power and barriers to enter the market must be taken into consideration as well.⁴⁸ Thus, in a position of market power, refusals to sell or export bans for instance, are very likely to constitute an abuse of a dominant position and therefore infringe Article 82 EC.

2.1.4 Agreements in the Pharmaceutical Sector

⁴² Hays (2004)

⁴³ Pharmamarkt Schweiz (2006)

⁴⁴ A blockbuster drug is a drug that generates more than \$1 billion of revenue per year for its owner.

⁴⁵ Novartis Media Release of April 24, 2006, available at <http://www.novartis.com/news/en/media.shtml>

⁴⁶ Pfizer Inc Supplemental Information of 2005, available at <http://mediaroom.pfizer.com>

⁴⁷ Pharmamarkt Schweiz (2006)

⁴⁸ Glynn (2005)

The Advocate General (AG) found in his opinion to the *Syfait-Case*,⁴⁹ that the pharmaceutical sector takes a special position where measures, taken to prevent or limit parallel trade, are to be assessed from a Competition Law perspective. The reasons brought forth by the AG are based on the special economics of the pharmaceutical sector. Apart from the regulation of price and distribution within the sector, it is the fact that broad parallel trade with drugs could be damaging to consumers, since profit loss for pharmaceutical undertakings results in lower expenses for R&D.

This argumentation was partly resumed in the case *GlaxoSmithKline Services Unlimited v Commission of the European Communities* that was decided by the Court of First Instance on September 27, 2006. The case at issue emerged, as the Spanish subsidiary of GlaxoSmithKline (GSK), which is a major manufacturer of pharmaceuticals based in the UK, adopted new general sales conditions in 1998. According to these new conditions, GSK was able to sell its pharmaceuticals to Spanish wholesalers at different prices, depending on which national sickness insurance scheme was going to reimburse the costs. The result was that medicaments, that were intended for another member state's market and that would therefore also be reimbursed there, could be sold at a higher price. The purpose for the introduction of this system was to prevent or at least to limit parallel exports from the low-price county Spain to high-price countries as particularly the UK.

GSK itself brought the case to the Commission in order to obtain a declaratory decision holding that the general sales conditions did not constitute an agreement infringing Article 81 paragraph 1 EC or that it would at least fall under the exemptions of Article 81 paragraph 3 as an agreement contributing to the promotion of technical progress. The Commission found that GSK's general sales conditions involved an agreement between undertakings and that this agreement was infringing Article 81 paragraph 1 EC. Further on it was found that GSK failed to provide evidence for that its behavior would be able to benefit from an exemption under paragraph 3. After the rejection of GSK's requests by the Commission, GSK appealed the decision to the European Court of First Instance.

The CFI partly invalidated the Commission's analysis. Although it was confirmed that the general sales conditions constitute an agreement between undertakings that is able to restrict competition, it was found that the Commission's main conclusion, saying that restricting competition was the object of this agreement, was incorrect. According to the decision, the Commission missed to duly consider the legal and economic context of the agreement. As a

⁴⁹ Case 53/03, Opinion of the Advocate General Jacobs

consequence of the peculiarity of the pharmaceutical sector, where prices are set by national governments, it can not be assumed that parallel trade would lead to lower prices for medicaments and that therefore, it does not directly contribute to the welfare of end-consumers. Indeed the Court found that the general sales conditions themselves may induce an economic advantage by contributing to innovation, which is the essential element of a pharmaceutical company, and that this aspect was not properly examined by the Commission. Based on these grounds, the Commission is compelled to reconsider GSK's requests so long as the case is not appealed before the ECJ within two month.⁵⁰

Although this may not be the end of this case, the decision of the CFI is welcomed by GSK as it is a step toward the recognition of the special characteristics of the pharmaceutical sector.⁵¹

2.1.5 Unilateral Conduct against Parallel Trade

An effective measure that had been taken by pharmaceutical companies in order to restrict parallel exports from low to high-price member states of the EU was to limit the supply of drugs to these countries to the amount consumed by its own population. The question whether cutting down the drug deliveries to prevent parallel trade constitutes a concept of agreement emerged in the *Bayer-Case*.

Bayer, which produces and markets drugs for the treatment of cardio-vascular diseases under the trade name Adalat, was confronted with brisk parallel trade of these compounds within Europe. As a consequence of price differences between EU members, it was especially the import of Adalat from Spain and France to the UK that caused large financial losses to Bayer. Bayer's defense against this parallel trade was a unilateral decision to cut drug deliveries to Spanish and French wholesalers. For this action, Bayer was condemned by the Commission to pay a penalty for infringement of Article 81 EC.

On appeal, the CFI overturned the Commission's decision, holding that Bayer's restriction on competition and parallel trade was not the purpose or the effect of any agreement between the parties involved. On the contrary it was the result of a unilateral policy of withholding supplies that had been implemented by Bayer in the course of its trade with wholesalers.

Upon challenges of the Commission and parallel traders, the ECJ upheld the decision of the CFI stating that "[t]he mere concomitant existence of an agreement which is in itself neutral

⁵⁰ Case T-168/01 and the related Press Release No 79/06

⁵¹ Press release of GlaxoSmithKline of September 27, 2006, available at <http://www.gsk.com/media/pressreleases.htm>.

and a measure restricting competition that has been imposed unilaterally does not amount to an agreement prohibited by that provision”.⁵² However the judgment also limited explicitly its ruling to the complaint of the Commission towards an infringement of Article 81 EC since there was no relevant agreement. The question whether Bayer’s behavior might have been an infringement of Article 82, namely an abuse of a dominant position, remained open.

The case that was supposed to answer this question was the *Syfait-Case*. Under similar conditions as in the *Bayer-Case*, the Greek subsidiary of GlaxoSmithKline decided to stop supplying certain products to Greek wholesalers, as they were involved in parallel trade of the products concerned to high-price member states and instead, to directly deliver them to pharmacies and hospitals. On notice of Greek pharmaceutical wholesalers, the Greek Competition Commission adopted interim measures and required GSK to fully meet the received orders from Greek wholesalers.

After a period of arguments between the parties, the Greek Competition Commission suspended the case and decided to refer some questions to the ECJ. Since there was no argument as to GSK’s dominant position in the market for at least one of the concerned drugs, the matter before the ECJ was limited to the issue of Article 82 EC.

Because of the high importance of this decision for pharmaceutical companies and for parallel traders, the decision was much longed for. However, instead of addressing the relevant points in this discussion, the ECJ decided on May 31, 2005 that it had no jurisdiction over the case. According to Article 234 EC, only Courts or Tribunals are qualified to refer questions to the ECJ and the Greek Competition Commission was not considered as such.⁵³ As a result of this disappointing decision, the interim measures imposed over GSK by the Greek Competition Commission remained in force and GSK had to continue to supply their products to wholesalers.

The opinion of the Advocate General Jacob in the *Syfait-Case* though came down on the side of GSK. He determined that a partitioning of the market was rather an inevitable consequence, than the intent of GSK while trying to protect its legitimate commercial interests. As a consequence of particular circumstances of the European pharmaceutical market, the restriction of supply even by a dominant pharmaceutical company with the intent to limit parallel trade was not automatically abusive, but should be capable of objective justification.

⁵² Case C-2/01 and C-3/01

⁵³ Case C-53/03

2.2 Coexistence of Free Trade and Price Regulation

A general question that comes up regarding the EU is, whether free trade and free movement of goods are generally consistent with governmental price regulation on a national level. Regarding Article 28 EC, it seems ambiguous if price regulation is legal at all. It looks as if a first justification for national price regulation is given in Article 30 EC, which says that Article 28 EC shall not prevent trade restrictions based on grounds of the protection of public health or human life. Moreover regarding ECJ case law,⁵⁴ restrictions on free movements of goods can never be justified by purely economic reasons. National price controls serve the purpose of keeping drug-prices low and thus constitute budgetary reasons.⁵⁵ Both cases that dealt with these issues were connected to foodstuff or food-related products. Relevant for the pharmaceutical industry was the *Roussel-Case* of 1983,⁵⁶ where the ECJ applied the developed principles to national price controls of pharmaceutical products.

The outcome of the *Roussel-Case* was, that national price regulation was not regarded a measure having an effect equivalent to quantitative restrictions and therefore not as being contrary to the free movement of goods by itself. Article 28 EC shall only come into play, when marketing of an imported pharmaceutical was impeded or even made impossible in comparison with domestic products. National price controls thus were perfectly legitimated and could stand as long as there was no discrimination.

As it was found that price fixing did not conflict with the free movement of goods, the ECJ took the position that there was no point in allowing pharmaceuticals for an exception to free trade within the EU. Although the position of the ECJ towards price controls was surprising, it recognized national regulations in the pharmaceutical sector as being an integral part of national economic policies and therefore left them in the power of the member states.

This position was upheld by the ECJ in several following cases however, the very recent case of *GSK v Commission*⁵⁷ seems to cut the argumentation line. Contrary to the *Roussel-Case* where the Court set the free movement of goods as a precondition and examined national price controls as being in compliance with it, the new case went out from price controls and questioned the legitimacy of the free movement of goods within the pharmaceutical sector. As already mentioned above the economic context and the peculiarity of the pharmaceutical

⁵⁴ Case 7/61

⁵⁵ Snell (2003)

⁵⁶ Case 181/82

⁵⁷ Case T-168/01

sector have to be taken into consideration and it seems possible that based upon that, restrictions of the free movement of goods are able of justification.

Chapter 3

Options for Switzerland

3.1 National Exhaustion – The Status Quo

The first option for Switzerland in questions about the future and the aim of national patent legislation, particularly with respect to the revision of the Patent Law, is to leave the issue of exhaustion unregulated as it is and to keep following the ruling of the Federal Supreme Court in the *Kodak-Case*.

This would practically mean to apply the principle of national exhaustion for patent protected goods. The Federal Supreme Court however also addressed the problem of abusive behavior of the local, respectively the import monopolist of the protected goods by clearly finding that artificial market segmentations and separations of the home from foreign markets shall be prohibited on the basis of the Cartel Act and that such behavior is to be punished. Since neither Swiss Patent Law nor international treaties included a provision defining a principle of exhaustion, the Supreme Court decision had legislative power. However, a strong basis to enforce the provisions set, through effective sanctions was missing in the time before the revision of the Cartel Act in 2004.

While the point of missing enforceability was partly remedied in 2004, there is another point that must be taken into consideration for assessing the status quo of national exhaustion. Although the Supreme Court decision has legislative power, there is no absolute reliability in this sentence and the Supreme Court is free to turn around its decision when dealing with another case. Regarding the different rulings for exhaustion of patents as compared to trademarks and copyrights and the heavy reproaches addressed to the Supreme Court in fact cast doubts in the legal certainty towards this issue.⁵⁸

⁵⁸ E.g. Hilty (2000), Zäch (2001)

3.2 *International Exhaustion*

With the introduction of the principle of international exhaustion in Switzerland, the right of the patent owner to the patent would be exhausted after the marketing of his product, no matter where on earth this marketing would have taken place. Since prices for all kinds of goods, including pharmaceuticals, are comparably high in Switzerland, such a policy change is generally predicted to lower prices for patented goods on the domestic market. Although the price reduction capacity of parallel imports surely is the strongest argument for the international exhaustion, the dimension of this positive effect can hardly be predicted.⁵⁹

Regarding negative effects, it is evidently no question that a liberalization of restrictions on parallel imports of patent protected products into Switzerland would degrade the rights attached to a patent and weaken the position of its holder. Authorizing parallel imports could have an announcement effect that less attention is paid to protect patent rights and this again could discourage research-intensive companies from setting up their business in Switzerland. Switzerland is a small country and poor in natural resources and therefore takes a high risk, when weakening the protection of innovation and of IP in general. The “small country” argument is however also a strong argument in favor of international exhaustion for patent rights in Switzerland. The harm of a policy change to the pharmaceutical industry for instance would be rather small, since the turnover of the big Swiss pharmaceutical companies within Switzerland accounts only for about one percent of their worldwide sales.⁶⁰

It is also quite obvious that, if consumers pay less for patented goods on the market, there is somewhere someone earning less with selling these products. The lower incomes of Swiss industry companies caused by lower prices or by a parallel importer participating on the market could have a negative long-term effect on these companies, compensating the lower income with less expenses for R&D, and therefore on the welfare of the whole Swiss society. In addition to the effects a regime change to international exhaustion would have on the industry in general, there are some special points that should be considered in respect to the pharmaceutical industry. The authorization of parallel imports of pharmaceuticals could cause difficulties in the preservation of medical safety standards in the drug-market. A liberalization of the ban on parallel imports would lead to a competition between different states’ regulatory systems. In such a scenario it would be the country with the lowest set price for pharmaceuticals that would profit, since drug distributors in other countries would order their

⁵⁹ Seco (2004)

⁶⁰ OECD Survey (2003)

assortments from there. Thereby the whole system of countries' provision of pharmaceuticals would be called into question.⁶¹

An issue that should be taken into consideration as well is how to proceed with pharmaceuticals reimported from countries without patent protection for pharmaceuticals. Following the European argumentation of this problematic as in the *Merck v. Stephar* case, albeit it has limited effect to the territory of the EEA applying the principle of regional exhaustion, the patent owner's rights would be exhausted also by putting a product on the market in a country without patent protection.

The conditions for Switzerland by applying this principle would of course not exactly be the same as the European, since the consequences would have global influence. The result would than be, that Switzerland had to set the terms contrary to the ECJ in *Merck v. Stephar* with respect to imports from countries without patent protection for pharmaceuticals.⁶²

A lift of the parallel import ban applying the European principle would make it practically impossible for pharmaceutical companies to sell drugs to poor or developing countries that often have no or deficient patent legislation, as they often purchase medicine far below the average market price in developed countries. It can not be denied, that there would be a high incentive for people living in developing countries or governments thereof to sell these products back again and get financial profit out of it. Parallel imports from such countries could damage the local industry of Switzerland, so that they were forced not to deliver pharmaceuticals to developing countries at lower prices any more. The harm such a measure would cause to the population of developing countries would of course be severe.

All in all there are advantages and disadvantages as well as risks and chances a policy change to international exhaustion would bring for Switzerland. An accurate forecast considering all affected parties however is difficult to make. As Switzerland's economic size is very limited, the impact, positive as well as negative, of such a change of policy seems to be manageable. Empirical studies carried out for the Federal Council predicted a rather small general economic benefit with a gain not exceeding 0.1 percent of the Gross Domestic Product. Market prices however, are predicted to fall between 14 to 32 percent for pharmaceutical products and 4 to 8 percent for consumer goods.⁶³ This was considered a small gain according to the Government's report to the Parliament.⁶⁴ Nevertheless, it would clearly constitute a

⁶¹ OECD Survey (2003)

⁶² Comte (1999)

⁶³ OECD Survey (2003)

⁶⁴ Bericht des Bundesrats (2002)

direct advantage for consumers, which then again could spend or invest the spare money into other goods or services and further support the economy.

For several reasons, it though seems to be more conceivable that consumers' benefits would be marginal. A comparison of Switzerland's prices for trademark protected consumer goods to prices of the same goods on an international level shows that, although Switzerland applies international exhaustion for trademarked goods, prices are still higher than in most of the other markets. It almost seems that it is only the parallel importer, who profits from international exhaustion by lining the price margin into his own pockets.⁶⁵

Another reason, why parallel imports of patented goods would rather be of minor financial impact to consumers and probably would not change consumers' buying power too much is that patented products do not belong to an average consumers everyday shopping. Irrespective of patent protected pharmaceuticals or cosmetic products, there are mostly branded products like foodstuffs that dominate consumer's expenses.

3.2.1 Limited International Exhaustion

An alternative to completely lifting the ban on parallel imports would be to apply international exhaustion to trade with some countries and to remain with the national exhaustion for others. The problems with parallel imports of pharmaceuticals could be eliminated by allowing limited parallel trade.

The idea would be to allow parallel imports from countries, which have adequate regulatory systems concerning the quality and the commercialization of pharmaceuticals. An additional criterion, that would tighten the circle of countries allowing parallel trade of drugs between them, would be only to include countries that are classified as high income by the World Bank.⁶⁶ This measure would cause more competition between industrialized countries, what again would have a lowering effect on prices. Applying this limited international exhaustion, pharmaceuticals could still be delivered to developing countries for a fair price, since the principle of national exhaustion would apply to them.

Another alternative to completely allow parallel imports would be to differentiate the principle of exhaustion by products. Again to take into consideration the individual circumstances concerning pharmaceuticals, they could be exempted from international exhaustion and parallel imports of drugs would remain prohibited.

⁶⁵ Economiesuisse (2006)

⁶⁶ Love (2004)

3.2.2 *Implied License Doctrine*

The implied license doctrine is a practice that has its origin in the UK and is the counterpart of the issue of exhaustion of continental European jurisdictions. Patent protection goes a step further under British law and allows the owner of a patent to control the resale of the already sold patented good. In cases of first product placements in a foreign country, this control can also have the form of an export, respectively a re-import restriction. As a matter of fact, these restrictions possibly apply also to third parties not buying the patented goods directly from the patent holder.

However, there are cases, where it is assumed that the patent owner has no objection against resale and parallel trade with his products and that he granted an “implied license” together with the sale of the good. This is particularly the case, when the owner of a patent places his product on a foreign market without explicitly provide resale restrictions. Under these conditions the implied license doctrine comes to the same results as the application of the principle of international exhaustion. Nevertheless, this case is the exception and the possibility of the patent holder to regulate resale of his goods through sales strategies and contractual provisions, namely through an explicit license, results in a system that is rather similar to national exhaustion of patent rights.⁶⁷

The Commercial Court of Zurich had decided the Kodak-Case⁶⁸ in favor of international exhaustion giving the patent holder the possibility to regulate the flow of goods on a contractual basis as practiced in the UK and Japan⁶⁹ with the implied license doctrine.

3.2.3 *Contract Limited International Exhaustion*

The option of limiting the extent of international exhaustion by contracts is not really an alternative to the full international exhaustion. It is more a strategy to limit damages for the industry. The prevention of re-imports of drugs into Switzerland could be achieved through vertical agreements of the pharmaceutical firms with its distributors. Hereunto, the pharmaceutical companies would have to contractually forbid their foreign purchasers to re-import the products or to sell them to parallel importers.

⁶⁷ Straus and Katzenberger (2002)

⁶⁸ ZR 97 (1998) Nr. 112

⁶⁹ The implied license doctrine was introduced by the Japanese Supreme Court in the cases *BBS Kraftfahrzeugtechnik AG v. Racimex Japan Corp., and Jap Auto Products Co.*

Enforcement of vertical agreements however is a risky undertaking. The first question is, whether the enforcement of such contracts is possible at all. Secondly, it is not sure if the Competition Commission would allow these kinds of vertical agreements and if so, what would happen, if they changed their policy in the near future.⁷⁰ Thirdly, in case of a breach of contract, it is only the contract partner that is liable, but not a third party who profits from the breach. As a final remark, it would be questionable if a lawsuit of a Swiss pharmaceutical company against a distributor of drugs in a developing country would end up in effective damage compensation.

3.3 Regional Exhaustion

The Federal Council of Switzerland has also taken into account and discussed an approach of Switzerland towards the EU, which applies the principle of regional exhaustion within the territory of the European Economic Area for all IP rights.

From the perspective of Switzerland, differences between the arguments for regional exhaustion do not differ that much from the arguments for international exhaustion. One strong argument against regional exhaustion for Switzerland however drops out in comparison with international exhaustion. The price differential for pharmaceuticals is not as significant between Switzerland and the EEA member states as between Switzerland and the rest of the world, including developing countries. The fear of re-imports of cheap pharmaceuticals from developing countries, which damage the Swiss industry as well as the population of the country where the re-imports come from, is therefore not justified anymore.

The overall consequences for Swiss consumers, the industry and economy would nearly be the same, or just a little bit understated for regional than for international exhaustion. A possible evidence for the small effect a regime change for patent rights would have on prices in Switzerland are again the prices for trademark protected goods. Although Switzerland has adopted a more liberal position compared to the EU, by allowing parallel imports of branded products, the price level in Switzerland is still higher than in the EU.⁷¹

⁷⁰ Parallelimporte und Patentrecht (2002)

⁷¹ Parallelimporte und Patentrecht: Regionale Erschöpfung (2004)

3.3.1 *Compatibility of Regional Exhaustion with TRIPS and GATT*

According to Article 6 of the TRIPS-Agreement,⁷² contracting states can themselves choose which principle of exhaustion they want to apply on intellectual property rights as long as it does not conflict with the principles of National Treatment of Article 3 and Most-Favored-Nation of Article 4 TRIPS. Both Article 3 and Article 4 are addressed to the treatment of nationals of member states. For the issue of exhaustion however, it is not the nationality of the parallel importer that is the decisive factor, but the origin of the goods. On this account, the introduction of the principle of regional exhaustion of Switzerland would not infringe the provisions of the TRIPS-Agreement.

As to the compatibility of such a policy change with the GATT-Agreement⁷³ the situation looks different. Unlike the TRIPS-Agreement, the Most-Favored-Nation Treatment under GATT does not proceed from the nationality of the holder of an intellectual property right but from “any advantage, favor, privilege or immunity granted by any contracting party to any product originating in or destined for any other country”.⁷⁴ With the introduction of regional exhaustion, Switzerland would allow parallel imports from the European Union. According to GATT’s Most-Favored-Nation principle, Switzerland would have to expand this trade liberalization to every other member state of the WTO submitting a request therefore, and would sooner or later end up with international exhaustion.

A possibility for Switzerland to circumvent the conflict with the GATT-Agreement would be to enter a bilateral agreement with the EU establishing a common customs union or a free-trade area as it is provided under Article XXIV GATT. In case such a bilateral agreement should be achieved, it seems very likely that the European Union would request the introduction of the principle of regional exhaustion in Switzerland for goods protected by trademarks and copyright. A policy change for trademarks and copyrights however, would result in more restrictive trade conditions for WTO members outside the EU, which itself could be questioned under Article XXIV GATT.⁷⁵

As regarding the conflict between the TRIPS Agreement, leaving the issue of exhaustion open, and the provisions of GATT, promoting free trade, proponents of international exhaustion suggest, that the principle of the WTO of trade liberalization should be taken into account to guide the interpretation of the TRIPS Agreement. On the other hand, taking all the

⁷² Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

⁷³ The General Agreement on Tariffs and Trade (GATT)

⁷⁴ GATT Article I paragraph 1

⁷⁵ Parallelimporte und Patentrecht: Regionale Erschöpfung (2004)

WTO agreements and the negotiating history of the TRIPS Agreement into consideration, there are also arguments saying that TRIPS is a *lex specialis*, or *sui generis*, which as far as concerning matters related to the protection of intellectual property, has absolute precedence over the GATT.⁷⁶

⁷⁶ Bronckers (1998)

Chapter 4

Revision of the Swiss Patent Law

By order of the Federal Council of Switzerland, the Federal Department of Justice and Police (FDJP) launched a consultation⁷⁷ on the preliminary draft of the partial revision of the Swiss Patent Law in December 2001. Based on the results of this consultation, the FDJP was assigned to analyze some problems in depth and to put them up for discussion. A second consultation was launched in June 2004 and resulted in a draft version of the Swiss Patent Law.⁷⁸

By the end of November 2005, the Federal Council of Switzerland submitted the draft Patent Law to the Parliament with the request for acceptance. At the moment the submission is discussed by the Committee for Legal Affairs (CLA).⁷⁹

The main part of the Patent Law revision deals with biotechnological inventions as patentability of gene sequences and particularly with regard to the adaptation of the Patent Law of Switzerland to the Biotechnology Directive 98/44/EC of the European Community. Other points of revision are the ratification of the Patent Law Treaty, the WTO-Agreement on compulsory licenses for the export of pharmaceutical products and the regulation about parallel imports.

4.1 Article 9a

The new Article 9a of the draft Patent Law was introduced to fill the loophole in the Swiss legislation concerning the issue of exhaustion and thus the problem with parallel imports of patented goods. In compliance with the position of the Federal Council, paragraph 1 of Article 9a states that goods, which have been put on the domestic market by the patent holder or with his consent, may be resold or used professionally. Coherent with that, the same applies to the

⁷⁷ Consultation (*German Vernehmlassung*) is a phase of the Swiss legislative procedure. Before the Federal Council of Switzerland submits a draft law to the parliament, the proposal goes through the process of consultation. During this process, political parties, cantons or any other interest groups comment on the draft so that it can be changed or adapted if necessary. The goal of the consultation is to enact broadly supported law preferably without a referendum.

⁷⁸ Federal Department of Justice and Police, available at <http://www.ejpd.admin.ch>

⁷⁹ The Swiss Assembly – The Swiss Parliament, Committee for Legal Affairs, available at http://www.parlament.ch/e/homepage/ko-kommissionen/ko-legislativkommissionen/kom_12_25

use of a protected process by the purchaser of a device to do so, that was placed into circulation lawfully (Article 9a paragraph 2). The central point of these two paragraphs concerning parallel imports into Switzerland is the term “domestic”. By this provision, the principle of national exhaustion would be codified in the Patent Law of Switzerland.

The relativization of Article 9a paragraphs 1 and 2 is included in paragraph 3 and is designed to avoid the problem of multiple protection. The draft Patent Law foresees in Article 9a, Paragraph 3 a provision, that the consent of the patent holder is not required to put on the domestic market patented goods, which are also protected through other intellectual property rights and to which the functional character of the patent protection has a subordinate importance.⁸⁰

Under this anti-abuse provision it shall not be possible to prevent parallel imports of goods protected by copyright or trademark law by equipping them with a patented part. However, the question would still remain, whether a feature of a product is considered to be of subordinate importance or not. An often cited example is the one of the perfume that is trademark protected and could be prevented from being parallel imported by enduing its flacon with a patented sprayer. In this case, it is the designative function of the trademark that comes to the fore and parallel imports based on the patent could not be prevented. A counter-example to this would be a branded car with a patented valve control that reduced gasoline consumption by the half. This would definitely be considered to constitute the innovative character of the car and therefore to prevent parallel imports based on the national exhaustion for patented goods in Switzerland.⁸¹

4.2 Effect of the Draft Patent Law with National Exhaustion

Concerning the provisions on the principle of exhaustion, the revised Patent Law would directly affect the parties involved without changing the practice, as it is today immediately. Compared to the effect the codification of international exhaustion in the new Patent Law would have, the effects of the draft Article 9a would only edge ahead. Nevertheless, some points would change and could substantially influence the behavior of companies trading internationally with patent protected goods in the marketplace.

⁸⁰ The original text of the draft Patent Law of Switzerland (E-PatG) is available in German, French and Italian under <http://www.admin.ch>.

⁸¹ Parallelimporte und Patentrecht: Regionale Erschöpfung (2004)

Since the *Kodak* decision has been criticized oftentimes as being based on shaky arguments and not accompanying the Supreme Court decisions in trademark and copyright cases,⁸² Article 9a could certainly increase legal certainty regarding parallel imports of patented goods. This certainty would also be increased as Switzerland is experienced in applying this principle and by the fact that national exhaustion is still the globally prevailing policy in this issue. Concerning Article 9a paragraph 3 about multiple protection and the provisions of the Cartel Act, which are supposed to intervene in cases of abusive trade restrictions, it would remain to be seen what would become the common practice of the authorities.

Although there is the possibility of limiting the monopolist's power against parallel imports through the Cartel Act, the codification of the national exhaustion in the Patent Law would cement the position of those interested in maintaining the high-price island Switzerland. The patent, which is supposed to be an incentive for innovation, would remain a state-aided barrier to market entry. The Argument that the codification of the national exhaustion would strengthen the rights of patent holders is not really consistent, since patent protection was never questioned in this context. If something is going to be undermined when lifting the ban for parallel imports, it would only be the price level.⁸³

4.3 Restrictions set by the Cartel Act

4.3.1 Article 3 Paragraph 2 of the Cartel Act

Article 3 paragraph 2 of the Swiss Cartel Act sets the provision to the practice that was provided by the Supreme Court of Switzerland in the *Kodak-Case* as to its point of intersection with intellectual property laws. Namely, the second sentence of Article 3 paragraph 2 of the Cartel Act says that “(...) import restrictions based on intellectual property rights fall to be assessed under this Act”.⁸⁴ The field of main application of this provision is obviously import restrictions based on patent rights, since trademark- and copyrights are exhausted internationally. This might change one day, when Switzerland decides to join the EU, respectively the EEA or in case of a policy change within the Federal Supreme Court.

As a result of the fact that opinions within Switzerland about the issue of exhaustion differ substantially, the applicability of the Cartel Act towards IP based trade restrictions, in case of

⁸² Hilty (2000)

⁸³ NZZ of May 6, 2006

⁸⁴ Cartel Act

a passage of the revised Patent Law, is of major importance. In fact, the Cartel Act would remain the only weapon against the arbitrariness of the powerful industry with respect to market foreclosure.

Prior to the implementation of the amended Cartel Act on April 1, 2004, the Competition Commission of Switzerland could only take declaratory decisions prohibiting anti-competitive restrictions. Fines could only be imposed after a party violated the law for a second time in the identical way. The first violation was, so to say, for free. As a consequence of these weak instruments, the ComCo was powerless in fighting unjustified competition restraints.

Considering publicity effective events, like the revelation of the vitamins-cartel⁸⁵ by the end of the 1990's, the impotence of the authority enforcing the act was an unsustainable situation. F.Hoffman-LaRoche for instance, that pioneered the vitamins-cartel was fined in the US with \$500 million and in the EU with €462 million, whereas the judgment in Switzerland was merely declaratory prohibiting the restrictions. Another point was the ruling of the Federal Supreme Court in the *Kodak-Case*, according to which the Cartel Act was supposed to restrict the power of patent holders in preventing parallel imports of patented goods into Switzerland. Before the revision, the Cartel Act was explicitly not applicable to competition issues emerging only from intellectual property rights.

After the revision and the commencement of the amended Cartel Act, the radius of operation and the power of the ComCo to impose fines and sanctions were increased. The possibility of direct sanctions for instance as provided in Article 49a is applicable to companies that participate to unlawful agreements and to such, that act unlawfully having a dominant position. Auxiliary means, like the possibility of dawn raids, provided in Article 42 paragraph 2, for a better access to evidence and a leniency program for whistleblowers furthermore, enforce the position of the Commission.

4.3.2 Economic Dependence

Apart from the revisions mentioned above, the Swiss Cartel Act was also amended with regard to the concept of dominant position. The new edition of Article 4 paragraph 2 says: "The term 'enterprises having a dominant position in the market' means one or more

⁸⁵ The famous Vitamins-Cartel was an agreement including hardcore restrictions as price fixing, market division and bid rigging, which was globally active in the time from 1989 to 2000 between 13 vitamin manufacturers as F.Hoffman-LaRoche and BASF.

enterprises being able, as regards supply or demand, to behave in a substantially independent manner with regard to the other participants (competitors, suppliers or customers) in the market.”⁸⁶ According to the terms in parenthesis, and this constitutes the substantial innovation of this article, the definition of dominant position was specified. This means that for the determination of a company’s dominant position, there are not only reasons of market structure that must be taken into consideration, but also concrete conditions of dependence. The relative relationship between supplier and customer, particularly if the customer is a distributor of the supplier’s products, must be regarded and can result in a relation of economic dependence.

Therefore, market power is not only established where a company has a superior position over a competitor in the market, but also where other companies, be it as supplier or as purchaser, are directly dependent of it.⁸⁷ Consequently the definition of market power was extended in both the horizontal and the vertical direction and the threshold for market power was reduced.⁸⁸

Even though it seems to be mainly small and medium-sized enterprises that are to be found in economic dependence of global players as a cause of special market situations, this is not necessarily the case. Actually, it was pointed out during the parliamentary consultation that not any form of economic dependence shall lead to a situation of dominant position. The new provision of Article 4 paragraph 2 shall not protect market structures that are not able to survive.⁸⁹ Furthermore it is to determine, whether a company itself is responsible for being in a dependent situation, e.g. due to strategic mistakes and risk concentrations, or if it was unavoidable to circumvent this situation because of existent market structures and whether there are adequate and reasonable alternatives or not. In the case such an unindebted dependent situation prove true, trade restrictions are to be challenged under Article 7 on unlawful practices of enterprises having a dominant position.⁹⁰

The challenging of classic agreements, as for instance restrictive distribution agreements, under Article 5 of the Cartel Act do not require the application of the concept of economic dependence, since the simple finding of market power is enough. The question after economic dependence is rather to be asked in cases of a company’s unilateral conduct, which aim at restricting competition or preventing parallel imports.

⁸⁶ Cartel Act

⁸⁷ Dähler und Krauskopf (2003)

⁸⁸ Zäch (2005)

⁸⁹ Explanatory report of the Federal Council of Switzerland to the amendment of the Cartel Act (2001)

⁹⁰ Zurkinden (2004)

Regarding the special situation of the pharmaceutical industry in connection with the possible codification of the principle of national exhaustion for patent protected goods in the revised Patent Law, the concept of economic dependence shall support the Competition Commission in future assessments based on Article 3 paragraph 2 of the Act. Nevertheless, the fact of abuse of a dominant position must be fulfilled and this is still not necessarily the case when restrictive behavior is justified by legitimate business reasons. It is self-evident that pharmaceutical companies' expenses on R&D depend on actual income as well as on predicted future income generated by sales of their products. Therefore, it is not just a business, but also a moral reason that may contribute to justify restrictive behavior. However, in case of discriminatory conduct with the mere objective to maintain the huge price differences for pharmaceuticals among equal countries, the concept of economic dependence will be helpful to assess an abuse of dominant position.

4.3.3 Assessment of Economic Dependence by the Swiss Competition Commission

At the moment, there is no case that has been investigated by the ComCo on the basis of Article 3 paragraph 2 and particularly in combination with Article 4 paragraph 2. The *Kodak-Case* about parallel import restrictions of patented goods is still under investigation from a competition perspective. However, a case that dealt with the issue of economic dependence and where the ComCo has set the conditions for an assessment of economic dependence is the so called *CoopForte-Case*. This case has nothing to do with parallel imports of patent protected goods, but questions the dependent situation of Swiss suppliers of consumer goods towards the distributor Coop, which was suspected to abuse its buying power. In the case of a pharmaceutical company restricting parallel imports of drugs on the basis of patent rights, the situation would be the opposite, namely the supplier having market power over the distributor and the conditions established by the Commission had to be inverted.

Nevertheless, the case establishes the direction in which a future investigation of the Swiss Competition Commission against a national enterprise trying to unjustifiably restrict parallel imports could go.

According to the *CoopForte* decision, economic dependence is given where a business relationship between two vertically integrated companies is of such intensity, that one of those is not able to escape from the market power of the other one. This means, that the dependent party would jeopardize its existence on the market by cancelling the business relations with

the independent one.⁹¹ Regarding a distributor of pharmaceuticals it seems practically unavoidable not to get into such a situation. Pharmaceutical companies that have a patent on an active compound have by law a monopoly on the market with this compound and therefore, there is no alternative source of procurement for it. The consequence of a refusal of the supplier to deal with a distributor would mean for him not to be able to supply the end-consumers with the required medicine any more. The pharmaceutical company on the other side does not have a disadvantage in losing one purchaser, since it has the possibility to choose the retailers it supplies with its products from a huge variety. These facts do not just show the dependency of drug suppliers on the manufacturing companies, it also shows implicitly two different levels of negotiation power in arranging trade and business conditions between supplier and distributor.

However, the question whether such a scenario would be decisive for the existence of a single distributor is not clear, since there were still thousands of other drugs and related products remaining that could be sold by the discriminated retailer. Even a decision of a major pharmaceutical company not to supply a pharmacy with products at all, may not endanger this pharmacy's existence. The market shares of pharmaceutical companies are in general too small to have this effect, since the turnover of a pharmacy with products of one drug manufacturer could at an outside estimate be comparable with the market share of this manufacturer. Nevertheless, the signaling effect of a supply-stop of a major pharmaceutical company on other companies or just the solidarity within the branch could influence this effect and therefore, this question should be regarded in detail for the assessment of economic dependence between supplier and distributor in the pharmaceutical sector. The threshold that was established by the ComCo in the *CoopForte-Case*, according to which the dependent company has to achieve at least 30 percent of its turnover with goods of the allegedly abusing supplier, is hardly ever reached in this case.

The second criterion that must be considered is related to the degree of coordination between the two businesses. Regarding a distributor, which is deemed to be in a situation of economic dependence towards a supplier, it is to control if the distributor is specialized in selling the supplier's products and if there are special measures taken by the distributor for selling these goods. Distributors of pharmaceuticals are of course highly specialized dealers and a rearrangement to other goods while using the same infrastructure is unthinkable. Additionally it is to consider that drug distributors did not betook themselves in the dependent situation nor have they been forced to do so by their suppliers. Drug distribution is regulated by law, thus

⁹¹ CoopForte (2005)

the only institutions entitled to sell pharmaceuticals to end-consumers are therefore highly specialized pharmacy stores.

The legal regulation of drug distribution could also turn the tables in a system like Switzerland, since drug manufacturers only have limited possibilities to bring their products to end-consumers. A single pharmacist may be helpless against a pharmaceutical company, whereas the organized Swiss Society of Pharmacists is not. Swiss pharmacists have taken up the cause of remaining neutral against the big corporations and are aware of the danger of the vertical integration between pharmacies and drug manufacturers.⁹² This certainly helps the small businesses to confine their level of economic dependence.

The whole process of assessment of an unlawful practice, in case a pharmaceutical company is trying to restrict parallel imports of drugs on the basis of patent law, is very complex and the question whether there is a situation of economic dependence between supplier and distributor is just a part of it. Starting from the relatively young legislation and the very few cases that have been investigated on these grounds, it is difficult to make a prediction on the outcome of a future case.

4.4 Comparison between Switzerland and the EU

Regarding the policies of exhaustion of patent rights, Switzerland embarks on a completely different strategy than the EU. The EU allows parallel trade between its members but reserves the possibility of restricting free movement of goods under special circumstances and for certain industry sectors as the pharmaceutical industry. Switzerland does exactly the opposite and forecloses its market thus provides the instrument of the Cartel Act as a corrective measure in cases of unjustified trade restrictions based on intellectual property rights. An alternative for Switzerland would have been – and may still is since the new Patent Law has not passed yet – to find a solution governed by intellectual property laws. Similar to the principle in the EU, it could be dogmatically easier and simpler to introduce the principle of free movement of goods but to leave the possibility open to exceptionally restrict parallel imports, where the marketing conditions for the patented product could not be chosen freely by the patent holder, for instance for pharmaceutical products.⁹³

⁹² 32 Theses of the Swiss Society of Pharmacists (Schweizerischer Apothekerverband), available at http://www.sav.ch/de/media/sav/Thesen_dt_DEF.pdf

⁹³ Zäch (2000)

However, considering the long term aim of the EU to establish an integrated and fully harmonized market, differences between the EU and Switzerland diminish. Regarding the EU as a single country it does nothing else than protecting its patent holders by prohibiting parallel imports from third countries. An elementary fact comparing Switzerland and the EU in this light is that the EU has the critical size for the occurrence of a fair and constructive competition that keeps prices on a reasonable level. Switzerland does not and therefore there is not enough competition preventing monopolists of fully capitalizing their price interests.

In quest of the optimal solution for the issue of exhaustion of patent rights there is definitely no model solution, which satisfies all involved parties. While the pharmaceutical companies try to keep prices for drugs high, these prices are never low enough for consumers. In the discussion of how to proceed with parallel imports, there are of course several other parties as the state, health insurances, parallel importers etc. that keep company with consumers and drug manufacturers. For the near future of Switzerland, it will be the revision of the Patent Law that attracts the attention of those involved.

5.1 Chances of the Draft Patent Law?

As mentioned above, the revision of the Patent Law has its beginning in 2001 and a decision on the actual draft will still be protracted. On September 7, 2006 the Committee for Legal Affairs of the National Council decided to liberate the subject matter of parallel imports from the submission and to treat it at a later time, as this topic still requires substantial analysis.⁹⁴

Although the Committee decided to drop the proposal of the Federal Council to include the national exhaustion in the draft Patent Law, the matter is not settled yet and regarding the numerous reports and studies on the topic, it is debatable, whether even more efforts are necessary to reach a solution or not. It seems that in Switzerland as well as in Europe the outcomes of such studies and reports analyzing developments, benefits and problems within the topic of exhaustion of patented goods, particularly pharmaceuticals, depend directly on what the orderer of the study wants or expects to hear. In the end, no matter what will be the decision of the Parliament, there will certainly be a study supporting it.

As an example, there shall be mentioned two studies that examined the benefits of parallel trade with pharmaceutical products in the European Union. The York Report⁹⁵ estimated direct savings for five European countries in 2002 at more than €600 million, whereas the

⁹⁴ Press release of the Committee for Legal Affairs of the National Council of September 8, 2006, available at http://www.parlament.ch/homepage/mm-mediennmitteilung.htm?m_id=2006-09-08_059_01&langId

⁹⁵ West (2003)

LSE report⁹⁶ concludes that consumers' benefits in the same countries are negligible. Another example is the different interpretation of the CFI decision in *GlaxoSmithKline v Commission* from the innovative pharmaceutical industry, as communicated by GSK and from the association of pharmaceutical parallel traders in Europe.⁹⁷

The same scenario can be found in Switzerland, where the pharmaceutical industry holds out the argument that the savings per head and year would be at CHF 4.25 after the liberalization of the drug market, while others argue to the contrary, that the pending loss for the pharmaceutical companies would be fractional.⁹⁸

Many opinions are already made, irrespective of what future analyses will bring along. The question, whether it is national, international or regional exhaustion that will prevail in the end, is impossible to answer at this time.

5.2 Opinions and Positions

Among the numerous parties interested in this issue, which opinions will possibly change over the time, there are several parties that represent an opinion given by their nature. Since consumer interests are involved, organizations and institutions protecting these interests are arguing at the very front in this debate. There is the price supervisor that stated a political appraisal that he is expecting parallel imports of pharmaceuticals, at least for hospitals, within two years.⁹⁹ His endeavors are supported by the Foundation for Consumer Protection (Stiftung für Konsumentenschutz), by the retail business, by tourism, farmers and other consumer friendly organizations. In its liability of maintaining competition, the Competition Commission of Switzerland is also favoring international or regional exhaustion of patent rights.

Within the government and the political parties, it is not clearly determinable, who takes sides with whom. In the past, the situation was somehow easier, since right-wing politicians used to support competition, while left-wing politicians were opposing this principle of Social Darwinism, according to which competition was eliminating inefficient market participants.¹⁰⁰

⁹⁶ Kanavos (2004)

⁹⁷ EAEPC-Press Release of September 27, 2006 available at http://www.eaepc.org/news_and_press/news.php?n=3

⁹⁸ NZZ am Sonntag of October 5, 2006

⁹⁹ Interview with Rudolf Strahm in „Kassensturz“ of September 9, 2006

¹⁰⁰ Wegelin (2006)

Today's situation looks different. Left-wing politicians of the Social Democrats (SP), the Green Party (Grüne) as well as the civic party of the Christian Democrats (CVP) of Switzerland widely support open markets in the hope of its lowering effect on prices.

The strongest supporter of the codification of the principle of national exhaustion in the new Patent Law is the pharmaceutical industry, backed by Economiesuisse, the largest umbrella organization representing the Swiss economy. Although it seems that the opponents of free movement of goods are in a limited number, there are many profiteers that sit in the shadow of the powerful industry. From the political side, there are the mainly the business oriented Federal Democratic Union (FDP) and the Swiss People's Party (SVP) that support "strong" patent rights with national exhaustion. However, it seems as business orientation is sometimes confused with interests in certain industry sectors.¹⁰¹

For the future scenario of the Parliament accepting the draft Patent Law as it is formulated now with the codification of national exhaustion, there are already parties that consider filing a petition for a referendum. In this case, it would be the population of Switzerland deciding the issue either in its own favor or in favor of the better lobbyist. A user survey carried out by CASH.ch¹⁰² with 605 participants probably shows the trend among the consumers in contrast to the consequences of the issue. On the question whether parallel imports shall be allowed for products from the EU, 287 (47%) said yes, 26 (4%) said no and 292 (48%) said: What are parallel imports?

¹⁰¹ Wegelin (2006)

¹⁰² Survey, available at <http://www.cash.ch/umfrage>

Chapter 6 Literature

Auswirkungen staatlicher Eingriffe auf das Preisniveau im Bereich Humanarzneimittel (Humanarzneimittelstudie), 2002, available at http://www.evd.admin.ch/imperia/md/content/dossiers/importations_paralleles/d/Studie_Humanarzneimittel.pdf

Botschaft zur Änderung des Patentgesetzes und zum Bundesbeschluss über die Genehmigung des Patentrechtsvertrags und der Ausführungsordnung, November 2005, available at <http://www.admin.ch/ch/d/ff/2006/1>

Bronckers, M. C. E. J., The Exhaustion of Patent Rights Under WTO Law, The International Intellectual Property System, Commentary and Materials, Part Two, Kluwer Law International, 1999

Clark, T., Growing pains: for pharma, the EU expansion won't pay off for at least a decade, Pharmaceutical Executive, May 2004

Comte, J.-L., Internationale Erschöpfung der Patentrechte?, sic! 1999, p.478-482

Cueni, T., Die Position der forschenden Pharmaindustrie Schweiz, Basler Schriften zur europäischen Integration, Nr. 72, 2005, available at http://www.europa.unibas.ch/cms4/uploads/media/BS72_03.pdf

Dähler, R., Krauskopf, P., Kartellgesetz-Revision – das Resultat der parlamentarischen Beratung, Die Volkswirtschaft – Das Magazin für Wirtschaftspolitik 10 2003, p. 7-13

Economiesuisse, Positionspapier – Parallelimporte und Patentrecht, 2006, available at <http://www.economiesuisse.ch/d/webexplorer.cfm?id=286&tld=1>

Explanatory report of the Federal Council of Switzerland to the amendment of the Cartel Act of November 7, 2001, available at <http://www.admin.ch/ch/d/ff/2002/2022.pdf>

GlaxoSmithKline, Press Release of September 27, 2006, available at <http://www.gsk.com/media/pressreleases.htm>

Glynn, D., Article 82 and price discrimination in patented pharmaceuticals: the economics, European Competition Law Review 2005, v. 26, n. 3, March, p. 135-143

Hays, T., Parallel importation under European Union law, London: Sweet & Maxwell, 2004

Heath, C., Parallel Imports of Patented Pharmaceuticals from the New EU Accession States, International Review of Industrial Property and Competition Law, 2004 Nr. 7, p. 776 ff.

Hilty, R. M., Verbot von Parallelimporten – Heimatschutz oder Schildbürgerstreich? Eine rechtliche Kritik, eine ökonomische Analyse – und ein Regelungsvorschlag zwischen schwarz und weiss, sic! 2000, 231-241

Kanavos, P. et al., The economic impact of pharmaceutical parallel trade in European Union member states: A stakeholder analysis, LSE Health and Social Care, London School of Economics and Political Science, 2004, available at <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers/Paper.pdf>

Kilchenmann, Ch., Bedeutung des Patentschutzes für die Basler Industrie – gestern und heute, WWZ-Diskussionspapier 04/03, 2004

Love, J., Flynn, S., Legal and Policy Issues Concerning Parallel Trade (aka Re-Importation) of Pharmaceutical Drugs in the United States, CPTech 2004, available at <http://www.cptech.org/ip/fsd/love03312004.pdf>

Neue Zürcher Zeitung NZZ, Bürokratie behindert Parallelimporte, November 30, 2005

Neue Zürcher Zeitung NZZ, Peinlicher Kampf der Pharmabranche gegen Parallelimporte, May 6, 2006

Neue Zürcher Zeitung NZZ am Sonntag, Angriff auf Novartis & Co, October 5, 2006

Notice of the Competition Commission of 18 February 2002 on the Competition Law Treatment of Vertical Agreements available at <http://www.weko.admin.ch/imperia/md/images/weko/43.pdf>

Novartis Media Release of April 24, 2006, available at <http://www.novartis.com/news/en/media.shtml>

OECD Economic Survey of Switzerland 2003, available at <http://www.oecd.org/dataoecd/51/50/25589663.pdf>

Parallelimporte und Patentrecht, Bericht des Bundesrats, 2002, available at http://www.evd.admin.ch/imperia/md/content/dossiers/importations_paralleles/d/TRI_SCHL_USSBERICHT_PARALLELIMPORTE_Dt.pdf

Parallelimporte und Patentrecht: Regionale Erschöpfung, Bericht des Bundesrates, 2004, available at http://www.evd.admin.ch/imperia/md/content/dossiers/importations_paralleles/d/rapport_final_envoi-wak_d_04-12-15.pdf

Pfizer Inc Supplemental Information of 2005, available at <http://mediaroom.pfizer.com>

Pharmamarkt Schweiz 2006, available at http://www.interpharma.ch/de/pdf/Pharma_Markt_Schweiz_06d.pdf

Saurer, M., Wettbewerbsverzerrende Preisregulierung?, Referat am 32. Seminar der Deutschen Verkehrswissenschaftlichen Gesellschaft, 1999, available at <http://www.industrieoekonomie.ch/Publikationen/preisregulierung.pdf>

Seco, Staatssekretariat für Wirtschaft, Warum erodieren Parallelimporte die Preisinsel Schweiz nicht stärker?, 2004, available at http://www.evd.admin.ch/imperia/md/content/dossiers/importations_paralleles/d/exploratorische_expertengespraech_plaut_economics_schlussbericht.pdf

Snell, J., Free Movement of Pharmaceutical Products: An Overdose of Cheap Drugs, European Law Review 2003, Nr. 5, p. 278-284

Stothers, C., Who Needs Intellectual Property?, Competition Law and Restrictions on Parallel Trade within the European Economic Area, European Intellectual Property Review 2005 Nr. 12, p. 458 ff.

Straus, J., Katzenberger, P., Parallelimporte – Rechtsgrundlagen zur Erschöpfung im Patentrecht, im Auftrag des Bundesrates, 2002, available at http://www.evd.admin.ch/imperia/md/content/dossiers/importations_paralleles/d/Rechtsgutachten_Erschoepfung.pdf

Weder, R., Barsuglia, G., Pharmapreise im Dreieck von Patentschutz, Parallelimporten und Preisregulierung, Die Volkswirtschaft – Das Magazin für Wirtschaftspolitik, 7/8 2006, p. 30-33

Wegelin, J., Sturm auf die Preisinsel, Cash Nr. 14, 2006

West, P., Mahon, J., Benefits to payers and patients from parallel trade, York Health Economics Consortium, 2003, available at http://www.york.ac.uk/inst/yhec/downloads/ParallelTrade_ExecSumm.pdf

Zäch, R., Parallelimporte patentgeschützter Güter nach Massgabe des Kartellgesetzes – Rechtslage gemäss Kodak-Urteil und Revisionsvorschläge, sic! 2001, p. 275-284

Zäch, R., Schweizerisches Kartellrecht, 2nd Edition, Bern 2005, p. 278-284

Zurkinden, P., Auswirkungen der KG-Revision auf Vertriebssysteme, SZW/RSDA 2/2004, p. 105-111

Cited laws

Act Concerning the Condition of Accession of the New Member States, O.J. L 236 of 23 September 2003, available at http://europa.eu.int/eur-lex/en/archive/2003/l_23620030923en.html

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), available at http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

Commission Regulation (EC) No 2790/1999, available in all EU languages under <http://eur-lex.europa.eu>

Directive 2001/83 EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Official Journal L – 311,

28.11.2004, p. 67 – 128, also available at
<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm>

Federal Act on Cartels and Other Restraints of Competition (Bundesgesetz über Kartelle und andere Wettbewerbsbeschränkungen), available in English at
<http://www.weko.admin.ch/imperia/md/images/weko/40.pdf> and in German at
<http://www.admin.ch/ch/d/sr/2/251.de.pdf>

General Agreement on Tariffs and Trade (GATT), available at
http://www.wto.org/english/docs_e/legal_e/legal_e.htm

Law on Drugs (Heilmittelgesetz), available at <http://www.admin.ch/ch/d/sr/8/812.21.de.pdf>

Swiss Patent Law (Bundesgesetz über Erfindungspatente), available in English at
http://www.wipo.int/clea/docs_new/pdf/en/ch/ch012en.pdf and in German at
<http://www.admin.ch/ch/d/sr/2/232.14.de.pdf>

Treaty establishing the European Community, available in all European languages under
<http://eur-lex.europa.eu>

Cases

Decision of the European Court of Justice in Case 15/74 *Centrafarm BV and others v Sterling Drug* and Case 16/74 *Centrafarm BV and others v Winthrop BV*, 1974

Decision of the European Court of Justice in Case 187/80 *Merck v Stephar and Exler*, 1981

Decision of the European Court of Justice in Case 181/82 *Roussel Laboratoria BV and others v The Netherlands*, 1983

Decision of the European Court of Justice in Case 42/84 *Remia and Others v Commission*, 1985

Decision of the European Court of Justice in Case 7/61 *Commission v. Italy*, (1961) and Case 216/84 *Commission v. France*, 1988

Decision of the European Court of Justice in Case T-17/93 *Matra Hachette v Commission*, 1994

Decision of the European Court of Justice in the joined Cases C-267-268/95 *Merck v Primecrown and Beecham v Europharm*, 1996

Decision of the Federal Supreme Court of Switzerland, BGE 122 III 469, *Chanel S.A. Genève et Chanel S.A. v EPA AG*, 1996

Decision of the Federal Supreme Court of Switzerland, BGE 124 III 321, *Imprafot AG v Nintendo Co. Ltd. and Waldmeier AG*, 1998

Decision of the Commercial Court of Zurich, ZR 97 Nr. 112, *Kodak SA v Jumbo-Markt AG*, 1998

Decision of the Federal Supreme Court of Switzerland, BGE 126 III 129, *Kodak SA v Jumbo-Markt AG*, 1999

Decision of the European Court of Justice in the joined Cases C-2/01 and C-3/01 in *BAI and Commission v Bayer*, 2004

Decision of the European Court of Justice in Case 53/03 *Syfait and others v GlaxoSmithKline plc and others*, 2005 and the Opinion of the Advocate General Jacobs delivered on 28. October 2004

Decision of the Competition Commission of Switzerland in *CoopForte*, RPW 1/2005, p. 146-170, available at <http://www.weko.admin.ch/publikationen/00212/RPW2005-1.pdf?lang=de>

Decision of the European Court of First Instance in Case T-168/01 *GlaxoSmithKline Services v Commission*, 2006 and the related Press Release No 79/06