EN

Case No COMP/M.5530 - GLAXO SMITH KLINE/ STIEFEL LABORATORIES

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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Markets and cases III: Financial services and Health-related markets

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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party:

Dear Sir/Madam,

Subject: Case No COMP/M.5530 - GlaxoSmithKline/ Stiefel Laboratories
Notification of 15 June 2009 pursuant to Article 4 and following a referral pursuant to Article 4(5) of Council Regulation No 139/2004[1]

I. INTRODUCTION

1. On 15 June 2009, the Commission received a notification of a proposed concentration pursuant to Article 4 and following a referral pursuant to Article 4(5) of Council Regulation (EC) No 139/2004[2] ("the Merger Regulation") by which the undertaking GlaxoSmithKline plc ("GSK", UK) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking Stiefel Laboratories, Inc. ("Stiefel", USA) by way of a corporate merger of a subsidiary GSK into Stiefel, as a result of which Stiefel will be wholly controlled by GSK.

II. THE PARTIES

2. GSK is a pharmaceutical company registered in United Kingdom. It is active in discovery, development, manufacture and commercialization of pharmaceutical products and consumer health related products worldwide.

1 OJ L 24, 29.1.2004 p. 1.

2 Ibid.

3. Stiefel Laboratories is a pharmaceutical company registered in USA, active in discovery, development, manufacture and commercialization of pharmaceutical products, in particular dermatological pharmaceutical and skin care products.

III. THE OPERATION

4. The notified operation consists in acquisition of control by GSK over Stiefel by way of a corporate merger of a subsidiary of GSK into Stiefel, as a result of which Stiefel will be wholly controlled by GSK. Therefore the transaction constitutes a concentration in the meaning of Article 3 of the Merger Regulation.

IV. COMMUNITY DIMENSION

5. The concentration does not have a community dimension within the meaning of Article 1 of the Merger Regulation as the Community–wide turnover of one of two undertakings concerned (Stiefel) is EUR […] million i.e. it is lower than EUR 250 million and Stiefel does not have an aggregate turnover of more than EUR 25 million in each of three Member States, as it achieves a turnover of more than EUR 25 million only in UK.[3]

6. Given the multiple filing requirements in at least three Member States (and more specifically in Austria, Germany, Greece, Ireland, Italy, Poland, Slovakia, Spain, and United Kingdom) and the cross-border nature of the transaction, the case was referred to the Commission under Article 4(5) of the EC Merger Regulation for the purpose of its competitive assessment. No Member State opposed to the referral.

V. RELEVANT MARKETS

Existing pharmaceutical specialities (or "finished dose pharmaceuticals")

7. The Commission identified the market for existing pharmaceutical specialities in its previous decisions.[4] According to the Commission, the market for existing pharmaceutical specialities could be further classified into therapeutic classes by reference to the Anatomical Therapeutic Chemical Classification ("ATC") devised by European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by Intercontinental Medical Statistics ("IMS"). The ATC classification consists of four different levels.

8. The third level, referred to as ATC3, allows medicines to be grouped in most cases according to their therapeutic indications (i.e. their intended use) and is generally taken as the starting point for the market definition. However, it may be appropriate to carry out analyses at other levels (e.g. ATC4), or across classes, if specific circumstances indicate that the ATC3 level is not the most appropriate for the purposes of the market definition.

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3 Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p1).

4 See e.g. Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*.

9. In the past the Commission has in several cases considered competition at the more detailed, molecule level.[5] The molecular level in the present case does not appear pertinent. The Parties do not generally overlap on the molecule level.[6]

Prescription and OTC pharmaceuticals

10. In its previous decisions the Commission considered the division within the existing pharmaceutical specialities between prescription (Rx) pharmaceuticals and over the counter (OTC) pharmaceuticals because medical indications (including possible side-effects), legal framework, marketing and distribution all tend to differ between the two categories of medicines, even when the active ingredients are identical.[7] In the present case the Parties accordingly provided market shares with respect to these categories for each affected ATC3, and where relevant, ATC4 class.

11. The Parties provided OTC market data based on the proprietary OTC classification of IMS. The IMS OTC classes are based on the intended use/indications of the products. In most cases there is an ATC3 class that corresponds to an IMS OTC class, although in some cases there are more than one IMS OTC classes corresponding to an ATC3 class. Parties provided OTC data both on the basis of both the IMS classification and also reconstructed the IMS OTC classification to provide OTC data corresponding to the ATC3 classification.

12. The question whether OTC or Rx pharmaceuticals belong to the same or to different markets and whether the IMS OTC classification is the relevant basis for market definition can be left open as the transaction does not raise competition concerns irrespective of these distinctions.

Horizontal overlaps

13. The Parties identified the following ATC3 classes in the existing pharmaceutical specialities market in which the transaction would lead to combined market shares of 15% or higher based on ATC3 or, where relevant, ATC4 or molecule level: dermatological antifungals (D1A), emollients & protectives (D2A), topical antipsoriasis products (D5A), topical viral infection products (D6D) and plain topical corticosteroids (D7A).

D1A Dermatological Antifungals

14. Dermatological antifungals are mainly used for the treatment of skin infections caused by fungus. This class includes both prescription and OTC pharmaceuticals. In its

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5 See case COMP/M.5253 *Sanofi-Aventis/Zentiva* or case COMP M.5295 – *Teva/Barr*.

6 In one ATC3 category, D5A, both Parties have products containing coal tar as one of the active ingredients. However, in the Parties' respective products coal tar is combined with other different ingredients in different formulations.

7 See f.ex. case COMP/M.5253 *Sanofi-Aventis/Zentiva,* case COMP/M.3751 *Novartis/Hexal*, COMP/M.3544 *Bayer Healthcare/Roche*, or case M.3394 *Johnson and Johnson/J&J MSD Europe*.

previous decisions the Commission identified the corresponding ATC3 category - dermatological antifungals - as a distinct product market.[8]

15. The ATC3 D1A class could be further divided into the following ATC4 classes: topical dermatological antifungals (D1A1); systemic dermatological antifungals (D1A2); and topical scalp antifungals (D1A3). In previous decisions the Commission examined the relevant product market at the ATC4 level but finally left the market definition open. The Parties do not overlap on the ATC4 or molecule level.

16. For the purpose of this decision, however, the exact product market definition can be left open since the transaction is not likely to lead to competition concerns in the D1A class, irrespective of the market definition chosen.

D2A Emollients & Protectives

17. Emollients and protectives are substances used to soften or soothe the skin. They are also used to correct dryness and scaling of the skin. Emollients and protectives are ingredients used for the manufacture of lipsticks lotions and other cosmetic products. This class includes both prescription and OTC pharmaceuticals. It is not subdivided into ATC4 classes and the Parties do not overlap on the molecule level.

18. For the purpose of this decision the exact product market definition can be left open since the transaction is not likely to lead to competition concerns in the D2A class, irrespective of the market definition chosen.

D5A Topical Antipsoriasis Products

19. Topical antisporiasis products are used for the relief of skin irritation resulting from psoriasis and are applied directly to the skin. This class includes both prescription and OTC pharmaceuticals. The ATC3 class D5A is not further subdivided into ATC4 classes.

20. Both Parties have products containing coal tar. Coal tar appears to be an active ingredient widely used in the products used for the topical treatment of psoriasis. It also has significant applications outside the pharmaceutical sector. The Parties's respective products include coal tar in combination with other active ingredients. GSK's products from the "Alphosyl" range contain coal tar in combination with allantoin and/or hydrocortisone. Stiefel's "Polytar" range contains coal tar in combination with other active ingredients including Arachis Hypogaea and Cade Oil. It is therefore arguable if the Parties do overlap on the molecule level the same way as was considered in previous decisions[9]. This notwithstanding, the competitive assessment also considered a hypothetical market composed of products containing coal tar at least as one of their active ingredients.

21. For the purposes of this decision the exact product market definition can be left open since the transaction is not likely to lead to competition concerns in the D5A class, irrespective of the market definition.

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8 See f.ex. Case COMP/M.5253 *Sanofi-Aventis/Zentiva* or case COMP/M.4341 *Johnson&Johnson/Pfizer.*

9 See f.ex. Case COMP/M.5253 *Sanofi-Aventis/Zentiva or M.5295 Teva/Barr*

D6D Topical anti-virals

22. Topical anti-virals are used to treat viral infections of the skin and are applied topically, usually as a cream or ointment but also sometimes as a spray or powder. This class includes both prescription and OTC pharmaceuticals.

23. The D6D ATC3 class is further subdivided into the following ATC4 classes: (i) topical antivirals (ATC4 class D6D1) which include topical forms of anti-virals (products targeting the underlying virus), e.g. acyclovir, idoxuridine and podophyllotoxin; and (ii) other topical products used in viral infections (ATC4 class D6D9) which include products used for the symptomatic treatment of viral infections such as herpes simplex.

24. In the D6D class the Parties are active with the following products (both products belong to the same ATC4 category, D6D1):

    - "Zovirax"(GSK) is indicated for treatment of skin infections produced by the herpes simplex virus, for example cold sores and genital herpes. Zovirax contains the active ingredient *acyclovir*. Zovirax is available both on prescription and over the counter. Zovirax also has a non-topical form falling into another ATC3 category J5B (Anti-virals).

    - "Wartec" (Stiefel) is indicated for the treatment of anogenital warts caused by the human papilloma virus. Wartec contains the active ingredient *podophyllotoxin.* Wartec is only available on prescription.

25. In a previous decision[10] the Commission considered the ATC3 category to be the relevant basis for analysing the D6D market.

26. The Parties submit that, although their products belong to the same ATC3 and ATC4 class, they have different indications and are not substitutable. In particular *acyclovir* (Zovirax) is a treatment used in infections caused by the herpes simplex virus, whereas podophyllotoxin (Wartec) is used to treat genital warts caused by the human papilloma virus. The Parties submitted doctors' prescription data from IMS for Europe in support of this argument. This data covers three years (2006-2008) and shows written prescription numbers per pharmaceutical for the leading five diagnoses in the D6D class for 14 EEA Member States based on a small sample of doctors and days. This data does not indicate any consistent substitution between acyclovir and podophyllotoxin for the diagnoses listed. Prescriptions for one product for diagnoses where another product has significant use were only sporadic.

27. The market investigation confirmed the lack of substitutability between acyclovir (Zovirax) and podophyllotoxin (Wartec) as they are used for different purposes i.e. for the treatment of different diseases (Zovirax is used mainly for treatment of cold sores and genital herpes and Wartec is used for the treatment of genital warts).

28. The basic distinction regarding the substitutability of the two products was indicated to be the type of virus/underlying disease they are targeting, which does not correspond to the ATC classification. This may serve as a starting point for delineating markets in this segment. Based on this distinction, Zovirax and Wartec belong to different relevant markets. However, the exact delineation of the respective markets to which Zovirax

[10] Case COMP/M.1846 *Glaxo Wellcome / Smithkline Beecham.*

and Wartec belong is not necessary in the present case, i.e. the market definition regarding other products used for the treatment of skin viral infections can be left open.

29. In addition to Wartec, Stiefel has another product called *Duofilm*. This is a product used for removing corns, calluses and warts, i.e. it is not a specific anti-viral product. It is used as a symptomatic treatment and does not target a virus specifically. Duofilm is essentially an acid that is used to burn corns, calluses and warts off. It is available both OTC and Rx. It contains *salicylic acid* as an active ingredient. Duofilm is available both on prescription and over the counter. According to the Parties, IMS classifies "Duofilm" in the ATC3 class D11A and in the OTC class 06L1 (wart, corn and callous removers excluding plasters). Topical Zovirax on the other hand is classified in the ATC3 class D6D and the IMS OTC class 06K1 (Cold sore treatments).

30. Topical anti-virals and other topical products used to treat skin infections appear to be a group of products where the IMS OTC classification does not exactly correspond to the ATC classification. According to the Parties, the OTC segment of the D6D ATC3 class can be best reconstructed by combining 06K1 and 06L1. Due to this reconstruction, however, an artificial overlap emerges between Duofilm and Zovirax.

31. None of respondents in the market investigation indicated Zovirax to be a close substitute/competing product to Duofilm.

32. Based on the results of the market investigation, the differences in their indications and mechanism of action, their different ATC3 and IMS OTC classification it appears that Duofilm and Zovirax do not belong to the same relevant market. However, the market definition can be left open as the transaction does not raise competition concerns irrespective of the market definition.

D7A Plain Topical Cortisteroids

33. Plain topical corticosteroids are used to reduce inflammation, redness and itching. They are most often used to treat atopic dermatitis or eczema but can be used for many other skin conditions as well.

34. The D7A class contains both – prescription and OTC pharmaceuticals. The ATC3 class D7A is not further subdivided into ATC4 classes and the Parties do not overlap on the molecule level.

35. For the purpose of this decision the exact product market definition can be left open since the transaction is not likely to lead to competition concerns in the D7A class, irrespective of the market definition chosen.

Contract manufacturing

36. According to the Commission's previous decisions contract manufacturing of finished dose pharmaceuticals (contract manufacturing) consists in the manufacturing under contract, on behalf of third party pharmaceutical companies, of finished pharmaceutical products, which may or may not include final packaging.[11]

[11] See case COMP/M.5253 *Sanofi-Aventis/Zentiva.*

37. In its previous decisions the Commission has left open whether contract manufacturing should be delineated further, e.g. by the technology needed to produce different forms of pharmaceuticals or by type of API used.[12]

38. Both Parties are active in contract manufacturing. The products they manufacture use standard technologies, i.e. they do not require any dedicated facilities and know-how, which would indicate the need to consider defining separate markets withn contract manufacturing.

39. For the purposes of the assessment of this transaction the exact definition of the market can be left open as the transaction is not likely to give rise to competitive concerns irrespective of the exact market definition.

GEOGRAPHIC MARKET DEFINITION

Existing pharmaceutical specialities (or "finished dose pharmaceuticals")

40. The Commission has found in its previous decisions, that the markets for existing pharmaceutical specialities are national at scope due to different regulatory controls for pharmaceutical products, differences in price setting and reimbursement between Member States.[13]

41. The Parties consider that there might be scope for defining broader geographic markets in the EEA however for the purposes of the notification they submitted the data on national markets.

42. The market investigation did not indicate a need to depart from the geographic market definition used in previous Commission decisions

Contract manufacturing

43. In its previous decisions the Commission indicated that the market for contract manufacturing was at least EEA-wide and likely to be a world-wide market, but left the market definition open.[14] For the purposes of the present transaction the market definition could be left open as the transaction does not lead to any competition concerns in the contract manufacturing market irrespective of the geographic market definition.

12 Ibid.

13 See e.g. Case COMP/M.4007 Reckitt *Benckiser/BOOT Healthcare International*; Case COMP/M.4198 *Bayer/Schering*.

14 Case COMP/M.5253 – *Sanofi-Aventis/Zentiva*.

VI. COMPETITIVE ASSESMENT

Horizontally affected markets

44. The transaction gives rise to a number of horizontally affected markets in the following ATC3 classes: D1A, D2A, D5A, D6D and D7A.

45. In previous decisions regarding the pharmaceutical sector the Commission considered that in markets where a concentration would give rise to combined market shares of below 35% and/or with an increment below 1% competition concerns are unlikely to arise[15].

D1A

46. In D1A GSK markets Clotrimazole Glao and Undofen Max (ATC4 category D1A1) and Stiefel markets Stieprox (ATC4 category D1A3). The Parties products do not overlap either on the ATC4 or the molecule level. In the ATC3 class the transaction would not lead to combined market shares exceeding 35%. The proposed transaction is therefore not likely to lead to competition concerns.

D2A

47. The D2A segment is not subdivided into ATC4 categories and the Parties do not overlap at the molecule level. At the ATC3 level the transaction would only give rise to a market share of over 35% in the OTC segment of the market in Poland (combined market share [40-50]%, Stiefel [30-40]%). There are a number of competitors in the D2A class, namely: Nepentes ([20-30]%), Almirall ([5-10]%) and others.

48. In Poland GSK is active with the product "Cutibaza". Stiefel is active in this class in Poland with a number of products of which "Oilatum" has the highest market share (more than [80-90]% of all Stiefel products in Poland). The other Stiefel products in D2A class in Poland are "Oilatum Plus", "Physiogel" and "Driclor pl".

49. The market investigation confirmed that the parties' products could be considered as substitues. However, it also confirmed the presence of a number of credible competitors to the Parties in Poland, in particular Nepentes, Almirall, Oceanic, Ziołolek and Schering Plough.

50. Given the existence of several credible competitors in the D2A segment in Poland as well as the small increment due to GSK ([0-5]%) the transaction is not likely to lead to competition concerns.

D5A

51. The D5A segment is not subdivided into ATC4 segments. The Parties, however, both have products containing coal tar as an active ingredient. The Parties overlap in the UK and Ireland, but the transaction would lead to combined market shares of over 35% in the ATC3 OTC level only in the UK (combined [30-40]%, Stiefel [20-30]%).

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15 The most recent decisions are Case COMP/M.5253 – *Sanofi-Aventis/Zentiva* and Case COMP/M.5295 *Teva/Barr.*

52. GSK is active in the UK market with the "Alphosyl" product range while Stiefel is active mainly with "Polytar" ([70-80]% of the products of Stiefel in D5A class in the UK). The other Siefel's products in D5A class in UK are "Oilatum" and "Polytar Plus".

53. According to the Parties there are a number of competitors to the Parties' products in the D5A segment in UK, e.g. Dermal ([10-20]%), UCB ([10-20]%), Johnson & Johnson ([10-20]%) and others.

54. The market investigation confirmed the existence of competitors to GSK and Stiefel in the D5A class in UK, such as: Dermal, Johnson & Johnson, Alliance and others.

55. Furthermore, market shares in UK remain below 35% if only products containing coal tar are included (also in the respective Rx and OTC segments).

56. As the parties' combined market share in the UK is only slightly over 35% and given the presence of credible competitors confirmed by the market investigation, the transaction is unlikely to lead to any competition concerns in the OTC segment of the D5A market in the UK.

D6D

57. As explained above Wartec and Zovirax are not substitutable. The overlap in the D6D class between these two products is therefore not relevant for the competitive assessment.

D6D OTC

58. The transaction would lead to a combined market share of 35% in France ([10-20]% increment by Stiefel's Duofilm)[16] in the combined 06K1/06L1 segment, which, according to the parties best corresponds to the ATC3 level classification.Competitors in this combined segment would include Omega Pharma ([20-30]%), Pierre Fabre ([5-10]%), Cooper France ([0-5]%) and others.

59. The market investigation indicated the following competitors to Duofilm in France: Pierre Fabre (Kerafilm, Tramsvercid); Tradiphar (Pommade Cochon) and Bailleul – Biogre (Verrufilm). As mentioned above, Zovirax was not indicated as a close substitute or competing product to Duofilm.

60. Based on the fact that Parties would have a market share of exactly 35% and the presence of other credible competitors to Duofilm, the transaction is unlikely to lead to competition concerns in the combined segment of the IMS classes 06K1 and 06L1 even in the unlikely scenario that Zovirax and Duofilm was considered to be in the same hypothetical relevant market.

D7A

61. The D7A segment is not subdivided into ATC4 categories and the Parties do not overlap at the molecule level. The transaction would lead to an affected market only in Portugal, where GSK markets several products (Dernovate, Betnelan, Cutivate and Eumovate), while Stiefel markets only one product, Lactitare. Parties would have a

16 Based on the overlap between Zovirax and Duofilm that would occur due to the reconstruction of the OTC segment of D6D by combining the IMS OTC classes 06L1 and 06K1,

combined market share of [20-30]% (Rx only) or [20-30]% (total D7A) with a marginal increment of <[0-5]% added by Stiefel. Given the small market share and increment, the transaction is unlikely to lead to competition concerns.

Vertically affected markets

62. The transaction could also lead to a number of technically affected markets resulting from the vertical relationships, as on the number of segments in existing pharmaceutical specialities (based on ATC3 class) the Parties' individual or combined market share is above 25% and both of the Parties are active in contract manufacturing, which is upstream to existing pharmaceutical specialities.

63. The Parties provide that in the dermatological sector, GSK and Stiefel are active in contract manufacturing to a very limited extent. Contract manufacturing in dermatological sector contribute to [0-5]% of total turnover of GSK and [0-5]% of total turnover of Stiefel. The Parties' products that are manufactured on a contract for third parties do not have the same API. The Parties also confirm that they both use standard technologies that are widely available and that their combined market shares would be below 15% on any hypothetical contract manufacturing market.

64. Furthermore, the Parties submit that they do not have an individual or combined market share in excess of 25% in any ATC3 class in any Member State where a third party has entered into a contract manufacturing arrangement with either GSK or Stiefel and sells products in the same ATC3 category.

65. The transaction is therefore unlikely to give rise to competition concerns in respect of contract manufacturing.

Potential competition

66. GSK […]Phase III dermatological products in the pipeline. Stiefel on the other hand has four pipeline products that have reached Phase III, […]of which is expected to be eventually launched in the EEA. These products would be classified in D10A and D5A when they reach the market. Based on IMS data, GSK does not have market shares in excess of 35% in either of these two classes either on the Rx or OTC segment. There is therefore no indication that the potential competition presented by these pipeline products would be more significant that the competitive pressure stemming from actual competitors.

67. Based on the above, the transaction is unlikely to lead to competition concerns due to pipeline products.

VII. CONCLUSION

68. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation (EC) No 139/2004.

For the Commission
(signed)
Neelie KROES
Member of the Commission