EUROPEAN COMMISSION
DG Competition

Case M.7813 - SANOFI / GOOGLE / DMI JV

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 23/02/2016

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EUROPEAN COMMISSION

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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 parties

Dear Sirs,

Subject: **Case M.7813 – Sanofi / Google / DMI JV**
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 19 January 2016, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[3] by which Sanofi S.A. ("Sanofi", France), through its wholly-owned subsidiary, Aventis Inc ("Aventis") and Google Inc. ("Google", United States), through its wholly-owned subsidiary Verily Life Sciences LLC ("Verily", United States)[4], acquire within the

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 OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation").

4 The Google group is in the process of restructuring. In particular, a new ultimate parent company, Alphabet Inc., has been established to hold all businesses of the Google group. Alphabet Inc. was incorporated in Delaware on 23 July 2015. It became Google's direct parent on 2 October 2015.

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meaning of Article 3(1)(b) of the Merger Regulation control of a newly created company constituting a joint venture (the "JV"), by way of purchase of shares (the "Transaction").

(2) Sanofi and Google are referred to as the "Parties".

1. THE PARTIES

(3) **Sanofi** is a global pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. The business of Sanofi includes three main activities: (i) pharmaceuticals for human use; (ii) human vaccines through Sanofi-Pasteur and (iii) animal health products through Merial. Aventis is a fully owned subsidiary of Sanofi.

(4) **Google** is a multinational technology company specialising in Internet-related search and products. It operates an Internet search engine and provides online advertising space on its own websites and partner websites. Google also offers a number of other online services and software products. **Verily** is a wholly-owned subsidiary of Google, which was established in order to group together Google's life sciences related projects. Verily has been involved, through various co-operations and investments, in several life sciences projects to date.

(5) **The JV** will offer services for the management and treatment of diabetes, including data collection and processing and data analysis (the "Services"). In addition, the JV may commercialise certain products, such as specialised continuous glucose monitoring devices ([Products the JV may supply in the future]), insulin pumps ([Products the JV may supply in the future]) and insulin ([Products the JV may supply in the future]) which can be used alongside the Services.

2. THE OPERATION

(6) On 13 August 2015, Google (through Verily) and Sanofi (through Aventis), entered into a Collaboration Agreement (the “Collaboration Agreement”) creating the JV.

Joint control

(7) Pursuant to the Collaboration Agreement, each of the Parties will hold a 50% ownership interest in the JV.

(8) The JV will be governed by a Board of Directors (“BoD”) consisting of five members. Google and Sanofi will each have the right to appoint two members of the BoD, and the fifth member will be the CEO. Each of Google and Sanofi will have the right to veto the hiring and termination of the CEO, giving each of them negative veto rights over the JV. Decisions will be made by the BoD by simple majority. Strategic decisions by the JV will require consensus between Google and Sanofi, requiring permanent cooperation. As a result, each of Google and Sanofi will have the right to veto strategic decisions regarding the JV’s business made by the BoD.

Alphabet Inc. is currently only the holding company for Google Inc. and does not otherwise carry out activities. Post-restructuring, Verily will become another direct subsidiary of Alphabet Inc.

Full-functionality

(9) Firstly, the JV's activities will go beyond the activities of its parent companies since neither Google nor Sanofi currently offer services using an integrated digital e-medicine platform for the management and treatment of diabetes. […] the JV may [Strategy regarding supply of products] source products from third-parties.

(10) Secondly, the JV will be able to independently determine its own commercial policy. The JV will establish strategic and business plans that will set forth its overall objectives, the activities to be performed by it or on its behalf and a timeline and budget for the completion of these activities. Moreover, the JV's CEO will be independent from Google and Sanofi, and the JV will also employ its own personnel.

(11) Finally, the JV will also be financially independent from Google and Sanofi. Once the initial capital contributions have been made, the JV will be self-funding, whether through revenue that it generates or arms' length third-party loans, at the determination of the BoD.

(12) Therefore, the JV will be a full-function joint venture that will perform all the functions of an autonomous economic entity, on a lasting basis.

(13) The Transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation.

3. EU DIMENSION

(14) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[5] [Sanofi: EUR 33,770 million; Google: EUR 43,596 million]. Each of them has a EU-wide turnover in excess of EUR 250 million [Sanofi's and Google's turnovers], but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.

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

4. RELEVANT MARKETS

(16) The JV will primarily offer the Services using an integrated digital e-medicine platform that will be developed by Google.[6] The JV may, in addition to offering the Services, supply products which can be used alongside the Services, including, but not limited to, Continuous Glucose Monitors ([Products the JV may supply in the future]) and an insulin pump ([Products the JV may supply in the future]) [Products the JV may supply in the future], as well as a new insulin formulation [Products the JV may supply in the future].

(17) The relevant markets analysed in the present decision are: (i) insulins; (ii) insulin delivery systems (such as insulin pumps); (iii) glucose monitoring systems; (iv)

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5 Turnover calculated in accordance with Article 5 of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C 95, 16.4.2008, p. 1).

6 The web portal for the services will be written for the most commonly used browsers, including Microsoft's Internet Explorer, Apple's Safari and Google's Chrome. Patients will be able to access the services using an application for Apple's iOS or Google's Android.

services for the management and treatment of diabetes using an integrated digital e-medicine platform; and (v) data analytics services.

i. Insulins

(18) Insulin is a hormone produced by beta cells in the pancreas that enables the body to absorb glucose from carbohydrates and to use that glucose for energy or store it for future use. Insulin is used in the treatment of diabetes because it helps stabilise blood glucose.

(19) In previous decisions, the Commission used the Anatomical Therapeutic Chemical Classification Index ("ATC classification system") devised by the European Pharmaceutical Marketing Research Association ("EphMRA") as a reference for the definition of the relevant product markets. The Commission has in particular referred to the third level (ATC3) as the starting point for defining the relevant product market. However, in a number of cases, the Commission found that the ATC3 level classification did not yield the appropriate market definition within the meaning of the Commission Notice on the Definition of the Relevant Market. As a result, where appropriate and based on the factual evidence collected during the market investigation, the Commission has defined the relevant product market at the ATC4 level or at a level of molecule or a group of molecules that are considered interchangeable so as to exercise competitive pressure on one another.[7] The overlap in therapeutic uses does not necessarily imply any particular economic substitution patterns between products.

(20) Insulins are grouped under ATC3 class A10A – *Insulins and analogues*, which is further sub-segmented according to the insulin's terms of onset (how quickly it acts), peak (how long it takes to achieve maximum impact) and duration (how long it lasts before it wears off). Most categories of insulin are grouped under the following four ATC4 classes: (i) fast-acting (A10AB); (ii) intermediate-acting (A10AC); (iii) long-acting (A10AE); and (iv) pre-mixed, i.e. intermediate- or long-acting combined with fast-acting (A10AD).[8]

(21) The Parties argue that the market for insulin should not be segmented according to the type of insulin, but only at the ATC3 level. However, the Parties state that even if the market is defined at ATC4 level the Transaction will not raise any competition concerns relating to insulins.

(22) The Parties consider that, if the Commission were to consider sub-segmenting the insulin market, fast-acting insulin is the only potentially relevant segment in the assessment of the Transaction, [Technical description of products the JV may supply in the future],[9] [Technical description of products the JV may supply in the future].

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7 See e.g. cases M.7559 – *Pfizer / Hospira*; M.7275 – *Novartis / GlaxoSmithKline Oncology Business*; M.6969 – *Valeant Pharmaceuticals International/Bausch & Lomb Holdings*; M.6705 – *Procter & Gamble/Teva Pharmaceuticals OTC II*, M.6613 – *Watson/Actavis*; and M.5865 –*Teva/Ratiopharm*.

8 The following segmentation corresponds to the World Health Organisation's version of the ATC classification. The EphMRA's version classifies Human Insulins and Analogues under ATC3 class A10C.

9 [Technical description of products the JV may supply in the future].

(23) The majority of diabetes Key Opinion Leaders ("KOL") that responded to the market investigation confirmed that there are no circumstances where long-acting insulin can be administered with an insulin pump, with one respondent indicating that "*having long-acting insulin in an insulin pump makes no advantage, but would increase insulin resistance for the patient […] a continuous infusion of long-acting insulin would make diabetes therapy in independent patients unmanageable, in dependent patients uncontrollable*".[10]

(24) The Commission has consistently considered that the markets for marketed finished dose pharmaceutical products are national.[11] For pipeline products, the Commission previously considered that the geographic scope of the relevant market is at least EEA-wide.[12]

(25) In view of the fact that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to insulins under any plausible market definition, the exact scope of the product and geographic market can be left open for the purposes of the competitive assessment of the Transaction.

ii. Insulin delivery systems

(26) Insulin can be administered using different modes of administration, including injections (with a syringe or an insulin pen) and insulin pumps:

a. An insulin pump is a small portable device attached to the patient's body that delivers constant amounts of fast-acting insulin via a catheter.

b. An insulin syringe is a disposable syringe with a capacity of 1 millilitre or less and a fine gauge needle attached, and graduation markings corresponding to insulin units. The insulin itself is sold in vials.

c. An insulin pen is either a disposable device or uses replaceable cartridges of insulin (re-usable pens). Before using a reusable insulin pens, the patient must load it with a cartridge of insulin, which, depending on the doses needed, may last for several days. When it is empty, the patient loads a new cartridge. Disposable insulin pens are pre-filled with insulin and thrown away when they are empty. The tip of insulin pens includes a fine, short disposable needle and patients turn a dial to select the correct dosage. Pen needles are sold separately.

(27) The Commission has not previously defined the relevant market for insulin delivery systems.

(28) According to the Parties, insulin pens and syringes are not fully substitutable with insulin pumps. The Parties argue that: (i) they cannot be used to administer the same types of insulin (i.e. pumps can only administer fast-acting insulins), (ii) the vast

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10 See replies to question 8 of Questionnaire Q1 – Diabetes Key Opinion Leaders.

11 See e.g. cases M.7379 – *Mylan / Abbott EPD-DM*, M.7276 – *GlaxoSmithKline / Novartis Vaccines Business (excl. Influenza) / Novartis Consumer Health Business*, M.7275 – *Novartis / GlaxoSmithKline Oncology Business* and M.5253 – *Sanofi-Aventis/Zentiva*.

12 See e.g. cases M.7559 – *Pfizer / Hospira*; M.7480 – *Actavis / Allergan*; M.7275 – *Novartis / GlaxoSmithKline Oncology Business*.

majority of pumps are very sophisticated and require patients to be knowledgeable about their disease and to monitor it closely, (iii) pumps are more precise, making them better suited for more sensitive patients or patients who need more flexibility, (iv) the switch from a pen to a pump requires significant training for the patient and (v) it also involves higher costs for the patient.

(29) Responses of diabetes KOL to the market investigation suggested that insulin pens and pumps may correspond to different categories of patients and circumstances, without reaching a consensus as to the criteria and need for a distinction.[13]

(30) In view of the fact that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to insulin delivery systems under any plausible market definition, the exact scope of the product and geographic market can be left open for the purposes of the competitive assessment of the Transaction.

iii. *Glucose monitoring systems*

(31) Diabetics need to regularly monitor the level of glucose in their body. Currently, glucose levels are principally measured by testing patients' blood. Many diabetics measure their blood glucose levels themselves using a Blood Glucose Meter ("BGM"). This requires the patient to prick his finger with a small needle called a lancet, draw a drop of blood from the finger and apply it to a test strip that is inserted into the BGM.

(32) Traditional BGMs however do not constantly monitor patients' glucose levels. To address this and facilitate better management of diabetes, Continuous Glucose Monitors ("CGMs") have been developed. CGMs generally have a sensor that is placed just under the skin using a small needle. The device measures the glucose levels in the interstitial fluid every few minutes, rather than in the blood. They display glucose levels in real time, enabling users to constantly monitor possible modifications in their blood glucose levels throughout the day.

(33) In a previous decision, the Commission indicated that the relevant market may be the supply of BGMs, ultimately leaving the market definition open.[14] The Commission did not analyse whether CGMs belong to such market.

(34) The Parties argue that CGMs and BGMs are not substitutable given that: (i) CGMs are more technologically sophisticated than BGMs; (ii) CGMs are not appropriate for all patients (iii) blood glucose levels are more accurate than the interstitial fluid glucose levels, and (iv) CGMs are materially more expensive than BGMs.

(35) Responses of diabetes KOL to the market investigation suggested that BGMs and CGMs may correspond to different categories of patients and circumstances, without reaching a consensus as to the criteria and need for a distinction.[15]

(36) In a previous decision, the Commission indicated that the market for the supply of BGMs may be national, ultimately leaving the market definition open.[16]

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13 See replies to question 7 of Questionnaire Q1 – Diabetes Key Opinion Leaders.

14 See case M.7787 – Panasonic Healthcare / Bayer's Diabetes Care Business.

15 See replies to question 9 of Questionnaire Q1 – Diabetes Key Opinion Leaders.

(37) In view of the fact that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to glucose monitoring systems under any plausible market definition, the exact scope of the product and geographic market can be left open for the purposes of the competitive assessment of the Transaction.

iv. *Services for the management and treatment of diabetes using an integrated digital e-medicine platform*

(38) According to the Parties, in response to the growing demand for integrated solutions in recent years, many companies have entered or expanded their activities in the management of diabetes, offering services using e-medicine platforms to provide: (i) data collection, (ii) data display, (iii) data storage, (iv) data analysis, and (v) data transmission.

(39) The Parties also submit that a range of functionalities which may differ from one company to the other is currently offered. Initially, most companies active in the market offered simple software programmes and/or apps that collect and store and, in some cases analyse, different types of data such as blood glucose levels, drug doses, food intake and physical activity. The rapid pace of technological evolution and the competitive dynamic between the providers of services for the management and treatment of diabetes means that functionalities are constantly added and developed.

(40) The Parties therefore argue that the market should not be segmented by reference to the functionalities provided at a particular point in time.

(41) According to the Parties, on the demand-side, the market is likely to be national in scope, in particular because of (i) language barriers, which are particularly important for services relating to health, and (ii) potential regulatory differences.

(42) The Commission has not yet defined the scope of the market for services provided on for the management and treatment of diabetes using an integrated digital e-medicine platform.

(43) In view of the fact that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to services for the management and treatment of diabetes using an integrated digital e-medicine platform under any plausible market definition, the exact scope of the product and geographic market can be left open for the purposes of the competitive assessment of the Transaction.

v. *Data analytics services*

(44) In previous decisions the Commission has considered data analytics services outside the healthcare sector. For example, in the context of marketing data analytics the Commission found that it was appropriate to differentiate between: (i) marketing information services, (ii) market research services, and (iii) media measurement services.[17] The Commission left open the question whether the provision of data

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16 See case M.7787 – Panasonic Healthcare / Bayer's Diabetes Care Business.

17 See e.g. cases M.6967 – BNP Paribas Fortis/Belgacom/Belgian Mobile Wallet; M.6956 – Telefónica/CaixaBank/Banco Santander/JV; and M.6314 – Telefónica UK/Vodafone UK/ Everything Everywhere/JV.

analytics services for mobile advertising constitutes a separate product market, and if so, whether it should be further segmented.

(45) The Parties argue that it is inappropriate to segment the market for data analytics on the basis of the type of data analysed. According to the Parties, the algorithms and tools that can be used to analyse healthcare data are comparable to those used for the analysis of other types of data. On the other hand, the storage and analysis of health data is the subject of regulation that does not apply to many other types of data, for safety and privacy reasons. In addition to the EU rules that protect sensitive personal data (including health-related personal data), national regulation can impose additional restrictions. However, the Parties argue that such regulatory restrictions are more relevant to the disclosure and use of the results of analysis than they are to the actual analysis itself and the algorithms used to carry out the analysis.

(46) Data analytics competitors responding to the market investigation expressed different views on the question as to whether the market for data analytics should be segmented on the basis of the type of data analysed.[18] Some respondents stated that the algorithms and tools used to analyse healthcare data are comparable to those used for the analysis of other types of data. According to one of these competitors, "*predictive algorithmic models are data agnostic, and not industry-specific. Instead, algorithms are more readily classifiable by the type of general pattern they are trying to predict*". Other competitors expressed the opposite opinion. One respondent observed that "*healthcare data analytics is much more diverse and complex and therefore would require more sophisticated algorithms and analytic tools than those used for the analysis of other types of data*". According to another competitor, "*The complexity and regulatory nature of the healthcare analytics industry creates significant complexity on the data itself, as well as in the structural separation and partitioning related to an individual's health status, access to care, treatment information, and outcomes. The level of complexity and depth of domain expertise that is necessary to apply and interpret analytics in a meaningful way differentiates analytics in healthcare from analytics in other areas*".

(47) The majority of data analytics competitors agree that the storage of health-related personal data is subject to European regulation that does not apply to other types of data.[19] According to one competitor, "*The Data Protection Directive (95/46/EC) identifies data concerning health as a "special category of data" which requires extra protection and may be processed only for specific purposes and under special conditions. Data concerning health is therefore subject to restrictions on storage that are greater than those that apply to other types of data*". Opinions are more divided as regards the application of specific regulation to the analysis of health data.[20]

(48) The Commission considers that in any event, the Transaction does not raise serious doubts as to its compatibility with the internal market regardless of whether there is a separate product market for algorithms for analysing healthcare data.

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18 See replies to question 6 of Questionnaire Q2 – Data analytics competitors.

19 See replies to question 7 of Questionnaire Q2 – Data analytics competitors.

20 See replies to question 8 of Questionnaire Q2 – Data analytics competitors.

(49) With regard to the scope of the geographic market, in a previous decision, the Commission indicated that the market for data analytics may be national, given the relevance of local presence, knowledge of the local markets and language, ultimately leaving the market definition open.[21]

(50) In view of the fact that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to data analytics services under any plausible market definition, the exact scope of the product and geographic market can be left open for the purposes of the competitive assessment of the Transaction.

5. COMPETITIVE ASSESSMENT

i. Insulins

(51) There are three main players for the supply of insulins and analogues (A10A) in the EEA: the market-leader Novo Nordisk ([40-50]% in 2014), followed by Sanofi ([20-30]%) and Eli Lilly ([20-30]%).

(52) In the sub-segment for fast-acting insulin (A10AB), Sanofi's market share was equal to [10-20]% at EEA-level, being the third largest supplier after Novo Nordisk ([50-60]%) and Eli Lilly ([20-30]%). At Member State level, Sanofi's market share was always below [30-40]%. [Strategy regarding pipeline product].

(53) The Parties further argue that competition will further increase as several companies have announced plans to enter the market by developing insulin biosimilars, in view of the fact that the patents protecting a number of insulin compounds have recently expired or will expire in the near future. In particular, the compound patent for Sanofi's Apidra is set to expire in Europe in September 2019.

(54) In view of the above and of all the evidence available to the Commission, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to insulins.

ii. Insulin delivery systems

(55) Sanofi and Google are currently not active in the supply of insulin pumps.

(56) According to the Parties, the market remains nascent and growing, with room for innovators, such as Insulet, Tandem and Asante, alongside larger players, including Medtronic, Roche and Animas (Johnson & Johnson).

(57) As for the supply of insulins, there are three main players for the supply of insulin pens in the EEA:[22] the market-leader Novo Nordisk ([40-50]% in 2014), followed by

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21 See e.g. cases M.6967 – BNP Paribas Fortis/Belgacom/Belgian Mobile Wallet; M.6956 – Telefónica/CaixaBank/Banco Santander/JV; and M.6314 – Telefónica UK/Vodafone UK/ Everything Everywhere/JV.

22 [Methodology used for calculation of share estimates for insulin pens].

Sanofi ([30-40]%) and Eli Lilly ([10-20]%). At Member State level, Sanofi's market share was always below [30-40]%.[23]

(58) In view of the above and of all the evidence available to the Commission, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to insulin delivery systems.

iii. *Glucose monitoring systems*

(59) Sanofi and Google are currently not active in the supply of CGMs.

(60) The Parties argue the market for CGMs is highly competitive, with the main players active in this market being Medtronic (global sales of EUR 203 million in 2014) and Dexcom (EUR 194 million), and to a less extent Abbott (EUR 6 million) and Menarini (EUR 2 million).

(61) As regards BGMs, Sanofi's market share in the EEA was equal to [0-5]% in the period July 2014 – June 2015, being the sixth biggest player after Roche, Bayer, Johnson & Johnson, Abbott and Menarini. At Member State level, Sanofi's market share was always below [10-20]%.

(62) In view of the above and of all the evidence available to the Commission, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to glucose monitoring systems.

iv. *Services for the management and treatment of diabetes using an integrated digital e-medicine platform*

(63) Neither Sanofi nor Google are active in the market for services for the management and treatment of diabetes using an integrated digital e-medicine platform.

(64) The Parties argue that the market is highly competitive and fragmented, with the following active players: Livongo, WellDoc's BlueStar, Telcare, Hygieia, Voluntis' Diabeo and One Drop. Morever, there are many companies entering or expanding their activities driven by technological innovation, namely Glooko, LabStyle Innovations, One Drop, Hygieia, etc. There are also many companies entering in collaboration agreements to produce innovative and useful solutions.

(65) This claim was confirmed during the Commission's market investigation. First, several competitors confirmed they are currently active or have plans to offer services for the management and treatment of diabetes using a digital platform. Second, around half of diabetes KOL that responded to the market investigation indicated that they have recommended and/or prescribed to their patients digital solutions (e.g. smartphone apps, websites, etc.) for managing their diabetes over the last three years,[24] while a minority acknowledged that they have used themselves such digital solutions for treating their patients' diabetes.[25] In particular, some KOLs demonstrated

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23 With the exception of Finland, France, Greece, Italy, Romania and Spain, where Novo Nordisk remains the largest players (save for Romania in 2014, where Sanofi had [40-50]%, Novo Nordisk [30-40]%, Eli Lilly [20-30]%).

24 See replies to question 10 of Questionnaire Q1 – Diabetes Key Opinion Leaders.

25 See replies to question 11 of Questionnaire Q1 – Diabetes Key Opinion Leaders.

knowledge of the following developers of digital platforms for the management and treatment of diabetes: DexCom, Diasend and Roche, as well as Esysta and mySugr to a limited extent. [26]

(66) One KOL highlighted "*a significant risk that the data analysis is used to make the patient more dependent on [Sanofi's] insulin*".[27] However, given that (i) neither Sanofi nor Google is currently active on the management and treatment of diabetes using an integrated digital e-medicine platform and (ii) Sanofi [Sanofi's market position] market position regarding fast-acting insulin in the EEA compared to direct competitors Novo Nordisk and Eli Lilly, this risk appears unlikely to materialise in the foreseeable future.

(67) In addition, one competitor of the Parties raised concerns about the possibility of the JV locking-in patients to the Services by limiting or preventing the portability of their data towards alternative platforms.[28]

(68) According to the Parties, data portability will be driven by patient demand and preferences and Google will support the JV in affording patient data portability in compliance with the applicable rules in this regard. In this context, the Parties stated that they do not intend to prohibit or prevent the export of data by patients or healthcare professionals and will work to enable the export of data in interoperable formats.

(69) The Commission notes that the Parties would lack the ability to lock-in patients by limiting or preventing the portability of their data given that, according to the draft General Data Protection Regulation ("GDPR"),[29] users will have the right to ask for data portability of their personal data. The draft GDPR states that data subjects have a right to receive a copy of their data in a structured and commonly used machine-readable format. Moreover, they have the right to transmit their data to another controller or to request the controller to transmit their data directly to another controller. Moreover, [Time of launch of the Services], there may be alternative providers who could establish themselves before the JV enters the market. Accordingly, there is no basis on which to assume that the JV will acquire market power that would allow them to foreclose rivals. In light of the above, the risk of the JV locking-in patients to the Services appears unlikely to materialise in the foreseeable future.

(70) For the purposes of this decision, the Commission notes that any privacy-related concerns flowing from the use of data within the control of the Parties do not fall within the scope of the EU competition law rules but within the scope of the EU data protection rules.[30]

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26 See replies to question 12 of Questionnaire Q1 – Diabetes Key Opinion Leaders.

27 See replies to question 13 of Questionnaire Q1 – Diabetes Key Opinion Leaders.

28 See minutes of a conference call held with a competitor dated 18 November 2015.

29 Article 18 of the draft General Data Protection Regulation, agreed upon by Council of Ministers and the European Parliament in trilogue on 15 December 2015, and to enter into force two years after final adoption.

30 One competitor raised concerns related to the risks to patient privacy and data security arising from the Transaction. [Strategy regarding access to data]. In this regard, the Commission notes that,

(71) In view of the above and of all the evidence available to the Commission, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to services for the management and treatment of diabetes using an integrated digital e-medicine platform.

v. Data analytics

(72) The JV will not offer data analytics services.[31] [Strategy regarding data analytics] the JV will make available the results of this data analysis to patients and healthcare professionals as part of the Services.

(73) The Parties argue that concerns are unlikely in relation to foreclosure of data analytics services, given the presence of alternative providers in this market.

(74) One competitor in data analytics submitted that, after the creation of the JV, Google would refuse to offer its data analytics tools and/or services used to analyse healthcare data to other third parties owning healthcare datasets.[32] However, a number of providers offering data analytics services and digital tools for the monitoring of diabetes do not expect a negative impact of the Transaction on price and availability of data analytics tools and/or services used to analyse healthcare data.[33]

(75) The main reason for market participants not to expect any impact is the fact that there are several providers of data analytics tools to analyse healthcare data, namely Optum, Truven, Cognizant, Oracle, Healthagen, IMS, Verisk, SAS, Cerner, SAP, Medasys, Compugroup, Microtest as well as medical device vendors like Siemens, Philips, and GE, and cloud computing firms like Amazon and IBM, among others.[34] In fact, according to one competitor, "*Advanced analytics of healthcare data is one of the fastest growing segments of both the healthcare IT technology space and data analytics technology space overall. It is highly likely that numerous firms will enter the market in some form or fashion in the next five years*".[35]

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according to the existing Data Protection Directive 95/46/EC, national implementing law as well as the new draft GDPR, the Parties would need each patient's explicit consent to legally use his data, most of which will be heavily regulated since it would relate to data such as individual's blood glucose levels, insulin levels and haemoglobin A1C levels.

31 [Google's commercial strategy].

32 See reply to question 12 of Questionnaire Q2 – Data analytics competitors.

33 See reply to question 13 of Questionnaire Q2 – Data analytics competitors.

34 See replies to question 9 of Questionnaire Q2 – Data analytics competitors. See also minutes of conference calls held with competitors dated 23 November 2015, 18 November 2015 and 2 December 2015. According to one competitor, "*Not only Google, but also Amazon, IBM, Apple, Microsoft, and several others are known to possess the capabilities and have platforms that could be customised to identify insights on the collected data and enable the user (HCP or person with diabetes) to use the knowledge generated for improved diabetes management. Even if Google were not to provide such solutions, […] is confident that enough players remain to suit their needs*" (see minutes of a conference call held with a competitor dated 18 November 2015). As to examples of collaborations for the provision of data analytics services, Novo Nordisk entered into a partnership with IBM to use the latter's cognitive computing capabilities built on the Watson Health Cloud unit, a development platform for health and wellness. In such unit, analytic technologies and machine learning are used to analyse the patients' data, such as health claims data, clinical data and connect it with medical information such as publications and medical guidelines.

35 See reply to question 10 of Questionnaire Q2 – Data analytics competitors.

(76) Moreover, a competitor – already offering BGMs and insulin pens on the market – has developed the data analytics tools in-house, without using third-party services.[36] Thus, it is in principle possible to independently develop such tools.

(77) In view of the above and of all the evidence available to the Commission, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to data analytics services.

vi. Conglomerate relationships

(78) The Commission also analysed the potential risk of conglomerate effects resulting from the Transaction, namely the possibility of the JV bundling together [Products the JV may supply in the future], the devices and the Services and/or limiting the interoperability with competing offerings[37], with the objective of foreclosing rivals.[38]

(79) According to the Parties, the adoption of a bundling strategy with the objective of foreclosing rivals is unlikely because the JV [JV's business model] incentive for the JV to achieve the best results for the greatest number of patients with diabetes, irrespective of the specific monitoring and insulin delivery device. Therefore, it is essential for the e-platform to support a large number of devices and products.

(80) As regards pumps and CGMs, [Source of products the JV may supply in the future] third-party device manufacturers that will manufacture them and then make them available to customers including, but not limited to, the JV. According to the Parties, the JV will then resupply [Products the JV may supply in the future] to customers. However, customers will be able to mix-and-match the different services and products provided by the JV. The JV may offer Services to customers […] who acquire alternative insulin delivery devices and CGMs either from the JV or from third parties. Moreover, the third-party manufacturers may supply these devices to customers and distributors other than the JV on a stand-alone basis or in connection with other health management platforms (i.e., they can be used with other services and other platforms).

(81) As regards insulin, [Products the JV may supply in the future], users will be able to acquire the Services on a stand-alone basis, and use insulin from other suppliers (e.g., Novo Nordisk and Eli Lilly).

(82) The Platform, the devices and the Services that the JV will offer will use open standards such as HTML, BluetoothSmart, and HTTPS to maximise interoperability.

(83) The Parties thus argue that users will be free to use the Services with third-party products (whether purchased from the JV or otherwise) [Source of products customers may purchase].

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36 See minutes of a conference call held with a competitor dated 5 January 2016.

37 One competitor raised concerns on this issue. See minutes of a conference call held with a competitor dated 18 November 2015.

38 One competitor raised an additional concern regarding potential foreclosure of competing service providers by limiting visibility of competing services in Google search engine. Given that the choice of a particular insulin device/product is generally made by healthcare professionals on the basis of the patient's specific needs, Google's ability to foreclose competing players via potentially discriminatory practices based on its Google search engine can be considered inexistent or if at all limited.

(84) As regards the ability to foreclose rivals via bundling/tying or limiting the interoperability with competing offerings, the Commission notes that currently neither the JV, nor the Parties have a market position that could be leveraged to exclude third-party device manufacturers, insulin providers or providers of digital services for the management and treatment of diabetes from these respective markets. In addition, the Commission notes that patients do not all use the same device/product and the choice of a particular device/product is generally made by healthcare professionals on the basis of the patient's specific needs. It remains uncertain that a material number, let alone a majority, of patients will use the devices [Products the JV may supply in the future] alongside the Services. Therefore, the Parties do not only lack the ability to foreclose rivals but also the incentive to do so given that by preventing third parties' insulins and devices to work with the Services and the Platform, the JV would drive patients away, making such a strategy unprofitable for the JV.

(85) In view of the above and of all the evidence available to the Commission, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to conglomerate effects.

6. CONCLUSION

(86) 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)
Carlos MOEDAS
Member of the Commission