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## Anticompetitive Marketing in the Context of Pharmaceutical Switching in Europe

*Bengt Domeij*<sup>1</sup>

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### Abstract

The article deals with the intersection between competition law rules on abuse of a dominant position and switching strategies employed by pharmaceutical originator companies. Switching is also known as ever-greening, product hopping or product life cycle strategies. It is one of the most topical issues in the patent-antitrust intersection today and consists in launching a slightly modified, second generation pharmaceutical, 1-2 years before the patent exclusivity expires for a first generation product. In this window originators try to migrate patients to a reformulated product. If successful, this will shield the originator from the effects of generic substitution for the first generation product. In the AstraZeneca-case the EU General Court held that a selective redrawing of marketing authorizations for a first generation product was an abuse of a dominant position under article 102 TFEU. This article focuses on other components in a switching strategy, especially the timing and content of marketing efforts by an originator company. Marketing is pro-competitive in almost all cases, but due to the special regulatory context in the pharmaceutical industry, marketing by an originator company can be used in an excluding fashion in the pharmaceutical industry. The conclusion is reached that casting the quality or price of the originator's first generation product in a bad light, in comparison with the second generation product during exclusivity for the first generation product, may be an abuse by a dominant firm falling foul of article 102 TFEU. It is in effect equivalent to negative comparative advertising messages concerning a competitor's soon to be launched product.

### 1 Introduction

In analysing medicines that for the first time faced generic competition during the years 2000-2007, the European Commission found that generics became available in the market at

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a cost that was about 25% lower than the price charged by originator companies before loss of exclusivity. Prices of generic medicines continued to fall thereafter and two years after generic entry the prices were on average 40% below the price charged by the originator company at the end of exclusivity. Due to competition from generics the average prices went down also for originator companies.<sup>2</sup>

The threats of reduced volumes and prices after generic entry have naturally spurred counter measures by originator companies. These tactics are sometimes referred to as life-cycle strategies or, perhaps more derogatory, as ever-greening or product hopping. The intent is to extend the privileged position enjoyed during exclusivity, if not for-ever, at least for some months beyond the patent, supplementary protection certificate or data exclusivity period. I will in this article concentrate on one of these strategies, namely originator companies trying to switch patients from medicines facing imminent loss of exclusivity, to a so-called second generation or follow-on, medicine. The findings in the EU Commission sector inquiry suggested that originator companies launched follow-on medicines and tried to switch patients in relation to 40% of medicines losing protection. Presumably, the more valuable a product is when exclusivity expires, the more likely switching-tactics are. Thus, switching is an important feature of the pharmaceutical landscape.

Switching commonly entails changing from one means of administering a drug (e.g., tablet) to another (e.g., capsule). Another type involves selecting molecule parts (known as “moieties”) by adding or removing compounds. A third is a combination of two or more active compounds that had previously been marketed separately.<sup>3</sup> These modifications may have therapeutic advantages, but they are rarely significant. In the sector inquiry, the EU Commission held that a common complaint from other actors than originator companies (generic companies and consumer organizations), were that follow-on products sometimes could be questioned because they lacked or had only minor therapeutic advantages over the first generation.<sup>4</sup>

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<sup>2</sup> EU Commission, Pharmaceutical Sector Inquiry – Preliminary Report Fact Sheet “Prices, time to generic entry and consumer savings”, fact sheet 1 at 1, available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact\\_sheet\\_1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_1.pdf), last accessed 15.4.2012.

<sup>3</sup> Carrier, M. A., ‘A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension Of Product Hopping’ *Vol. 62 Florida Law Review* at 1017 (2010). Available at SSRN: <http://ssrn.com/abstract=1587818>.

<sup>4</sup> It is concluded in the sector inquiry that: “In the course of the sector inquiry generic companies and consumer associations sometimes questioned the actual improvement of certain categories of changes, in particular with respect to their therapeutic benefits.” Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report at 14, available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf), last accessed 15.4.2012.

The originator company has in the switching context clearly done some innovative work, because the follow-on product has been awarded a patent. However, patentability requirements are low. The technical and therapeutical results when reformulating a known pharmaceutical are unpredictable to a degree, even for a person skilled in the art, which may be enough to make the reformulation patentable. With the patent, the follow-on product is shielded from direct copying. The available generics will be identical with the first generation product but, crucially, not with the second generation product. This will be enough to prevent generic substitution if physicians prescribe the follow-on product. Originating companies, therefore, do not have to improve the product significantly to profit from a switching strategy.<sup>5</sup> As an industry insider candidly admitted: “The goal of reformulation as a means of generic defense is clear: to prevent the substitution of the branded product by generics on patent expiry.”<sup>6</sup> If switching is successful, the probability decreases significantly that generics after patent expiry for the first generation will gain a significant share of the market.

On average, the launch of the follow-on product takes place one year and five months before loss of exclusivity for the first generation medicine.<sup>7</sup> From launch and until expiry of exclusivity for the first generation, originator companies undertake intensive marketing efforts with the aim of migrating a substantial number of patients to the new medicine.<sup>8</sup> Doctors are at this time presented with a choice between two branded products, usually offered at the same price (sometimes even with a slightly lower price for the new product) and often with an uncontested message that the new product is better.<sup>9</sup>

Legal means of scrutinizing a switching strategy are available if the company is deemed to be dominant. Acts performed in the context of a switching strategy may then be abuses under article 102 of the Treaty on the Functioning of the European Union (TFEU). The question remains, however, what parts of the strategy that are abusive or if switching in its entirety is merely a legitimate way for the originator to remain competitive through innovative product

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<sup>5</sup> “[I]t is sufficient to alter the branded product only to the extent that it is no longer the same as the product that the generic companies are using as reference for their [medicinal authority applications]. This prevents pharmacies substituting generic product for the reformulated brand product . . .” Perrett, S, ‘The Modified-Release Drug Delivery Landscape: The Commercial Perspective’, at 1-2, in *II Modified-Release Drug Delivery Technology*, Michael J. Rathbone et al. eds., 2d ed. 2008. Quoted from S.D. Shadowen, K.B. Leffler & J.T. Lukens, ‘Anticompetitive Product Changes In The Pharmaceutical Industry’, *Rutgers Law Journal*, Vol. 41:1&2, at 7 (2009). Available at SSRN: <http://ssrn.com/abstract=1792864>.

<sup>6</sup> Ibid.

<sup>7</sup> Pharmaceutical Sector Inquiry – Preliminary Report, “Prices, time to generic entry and consumer savings”, fact sheet 2 at 5, available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact\\_sheet\\_2.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf), last accessed 15.4.2012.

<sup>8</sup> Shadowen et al, (supra n 5), at 49

<sup>9</sup> Ibid at 51.

development, just as any other company would be when introducing a new version of a product as the old one becomes uncompetitive.<sup>10</sup>

This chapter is structured with a first section dealing with a switching scenario in which the originator company redraws a marketing authorisation for the first generation product. This has been found to violate article 102 TFEU in the AstraZeneca-case. Secondly, rules on generic substitution in pharmacies in Sweden are described as an example. A discussion of this subject-matter is necessary to gain an understanding of why there after a certain point in time will be no marketing of the first generation product or of any introduced generic versions of it, but only marketing of the patented follow-on product. Thirdly, I focus on the marketing of the follow-on product and assess it under article 102 TFEU.

## **2 Withdrawal of marketing authorization for the first generation product**

The EU Commission explained in the sector inquiry that it does not consider the introduction of an improved version of a medicine a competitive problem. Incremental research was deemed important.<sup>11</sup> It can lead to significant enhancement of existing products, benefiting patients. However, a retraction of the marketing authorization for the older version has been deemed a potential competitive problem. But before discussing this finding in the context of the AstraZeneca-case, it is necessary to explain the so called abridged applications for marketing authorisation of generics.

Generics are products with the same qualitative and quantitative composition in active substances and the same pharmaceutical form (inactive substances) as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated in trials.<sup>12</sup> If these conditions are met, a generic applicant for marketing

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<sup>10</sup> Westin, J, 'Product Switching in the Pharmaceutical Sector – an Abuse or Legitimate Commercial Consideration?', [2011] *E.C.L.R.* Issue 12 at 595.

<sup>11</sup> Pharmaceutical Sector Inquiry, Communication, (supra n. 4), at 14.

<sup>12</sup> 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, article 10 as amended by 2004/27/EC, provides that a 'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies [The amount of drug that finally reaches the site of action is known as the bioavailability, directly impacting on the effectiveness and tolerability of a drug. For a generic medicine to be considered bioequivalent, the European Medicines Agency (EMA) requires that the bioavailability lies between 80% and 125% of the original branded medicine]. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be

authorisation is exempted from the requirement to prove safety and efficacy through pre-clinical tests and clinical trials, and the competent medicinal authority relies on proof of safety and efficacy provided by the reference product. Using the reference product's dossier in an abridged application for marketing authorization, will save time and money for generic entrants. Under the old wording of the legislation on marketing authorisation – Directive 2001/83 on the Community code relation to medicinal products for human use<sup>13</sup> – a generic entrant could only benefit from the abridged procedure if the reference product was still on the market (or at least its marketing authorisation was still upheld). However, in 2005 the directive was amended, to the effect that a marketing authorization survives the discontinuation of the originator product for three years.

Under the old rules, in the 1990s, AstraZeneca withdrew the marketing authorization in Denmark, Norway and Sweden for the original Losec product (in capsule form) as it was replaced by the second generation Losec MUPS product (tablet dispersible in water) which was benefitting from additional patent protection. The EU General Court found in case T-321/05 on 1 July 2010 that the selective withdrawal of marketing authorisations was an abuse of a dominant position (the “second abuse” in the case).<sup>14</sup> AstraZeneca argued in the General Court that it had no longer any commercial interest in selling Losec capsules, and therefore there was an objective justification to withdraw the marketing authorization. However, the Court held that the deregistrations were “not based on the legitimate protection of an investment designed to contribute to competition on the merits” (paragraph 812). Moreover, the General Court held that a dominant undertaking cannot use regulatory procedure so as to prevent market entry or make entry more difficult for competitors. Any such use of regulatory procedures must be related to competition on the merits by the dominant undertaking or otherwise be supported by objective justification, in order not to be an abuse.

As mentioned the rules on abridged applications for generics have been amended. It is no longer enough to withdraw marketing authorization to prevent generic entry. In article 10 of directive 2001/83 it is provided that an applicant for marketing authorization shall not be required to provide the results of pre-clinical tests and of clinical trials if the applicant can demonstrate that the medicinal product is a generic of a reference medicinal product which is

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considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.”

<sup>13</sup> Directive 2001/83 on the Community code relation to medicinal products for human use [2001] OJ L311/67.

<sup>14</sup> AstraZeneca v. Commission of the European Communities (C-457/10 P) [2010] OJ C301/18. AstraZeneca has appealed.

or has been authorised for not less than eight years in a Member State or in the Community. Furthermore, with the amendments introduced by directive 2004/27 it is now provided in article 24, paragraph 4, of directive 2001/83 that any authorisation which within three years of its granting is not followed by the actual placing on the market of the authorised product in the authorizing Member State shall cease to be valid. A marketing authorization survives the discontinuation of the originator product for three years. Presumably this window is enough for generic companies to file an abridged application. This particular part of a switching strategy – abandoning a market authorisation – seems to have been made ineffective by amendments to EU legislation.

### 3 Generic substitution in pharmacies

The inability to prevent generic entry by withdrawal of a marketing authorisation, makes it only more important to switch patients to the second generation. Any patients not switched by the originator will due to rules on generic substitution in pharmacies automatically be supplied with the cheapest available generic. This situation is the result of an increasing political trend in recent years to promote the use of generic drugs.<sup>15</sup> Politicians are under pressure to reduce health care budgets and the use of patented expensive medicines is an easy target. Contributing to the use of generics is also a growing realization that there is very limited if any, cross-fertilization between high pharmaceutical outlays and R&D-spending by pharmaceutical companies.<sup>16</sup> R&D is located where R&D is most efficiently performed, not where the markets are. Generic substitution is probably the most efficient political tool to increase use of generics. It is a term that describes a scheme allowing or obliging pharmacists to dispense a generic version of a medication, even if the doctor had written the prescription for a specific brand. Generic substitution for reimbursed drugs was introduced in Sweden on 1 October 2002.<sup>17</sup>

The aim of the Swedish reform was to reduce costs for off-patent pharmaceuticals, through increased price competition from generic pharmaceuticals. The Swedish Medical Products Agency [SMPA] now continuously updates a list of products considered to be substitutable. The criteria are that they are deemed medically equivalent. The products must

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<sup>15</sup> Andersson K. A, Petzold M. G, Allebeck P. and A. Carlsten, 'Influence of mandatory generic substitution on pharmaceutical sales patterns: a national study over five years' *BMC Health Services Research* 2008, **8**:50 at 1. The electronic version of this article is the complete one and can be found online at: <http://www.biomedcentral.com/1472-6963/8/50>, last accessed 15.4.2012.

<sup>16</sup> Jack, Andrew 'Ailments encapsulated', *Financial Times* 16 February 2012 at 7,

<sup>17</sup> Swedish Act (2002:160) on Pharmaceutical Benefits, etc.

have the same active pharmacological substance and also the same strength and a comparable package size.<sup>18</sup> Pharmacy personnel are in these cases obliged to offer the patient the cheapest available substitutable drug according to the SMPA's list.<sup>19</sup> Physicians can restrict substitution, though, for medical reasons. A patient can also oppose substitution and retain a more expensive product, given that he or she pays the price difference between the prescribed and the cheapest (reimbursed) product out of pocket. The system is designed to guarantee that only the generic offered at the lowest price garner any sales. Price competition among generics and with the first generation product from the originator, is very intense because manufacturers can continuously update the price they ask for their substitutable products and the SMPA will amend their lists accordingly. The whole market for an off-patent medicament will be satisfied by the cheapest generic, except for a small number of cases where substitution is restricted.

The purpose of generic substitution is to cancel out certain prescribing habits of physicians. Doctors in most countries are subject to a vast array of drug promotion, which includes so called detailing (sales calls to doctor's offices), direct mailings, free drug samples, medical journal advertising and sponsored continuing medical education programs. Personal contacts with physicians have perhaps been the most important component in pharmaceuticals sales.<sup>20</sup> The purpose of pharmaceutical marketing has been to install a brand-name recall in physicians. Generic substitution counters this at a different level of the distribution chain (at the pharmacies). Effects of trade marks on off-patent pharmaceuticals are taken out of the competitive equation.<sup>21</sup>

One study completed after the introduction in Sweden of generic substitution has indicated a degree of success.<sup>22</sup> The research showed a proportionally larger increase in the volumes of dispensed substitutable (off-patent) pharmaceuticals, compared with non-substitutable (on-patents) pharmaceuticals, after the introduction of generic substitution. This was interpreted as evidence that physicians were aware of the system of substitution and therefore the price reduction available for substitutable pharmaceuticals. This is, however, far from conclusive evidence of the social value of generic substitution at pharmacies. Perhaps

<sup>18</sup> 8 § Swedish Act (1992:859) on Pharmaceuticals.

<sup>19</sup> 21 § Swedish Act (2002:160) on Pharmaceutical Benefits, etc.

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<sup>20</sup> Brezis M., 'Big pharma and health care: unsolvable conflict of interests between private enterprise and public health'. *Israel Journal of Psychiatry Related Science*, Issue 45 (2) at 83–9, discussion 90–4 (2008) and Sufrin C.B., Ross J.S., 'Pharmaceutical industry marketing: understanding its impact on women's health', *Obstetrical & Gynaecological Survey* 63 (9) at 585–96 (September 2008).

<sup>21</sup> Josefson, P. 'Tidsbegränsat varumärkesskydd för originalläkemedel – när det offentliga betalar väger immaterialrätten lätt', *Nordic Intellectual Property Review (NIR)* (2009) at 269.

<sup>22</sup> Andersson, et al., (supra n. 15).



total spending could have been reduced further if prices for generics were not the only policy focus.

#### 4 Switching facilitated by generic substitution

Rules on generic substitution in pharmacies obviously lead to increased price competition for a first generation product, but I will try to furnish an explanation as to why this will have an important unintended adverse effect: it will shield a follow-on product from effective competition. As with medicines, the adverse effects may make the beneficial effects not worth having. In the following section, I will then provide some tentative suggestions regarding article 102 TFEU and switching strategies. I will argue that some forms of marketing by originator companies of their second generation product, are abuses of a dominant position.

It has already been said that in a switching strategy the originator will *before* patent expiry for the original product introduce a follow on product. It has been claimed that projected sales for the follow-on product in the first three years after generic entry is nearly three times higher in this case, than if the reformulation (e.g. replacing a twice-daily version with one taken once a day) occurred only after generic entry.<sup>23</sup> The commercial significance of this is evident from the fact that generic entry will, at least in a few years, capture most if not all of the market for the first generation product. Substantial profits can only realistically be derived from the follow-on product.

An integral and important part of a switching strategy is intense marketing of the second generation product during the final phase of the exclusivity for the first generation product. Marketing is, of course, not normally anti-competitive.<sup>24</sup> It may be a problem, though, if significant marketing of the first generation product is not maintained. It will mean that consumers and physicians may be unable to discover the relative value of the products. When marketing of the second generation product is ramped up, the first generation will in a short time frame drastically fall in price. But physicians and patients are unlikely to understand this pending market change. Nor will they after generic entry decide to switch

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<sup>23</sup> Pharmaceutical Sector Inquiry, (supra n. 7.) at 6.

<sup>24</sup> Advertisement may e.g. be socially efficient if advertisement spending is less than the costs reductions that will be available to buyers when they can reduce their search costs and still find the best alternative. See Stigler, G. J. 'The Economics of Information', *Journal of Political Economy* Vol. 69, Issue 3 at 213 (June 1961) and see for a discussion on how trademarks are means to economize on search costs, Landes, W, and R. Posner, 'Trademark Law: An Economic Perspective', *Journal of Law and Economics* Vol. 30(2) at 265 (1987).

back. Patients will stay on the second generation prescription, partly because rules on generic substitution lead to a lack of marketing of the first generation, partly because doctors are generally hesitant to change what is a tolerated medicament.

Generics will not be marketed because after exclusivity and as generic substitution kicks in, any prescriptions of the first generation product or any specific generic automatically result in sales of the cheapest available generic. Marketing of the first generation product will become ineffective and therefore come to a halt some time before the end of the exclusivity.<sup>25</sup> As the second generation is introduced marketing efforts by the originator will have shifted. In fact, the originator will often highlight the advantages of the new product compared to the old.<sup>26</sup> The generic companies, on their side, have small or no incentives to invest in marketing. Their sole mode of competition is price, because any medically equivalent branded or generic medicine will be substituted by the pharmacist to the cheapest product available in the SMPA list. Thus, after launch of the second generation product, no sales representatives or any other form of marketing efforts will be dedicated to the first generation product. This leads to doctors receiving “an entirely one-sided presentation” of the relative merits of the products.<sup>27</sup> It has been concluded that:

“Unlike brand manufacturers, generic manufacturers cannot profitably exploit the price disconnect by detailing doctors. Detailing is very expensive and generally is not economically feasible once generics are available. If multiple generics of a product are or will soon be available, a manufacturer cannot profitably promote a generic product to doctors because a pharmacist could easily substitute some other manufacturer’s generic version of the same drug. Thus, if one generic seller promotes the product to doctors, other generic sellers can free ride on that promotion by having lower costs and offering prices below the promoting seller’s cost. For the same reason, brand manufacturers typically also stop detailing and otherwise promoting the brand product once generic versions are available. This post-generic-entry free-riding makes active promotion of the product by anyone – brand and generic manufacturers alike – economically infeasible. Unable to exploit the price disconnect by detailing doctors,

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<sup>25</sup> Josefson, (supra n. 21), at 272.

<sup>26</sup> Carrier, (supra n. 3,) at 1019.

<sup>27</sup> Ibid.

generic manufacturers make sales by offering low prices to pharmacies ... to substitute the generic for the brand.”<sup>28</sup>

This discrepancy in marketing resources weakens competition between the generics of the first generation product and the patented follow-on product. Reformulation combined with unequal marketing resources, eliminates both price and quality competition between two close substitutes. The originator switches its promotion to the new product and generics are not able to promote their product, leaving doctors incapable of effectively compare the second generation medicine and the first version. True, doctors may receive comparative information through academic studies and symposia, and specialist doctors may conduct their own comparisons by analysing the competing products. However, a mix of medically based concerns about switching to something new for the patient which may be a marginal disadvantage for some patients and the almost complete lack of marketing for the first generation product, probably leads to unnecessary levels of consumption of expensive follow-on pharmaceuticals.<sup>29</sup> Generic substitution, aimed at cost reductions, may therefore have the opposite effect and raise overall pharmaceutical expenditure. It is quite plausible that weak competition between second generation products and generics may be socially more costly, than the social gains from the price competition generic substitution creates between the first generation branded medicine and generics by other manufacturers. Another potentially damaging effect from switching strategies facilitated by rules on generic substitution is that originator companies will gear their R&D budgets towards incremental improvements of their existing pharmaceuticals, rather than socially more valuable but uncertain radical research avenues.

During the period 2003–2006, i.e. in the immediate after-math of the introduction of generic substitution in Sweden, the total public costs for subsidising pharmaceuticals rose. The rise occurred despite the expiry of exclusivity for some block buster medicines. Since 2006 the costs for prescription pharmaceuticals in Sweden have continuously increased, in a steady fashion. Year and costs in Swedish crones have been: 2006: 23 252 millions; 2007: 24 290 millions; 2008: 25 228 millions; 2009: 25 476 millions; 2010: 25 574 millions; 2011: 25 908 millions.<sup>30</sup> True, it is possible that various reforms, including generic substitution, have helped to restrain pharmaceutical expenditure, following a period of even higher, double

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<sup>28</sup> Shadowen, Leffler, Lukens, (supra n.5) at 7.

<sup>29</sup> Josefson, (supra n.21) at 273.

<sup>30</sup> Läkemedel – statistik för år 2011 table 2, at 20, available at <http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/18654/2012-3-28.pdf>, last accessed 15.4.2012

digit, growth in the 1990s.<sup>31</sup> But this is uncertain. Undeniably, total costs have increased and this is probably partly due to successful switching strategies and the weak competition between generics and second generation medicines. Lack of competition between generics and second generation products is of course not peculiar to Sweden, but has been deemed one of the most concerning issues in the patent-antitrust intersection today.<sup>32</sup>

The Swedish legislator appears to have assumed that the risks inherent in switching to follow-on medicines with marginal therapeutical advantages, could be handled by the negotiations that must take place between an originator company and the SMPA. The SMPA should only accept proposed prices after a comprehensive analysis of the pharmaceutical's therapeutic benefits, whereby consideration is also given to a comparison with available older products. A small therapeutic benefit should only allow a small price increase over existing therapies. However, this is a regulatory process infused by uncertainties and with potential for gaming of the process. The stakes are high for the originator company and there is never a clear answer to the therapeutic value of a follow-on product. ~~It may, I believe, be too much to~~ ask of the SMPA that they will be able to set a price that truly reflects the sometimes marginal improvements of a follow-on product compared to the first generation product.<sup>33</sup> This type of dynamic competition is typically better handled by a well-functioning market than by a regulator, which brings us back to the realm of competition law.

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## 5 Tentative solution under article 102 TFEU

It is beyond the scope of this article to provide anything but some tentative suggestions concerning ways to address switching under competition law. A starting point will be that it may not be enough merely to hold that switching strategies are unlawful when dominant manufacturers withdraw the marketing authorization for the original product, as the General Court held in the AstraZeneca case:

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<sup>31</sup> Moïse, P, and E. Docteur, 'Pharmaceutical Pricing and Reimbursement Policies in Sweden', *OECD Health Working Papers* No. 28. Available at SSRN: <http://ssrn.com/abstract=1329310>.

<sup>32</sup> Carrier, (supra n. 3), at 1009.

<sup>33</sup> Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report, (supra n. 4), at 14-15, in which the EU Commission held that: "Stakeholders and in particular originator companies, also complained about the uncertainty of prices/reward when developing new medicines. The duplication of national assessments that try to establish the 'added value' of the new medicine over and above existing medicines was specifically mentioned. There is general interest in cross-border collaboration on scientific aspects of added value assessments. In this respect the Commission points to the fact that the duplication of the scientific assessments in the Member States results in additional costs, which are ultimately borne by the consumers/tax payers. Also there is a risk of contradicting decisions on essentially the same questions. Moreover, at this stage smaller Member States do not always have the means for the scientific assessments and thus do not benefit from the possibilities available to larger Member States."

“In the present case, there is no reason to reproach AZ either for launching Losec MUPS or for withdrawing Losec capsules from the market, since those acts were not such as to raise the legal barriers to entry complained of by the Commission that were capable of delaying or preventing the introduction of generic products and parallel imports. By contrast, the deregistration of the Losec capsule marketing authorisations cannot be regarded as within the scope of competition on the merits.”<sup>34</sup>

This holding in the AstraZeneca case – that the only questionable tactic is the withdrawal of the marketing authorisation for the first generation – is not fully supportable from the perspective of either economics or law. The General Court simply assumed that the launch of Losec MUPS provided a new alternative and therefore did not raise legal barriers to entry. Of course, the law seeks to foster innovation and any claim that an introduction of a new product is anticompetitive should be met with a great deal of skepticism. However, it is too simplistic to assume that “launch” of a new product merely entails passively making the product available for consumers. In almost all cases marketing is necessary and competition law scrutiny could be focused on this, rather than on the originator’s technical product development. Even a small modicum of product improvement is beneficial for someone, but marketing is, from a competition and economic perspective, a more ambivalent practice and an easier target for scrutiny.<sup>35</sup> True, marketing is of course fully legitimate for a dominant firm launching a new product. Under article 102 TFEU, marketing of a second generation product can therefore not in and by itself be an abuse. I will argue, though, that certain specific and well-defined marketing efforts abuse a dominant position in the special context of the pharmaceutical field. The marketing will prevent the up-take of generics and constitute deviations from competition on the merits.

For a host of reasons, it is evidently important with high standards concerning marketing of pharmaceuticals, but from a competition perspective this is especially true in the time-span between the launch of the follow-on product and the loss of exclusivity for the first generation medicine (typically a period one year and five months).<sup>36</sup> Still, it is probably too

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<sup>34</sup> Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-0000 (not yet officially reported) at points 811-812.

<sup>35</sup> Becker and Murphy note that “[m]ost economists and other intellectuals have not liked advertisements that provide little information” and that persuasive advertising is claimed to “change and distort tastes”. See Becker G and K. Murphy, ‘A Simple Theory of Advertising as a Good or Bad’, *Quarterly Journal of Economics* at Vol. 108 at 941 (1993).

<sup>36</sup> Pharmaceutical Sector Inquiry, (supra n. 7), at 5.

harsh to generally ban marketing of the second generation product even in this crucial time span. The reason being that there is no point for an originator to try to develop a new product, if it cannot effectively be brought to the attention of buyers. One could, though, reasonably deem it abusive of a dominant position to negatively compare the first generation product with the second generation product in this period. A dominant firm's price or quality comparisons between its first and second generation pharmaceutical in a marketing context should, I believe, be deemed abusive as long as the first generation product is still benefitting from exclusivity.

In effect, negative statements concerning the first generation product are in this period statements directed at soon to be launched generic products. It is not obvious, but in the switching window any marketing messages formally directed at the first generation product are in practice concerned with competitors' future generic products. This is a direct consequence of the rules on generic substitution and discrediting statements concerning competitors' products are normally not allowed under EU marketing law.<sup>37</sup> The risks that consumers will be misled are too high. In this particular time period, patients and doctors will not be able to fully evaluate promoted medical benefits of the second generation, taking into account the drastic drop in price that is about to occur for the first generation product. Negative statements are likely to mislead about the relative value of the soon to be launched generics, due to generic companies inability to respond. During exclusivity generics may not legally be marketed due to the patent on the first generation product. After patent expiry generics cannot realistically be market for economic consequences flowing from the rules on generic substitution.

Another rationale for not accepting negative statements concerning the first generation product as competition on the merits, is that resulting patient migration is not profit maximizing for the originator absent the competitive changes that will arise in the near future for the first and second generation products. When the comparative advertisement is made the second generation product is normally no more profitable than the first generation product for the originator. The marketing is only profit-maximizing because switched patients will after migration be mostly captured, i.e. not exposed to pending generic competition. They are locked in due to a lack of marketing funds for generics and rigidities in physicians prescribing practices. If a profit-maximizing firm engages in conduct that would not be

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<sup>37</sup> Directive 2006/114/ of 12 December 2006 concerning misleading and comparative advertising, article 4 (d): "Comparative advertising shall, as far as the comparison is concerned, be permitted when the following conditions are met ... it does not discredit or denigrate the trade marks, trade names, other distinguishing marks, goods, services, activities or circumstances of a competitor ..."

economically rational (i.e. increase overall profits) absent a reduction in competition, then it can be inferred that the firm was aware of and motivated to achieve that anticompetitive effect.<sup>38</sup> Negative messages in general about the first generation product and comparisons with the second generation product in particular, are not profit-maximizing for the originator in the short time frame, but will be when competition develops differently in the near future for the first and second generation products. In *Hoffmann-LaRoche* the ECJ held that by prohibiting the abuse of a dominant position, Article 102 TFEU covers not only abuse which may directly prejudice consumers, but also abuse which indirectly prejudices them by impairing the effective competitive structure.<sup>39</sup> This statement has been endorsed in several subsequent judgments.<sup>40</sup> Switching will do just that. Under the *Hoffman-LaRoche* standard a dominant firm may also not take advantage of its position to prevent the growth of new competition. Again, negative statements concerning its own first generation product are designed to delay the future increase of generic sales.

In the telecommunication field, the Commission has deemed it to be abusive to make random changes of primary product specifications that render secondary products of competitors useless or give the producer of the primary product a significant head start on the secondary product market. In the case in question a company operating a navigation radio network abused its dominant position for the secondary products, radio receivers for shipping, when it randomly changes the radio signals sent from the land-based stations operated by the dominant company.<sup>41</sup> The company also made unjustified claims that the changes in frequencies amounted to technical improvements, when in reality they were merely intended to make life more difficult for manufacturers of competing radio receivers. The parallel could be that a dominant company is allowed to modify its product, even when the modifications amount to no significant improvement (change of frequency or chemical composition), but it may not use the particular modification procedures for gaining a competitive advantage, such as a head-start.

It must be added that, of course, marketing in ordinary circumstance is overwhelmingly pro-competitive. Any conclusion that the marketing is anti-competitive must not be taken lightly. Branding is a significant cost and generally only worth doing when there is something

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<sup>38</sup> Shadowen, Leffler, Lukens, (supra n. 5), at 76.

<sup>39</sup> C-85/76, *Hoffmann-LaRoche v. Commission*, [1979] ECR 461 par. 125.

<sup>40</sup> See joined cases 40-48, 50, 54-56, 111, 113-114/73, *Suiker Unie and others v. Commission* [1975] ECR 1663, paras 125 and 526, case 27/76 *United Brands v. Commission* [1978] ECR 207, paras 159 and 183, case 202/07 P *France Telecom v. Commission*, 2 April 2009.

<sup>41</sup> 89/113/EEC: Commission Decision of 21 December 1988 relating to a proceeding under Articles 85 and 86 of the EEC Treaty (IV/30.979 and 31.394, Decca Navigator System).

of substance to promote (otherwise the brand quickly becomes worthless and expenditure on the brand is lost).<sup>42</sup> But efforts discouraging sales of the originator's old pharmaceutical products is, I believe, a special case, arising not mainly because of substantive product developments but due to two visible and upcoming regulatory events: patent expiry and generic substitution. It is not common commercial practice, e.g. by car or IT manufacturers, to actively discourage sales of an older version, at least not as long as the old version is just as profitable as the new version. Originator companies are, of course, fully aware of the chain of event that will be set in motion by patent expiry and rules on generic substitution. Competition law cannot fulfil its function properly if it is blind to the fact that in special cases marketing may have anti-competitive effects.

## **6 Conclusions**

This article has described switching strategies employed by pharmaceutical originator companies and tried to analyse what, if any, activities beyond the withdrawal of a marketing authorization (identified as anti-competitive in the AstraZeneca-case), may be abuses of a dominant position under article 102 TFEU. The focus has been on marketing due to its importance and the glaring differences between generic companies and originators in this respect. The conclusion reached is that marketing is, of course, pro-competitive in most cases, but due to the special regulatory context in the pharmaceutical industry, it may be necessary to evaluate marketing differently. Marketing by an originator company can be used to salvage customer groups from falling into up-coming generic competition. Still, dynamic, Schumpeterian, competition is probably too important for a ban on all marketing of a second generation product during the last phase of patent protection for a first generation product. Only a practice of casting the qualities of the first generation product in a bad light is, I believe, an abuse by a dominant firm. It is in effect discrediting a competitor's upcoming product, something usually not allowed for any company and a dominant firm has a special responsibility under article 102 TFEU not to impair competition.

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<sup>42</sup> See empirical findings to this effect in Demsetz,H, 'The Effect of Consumer Experience on Brand Loyalty and the Structure of Market Demand,' *Econometrica* 30:1 at 22 (1962).