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EUROPEAN COMMISSION
DG Competition

Case M.7787 - PANASONIC HEALTHCARE / BAYER'S DIABETES CARE BUSINESS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 23/11/2015

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EUROPEAN COMMISSION

Brussels, 23.11.2015
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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

To the notifying party:

Dear Sir/Madam,

Subject: **Case M.7787 – PANASONIC HEALTHCARE / BAYER'S DIABETES CARE BUSINESS**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

(1) On 22 October 2015**,** the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Panasonic Healthcare Holding Co., Ltd. ("PHCHD", Japan), holding company of Panasonic Healthcare ("PHC"), indirectly controlled by private equity funds managed by affiliates of KKR & Co. L.P. ("KKR", USA), acquires within the meaning of Article 3(1)(b) of the Merger Regulation, sole control of Bayer AG's diabetes care business ("BDC", Germany) by way of purchase of shares and assets.[3]

(2) PHC and BDC are designated hereinafter as "the Parties".

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1 OJ L 24, 29.1.2004, p. 1 ('the Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

2 OJ L 1, 3.1.1994, p.3 ("the EEA Agreement").

3 Publication in the Official Journal of the European Union No C 357, 29.10.2015, p.16.

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1. THE PARTIES

(3) PHCHD is a Japanese company active worldwide, through its operating company PHC, in developing, manufacturing, selling and servicing medical equipment. PHCHD has 15 subsidiaries in Asia, North America and Europe (including one European subsidiary, Panasonic Biomedical Sales Europe B.V.). One of the areas PHC is active in is in vitro diagnostic ("IVD") devices (for example, blood monitoring systems).

(4) KKR is a global asset manager and provider of financial advisory services.

(5) BDC is active in the distribution of blood glucose monitoring systems ("SMBG systems").

2. THE OPERATION AND THE CONCENTRATION

(6) The Transaction will be effected by way of purchase of shares and assets within the conditions set forth in the Share and Asset Purchase Agreement ("SAPA") entered into by the Parties on 8 June 2015. Under the SAPA, PHCHD will acquire (i) all of the shares in Delphi Diabetes Care Deutschland GmbH ("NewCo"), a newly established company for the purpose of receiving certain assets, rights and obligations relating to certain data and a database exclusively used for the business of BDC, and (ii) assets pertaining to the activities belonging to BDC, currently embedded with various subsidiaries of Bayer AG, pursuant to a number of local asset deal agreements with such subsidiaries.

(7) The Transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

3. EU DIMENSION

(8) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (KKR: EUR […]; BDC: EUR 900 million[…]).[4] Each of them has an EU-wide turnover in excess of EUR 250 million (KKR: EUR […]; BDC: EUR […]), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.

(9) The notified operation therefore has an EU dimension.

4. COMPETITIVE ASSESSMENT

(10) SMBG systems manufacturers and distributors can be either vertically integrated or non-vertically integrated, depending on whether they perform both manufacturing and distribution in-house.

(11) PHC manufactures SMBG systems; it does not distribute them, but relies on third-party distributors (BDC to a very large extent). BDC does not manufacture SMBG systems, but only distributes systems manufactured by third parties, mainly PHC's. BDC is PHC's primary distributor of SMBG systems, accounting for most of

4 Turnover calculated in accordance with Article 5 of the Merger Regulation.

PHC's systems sales worldwide and almost all in the EEA. Consequently, there is a vertical relationship between the Parties regarding SMBG systems.[5]

4.1. Product market definitions

(12) SMBG systems are used by patients at home to measure glucose concentration in capillary blood samples. They are commonly composed of a glucose meter and disposable sensors (also called "reagent" strips, "test" strips, or assays) which are inserted into the meter.

(13) Glucose meters are portable, handheld, battery operated instruments used in conjunction with disposable sensors to rapidly measure glucose concentration in a small sample of blood. Sensors are disposable strips on which a very small blood sample is laid and that are inserted in the meter for glucose reading. Measurements rely on electrochemical or color responses which are automatically measured and equated to glucose concentration in the sample. In the EEA sensors are proprietary and patent-protected and can be used with only one brand of meter, which means that the glucose meters and sensors of one company cannot be used interchangeably with those of another.

(14) SMBG systems also use a lancing device to draw a very small amount of blood from a patient's finger. These are spring-powered, pen-size contraption devices that advance and retract a small sharp piece of metal called a lancet. Unlike sensors, lancing devices are generic and can be used with any SMBG system. Besides, lancing devices can also be used in other sectors such as lactate testing (professional sports) or for coagulation supervision.

4.1.1. Supply of SMBG systems

(15) The Parties submit that they are not aware of any Commission decision concerning SMBG systems. They however argue that such systems fall within the wider category of IVD devices.

(16) In previous cases, the Commission indicated that clinical IVD systems comprise the manufacture and sale of tests (in essence, the sensors) and related equipment/instruments (in essence, the meters) for the purpose of conducting tests outside the human body.[6]

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5 Both Parties are also active in the area of lancing devices, but these do not give rise to competitive concerns. BDC produces lancing devices solely for sale with its SMBG meter kits and does not supply lancing devices to third parties manufacturers or distributors for sale on a stand-alone basis. PHC manufactures and sells lancing devices, but only in[non-EEA country]. Should the market for lancing devices be deemed worldwide in scope, no affected markets would arise under any plausible product market definition.

6 Hoffmann La Roche/Boehringer Mannheim Case No. IV/M.950 (1998), paragraphs 25 to 44; Siemens/Bayer Diagnostics, Case No. COMP/M.4321 (2006), paragraph 10; Siemens/Dade Behring Case No. COMP/M.4865 (2007), para. 7; Abbott/Solvay, Case No. COMP/M.5661 (2010), paragraph 19; Danaher/Beckman Coulter, Case No. COMP/M.6175 (2011), paragraph 7.

(17) In its analysis,[7] the Commission relied on the classification of IVD tests used by the European Diagnostic Manufacturers Association ("EDMA"). EDMA classifies IVD reagents in six main categories: Clinical Chemistry (11), Immunochemistry (12), Haematology/Histology (13), Microbiology (14), Infectious Immunology (15) and Genetic Testing (16). Within each of these categories, the EDMA further classifies IVD tests into three levels that constitute progressively narrower segments.

(18) SMBG sensors are considered as reagents, belonging to EDMA level category 11, "Clinical Chemistry". Clinical chemistry diagnostics are primarily used to test for glucose, cholesterol, sodium, and other substances found in large concentrations in the blood stream. SMBG sensors further fall within the 2nd level category 11.70, "Clinical Chemistry - Rapid Tests & Point of Care".

(19) In addition to the classification of reagents, EDMA offers a classification of (i) IVD instruments and consumables, (ii) after sales, (iii) supporting software and (iv) sample containers.

(20) The Parties submit that SMBG meters are considered as instruments and consumables, falling within the EDMA level category 21 (chemistry and immunochemistry instruments). They can then be further classified within the 2nd level category, under category 21.07 ("chemistry / immunochemistry rapid test + POC, "point of care").

(21) The Commision held that all clinical chemistry tests and instruments belong to the same market for clinical chemistry systems since (i) they have common characteristics, (ii) on the demand side, customers regularly buy almost all of their requirements for such tests and instruments from one source and, (iii) on the supply side, all major suppliers offer the same range of instruments and reagents.[8]

(22) The Commission further considered whether a segmentation of the relevant product markets should be made between tests and instruments and found this further segmentation to be unnecessary as IVD instruments are usually proprietary or "technically closed", i.e. the reagents of one manufacturer cannot be used with equipment of any other manufacturer and vice versa.[9]

(23) The Parties submit that there is one relevant market for SMBG systems, including both the instrument (the meters) and the reagent test strip as SMBG systems are proprietary and sensors supplied by one manufacturer cannot be used with meters supplied by another. Indeed, there are no generic or universal sensors currently

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7 Thermo Fisher/Phadia, Case No COMP/M. 6293 (2011), paragraph 8.

8 Hoffmann La Roche/Boehringer Mannheim, Case No COMP/ M. 950 (1998), paragraphs 34 to 37 ; Bayer/Chiron Diagnostics, Case No COMP/M. 1325 (1998), paragraph 15.

9 Hoffmann La Roche/Boehringer Mannheim, Case No COMP/M.950, paragraphs 28 to 31; Siemens/Bayer Diagnostics, Case No COMP/M.4321 (2006), paragraph 19; Thermo Fisher/Phadia, Case No COMP/M. 6293 (2011), paragraph 19.

offered in the EEA (in the United States, generic versions of sensors for Johnson & Johnson's OneTouch SMBG meters have recently become available).[10]

(24) The Parties submit that there can be a further delineation, that is a market for the supply of SMBG systems by non-vertically integrated manufacturers to distributors.

(25) The market investigation did not provide indications to depart from the Parties' view that there is a relevant market for SMBG systems. In particular, it confirmed that each meter needs a proprietary type of strip.[11]

(26) The exact product market definition, and in particular the distinction between vertically integrated and non-vertically integrated manufacturers of SMBG systems, can in any event be left open as the Transaction raises no competition issues under any market definition.

4.1.2. Distribution of SMBG systems

(27) The Parties submit the downstream market for the distribution of SMBG systems includes vertically integrated and non-vertically integrated distributors.

(28) The exact product market definition can be left open as the Transaction raises no competition issues under any market definition.

4.2. Geographic market definitions

(29) Concerning the manufacture of SMBG systems, the Parties note that the Commission has considered that markets for the provision of medical devices on an OEM basis or markets for contract manufacturing services are at least EEA-wide, and possibly wider.[12]

(30) The Parties agree with this approach because (i) usually suppliers of SMBG systems have centralized production,[13] (ii) in Europe, there is a single marketing requirement need to sell into the EEA, the CE mark, (iii) are no specific barriers for transportation of SMBG systems or barriers to trade.

(31) Concerning the distribution of SMBG systems, the Parties, in line with previous Commission decisions,[14] suggest that the downstream IVD market as national in scope, because of primarily with regard to demand side considerations such as (i) the national organization of suppliers' distribution networks, (ii) the fact that customers tend to buy their reagents and instruments in their home country due to

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10 In any case, even if the Commission were to distinguish between meters and sensors, the market shares would be largely similar given the proprietary nature of the overall system.

11 Agreed non-confidential minutes of a conference call with Roche, 9 October 2015.

12 GE/Abbott Diagnostics Division, Case No COMP/M. 4569 (2007), paragraph 15; Sanofi-Aventis-Zentiva, Case No COMP/M. 5253 (2009), paragraph 191; Abbott/Solvay, Case No COMP/M. 5661 (2010), paragraph 16; Thermo Fisher / Phadia, Case No COMP/M. 6293 (2011), paragraph 69.

13 PHC manufactures its SMBG systems only in[non-EEA countries].

14 Danaher/Beckman Coulter, Case No. COMP/M.6175, para. 18.

their need for rapid and reliable service to ensure continuous availability of these products and (iii) the considerable price differences existing among Member States that reflect the divergences in national health policies, social security regulations and the technology used in laboratories.

(32) In any event, the question of the exact geographic scope of the markets concerned can be left open as the Transaction raises no competition issues under any market definition.

4.3. Competitive assessment

(33) PHC currently has two distribution partners for its SMBG systems, BDC and Arkray.

(34) PHC's worldwide sales of SMBG systems to BDC represented [75-100]% of PHC's total 2014 sales of SMBG systems (and [75-100]% of its direct sales in Europe). Indeed, BDC has:

a. […] rights to distribute PHC's second-generation of SMBG systems in certain territories, including certain EEA Member States; and

b. a […] agreement with PHC for the distribution of its so-called "third-generation" SMBG systems.[15]

(35) On the other hand, Arkray currently has:

a. a […] agreement with PHC for the distribution of its so-called "first-generation"[16] SMBG systems; and

b. […] distribution rights for certain models of PHC's so-called "second-generation"[17] SMBG systems in certain EEA countries ([…]).

(36) The SMBG systems sold by BDC are manufactured by a number of external suppliers, mainly PHC (around [75-100]% and [75-100]% of BDC's worldwide and EEA sales, respectively), […].

(37) PHC's share on the upstream market for the manufacture of SMBG systems is below 25% under all but one possible market definitions. The only exception is the narrower upstream market for the supply of SMBG systems on an OEM basis by non-vertically integrated manufacturers to distributors, where PHC's market share in the EEAwould be [40-50]%, but the Parties stress that therein the sales of the major vertically-integrated suppliers are not included.

(38) In the downstream market for the distribution of SMBG systems, BDC's share exceeds 30% (by value or by volume) in the following Member States: Croatia

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15 In the form of a long-term […] relationship, including […].

16 As of June 2016, the first-generation SMBG systems will be prohibited from being supplied in the EEA if they are not redesigned to meet the latest ISO standard (ISO15197-2013).

17 The second-generation SMBG systems may also not meet the latest ISO standard but Arkray is conducting the appropriate clinical trials in order to check the complience with those requirements.

([30-40%), Denmark ([40-50]%), Finland ([40-50]%), Germany ([30-40%), Greece ([40-50]%), Norway ([30-40]%), Poland ([30-40]%) and Slovenia (40-50]%). The large majority of these sales are achieved by sales of PHC's SMBG systems, under the existing distribution agreement. If these volumes were to be excluded, BDC's share would not exceed 5% in any Member State.

(39) The transaction will lead to the vertical integration of PHC's manufacturing and BDC's distribution activities for SMBG systems. Both input forclosure and customer forclosure can however be excluded, for the reasons set out below.

(40) Regarding input foreclosure, it should be noted first that the main competitors of BDC in the downstream distribution market are the three vertically integrated competitors (Roche, Abbott and J&J), which between them account for around [60-70]% of the total downstream market and would not be affected by an input foreclosure strategy.

(41) Second, PHC has already an […] distribution agreement with BDC for its main products (the third-generation SMBG systems). The pre-merger situation will therefore remain unchanged in relation to these products. As regards the first- and second-generation SMBG systems, which are also distributed by Arkray, PHC submits that it will continue to supply those to Arkray. More importantly, Arkray has indicated that it is not concerned by the Transaction, as Arkray's purchases from PHC are […], and they represent a small part of its overall business.[18]

(42) The fact that PHC has traditionally chosen to distribute its SMBG systems through […] distribution agreements, and not to make them available in an "off the shelf" manner, means that there are no other distributors of PHC's SMBG systems who, potentially, risk to be affected by the transaction.

(43) Customer foreclosure can also be excluded in the 8 EEA Member States for which the downstream market is vertically affected, given that PHC's SMBG systems (supplied from BDC on an […]) account for around [75-100]% of BDC's sales in this segment. If such sales were to be discounted, BDC's market shares would fall to no more than 5%. Moreover, the remaining suppliers of BDC either provide soon to be discontinued products, or could have access to other distributors. There are at least 20 other non-vertically integrated distributors of SMBG systems besides BDC active in the EEA, including Menarini, Sanofi, Merck, GE, Wellion, ForaCare, Diamet. Consequently, non-vertically integrated manufacturers of SMBG systems will continue to have many alternative distributors for their products.

(44) Consequently, no competition concerns arise regarding the vertical relationship between the Parties.

18 Agreed non-confidential minutes of a conference call with Arkray, 8 October 2015.

5. CONCLUSION

(45) For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission
(signed)
Margrethe VESTAGER
Member of the Commission