EUROPEAN COMMISSION
DG Competition

Case M.8523 - BD / BARD

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 18/10/2017

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EUROPEAN COMMISSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 18.10.2017
C(2017) 7105 final

PUBLIC VERSION

To the notifying party:

Subject: **Case M.8523 - BD / BARD**
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

Dear Sir or Madam,

(1) On 30 August 2017, the European Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ("Merger Regulation") by which Becton, Dickinson and Company ("BD" or "the Notifying Party", US) proposes to acquire full control over C. R. Bard, Inc. ("Bard", US) within the meaning of Article 3 (1)b of the Merger Regulation (the "Transaction"). BD and Bard are referred to as the "Parties".

1. THE PARTIES AND THE OPERATION

(2) BD is a US based company, active globally in medical devices, in particular in the area of diagnosis, medication management, drug delivery devices, diagnostic devices, infection prevention, diabetes management, genomics, and operational software for surgical and interventional procedures. BD's medical devices include devices for use in biopsy procedures. BD has entered the biopsy activity via the acquisition of CareFusion in 2015.[3] BD has no direct presence in the EEA for the commercialisation of biopsy devices, but is active in the EEA via distributors.

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 See M.7459 – Becton Dickinson and Co. / CareFusion.

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu.

(3) Bard is a US based company active on a global basis in the design, manufacturing, packaging, distribution and sale of medical, surgical, diagnostic and patient care devices. Bard offers in particular vascular, urology, oncology and surgical speciality products, including biopsy devices.

2. THE CONCENTRATION

(4) The Transaction consists in the acquisition by BD of the entire share capital of Bard (in exchange for a payment in cash and BD's stock to Bard's current shareholders).[4] Therefore, the Transaction consists in the acquisition by BD of sole control over Bard.

(5) In the light of the above, the Transaction constitutes a concentration pursuant to Article 3(1)b of the Merger Regulation.

3. EU DIMENSION

(6) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (BD: EUR 10 508 million; Bard: EUR 3 355 million). Each of them has an EU-wide turnover in excess of EUR 250 million (BD: EUR […]; Bard: EUR […]), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The Transaction therefore has an EU dimension pursuant to Article 1(2) of the Merger Regulation.

4. RELEVANT MARKETS

(7) Overlaps between the Parties' activities in the EEA are limited to horizontal overlaps in the area of biopsy devices and tissue markers, which constitute only a relatively small part of their respective businesses.[5]

4.1. Biopsy devices

4.1.1. Introduction

(8) A biopsy is a procedure involving the removal of tissue in order to examine it for diseases. Biopsies are performed using different methods:

> (a) Surgical biopsies refer to the removal of tissue by open or laparoscopic surgery. These procedures are performed with the patient under general anaesthesia.

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4 Agreement and plan of merger dated as of 23 April 23 2017 among C.R. Bard, Inc., Becton, Dickinson and Company and Lambda Corp.

5 While the Parties' combined turnover in the EEA exceeds EUR […], the combined sales of all types of biopsy devices, including biopsy needles as well as tissue markers, in the EEA amount to less than EUR […] ([…]). More specifically the turnover related to biopsy area includes EUR […] of combined BD's and Bard's sales of all biopsy devices, including CNB devices, FNA, and VAB (as will be further explained) as well as EUR […] combined sales of tissue markers.

(b) Percutaneous and vacuum-assisted biopsies refer to the removal of a tissue sample using a biopsy device, under local anaesthesia. Relevant overlaps between the Parties are limited to these types of biopsies.

(9) Biopsy devices comprise various types of products used to remove samples of body tissue to allow examination and detection of specific diseases, predominantly cancer.

(10) Different biopsy devices exist for bone marrow biopsies and soft tissue biopsies. Bone marrow is the spongy material found in the centre of most large bones in the body; a biopsy device needs to perforate the bone to extract a sample from the inside. Soft tissue refers to all other organs from which samples can be extracted for further analysis.

(11) Biopsy devices for soft tissues use different techniques to extract tissue samples with needles. There are (i) Core Needle Biopsy (CNB) devices, (ii) Fine Needle Aspiration (FNA) devices; and (iii) Vacuum Assisted Biopsy (VAB) devices.

(i) Core Needle Biopsy (CNB) devices

(12) Core Needle Biopsy (CNB) devices consist of a "gun" handle (which is either re-usable or single-use) and of a single-use needle. The gun handle is spring loaded and allows the practitioner to move the needle in and out of the target tissue quickly. The needle is wide and hollow, to allow insertion into the patient's tissue, cutting and extraction of a cylinder of tissue. Local anaesthesia is usually used for CNB procedures. CNB devices can be automatic, semi-automatic or manual. Semi-automatic devices offer a "delay" mode in which the tissue has time to settle, allowing the physician to verify or reposition the device before cutting the tissue sample from the organ.[6] Re-usable and single-use CNB devices exist.

(ii) Fine Needle Aspiration (FNA) devices

(13) Fine Needle Aspiration (FNA) devices are basically thin needles that are inserted into the patient's tissue to extract fluid and cells. FNA devices are always single-use and fully manually operated; they are available in a variety of sizes. FNA devices have narrow gauge needles (18G, 20G or 22G) that are connected to a syringe to collects fluid.[7] Therefore, while CNB devices are used to collect tissue samples, FNA devices can collect single cells or liquids only. Samples taken with CNB devices can thus be used for histology analysis, while samples taken with FNA devices can typically only be used for cytology analysis.[8]

(iii) Vacuum Assisted Biopsy (VAB) devices

(14) Vacuum Assisted Biopsy ("VAB") devices are used only in breast biopsies. During the VAB procedure, a probe is inserted into the area of interest and a vacuum in the VAB device draws tissue into a sampling chamber within the

6 Information provided in Form CO and confirmed by market participants (cf. non-confidential minutes of the call with a practitioner, 17 August 2017).

7 Information provided in Form CO and confirmed by market participants (cf. non-confidential minutes of the call with a practitioner, 14 August 2017).

8 Information provided in Form CO.

probe, where the tissue is then cut with a rotating cutting device. A VAB device can take multiple samples from multiple locations during one procedure.[9]

(15) VAB devices retrieve the largest sample size and are more intrusive than the other two biopsy methods. Vacuum assisted biopsies are considered the most diagnostically accurate of the three biopsy methods because of the larger samples of tissue that can be extracted. VAB devices are also significantly more expensive than CNB devices.[10]

(16) Both BD and Bard produce and market FNA devices and CNB devices. Bard is also one of the main suppliers of VAB devices and tissue markers (used following the biopsy procedures to mark the place of biopsy for future reference). BD has not marketed VAB device nor tissue marker, but it has been developing a new biopsy device […] ([…], see section 5.3. below) and a new tissue marker ([…], see section 5.5. below).

4.1.2. Relevant product markets

4.1.2.1. The Commission's prior decisional practice

(17) The Commission has previously considered differentiating between FNA and CNB devices but left the precise market definition open.[11] The Commission also considered the possible distinction between soft tissue needles and bone marrow biopsy needles, based on the fact that different types of needles are used in different biopsies. The Commission further considered a possible distinction of biopsy devices based on automatization (into manual, semi-manual or automatic) or reusability (single-use and re-usable needles). Ultimately, the Commission left the definition of the market for biopsy needles open.[12]

(18) VAB devices, which are used only in breast biopsy, have not been considered in previous decisions of the Commission

4.1.2.2. The Notifying Party's view

(19) The Notifying Party considers that soft tissue and bone marrow biopsy devices should be distinguished. Bone marrow biopsies require specialist bone marrow devices in order to take a sample of liquid marrow (bone marrow aspiration) or a solid piece of marrow (trephine biopsy). According to the Party, soft tissue biopsy devices cannot be used in bone marrow biopsy procedures.

(20) As regards soft tissue biopsy devices, the Notifying Party further claims that CNB devices, FNA devices, and VAB devices each form distinct product markets.

(21) FNA and CNB devices are used for different purposes and different from the more sophisticated VAB devices. The Notifying Party further claims that FNA devices are fully commoditized and much cheaper than CNB devices and that the

9 Information provided in Form CO and confirmed by market participants (cf. non-confidential minutes of the call with a practitioner, 17 August 2017).

10 Information provided in Form CO and confirmed by market participants (cf. non-confidential minutes of the call with a practitioner, 17 August 2017).

11 M.7459 – Becton Dickinson and Company / CareFusion, para. 135.

12 M.7459 – Becton Dickinson and Company / CareFusion, para. 132-135.

use of FNA devices is gradually declining; its use in biopsy procedures is residual.

(22) As regards CNB devices, the Notifying Party considers that these can be differentiated by tissue type in addition to the above mentioned differentiation between bone marrow and soft tissue segmentation. In relation to devices for soft tissues, differentiations can be made for each tissue type, in particular including breast, prostate, lung, liver, thyroid, and kidney. The Notifying Party submits that CNB devices are specifically designed for one type of these tissues and are therefore used by physicians with different specialisations.

(23) According to the Notifying Party, the main factors distinguishing devices appropriate for different soft tissue types include: (i) length and gauge; (ii) whether the device can take a full core sample; (iii) whether the device is automatic, semi-automatic or manual; and (iv) whether the device is re-usable. The specific design of a CNB device with its features and characteristics specifies for which type of soft tissue the device is dedicated. Table 1 shows the different characteristics of CNB devices and the specific tissue for which they are typically used.

Table 1. Common gauge size and length by tissue type:

Soft tissue	Gauge Size						Length (cm)					
	22	20	18	16	14	12	6	9	11	15	20	25
Breast					X	X		X	X			
Prostate			X									X
Lung	X	X	X						X	X	X	
Liver/Kidney			X	X					X	X		
Thyroid	X	X					X					

Source: Form CO, Table 1.

(24) The Notifying Party considers that CNB devices should not be further segmented in manual, semi-automatic and automatic devices. According to the Notifying Party, there are no significant differences from manufacturing, technology and usage perspective between these three types of CNB devices.

4.1.2.3. The Commission's assessment

(a) Possible distinction between biopsy devices used for bone-marrow biopsy procedures and biopsy devices used for soft tissue biopsy procedures.

(25) The market investigation results indicate that bone-marrow and soft tissue biopsy devices are not substitutable from a demand side perspective. All the respondents to the market investigation (i.e. both customers and suppliers of biopsy devices) indicate that soft tissue biopsy devices cannot be used in bone marrow biopsy and vice versa.[13] As explained by one of the suppliers of biopsy devices: *"Bone*

13 Replies to questionnaire Q1 – competitors, question 21.

marrow biopsy and soft tissue biopsy are two completely separate issues. With soft tissue biopsy vital organs like liver, kidney (renal), lung, prostate are being punctured. With bone marrow biopsy, the needles are much larger in size because they need to be strong enough to penetrate the bone - which is very hard and dense - as opposed to skin and tissue. It is wrong to compare these two devices."[14]

(26) On the basis of the market investigation results, the Commission therefore considers that bone marrow biopsy devices and devices used for soft tissue biopsies form distinct product markets.

(b) Possible distinction between FNA and CNB devices

(27) The market investigation results indicate that 'a distinction should be made between FNA and CNB devices.

(28) FNA devices extract only liquid and/or cells and cannot be used to analyse histology.[15] As explained by practitioners, FNA devices are more adequate for cytology, i.e. cell sampling, but are not reliable for biopsies aiming at the extraction of tissue samples. During the market investigation, one radiologist explained: *"FNA devices are used for extraction of liquids or single cells and are no longer used for breast cancer biopsies. This is because for a reliable cancer diagnosis it is important not only to obtain the cells of the sample but also to see the structure of the tissue (which is not possible with FNA). FNA devices are sometimes used for biopsies in the axilla* [the area of the armpit] *but not the breast itself."*[16] During the market investigation, some practitioners indicated that they do not use FNA devices at all, since they are not relevant for biopsies for histology analysis *"where the structure of the tissue taken needs to be kept intact"*.[17]

(29) FNA devices are less invasive than CNB devices but have higher risks of so called false negative results, wrongly indicating non-existence of cancerous cells. Therefore, CNB devices are used in biopsies of suspicious solid lesions when it is necessary to determine the tissue structure in histology analysis for the identification of malign lesions, and the subsequent choice of a specific treatment.

(30) In view of the results of the market investigation and in particular the different circumstances under which FNA and CNB devices can be used, the Commission concludes that FNA devices form a separate market from CNB devices.

(c) Possible distinction between CNB and VAB devices

(31) The market investigation results indicate 'that CNB devices and VAB devices belong to distinct product markets. Virtually all the respondents to the market investigation indicated that neither FNA nor VAB devices can be considered as substitutes of CNB devices.[18] During the market investigation one of the experts

14 Replies to questionnaire Q1 – competitors, question 21.2.

15 Replies to questionnaire Q 2 – customers, question 27.

16 Non-confidential minutes of the call with a practitioner, 16 August 2017.

17 Non-confidential minutes of the call with a practitioner, 17 August 2017.

18 Replies to questionnaire Q 2 – customers, questions 27, 28 and 29.

performing breast biopsies, for instance, explained: *"In general VAB devices and CNB devices are complementary; there are clear indications which of the two devices to use and they are not perceived as substitutes"*.[19] In particular:

(32) First, VAB devices are used only in breast, whereas CNB devices are used in different body soft tissue (like prostate, lung, liver, kidney, and thyroid in addition to breast).[20]

(33) Second, CNB devices can only be used to take one small sample of soft tissue while VAB devices can be used to take multiple samples from multiple locations during the same procedure. For this reason, when the lesion is very small, a VAB device would be preferred: such a small lesion would be difficult to target and thus taking multiple samples with a VAB device would minimise the risk of missing the target.[21]

(34) Third, CNB devices are typically used with ultrasound guidance while VAB devices are designed to be used in more complex stereo-tactic imaging techniques required for specific types of cancers that are invisible under ultra-sound (including for example micro-calcifications that can be seen in mammography procedures). As a practitioner explained: *"typically the type of cancer defines which technique is used: biopsies related to tumours that are visible with ultra-sound imaging are typically taken with CNB devices while samples from small anomalies visible only in mammography or MRI are typically taken with VAB devices."*[22]

(35) Fourth, in some circumstances, VAB can be used to remove calcifications and thus, replace the surgery. During the market investigation, one of the doctors explained: *"VAB procedures are typically used in cases where micro-calcifications exist that are not visible under ultra-sound or in case a first CNB biopsy has not provided clear results (in particular if there is no concordance between radiologist's expectations and pathologist's findings). VAB will also be used for high-risk lesions to minimise the risk of false negative results). In some cases VAB may be used to avoid surgery, when it leads to a complete removal of the lesion."*[23]

(36) Fifth, VAB devices are significantly more expensive that CNB devices (VAB devices cost EUR 300-400 per procedure compared to EUR 30-40 per CNB device).

(37) Sixth, VAB devices are more invasive than CNB devices and VAB procedures may have a higher risk of complications than FNA or CNB devices, as explained by one of the experts: "*CNB devices are typically thinner and less invasive for the patient and create less damage to the tissue than VAB devices*".[24]

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19 Non-confidential minutes of the call with a practitioner, 17 August 2017.

20 Non-confidential minutes of the call with a practitioner, 16 August 2017 and Non-confidential minutes of the call with a practitioner, 17 August 2017.

21 Non-confidential minutes of the call with a practitioner, 16 August 2017.

22 Non-confidential minutes of the call with a practitioner, 8 August 2017.

23 Non-confidential minutes of the call with a practitioner, 17 August 2017.

24 Non-confidential minutes of the call with a practitioner, 8 August 2017.

(38) In view of the above, the Commission concludes for the purpose of this case, that CNB devices form a distinct product market, separate from VAB devices.

(d) Possible distinction between CNB devices used for different soft tissues

(39) In order to obtain samples of tissues in different parts of the human body with different characteristics, and subject to different types of disease, CNB devices of different sizes and features are needed to reach the tissue and obtain a clinically adequate sample. The main factors distinguishing devices appropriate for different soft tissue types include: (i) length and gauge; (ii) whether the device can take a full core sample; (iii) whether the device is automatic, semi-automatic or manual; and (iv) whether the device is re-usable.[25]

(40) The results of the market investigation are not conclusive as regards the distinction between various CNB devices used for soft tissues. On the one hand, different tissues require different needle sizes (both in length and gauge). On the other hand, there are needle sizes that can be used in various tissues,[26] and CNB devices are not developed for a specific tissue, but as general devices offered for use in various tissues.[27]

(41) During the market investigation, suppliers of CNB devices confirmed that they produce CNB devices for various soft tissues, and that they produce CNB devices of different length and gauge-sizes on the same production line.[28] The market investigation results also indicate that the majority of suppliers offer CNB devices for use in various tissues, and they do not specialise in a particular tissue.[29] The majority of customers who responded to the market investigation indicate that all suppliers of CNB devices offer CNB devices for all soft tissues, but approximately one third of the responding customers consider that the suppliers tend to offer only some types of CNB devices and specialise in certain tissues.[30] Furthermore, when assessing the position of various suppliers of CNB devices (in particular BD and Bard) or commenting on their strengths and weaknesses, the vast majority of the respondents to the market investigation do not distinguish by the type of tissue concerned.[31]

(42) The Commission concludes in light of the above, that for the purpose of this case, the precise market definition can be left open as the transaction raises serious doubts as to its compatibility with the internal market irrespective of whether the relevant product market is defined as one market for all soft tissue CNB devices, or whether this market would be segmented according to different tissues.[32]

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25 Replies to questionnaire Q2 – customers, question 5.

26 Replies to questionnaire Q2 – customers, question 5.

27 Replies to questionnaire Q1 – competitors, question 6.

28 Replies to questionnaire Q1 – competitors, question 9.1.

29 Replies to questionnaire Q1 – competitors, question 6.

30 Replies to questionnaire Q2 – customers, question 6.

31 Replies to questionnaire Q1 – competitors, questions 25, 28 and 29.

32 See below, paragraph 101.

(e) Possible distinction between automatic, semi-automatic, and manual CNB devices

(43) CNB devices with various functionalities exist: automatic, semi-automatic or manual. During the market investigation, some doctors suggested that some of these functionalities are better suited for specific tissues than other, for example automatic devices would be advantageous for harder tissues while manual devices could be used in softer tissues. In the same vein, semi-automatic or manual devices could be preferable in highly sensitive body parts. However, the responding practitioners generally consider that these are not significant differences. As explained by one of the responding doctors, practitioners specialised in certain tissue are familiar with each of the three types (manual, semi-automatic, and automatic) and choose the types of devices they want to use according to their personal preferences.[33] Another doctor explained along the same lines: "*Various types of CNB devices are available, e.g. automatic, manual etc. but with no major differences, the choice between those depends to a large extent on the doctor's preference."*[34]

(44) In view of the above, the Commission considers that manual, automatic and semi-automatic CNB devices belong to the same relevant product market.

(f) Possible distinction between single-use and re-usable CNB devices

(45) While the needle of any biopsy device is always designed for single-use, CNB devices exist as single-use (disposable) and re-usable devices. In the latter case, the handle ("gun") can be sterilised and re-used. Customers purchase both single-use and re-usable CNB devices and most of the suppliers would likely be able to offer both types.[35] However, as regards the Parties, only Bard produces single-use and re-usable devices while BD commercialises only single-use devices.

(46) The results of the market investigation suggest that in some countries, or for certain procedures re-usable devices are more commonly used, while in other countries, or simply due to the doctor's preference, single-use devices would be preferred.[36] One of the practitioners acknowledged that, while for hygienic reasons she prefers single-use devices, *"there is no fundamental difference from a technical point of view between re-usable and disposable CNB devices"*.[37]

(47) The market investigation results further show that a majority of practitioners having replied to the questionnaire use single-use devices. In addition, there seems to be a trend to use rather the single-use biopsy devices as explained by one responding supplier: "*more cost-conscious customers use reusable devices,*

33 Non-confidential minutes of the call with a practitioner, 17 August 2017.

34 Non-confidential minutes of the call with a practitioner, 16 August 2017.

35 The vast majority of competitors indicated that either all suppliers offer both types of devices (more than 40% of respondents) or that even if suppliers do not offer both types, once they offer one type of CNB device (e.g. disposable device) it is easy to start supplying the other type (e.g. re-usable device) (more than 40% of respondents). Only one competitor indicated that it is not easy to be able to produce both disposable and re-usable CNB device (Replies to questionnaire Q1 – competitors, question 11).

36 Non-confidential minutes of the call with a practitioner, 16 August 2017.

37 Non-confidential minutes of the call with a practitioner, 17 August 2017.

but there is now a rapid migration in Europe away from reusable guns to disposable in order to reduce the risk of infection".[38]

(48) The customers who responded to the market investigation questionnaire explained that the re-usable devices tend to be cheaper (because they can be used in multiple procedures) and may have some functional advantages (for instance, they may be more solid or have higher spring force) but they also mention that these devices may be heavier and require cleaning. One of the responding hospitals indicated that when using re-usable CNB devices one needs to have several handles because of the time needed for sterilising them.[39] As for the single-use devices, they tend to be lighter and thus easier to manipulate, they are more common and offered in wider range, but they are also more expensive.[40]

(49) The Commission concludes in light of the above, that for the purpose of this case, the precise market definition can be left open as the transaction raises serious doubts as to its compatibility with the internal market irrespective of whether the relevant product market is defined as comprising single-use and re-usable CNB devices or should be further segmented into these two categories.[41]

4.1.3. Relevant geographic market

4.1.3.1. The Commission's prior decisional practice

(50) As regards the geographic market definition, in past decisions, the Commission considered that in the area of biopsy devices the market could be national or EEA-wide in scope.[42] For pipeline products, in previous cases the Commission considered that since pipeline products need to be assessed with reference to the R&D in a given area and if the extent that R&D for the relevant products is global, the geographic scope of the relevant market should be global or at least EEA-wide.[43]

4.1.3.2. The Notifying Party's view

(51) The Notifying Party submits that there is significant evidence suggesting that the relevant geographic market for biopsy needles is EEA-wide. For example, European markets for medical devices such as biopsy needles are characterised by low regulatory barriers, the organization of production is homogenous on a EEA-wide basis, and transport costs are low.

4.1.3.3. The Commission's assessment

(52) The market investigation results suggest that the market could be national in scope. For example, many competitors have different sales prices in different

38 Replies to questionnaire Q1 – competitors, question 12.

39 Replies to questionnaire Q2 – customers, question 32.

40 Replies to questionnaire Q2 – customers, question 32.

41 See below, paragraph 102.

42 M.7459 – Becton Dickinson and Co. / CareFusion, para. 138.

43 See e.g. cases M.7559 Pfizer / Hospira, M.7480 – Actavis / Allergan and M.7275 – Novartis / GlaxoSmithKline Oncology Business.

European countries, reimbursements schemes are different or there are differences in the tender processes.[44]

(53) The Commission concludes in light of the above, that for the purpose of this case, the precise market definition can be left open as the transaction raises serious doubts as to its compatibility with the internal market irrespective of whether the relevant geographic market is defined as EEA-wide or should be further segmented into national markets.

4.1.4. Conclusion

(54) In view of the above and the results of the market investigation, the Commission concludes that biopsy devices for bone marrow and biopsy devices for soft tissues belong to different product markets and that FNA, CNB, and VAB devices each form separate product markets. Furthermore, for the purpose of this case the Commission considers that automatic, semi-automatic, and manual CNB devices belong to the same relevant product market.

(55) The Commission further concludes that for the purpose of this case, questions about potential further segmentations of the relevant market can be left open as the transaction raises serious doubts as to its compatibility with the internal market irrespective of whether CNB devices for soft tissues form one relevant product market, or whether this market should be segmented according to different soft tissues. The same applies to a potential segmentation between single-use CNB devices and re-usable CNB devices.

(56) The Commission further concludes in light of the market investigation results that the relevant geographic market could be national or EEA-wide in scope, but the exact geographic market definition can be left open, as the transaction raises serious doubts as to its compatibility with the internal market irrespective of whether the relevant geographic market is EEA-wide or segmented into separate national markets.

4.2. Tissue markers

4.2.1. Introduction

(57) Tissue markers are small items placed following biopsy procedures to help the physician re-locate the biopsy site for future reference. Markers are only used in breast biopsies and only in procedures conducted with CNB or VAB devices. Breast biopsy markers are used for two primary functions:

(a) to mark the area of tissue extracted following a biopsy in order to locate the site for follow-up treatment, imaging, and for further surgery or biopsies if necessary; and

(b) to mark a lesion before chemotherapy treatment in order to assess the success of the treatment of the malignant tissues.

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44 Replies to questionnaire Q1 – competitors, question 23 and 24.

4.2.2. Relevant product market

4.2.2.1. The Notifying Party's view

(58) The Notifying Party considers that tissue markers should be differentiated in (i) VAB breast markers and (ii) CNB breast markers.

(59) The Notifying Party explains that VAB breast markers used in procedures conducted with VAB devices are introduced via the VAB device during the procedure. VAB markers are therefore tailored for specific VAB devices. On the other hand, CNB breast markers are inserted with specific introducers, independently from the CNB device, after the core needle biopsy has been concluded. Unlike with a VAB procedure, inserting the marker into the human body is not a procedure integrated into the CNB procedure. Instead, it involves a two-stage process, consisting first in the biopsy itself, followed separately by the insertion of the marker. As a result of this distinction, it would be possible to use any tissue marker irrespective of the types of CNB device used.

(60) The link between the VAB device and dedicated tissue markers can further be seen from the fact that the primary competitors in VAB breast markers are the same companies that manufacture VAB devices.

4.2.2.2. The Commission's assessment

(61) The market investigation results indicate that tissue markers dedicated for use in CNB procedures can be used in combination with any CNB device.[45] A dedicated link between a specific CNB device and a marker therefore does not seem to exist. One of the practitioners explained: *"there is no direct link between the producer of the biopsy device and the marker. In theory, any marker can be used regardless of the specific core needle biopsy device used. It's different with VAB technic because there are different probe lengths, so you need often to use the same manufacturer for VAB and Markers."*[46]

(62) The market investigation results also support the view that tissue markers exist that are specifically earmarked for use with specific VAB devices (in particular due to the delivery device offered with the marker). In particular, one supplier indicated that it offers tissue markers that are specifically designed to be used with one of their own biopsy devices.[47]However, during the market investigation, two suppliers of tissue markers also explained that their markers can be used with any type of device (CNB or VAB devices) from any producer.[48] Therefore, although it cannot be ruled out that the market for tissue markers could be further segmented because of different features of VAB dedicated markers as compared to others, such a differentiation is not obvious given the mixed results of the market investigation.

(63) The Commission concludes in light of the above, that for the purpose of this case, the precise market definition can be left open as the transaction raises serious

45 Replies to questionnaire Q2 – customers, question 42.

46 Non-confidential minutes of the call with a practitioner, 14 August 2017.

47 Replies to questionnaire Q1 – competitors, question 18.

48 Replies to questionnaire Q1 – competitors, question 18.

doubts as to its compatibility with the internal market irrespective of whether the relevant product market is defined as one market for all tissue markers or further segmented into tissue markers to be used with CNB devices on the one hand and tissue markers to be used with VAB devices on the other hand.

4.2.3. Relevant geographic market

(64) Hospitals conducting breast biopsies also purchase tissue markers and tender these purchases under the same procedures (although in the majority using separate tender processes) as biopsies devices.[49] In the case at hand, no overlap exists between existing products on the market because BD has no tissue marker available; it however has a pipeline product that will be marketed in the future. For pipeline products, taking into account that the R&D activity is typically global, the Commission previously considered that the geographic scope of the relevant market is at least EEA-wide.[50] Also in this case there is no indication that the product under development would be offered only in specific geographies. To the contrary, it seems rational to commercialise a new product on a global scale once all necessary regulatory approvals have been received.

(65) In light of the above, the relevant market for tissue markers is likely to be at least EEA-wide. However, the Commission concludes that for the purpose of this case, the precise geographic market definition can be left open as the transaction raises serious doubts as to its compatibility with the internal market irrespective of whether the relevant geographic market is defined as EEA-wide or global.

4.2.4. Conclusion

(66) In light of the above, the Commission considers that a separate market for tissue markers exist that may be segmented into CNB and VAB specific markers. However, the Commission concludes that for the purpose of this case, the precise market definition can be left open as the transaction raises serious doubts as to its compatibility with the internal market irrespective of such a potential segmentation.

(67) The Commission further concludes that the relevant geographic scope of this market can be left open as the transaction raises serious doubts as to its compatibility with the internal market irrespective of whether the relevant geographic market is defined as EEA-wide or global.

5. COMPETITIVE ASSESSMENT

5.1. Introduction

(68) The Transaction would lead to affected markets in the area of i) soft tissue CNB devices, and ii) tissue markers.[51]

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49 Replies to questionnaire Q2 – customers, question 10.1.

50 See e.g. cases M.7559 Pfizer / Hospira, M.7480 – Actavis / Allergan and M.7275 – Novartis / GlaxoSmithKline Oncology Business.

51 Overlaps exist also in Fine Needle Aspiration (FNA) devices and Core Needles Biopsy (CNB) devices used for bone marrow, but no affected markets arise. The Transaction also leads to other

(69) The Parties' activities currently do not overlap in VAB devices because BD does not market such a product.

(70) Markets for FNA devices would only be affected in Poland and in Germany but in both countries the combined markets shares remain below [20-30]% with the increment brought by BD being less than [0-5]% and the HHI delta below [100-200].[52] On that basis, the Commission considers that it is unlikely that the Transaction would significantly impede effective competition in respect of those potential markets.

(71) A potential market for bone marrow biopsy devices would not be affected in any national or EEA-wide market.

(72) In the light of the above, the Commission's further assessment relates to the affected (potential) markets for soft tissue CNB devices (section 5.2.), a current pipeline project in the field of biopsy devices that might compete with CNB or VAB devices (section 5.3.), and tissue markers (section 5.5).

5.2. Soft tissue CNB devices

5.2.1. *EEA-wide market shares*

(73) On a potential EEA-wide market for all soft tissue CNB devices, combined market shares of the Parties would reach [40-50]% after the Transaction (with an increment of [10-20]%). The next largest supplier, Argon, has a market share of [10-20]% in the EEA.[53]

(74) When assessing tissue-specific CNB devices, affected markets would arise in relation to breast CNB devices with [50-60]% combined market share (with an increment of [10-20]%), lung CNB devices with [40-50]% combined market share (with an increment of [5-10]%), liver and kidney CNB devices with [30-40]% combined market share (with an increment of [0-5]%), and thyroid CNB devices with [40-50]% combined market share (with an increment of [5-10]%).

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overlaps in particular in the area of drainage catheters and IV start packs but not in the EEA, where Bard's products are not commercialised.

52 In Germany the combined market shares reach [20-30]% with an increment brought by BD of [0-5]%, being the HHI increment [0-100]. In Poland the combined market shares reach [20-30]% with an increment brought by BD of [0-5]%, being the HHI increment [100-200].

53 The Parties estimate the total market size for this market to amount to EUR [50-60] million.

Table 2: Market share overview for different soft tissue CNB devices at EEA level based on value 2016:

	Bard	**BD**	**Combined**	**Argon**
All soft tissue	[30-40]%	[10-20]%	[40-50]%	[10-20]%
Breast	[30-40]%	[10-20]%	[50-60]%	[10-20]%
Prostate	[50-60]%	[0-5]%	[50-60]%	[10-20]%
Lung	[5-10]%	[30-40]%	[40-50]%	[10-20]%
Liver and Kidney	[30-40]%	[0-5]%	[30-40]%	[5-10]%
Thyroid	[5-10]%	[30-40]%	[40-50]%	[10-20]%

(75) Should the market for soft tissue CNB devices be segmented in separate markets for re-usable soft tissue CNB devices and single-use soft tissue CNB devices, there would be no overlap on the market for re-usable devices, as BD is not present there. On the market for single-use soft tissue CNB devices, the Parties' combined market share would amount to [40-50]% in the EEA, with an increment of [10-20]% brought by BD. The second largest supplier would be Argon with the market share of [5-10]%, followed by HS with the market share of [5-10]% and Cook with the market share of [5-10]%.[54]

5.2.2. *Market shares at national level*

(76) Should the market be assessed at the national level, markets would be affected in 13 countries either on an overall market for soft tissue CNB devices or (potential) narrower markets for CNB devices for specific tissues. Table 3 below provides an overview of market shares for those affected markets.

(77) The Transaction would lead to combined market shares of more than [40-60]% in six Member States, namely Denmark, Finland, France, Ireland, Sweden and the United Kingdom on the overall market for soft tissue CNB devices.[55] The increment brought by the Transaction is significant in all these countries except for Denmark and Sweden.[56]

54 Based on value 2016. Data provided by the Parties.

55 In Norway market shares reach [50-60]% on the potential market for liver and kidney CNB devices, but the increment brought by BD is less than [0-5]%.

56 In Denmark, market shares reach [60-70]% on the market for all soft tissue CNB devices, but the increment brought by BD is less than [0-5]%. Similarly, in Sweden the combined market share amounts to [60-70]% with the increment of [0-5]% brought by BD.

Table 3: Market share overview for all soft tissue CNB devices based on value 2016, for all the countries, in which the Transaction leads to an affected market based on plausible product market definition:

	Bard	**BD**	**Combined**	**Argon**
All EEA	[30-40]%	[10-20]%	[40-50]%	[10-20]%
Austria	[20-30]%	[0-5]%	[20-30]%	n.a.
Belgium	[20-30]%	[0-5]%	[30-40]%	n.a.
Denmark	[60-70]%	<[0-5]%	[60-70]%	n.a.
Finland	[50-60]%	[5-10]%	[60-70]%	[10-20]%
France	[40-50]%	[5-10]%	[50-60]%	[10-20]%
Germany	[40-50]%	[0-5]%	[40-50]%	[20-30]%
Ireland	[30-40]%	[20-30]%	[50-60]%	[20-30]%
Italy[57]	[10-20]%	[0-5]%	[10-20]%	[5-10]%
Norway	[40-50]%	<[0-5]%	[40-50]%	n.a.
Poland[58]	[10-20]%	[0-5]%	[10-20]%	n.a.
Spain	[20-30]%	[0-5]%	[20-30]%	[20-30]%
Sweden	[60-70]%	[0-5]%	[60-70]%	n.a.
UK	[20-30]%	[30-40]%	[60-70]%	[10-20]%

(78) On a national level, significant overlaps also occur on several of the potential markets for CNB devices for specific tissues. This is the case for Finland, France, Ireland, Sweden and the United Kingdom. Market shares for these countries are analysed below on the plausible markets for CNB devices segmented according to the type of tissue in which they are used (breast, prostate, lung, liver and kidney, and thyroid).

Finland

(79) In Finland, affected markets would be the potential overall market for soft tissue CNB devices where the Parties' combined market share is [60-70]% (with an increment of [5-10]%); as well as the potential tissue-specific markets for breast CNB devices where the Parties' combined market share is [60-70]% (with an increment of [0-5]%); lung CNB devices where the Parties' combined market share is [50-60]% (with an increment of [10-20]%); liver and kidney CNB devices where the Parties' combined market share is [70-80]% (with an increment

57 In Italy, only the potential market for prostate biopsy CNB devices is technically affected with a combined market share of [20-30]%, but a very small increment (<[0-5]%).

58 In Poland, the potential market for prostate biopsy CNB devices is technically affected with a combined market share of [20-30]%, but a very small increment (<[0-5]%).

of [10-20]%); and thyroid CNB devices where is the Parties' combined market share is [70-80]% (with an increment of [20-30]%).

Table 4: Market share overview for soft tissue CNB devices in Finland based on value 2016:

Finland	Bard	BD	Combined	Argon
All soft tissue	[50-60]%	[5-10]%	[60-70]%	[10-20]%
Breast	[60-70]%	[0-5]%	[60-70]%	[10-20]%
Prostate	[50-60]%	n.a.	[50-60]%	[20-30]%
Lung	[10-20]%	[40-50]%	[50-60]%	[5-10]%
Liver and Kidney	[60-70]%	[10-20]%	[80-90]%	[0-5]%
Thyroid	[20-30]%	[50-60]%	[80-90]%	[5-10]%

France

(80) In France, affected markets would be the potential overall market for soft tissue CNB devices where the Parties' combined market share would reach [50-60]% (with an increment of [5-10]%); as well as the potential tissue-specific markets for breast CNB devices where the Parties' combined market share is [60-70]% (with an increment of [10-20]%); lung CNB devices where the Parties' combined market share is [40-50]% (with an increment of [5-10]%); liver and kidney CNB devices where the Parties' combined market share is [50-60]% (with an increment of [5-10]%); and thyroid CNB devices where the Parties' combined market share is [30-40]% (with an increment of [10-20]%).

Table 5: Market share overview for soft tissue CNB devices in France based on value 2016:

France	Bard	BD	Combined	Argon
All soft tissue	[40-50]%	[5-10]%	[50-60]%	[10-20]%
Breast	[50-60]%	[10-20]%	[60-70]%	[10-20]%
Prostate	[60-70]%	n.a.	[60-70]%	20%
Lung	[5-10]%	[30-40]%	[40-50]%	[10-20]%
Liver and Kidney	[50-60]%	[5-10]%	[50-60]%	[10-20]%
Thyroid	[10-20]%	[10-20]%	[30-40]%	[10-20]%

Ireland

(81) In Ireland, affected markets arise in relation to a potential overall market for soft tissue CNB devices with [50-60]% combined market share (with an increment of [20-30]%); as well as the potential markets for breast CNB devices with [80-90]% combined market share (with an increment of [30-40]%); lung CNB devices with [50-60]% combined market share (with an increment of [10-20]%); liver and kidney CNB devices with [20-30]% combined market share (with an increment of [0-5]%); and thyroid CNB with [40-50]% combined market share (with an increment of [5-10]%).

Table 6: Market share overview for soft tissue CNB devices in Ireland based on value 2016:

Ireland	Bard	BD	Combined	Argon
All soft tissue	[30-40]%	[20-30]%	[50-60]%	[20-30]%
Breast	[30-40]%	[50-60]%	[80-90]%	[5-10]%
Prostate	[40-50]%	n.a.	[40-50]%	[30-40]%
Lung	[10-20]%	[40-50]%	[50-60]%	[20-30]%
Liver and Kidney	[20-30]%	[0-5]%	[20-30]%	[30-40]%
Thyroid	[5-10]%	[30-40]%	[40-50]%	[20-30]%

Sweden

(82) In Sweden, the combined market share with regard to all soft tissue CNB devices amounts to [60-70]% (with an increment of [0-5]%), to [80-90]% with regards to thyroid (with an increment of [20-30]%), to [60-70]% with regard to breast CNB devices (with an increment of [0-5]%), to [30-40]% with regards to lung CNB devices (with an increment of [0-5]%) and to [60-70]% with regards to Liver and Kidney (with an increment of [0-5]%).

Table 7: Market share overview for soft tissue CNB devices in Sweden based on value 2016:

Sweden	Bard	BD	Combined	Argon
All soft tissue	[60-70]%	[0-5]%	[60-70]%	n.a.
Breast	[60-70]%	[0-5]%	[60-70]%	n.a.
Prostate	[70-80]%	n.a.	[70-80]%	n.a.
Lung	[30-40]%	[0-5]%	[30-40]%	n.a.
Liver and Kidney	[60-70]%	[0-5]%	[60-70]%	n.a.
Thyroid	[50-60]%	[20-30]%	[80-90]%	n.a.

United Kingdom

(83) In the United Kingdom, affected markets arise in relation to all soft tissue CNB devices with [60-70]% combined market share (with an increment of [20-30]%), breast CNB devices with [90-100]% combined market share (with an increment of [20-30]%), prostate CNB devices [40-50]% combined market share (with an increment of [0-5]%), lung CNB devices with [70-80]% combined market share (with an increment of [0-5]%), liver and kidney CNB devices with [40-50]% combined market share (with an increment of [10-20]%) and thyroid CNB devices with [50-60]% combined market share (with an increment of [0-5]%). The market investigation results also suggest that BD and Bard are [significant] providers […] for CNB devices.

Table 8: Market share overview for soft tissue CNB devices in the UK based on value 2016:

UK	Bard	BD	Combined	Argon
All soft tissue	[20-30]%	[30-40]%	[60-70]%	[10-20]%
Breast	[20-30]%	[70-80]%	[90-100]%	[0-5]%
Prostate	[40-50]%	[0-5]%	[30-40]%	[20-30]%
Lung	[0-5]%	[70-80]%	[70-80]%	[5-10]%
Liver and Kidney	[30-40]%	[10-20]%	[40-50]%	[10-20]%
Thyroid	[0-5]%	[50-60]%	[50-60]%	n.a.

Situation in other national markets

(84) Even in markets in which the Parties' combined market shares are below [50-60]%, the Transaction would lead to strengthening of the leading position of one Party by adding the other Party's shares. Affected markets arise, both in the potential overall market for soft tissue CNB devices as well as on potential tissue-specific segments, in Austria, Belgium, Germany, and Spain.[59]

(85) In Austria, Bard has a share of [20-30]% on a market for soft tissue CNB devices. While BD's share on the market for soft tissue CNB devices amounts to only [0-5]%, it is significantly stronger on a potential segment for lung CNB devices, where it holds [10-20]% market shares and BD an additional [10-20]%.

(86) In Belgium, the situation is comparable, with the Parties reaching combined shares on the market for soft tissue CNB devices of [30-40]% with an increment

[59] In Italy, only the potential market for prostate biopsy CNB devices is technically affected with a combined market share of [20-30]%, but a very small increment (<[0-5]%). In Poland, the potential market for prostate biopsy CNB devices is technically affected with a combined market share of [20-30]%, but a very small increment (<[0-5]%).

of [0-5]% brought by BD. In addition, BD holds [10-20]% of the potential lung specific segment leading to a combined share of [20-30]%.

(87) In Germany, the combined shares on the market for soft tissue CNB devices reach almost [40-50]%, with an increment of [0-5]% brought by BD. Here, market shares for breast specific CNB devices are even slightly higher. BD is again strongest in lung-specific CNB devices where combined market shares would reach [20-30]% with an increment of [10-20]% brought by Bard. In addition, combined market shares would also slightly surpass [30-40]% in thyroid specific CNB devices, with an increment of [0-5]% coming from BD.

(88) In Spain, the market for soft tissue CNB devices would be affected with combined shares of [20-30]% (with an increment of [0-5]% brought be BD). Further affected markets arise on the potential tissue-specific markets: for breast CNB devices (combined shares of [40-50]% with an increment of [5-10]%); prostate CNB devices (combined shares of [30-40]% with an increment of [0-5]%); and thyroid CNB devices (combined shares of [20-30]% with an increment of [5-10]%).

5.2.3. Overall assessment

(89) Combined market shares in several EEA countries exceed [50-60]%, the threshold above which a position of dominance may be presumed.[60] In the United Kingdom, market shares reach even [90-100]% with an increment of [20-30]%, resulting with the merged entity having a position close to absolute monopoly.

(90) The market investigation results confirm that the merged entity would have a dominant position in relation to soft tissue CNB devices in some EEA countries and also in relation to the markets for certain soft tissue CNB devices (in a number of EEA countries).

(91) The vast majority of customers who responded to the market investigation consider that Bard is the market leader on the market for CNB devices.[61] As regards the second largest player, the customers' replies are mixed (mainly depending on the country of customer's activity): some customers consider BD to be the second largest supplier of CNB devices, some customers mention Argon as the second largest player. Overall, however, those customers who do not consider Bard to be the number 1 supplier of CNB devices indicated that BD is the number one supplier on this market (and Bard the number 2).[62]

(92) From the responding competitors, all meaningful responses indicated that Bard is the market leader and the majority of respondents indicated that BD is its closest competitor in the EEA, followed by Argon.[63] According to a competitor, the Transaction "*would combine two very large market share holders that compete very closely*".[64] While Bard might be perceived as the more advanced player

60 See paragraph 17 of the Guidelines on the Assessment of Horizontal Mergers (OJ C 31, 5.2.2004, p. 5).

61 Replies to questionnaire Q2 – customers, question 12.

62 Replies to questionnaire Q2 – customers, question 12.

63 Replies to questionnaire Q1 – competitors, questions 25 and 30.

64 Reply to questionnaire Q1 – competitors, question 41.1.

because of its activities in VAB devices where BD is not active, such a differentiation does not seem to hold true when comparing only the more standardised CNB devices.[65]

(93) Customers who responded to the market investigation consider that Bard is very competent and reliable supplier, who offers high quality products and has a wide range of biopsy products. The customer's perception of BD as reported in their replies to the market investigation is almost the same: BD is described as a reliable supplier with good reputation, offering good quality products.[66] The market investigation results have not revealed any evidence suggesting that BD and Bard specialise in different areas of soft tissue CNB devices or that they offer products of different quality or price. The only exception is the fact that Bard is strong also in re-usable CNB devices, while BD is not present in this market segment.

(94) An important majority of competitors who responded to the market investigation consider that the Transaction would have an impact on the market for CNB devices in the EEA.[67] In general, the respondents to the market investigation, who raise concerns about the impact of the Transaction, do not specify whether these concerns relate to CNB devices indicated for a specific tissue, or to single-use devices only.[68]

(95) While customers' responses typically relate to the situation in the geographic area in which they are present, most of the competitors provide their submission in relation of the overall EEA market. The Commission notes that as demonstrated by the market share data regarding soft tissue CNB devices at national level, Bard tends to be the market leader in most of the EEA countries, while the position of BD is typically more modest. These differences are reflected in the responses of customers to the market investigation. Competitors, however, who in general provide replies in relation to the whole EEA market, more consistently consider that the Transaction raises competition concerns in the area of soft tissue CNB devices.[69]

(96) One of the competitors stated that the Transaction would lead to "*dominance in the market*".[70] Another competitor indicated that "*these both companies together will have a dominant position [...] and could be able to dictate prices in the biopsy device market over volume and bundle deals by their market power*".[71]

(97) The same concern was also confirmed by another customer who claimed that "*the transaction is particularly problematic because the parties have a dominant position on the UK market*".[72] This market participant further explained that the

65 Replies to questionnaire Q1 – competitors, question 25, 30 and 31.

66 Replies to questionnaire Q2 – customers, questions 16 and 17.

67 Replies to questionnaire Q1 – competitors, question 41.

68 Replies to questionnaire Q1 – competitors, question 41 and 41.1

69 Replies to questionnaire Q1 – competitors, question 41 and 41.1

70 Reply to questionnaire Q1 – competitors, question 41.1.

71 Reply to questionnaire Q1 – competitors, question 41.1. Reply by competitor active in Germany, where the Parties' combined market share in soft tissue CNB devices amounts to [40-50]% with an increment of [0-5]%.

72 Non-confidential minutes of the call with a market participant, 21 August 2017.

Transaction could significantly reduce choice on the UK market and that the UK National Health Service would struggle during the price negotiations.[73]

(98) While it is true that other suppliers remain present on the market, in particular Argon, Leica, Gallini, Somatex, and TSK Laboratory with different market shares depending on the country and type of tissue, given the merged entity's market shares exceeding [50-60]% on a number of markets, such smaller competitors are unlikely to act as a sufficient constraining influence. Furthermore, the market investigation results reveal that customers' switch very rarely. Some of the customers indicate that they have been using products of the same supplier (or two suppliers) for years because these products are reliable and the practitioners would not risk switching to less known products.[74] This situation is also due to the fact that typically the physicians decide on the type of device to be purchased, rather than the purchasing department which could be more price-oriented; as explained by one of the doctors: *"Physicians decide on the type of devices used, on the type of needles and on every other specificity of the device. Procurement departments in hospitals will buy whatever is needed from a medical point of view."* [75] The majority of customers who responded to the market investigation confirmed that the choice of a [biopsy] device is strictly influenced by the physician.[76]

(99) Taking into account these barriers to switching, the Parties' very high market shares exceeding [50-60]% on a number of markets and a small number of alternative suppliers who would likely constrain the merged entity's market power, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market in the area of soft tissue CNB devices.

(100) Also in the other affected markets, where the Parties' combined market shares are below [50-60]%, the other competitors are unlikely to act as constraining influence given the significant distance between the share of the merged entity and the second largest player[77] and therefore remove the serious concerns about the loss of competition due to the Transaction resulting in a significant reduction of choice for customers (physicians).

(101) With regard to potential markets for CNB devices for specific tissues, this finding would not change materially. In particular competitors name Bard and BD among the top 3 suppliers for CNB devices for most types of tissue.[78]

(102) Similarly, as regards the potential distinction between single-use and re-usable CNB devices. While the Parties' do not compete on the market for re-usable CNB devices, the assessment of the Transaction would not change when the market for single-use soft tissue CNB devices is considered.

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73 Non-confidential minutes of the call with a market participant, 21 August 2017.

74 Non-confidential minutes of the call with a practitioner, 16 August 2017.

75 Non-confidential minutes of the call with a market participant, 8 August 2017.

76 Replies to questionnaire Q2 – customers, question 14.

77 In Germany and Spain, the combined market shares of the Parties would be more than […] times larger than the second player on these markets ([name]).

78 Replies to questionnaire Q1 – competitors, question 26 and questionnaire Q2 – customers, question 13.

(103) In response to the market investigation the market participants have also indicated that innovation might be harmed by the Transaction, having a negative impact on the competition in R&D and innovation in the area of CNB devices. One market participant considers that there would be little incentive for new entrants and innovative efforts based on the very large market share position of the combined entity and minimal remaining competition and that the combined BD/Bard organization will also have little incentive to innovate in CNB, given its control over the market.[79]

(104) Given the Parties' combined market shares and on the basis of all the evidence gathered during the market investigation and in particular the evidence pointing at the fact that the Parties are close competitors and that the Transaction forms a threat to innovation in the market for CNB devices more generally, the Commission considers that the Transaction raises serious doubts as regards its compatibility with the internal market in respect of soft tissue CNB devices. This finding holds true irrespective of a potential tissue specific segmentation of the relevant product market for soft tissue CNB devices and irrespective of the potential distinction between re-usable and single-use soft tissue CNB devices.

5.3. Pipeline product "[name]"

5.3.1. Overview of pipeline project

(105) In addition to the horizontal overlaps between marketed products, the Transaction would also raise concerns in relation to a pipeline product: the "[name]" biopsy device.

(106) […]. Based on internal documents, as well as the submissions by experts who have been consultants for the development […]. [80]

(107) The Notifying Party claims that this new biopsy device responds to currently unmet needs of physicians and is therefore not in direct competition with any of the existing products of the Parties. The mechanism of [name] is different from that of VAB and CNB devices. […].[81]

(108) [Assessment of pipeline project in relation to existing CNB and VAB devices]. [82]

5.3.2. The Commission's assessment

(109) Based on the results of the market investigation, in particular the BD's internal documents and the testimonies of the experts who have been testing the [new] device, the Commission considers that the [new] device has multiple features that are innovative.[83] Given that the device is not yet commercialised, the precise competitive pressure it could exert on existing products cannot be conclusively assessed. However, in light of the specific features described above, it seems

79 Non-confidential minutes of the call with a market participant, 21 August 2017.

80 Internal documents of BD: […]. Non-confidential minutes of the call with the key opinion leader of 6 September 2017.

81 Internal documents of BD: […].

82 Internal documents of BD: […]. Non-confidential minutes of the conference call with the key opinion leader,6 September 2017.

83 Non-confidential minutes of the call with key opinion leader, 6 September 2017.

likely that the new product would be in direct competition with both VAB and CNB devices.

(110) […].[84][…].[85]

(111) The Commission therefore considers that it cannot be excluded that the [new]product, once fully commercialised, will be in direct competition with existing CNB and VAB devices from the Parties. In particular, absent the Transaction, BD with [the new device] could exert an important competitive on the market leader, Bard.

(112) Given the strength of the merged entity in relation to CNB products discussed above, the overlap between the pipeline product, [name], and the existing products of the merged entity, the Commission considers that the Transaction raises serious doubts as to the compatibility of the Transaction with the internal market, in respect of the market for soft tissue CNB devices and its plausible segments.[86]

(113) As indicated in section 5.3.1 above it is also likely that [the new device] could compete with VAB devices. The Commission notes that currently on an EEA-wide basis, only three players are active on the market for VAB devices. Two suppliers have market shares of more than [40-50]%: Bard and Hologic, while Leica has the remaining share of less than [20-30]%. The market is therefore highly concentrated. The Parties estimate the EEA market for VAB devices to amount to almost EUR [40-50 milion], constantly growing over the last three years. Taking this into account it seems likely that, absent the Transaction, BD could become a strong challenger on the VAB market, having already presence in other types of biopsy devices and using [new device], with its unique features and attractive pricing, as compared to VAB devices. It seems further plausible that post-Transaction, the merged entity would not have the same incentives to develop and commercialise the [new] product given Bard's strong position in VAB devices and the likelihood that [the new product] could cannibalise Bard's revenues in the VAB area.

(114) In light of the above and given the strong position of the merged entity on the markets for soft tissue CNB devices and VAB devices, the Commission considers that the incentives to fully develop and commercialise the new product would be reduced by the Transaction regardless of its final positioning closer to existing CNB or VAB devices.

5.4. Conclusion on soft tissue CNB devices and [the new product]

(115) In view of the above, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market (absent the Proposed Remedies, see section 6) due to its likely horizontal non-coordinated effects in markets for soft tissue CNB devices and its plausible segments. In

84 Internal documents of BD: […]. Also, non-confidential minutes of the conference call with the key opinion leader,6 September 2017.

85 […].

86 See Section 5.2. above for a detailed market shares analysis and competitive assessment of the relevant markets for CNB devices.

particular, such serious doubts arise on an EEA-wide level as well as in several national markets, including Finland, France, Ireland, Sweden, the UK, Austria, Belgium, Germany, and Spain.

(116) In addition, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market (absent the Proposed Remedies, see section 6) due to its likely detrimental effects on innovation, given the change of incentives to fully develop and commercialise the [new] product which is likely to compete either on the market for CNB devices, VAB devices, or both.

5.5. Tissue markers

5.5.1. Overview of tissue marker market

(117) While Bard offers tissue markers, BD has no marketed products but it is currently developing such a tissue marker ([…]). Bard is the market leader in the EEA in tissue markers.

(118) The Notifying Party estimates that Bard has [40-50]% market shares in a potential market encompassing all tissue markers. The market is concentrated with only three suppliers with more than [5-10]% market share (Leica [30-40]%; Somatek [10-20]%). The Parties estimate that the total market size for tissue markers in the EEA was more than EUR [20-30] million in 2016 with a clear growth trend over the last three years. The Notifying Party submits that the market share of sales of markers in each individual EEA country does not vary considerably from its overall EEA share.

(119) The competitive assessment would remain the same, if a distinction should be made between CNB and VAB tissue markers. Bard is the leader in this potential market for CNB markers with a market share of [30-40]%, while Leica has [20-30]% market share and Somatex has [20-30]% market share.[87]

5.5.2. Project [name]

(120) The Notifying Party claims that the pipeline product that it has been developing in the context of its project "[name]" is a CNB marker. Internal documents show that […].[88]

(121) […].

5.5.3. The Commission's assessment

(122) […].[89]

(123) […].[90][…].[91]

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87 Notifying Party's submission of 13 September 2017: Breast Biopsy Markers - Competitive Landscape.

88 Internal document of BD, […].

89 Internal document of BD. […]

90 Internal document of BD. […].

91 Internal documents: […].

(124) In light of the above, the Commission considers it likely that the development project contains valuable assets that could have had a positive impact on the market for tissue markers by bringing innovation to the market and increasing choice for physicians. The mere fact that the project was discontinued after the announcement of the Transaction is sufficient to raise doubts as to whether the project might have been continued in the absence of the Transaction.

(125) The Commission therefore considers that the Transaction (absent the Proposed Remedies, see section 6) raises serious doubts as to its compatibility with the internal market due to its likely horizontal non-coordinated effects in the market for tissue markers because of the existing overlaps between existing and pipeline products of the Parties.

6. PROPOSED REMEDIES

(126) For the reasons set out above, the Commission concludes that the Transaction gives rise to serious doubts as regards its compatibility with the internal market, resulting from the horizontal overlaps between the Parties' activities in markets for (i) CNB devices and (ii) tissue markers.

(127) In order to render the concentration compatible with the internal market, the undertakings concerned have modified the notified concentration by entering into commitments, submitted to the Commission on 27 September 2017 (the "First Commitments"). The Commission tested the First Commitments and provided feedback to the Parties. In response to this, the Parties submitted an improved set of Commitments on 10 October 2017 (the "Final Commitments") that are annexed to this decision and form an integral part thereof.

6.1. Framework for the assessment of commitments

(128) When a concentration raises competition concerns, the merging parties may seek to modify the concentration in order to resolve those competition concerns and thereby obtain clearance for the concentration.[92]

(129) The commitments must eliminate the competition concerns entirely and must be comprehensive and effective in all respects. The commitments must also be proportionate to the competition concerns identified.[93] Furthermore, the commitments must be capable of being implemented effectively within a short period of time as the conditions of competition on the market will not be maintained until the commitments have been fulfilled.[94]

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92 Commission Notice on remedies acceptable under the Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (OJ C 267, 22.10.2008, p. 1–27), (the 'Remedies Notice'), paragraph 5.

93 Recital 30 of the Merger Regulation. The General Court set out the requirements of proportionality as follows: 'the *principle of proportionality requires measures adopted by Community institutions not to exceed the limits of what is appropriate and necessary in order to attain the objectives pursued; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued'* (T-177/04 *easyJet v Commission* EU:T:2006:187, paragraph 133).

94 Remedies Notice, paragraphs 9, 10, 11, 63 and 64.

(130) Structural commitments proposed by the parties to a concentration will meet that condition only in so far as the Commission is able to conclude, with certainty, that it will be possible to implement them and that the new commercial structures resulting from them will be sufficiently workable and lasting to ensure that the significant impediment to effective competition which the commitments are intended to prevent, will not be likely to materialise in the relatively near future.[95]

(131) In assessing whether proposed commitments are likely to eliminate the serious doubts to which the concentration would otherwise give rise, the Commission will consider all relevant factors relating to the proposed remedy itself, including, inter alia, the type, scale and scope of the remedy proposed, judged by reference to the structure and particular characteristics of the market in which the competition concerns arise, including the position of the parties and other players on the market.[96]

(132) Based on these principles as well on the principles related to the implementation and effectiveness of all types of commitments set out in paragraphs 13 and 14 of the Remedies Notice, the Commission has assessed the commitments put forward by the Notifying Party in the present case.

6.2. Description of the First Commitments

(133) The First Commitments consist in the divestiture of BD's CNB devices global business, the BD's CNB pipeline product ([name]) and the BD's tissue marker pipeline product (developed in the context of Project [name]).

6.2.1. Scope of the First Commitments

(134) The First Commitments include the divestment of the CNB Business on a global basis and the transfer of the relevant tangible and intangible assets, licenses permits and authorizations, transitional arrangements and contracts listed below, to manufacture, market, sell and distribute BD's CNB devices.

(135) The Divestment Business will include the following tangible assets:

(a) BD's entire soft tissue CNB product lines, including products marketed under the brands Achieve, Temno, Temno Evolution and Tru-Cut (products: Achieve, Pink Achieve, Temno, Original Temmo, Temno Evolution, Tru Cut and Adjustable Coaxial Temmo -ACT-).

(b) Manufacturing equipment and machinery owned by BD and used in finished goods manufacturing of the above product lines, […].

(c) The inventory of finished goods to the extent related exclusively or predominantly to BD's soft tissue CNB product line and owned by BD as of the date of Closing, as well as all rights to market and sell such inventory.

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95 Judgment of 14 December 2005, *General Electric* v *Commission*, T-210/01, EU:T:2005:456, paragraph 555; Judgment of 6 July 2010, *Ryanair* v *Commission*, T-342/07, EU:T:2010:280, paragraph 453.

96 Remedies Notice, paragraph 12.

(136) The Divestment Business will include the following intangible assets:

(a) Contracts of BD exclusively or predominantly related to the CNB product lines or necessary to operate the Divestment Business.

(b) Patents and patent applications used by BD exclusively or predominantly in BD's soft tissue CNB product line and pipeline projects. The Divestment Business will also include an "unblocking license", a perpetual, royalty-free, sub-licensable, worldwide license under BD's retained patents and trade secrets to the extent necessary to own and operate the soft tissue CNB product line and pipeline projects.

(c) Know-how: BD will transfer the trade secrets, confidential know-how and other intellectual property owned by BD that are used by BD exclusively or predominantly in BD's soft tissue CNB product line (including tissue markers) and pipeline projects.

(d) The Divestment Business will also include an "unblocking license", a perpetual, royalty-free, sub-licensable, worldwide license to use other IP, know-how, customer data, trade secrets or other confidential information to the extent necessary to own and operate the soft tissue CNB product line and pipeline projects.

(e) Trademarks: Achieve, Temno, Temno Evolution and Tru-Cut (products: Achieve, Pink Achieve, Temno, Original Temmo, Temno Evolution, Tru Cut and Adjustable Coaxial Temmo -ACT-).

(f) At the option of the purchaser, the Divestment Business will include up to three Key Personnel, of which two are currently working in the CNB business of BD:

– […].

– […].

(137) The First Commitments include all information, reports, clinical trials results, design history files, regulatory documentation, clinical data, prototypes and all documentation necessary to ensure the viability of [the] pipeline product.

(138) The Divestment Business will include the following licences, permits and authorizations:

(a) All licenses, permits and authorizations issued by any governmental organization specifically identified by reference to a schedule.

(b) BD will also provide the purchaser with transition services […] with respect to contracts in the Divestment Business for which contract consents and/or governmental approvals are needed but not obtained prior to Closing.

(139) The First Commitments comprise transitional arrangements [relating to business support functions and capability building].

(140) The First Commitments include a transitional contract manufacturing agreement at actual cost ("CMA") […], entered into by BD and the purchaser for the supply of the BD soft tissue CNB products.

(141) The soft tissue markers Divestment Business comprises all information, reports, design history files, clinical data, prototypes and all documentation necessary to ensure the viability of the Marker pipeline product.

(142) The First Commitments include as well, at the option of the purchaser, an […] Engineer R&D […].

(143) In addition the Notifying Party has entered into related commitments, *inter alia* regarding the separation of the divested businesses from their retained businesses, the preservation of the viability, marketability and competitiveness of the divested businesses, including the appointment of a monitoring trustee and, if necessary, a divestiture trustee.

6.2.2. The purchaser criteria

(144) In order to be approved by the Commission, the purchaser must fulfil the following criteria:

(a) be independent of and unconnected to the Parties and their Affiliated Undertakings;

(b) have the financial resources, proven expertise, R&D, manufacturing, marketing and sales, logistics, and finance / IT administration capabilities and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors. In particular, after Closing the purchaser must have the capability, either directly or through third parties to cover at least 80% of BD's current sales in the EEA and to sterilize its CNB products;

(c) neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns.

6.2.3. The Notifying Party's view on the suitability of the First Commitments

(145) The Notifying Party submits that the Divestment Business creates the conditions for the emergence of a new competitive entity, or the strengthening of an existing competitor, in the area of soft tissue CNB devices.

(146) The Notifying Party claims that given that the Divestment Business encompasses the entirety of BD's soft tissue CNB product line, both globally and in the EEA, the First Commitments will remove the overlap between the Parties in this product area in its entirety.

(147) Upon acquiring the Divestment Business, the purchaser will have all assets necessary for immediate entry or expansion in the sale of soft tissue CNB products. The acquisition of the Divestment Business will allow the purchaser to establish a direct relationship with suppliers and customers at the global and EEA level.

(148) Upon acquiring the Divestment Business, the purchaser will have all the necessary elements for a viable and competitive business with access to a broad and geographically diverse customer base. It will allow the purchaser to effectively enter or expand in the supply of soft tissue CNB devices timely and on a lasting basis, and will create a new viable competitor or strengthen an existing competitor.

(149) The purchaser will be an experienced undertaking and, upon acquiring the Divestment Business, will have all tangible and intangible assets (including intellectual property rights), sales, sourcing and supply arrangements and distributor lists and records, it requires to be able to compete in the supply of soft tissue CNB devices. Therefore, upon acquiring the Divestment Business, the purchaser will have all the necessary elements to compete effectively in the market place.

7. ASSESSMENT OF THE PROPOSED REMEDIES

(150) As explained in this decision, the serious doubts as to the compatibility of the Transaction with the internal market reside in the combination of BD and Bard's activities in the soft tissue CNB devices and tissue markers.

(151) The First Commitments consist in the divestment of BD's CNB global business, BD's CNB pipeline product [name] and BD's tissue marker pipeline product (developed in the context of Project [name]). Therefore, the First Commitments cover all potential markets in respect of which the Commission has serious doubts as regards the compatibility of the Transaction with the internal market.

7.1. CNB devices and biopsy device pipeline product

(152) The Divestment Business includes the relevant manufacturing equipment, with which all the BD's CNB devices are manufactured. The divestiture of the whole plant owned by BD would not be proportionate. BD estimates that the Divestment Business accounts for just [10-20]% of the total volume produced at the facility and only [10-20]% of the facility's total value of production.

(153) The Divestment Business also includes finished goods inventory, contracts of BD related exclusively or predominantly to CNB product lines, patents and patents applications, know-how, trade secrets and other intellectual property, related regulatory approvals, trademarks, all information related to the pipeline projects, regulatory records, transitional services and key personnel at the option of the purchaser.

(154) The Divestment Business is worldwide in scope and therefore will completely remove the overlap in CNB devices on a global basis.

(155) The [name] project being divested include all BD's existing assets and documentation, information, reports, clinical trials results, design history files, regulatory documentation, clinical data and prototypes to ensure the viability and development of the new biopsy needle. At the option of the purchaser, it will also include a […] R&D Engineer […].

(156) The market test confirmed that, provided that a few small improvements are made to the First Commitments (section 7.3), they are sufficient to eliminate the serious doubts as to the compatibility of the Transaction with the internal market, as they are feasible, comprehensive and include all necessary assets for the successful transfer of BD's CNB devices business.

(157) Almost all respondents to the market test consider that it is feasible to transfer the production lines in a reasonable timeframe from BD's manufacturing plant to the purchaser's facility, irrespective of the location of the purchaser facility.[97]

(158) A vast majority of the respondents to the market test considers that the assets included in the CNB Divestment Business are comprehensive and contain all necessary elements for the successful transfer of BD's CNB business.[98]

(159) The market test also confirmed that the transfer of customers' information available as provided for in the First Commitments is sufficient for a purchaser to effectively reach customers and compete with the merging entity without erasing the customer base.[99]

(160) While a majority of the respondents to the market test consider that the transfer of the key personnel specified in the commitments would be sufficient to ensure the viability and competitiveness of the Divestment Business, some market participants claim that, depending on the identity and capacities of the purchaser, some extra key personnel could be necessary, in particular staff with expertise in quality management and regulatory affairs.[100]

(161) An important majority of the respondents to the market test consider that the duration of the transitional supply of components for manufacturing CNB devices and BD's support for the production transfer as described in the Commitments is sufficient.[101] Most competitors consider that it is important that the purchaser be active in the interventional radiologist area.[102]

(162) Virtually all respondents to the market test consider that divestment business is sufficiently attractive for a purchaser.[103] The market test also confirmed that the divestment business is a viable business and the purchaser criteria are sufficient.[104]

(163) With regard to the CNB pipeline product [name], the majority of the respondents to the market test consider that the key personnel specified in the First Commitments would be sufficient to successfully develop and bring to the market a pipeline product in the area of CNB devices.[105]

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97 Replies to questionnaire R1 – competitors, question 1; questionnaire R2 – distributors, question 2.

98 Replies to questionnaire R1 – competitors, question 5; questionnaire R2 – distributors, question 4.

99 Replies to questionnaire R1 – competitors, question 7; questionnaire R2 – distributors, question 6.

100 Replies to questionnaire R1 – competitors, question 10.

101 Replies to questionnaire R1 – competitors, questions 14 and 15.

102 Replies to questionnaire R1 – competitors, question 19.

103 Replies to questionnaire R1 – competitors, question 23.

104 Replies to questionnaire R1 – competitors, questions 17 and 18; questionnaire R 2 – distributors, questions 13 and 14.

105 Replies to questionnaire R1 – competitors, question 27.

7.2. Tissue markers

(164) The soft tissue markers Divestment Business comprises all information, reports, design history files, clinical data, prototypes and all documentation available regarding the marker pipeline product.

(165) The First Commitments include as well, at the option of the purchaser, a […] Engineer R&D […].

(166) Therefore, the purchaser will be in the same position as BD when considering how to continue this project. Virtually all respondents to the market test confirmed that the marker pipeline product is attractive for a purchaser and a good complement to biopsy devices.[106]

(167) The majority of the respondents to the market test consider that the key personnel specified in the First Commitments would be sufficient to successfully develop and bring to the market a pipeline product in the area of tissue markers.[107]

7.3. Final Commitments

(168) While the market test results broadly confirmed the suitability of the commitments, the following changes that have been suggested by the respondents to the market test have been introduced in the Final Commitments.

(169) First, it is clarified that the Schedule and its Appendices form an integral part of the Final Commitments and therefore of this decision.

(170) Second, the definition of the Assets to be transferred has been clarified to include all Assets mentioned in the Schedule and its Appendices. The transfer of additional assets that are necessary to ensure the viability and competitiveness of the Divestment Business, insofar as they are not specifically mentioned in the Schedule, should take the identity and capabilities of the purchaser into account.

(171) Third, the purchaser Criteria have been clarified to ensure that a suitable purchaser has proven expertise in interventional radiology as well as regulatory capabilities in addition to the criteria initially specified.

(172) Fourth, the Schedule has been updated to clarify that Assets specified in Appendix 1 include all documentation (for example, machine records, design history files and technical files) related to this manufacturing equipment and machinery.

(173) Fifth, the Schedule has been updated to clarify that other intangible assets include, where applicable, the CE mark.

(174) Sixth, the period during which BD provides transition services to the purchaser has been prolonged to […] and includes services related to [business support functions].

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106 Replies to questionnaire R1 – competitors, question 30; questionnaire R2 – distributors, question 24.

107 Replies to questionnaire R1 – competitors, question 29.

(175) All these changes have been incorporated and form an integral part of the Final Commitments as annexed to this decision.

(176) For the reasons outlined above, the Commission concludes that the Final Commitments entered into by the undertakings concerned and as submitted to the Commission on 10 October 2017 are sufficient to eliminate the serious doubts as to the compatibility of the Transaction with the internal market in respect of soft tissue CNB devices and tissue markers. The full text of the Final Commitments is annexed to this Decision as Annex I and forms an integral part thereof.

8. CONDITIONS AND OBLIGATIONS

(177) Pursuant to the second subparagraph of Article 8(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the internal market.

(178) The fulfilment of the measure that gives rise to the structural change of the market is a condition, whereas the implementing steps which are necessary to achieve this result are generally obligations on the parties.

(179) Where a condition is not fulfilled, the Commission's decision declaring the concentration compatible with the internal market is no longer applicable. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(6) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.

(180) In accordance with the basic distinction between conditions and obligations set out above, the decision in this case is conditional on full compliance with the requirements set out in Section B of the Final Commitments, which constitute conditions. The remaining requirements set out in the other Sections of the said commitments are considered to constitute obligations.

9. CONCLUSION

(181) For the above reasons and on the basis of the available evidence, the Commission has decided not to oppose the Transaction as modified by the Final Commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in section B of the Commitments annexed to the present decision and with the obligations contained in the other sections of the said Commitments. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission
(Signed)

Julian KING
Member of the Commission

OCTOBER 10, 2017

Case COMP/M.8523 – BD / BARD

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "***Merger Regulation***"), Becton, Dickinson and Company (including its Affiliated Undertakings, "***BD***") hereby enters into the following Commitments (the "***Commitments***") vis-à-vis the European Commission (the "***Commission***") with a view to rendering BD's acquisition of C. R. Bard, Inc. (including its Affiliated Undertakings, "***Bard***", and, together with BD, the "***Parties***") (the "***Transaction***") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Transaction compatible with the internal market and the functioning of the EEA Agreement (the "***Decision***"), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "***Remedies Notice***").

The Schedule and its Appendices form an integral part of the Commitments.

Section A. Definitions

1. For the purposes of these Commitments, the following terms shall have the following meaning:

   - **Affiliated Undertakings**: undertakings controlled by the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated

Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "***Consolidated Jurisdictional Notice***").

- **Assets**: the assets that are necessary to ensure the viability and competitiveness of the Divestment Business, and insofar as they are not specifically mentioned in the Schedule taking into account the identity and capabilities of the Purchaser, as indicated in Section B, paragraph 6 and as described in more detail in the Schedule.

- **BD**: Becton, Dickinson and Company, incorporated under the laws of the State of New Jersey (U.S.), with its registered office at 1 Becton Drive, Franklin Lakes, New Jersey 07417, U.S., and its Affiliated Undertakings

- **Closing**: the transfer of the legal title to the Divestment Business to the Purchaser.

- **Closing Period**: the period of [Confidential] from the approval of the Purchaser and the terms of sale by the Commission.

- **Confidential Information**: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

- **Conflict of Interest**: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

- **Divestment Business**: the assets as defined in Section B and in the Schedule which BD commits to divest.

- **Divestiture Trustee**: one or more natural or legal person(s) who is / are approved by the Commission and appointed by BD and who has / have received from BD the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

- **Effective Date**: the date of adoption of the Decision.

- **First Divestiture Period**: the period of [Confidential] from the Effective Date.

- **Hold Separate Manager**: the person appointed by BD to manage the day-to-day operation of the Divestment Business under the supervision of the Monitoring Trustee.

- **Key Personnel**: those production and R&D personnel currently involved in the Divestment Business and listed in the Schedule.

- **Monitoring Trustee**: one or more natural or legal person(s) who is / are approved by the Commission and appointed by BD, and who has / have the duty to monitor BD's compliance with the conditions and obligations attached to the Decision.

- **Parties**: BD and Bard.

- **Personnel**: BD employees, including Key Personnel, that will be responsible for the implementation of paragraphs 9 to 12 of these Commitments.

- **Purchaser**: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

- **Purchaser Criteria**: the criteria laid down in paragraph 17 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

- **Schedule**: the schedule to these Commitments describing more in detail the Divestment Business.

- **Trustee(s)**: the Monitoring Trustee and / or the Divestiture Trustee as the case may be.

- **Trustee Divestiture Period**: the period of [Confidential] from the end of the First Divestiture Period.

Section B. The commitment to divest and the Divestment Business

Commitment to divest

2. In order to maintain effective competition, BD commits to divest, or procure the divestiture of, the Divestment Business by the end of the Trustee Divestiture Period to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 of these Commitments. To carry out the divestiture, BD commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If BD has not entered into such an agreement at the end of the First Divestiture Period, BD shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

3. The Transaction shall not be implemented before BD or the Divestiture Trustee has entered into a final binding sale and purchase agreement for the sale of the Divestment Business and the Commission has approved the purchaser and the terms of sale in accordance with paragraph 18.

4. BD shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, BD or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 18; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

5. In order to maintain the structural effect of the Commitments, the Parties shall, for a period of ten (10) years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from BD showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the Transaction compatible with the internal market.

Structure and definition of the Divestment Business

6. The Divestment Business consists of BD's global soft tissue core needle biopsy ("***CNB***") product line, including the pipeline project [Confidential], as well as CNB markers, which includes the pipeline project [Confidential]. The structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business includes all the assets that are necessary to ensure the viability and competitiveness of the Divestment Business, taking into account the identity and capabilities of the Purchaser, as indicated in Section B, paragraph 6 and as described in more detail in the Schedule, in particular:
   (a) all tangible and intangible assets (including intellectual property rights);
   (b) all licenses, permits and authorizations issued by any governmental organisation for the benefit of the Divestment Business;
   (c) all contracts, leases, commitments and customer orders of the Divestment Business; customer, credit and other records of the Divestment Business; and
   (d) at the option of the Purchaser, the Key Personnel.

   For the avoidance of doubt, the Divestment Business shall include only the Assets described in the Schedule and, at the option of the Purchaser, Key Personnel listed in the Schedule. Notwithstanding the foregoing, Purchaser shall remain free to hire any associate not included in the Key Personnel who is currently working in the Divestment Business.

7. For the avoidance of doubt, the Divestment Business shall, *inter alia*, not include:

   (a) any manufacturing facilities of the Parties;

   (b) any employees or other personnel of the Parties, except for, at the option of the Purchaser, Key Personnel;

   (c) any tangible or intangible assets, authorizations and agreements which are not necessary to ensure the viability and competitiveness of the Divestment Business, taking into account the identity and capabilities of the Purchaser.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

8. From the Effective Date until Closing, BD shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and

shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular BD undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, to encourage all Key Personnel to be transferred, at the option of the Purchaser, with the Divestment Business, and not to solicit or move any Key Personnel to BD's remaining businesses. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Business, BD shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. BD must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission

Hold-separate obligations

9. BD commits, from the Effective Date until Closing, to procure that the Divestment Business is kept separate from the businesses that BD will be retaining and, after closing of the Transaction to keep the Divestment Business separate from the businesses that BD is retaining and to ensure that unless explicitly permitted under these Commitments: (i) management and staff of the businesses retained by BD, other than the Personnel, have no involvement in the Divestment Business; (ii) the Personnel and the Hold Separate Manager have no involvement in any business retained by BD and do not report to any individual outside the Divestment Business, except to the extent explicitly permitted under paragraphs 10 and 11 below or to the extent strictly necessary to assist in the transfer of the Divestment Business, maintain the viability of the Divestment Business and/or permitted by the Monitoring Trustee.

10. Until Closing, BD shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed in accordance with paragraph 9 above. Immediately after the adoption of the Decision, BD shall appoint a Hold Separate Manager. The Hold Separate Manager shall manage the Divestment

Business independently and in the best interest of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by BD. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 8(c) of these Commitments. The Commission may, after having heard BD, require BD to replace the Hold Separate Manager.

11. BD commits to take all reasonable steps to ensure that the Personnel shall not use any Confidential Information from the Purchaser other than information strictly required to assist in the transfer of the Divestment Business concerned, and they shall disclose such information to other BD personnel only to the extent strictly required to assist in the transfer of the Divestment Business concerned and subject to the same confidentiality obligations.

Ring-fencing

12. BD shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business. Any such Confidential Information obtained by BD before the Effective Date will be transferred to the Purchaser and not be used by BD, upon Closing. BD may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business; which is reasonably required to maintain the viability of the Divestment Business; and/or the disclosure of which to BD is required by law.

Non-solicitation clause

13. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertaking do not solicit, the Key Personnel transferred, at the option of the Purchaser, with the Divestment Business for a period of [Confidential] after Closing.

Due diligence

14. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, BD shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

(a) provide to potential purchasers sufficient information as regards the Divestment Business; and
(b) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

15. BD shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than ten (10) days after the end of every month following the Effective Date (or otherwise at the Commission's request).

16. BD shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

17. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

(a) be independent of and unconnected to the Parties and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);

(b) have the financial resources, proven expertise in interventional radiology, R&D, manufacturing, marketing and sales, regulatory, logistics, and finance / IT administration capabilities and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors. In particular, after Closing the Purchaser must have the capability, either directly or through third parties (under own agreements or under existing agreements of the Divestment Business of which the respective third parties have consented to transfer the agreement to the Purchaser), to cover at least 80% of BD's current sales in the EEA and to sterilize its CNB products;

(c) neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed, and must, in

particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business (the before-mentioned criteria for the purchaser hereafter the "***Purchaser Criteria***").

18. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When BD has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one (1) week to the Commission and the Monitoring Trustee. BD must be able to demonstrate to the Commission that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets or one or more Key Personnel, or by substituting one or more Assets or one or more Key Personnel with one or more different assets or different personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment procedure

19. BD shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. BD commits not to close the Transaction before the appointment of a Monitoring Trustee.

20. If BD has not entered into a binding sale and purchase agreement regarding the Divestment Business one (1) month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by BD at that time or thereafter, BD shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

21. The Trustee shall:
    (i) at the time of appointment, be independent of the Parties;

(ii) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and
(iii) neither have nor become exposed to a Conflict of Interest.

22. The Trustee shall be remunerated by BD in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by BD

23. No later than two (2) weeks after the Effective Date, BD shall submit the name or names of one or more natural or legal persons whom BD proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one (1) month before the end of the First Divestiture Period or on request by the Commission, BD shall submit a list of one (1) or more persons whom BD proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

24. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one (1) name is approved, BD shall appoint or cause to be appointed the

person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one (1) name is approved, BD shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one (1) week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by BD

25. If all the proposed Trustees are rejected, BD shall submit the names of at least two (2) more natural or legal persons within one (1) week of being informed of the rejection, in accordance with paragraphs 19 and 24 of these Commitments.

Trustee nominated by the Commission

26. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom BD shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

27. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or BD, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

28. The Monitoring Trustee shall:

(i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(ii) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its

continued economic viability, marketability and competitiveness and monitor compliance by BD with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the businesses retained by BD, in accordance with paragraphs 8 and 9 of these Commitments;

(b) supervise the management of the Divestment Business, in accordance with paragraph 10 of these Commitments;

(c) with respect to Confidential Information:

- determine all necessary measures to ensure that BD does not after the Effective Date obtain any Confidential Information relating to the Divestment Business,

- in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

- make sure that any Confidential Information relating to the Divestment Business obtained by BD before the Effective Date is eliminated and will not be used by BD, and

- decide whether such information may be disclosed to or kept by BD as the disclosure is reasonably necessary to allow BD to carry out the divestiture, maintain the viability of the Divestment Business and/or as the disclosure is required by law;

(d) monitor the splitting of assets and the allocation of Personnel between the Divestment Business and BD;

(iii) propose to BD such measures as the Monitoring Trustee considers necessary to ensure BD's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(iv) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:

(a) potential purchasers receive sufficient and correct information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and
(b) potential purchasers are granted reasonable access to the Personnel;

(v) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(vi) provide to the Commission, sending BD a non-confidential copy at the same time, a written report within fifteen (15) days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of Personnel so that the Commission can assess whether the Divestment Business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(vii) promptly report in writing to the Commission, sending BD a non-confidential copy at the same time, if it concludes on reasonable grounds that BD is failing to comply with these Commitments;

(viii) within one (1) week after receipt of the documented proposal referred to in paragraph 18 of these Commitments, submit to the Commission, sending BD a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets or one or more Key Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser;

(ix) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

29. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and obligations of the Divestiture Trustee

30. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 17 and 18 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to affect the sale. The Divestiture Trustee shall protect the legitimate financial interests of BD, subject to BD's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

31. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within fifteen (15) days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to BD.

III. <u>Duties and obligations of BD</u>

32. BD shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of BD's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and BD and the Divestment Business shall provide the Trustee upon request with copies of any document. BD and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

33. BD shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. BD shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the

information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. BD shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

34. BD shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, BD shall cause the documents required for effecting the sale and the Closing to be duly executed.

35. BD shall indemnify the Trustee and its employees and agents (each an "**Indemnified Party**") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to BD for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

36. At the expense of BD, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to BD's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should BD refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard BD. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 35 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served BD during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

37. BD agrees that the Commission may share Confidential Information proprietary to BD with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.

38. BD agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and

they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

39. For a period of ten (10) years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, discharge and reappointment of the Trustee

40. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

(a) the Commission may, after hearing the Trustee and BD, require BD to replace the Trustee; or

(b) BD may, with the prior approval of the Commission, replace the Trustee.

41. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-26 of these Commitments.

42. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The review clause

43. The Commission may extend the time periods foreseen in the Commitments in response to a request from BD or, in appropriate cases, on its own initiative. Where BD requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one (1) month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to BD. Only in exceptional

circumstances shall BD be entitled to request an extension within the last month of any period.

44. The Commission may further, in response to a reasoned request from BD showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to BD. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into force

45. The Commitments shall take effect upon the date of adoption of the Decision.

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duly authorised for and on behalf of BD

SCHEDULE

1. The proposed Commitments offered by BD consist of the divestiture to the Purchaser of BD's global soft tissue CNB product line, as defined in the Schedule, including the tangible and intangible assets listed below (hereinafter referred to as the "**Divestment Business**").

2. The Divestment Business is comprised of the following tangible assets:

   (a) The inventory of finished goods to the extent exclusively or predominantly related to BD's soft tissue CNB product line and owned by BD as of the date of Closing, as well as all rights to market and sell such inventory;

   (b) The manufacturing equipment and machinery owned by BD and used in finished goods manufacturing of BD soft tissue CNB products [Confidential]. A non-exhaustive list is included at **Appendix 1** to the Commitments. This includes all documentation (for example, machine records, design history files and technical files) related to this manufacturing equipment and machinery;

   (c) All business records, books of account, financial records, and tax records to the extent pertaining to BD's soft tissue CNB product line and pipeline projects. All information, including customer and supplier lists and details, product and pricing information, account histories, research data and commercial data to the extent relating exclusively to BD's soft tissue CNB product line, pipeline projects or the Divestment Business. BD will transfer also documents that relate to both BD's soft tissue CNB product line and other product lines, redacting the portion unrelated to the product line being transferred; and

   (d) All sales and promotional literature and other sales-related materials to the extent used or held for use exclusively or predominantly in BD's soft tissue CNB product line and pipeline projects.

3. The Divestment Business is comprised of the following intangible assets:

   (a) **Pipeline products**: All pipeline products and projects initiated before Closing, including [Confidential], and exclusively or predominantly related to BD's soft tissue CNB product line (including tissue markers) that are reflected in the books and records.

   (b) **Patents**: BD will transfer or license the patents and applications, including the rights thereto, owned by BD that are used by BD exclusively or predominantly in BD's soft tissue CNB product line and pipeline projects (including tissue markers). A non-exhaustive list of the patents and applications to be transferred is included at **Appendix 2** to the Commitments.

(c) **Know-how**: BD will transfer the trade secrets, confidential know-how, confidential customer data, or other confidential information and other intellectual property owned by BD that are used by BD exclusively or predominantly in BD's soft tissue CNB product line (including tissue markers) and pipeline projects.

(d) **Brands**: BD will transfer the Achieve™, Pink Achieve™, Temno™, Original Temno™, Temno Evolution™, Adjustable Coaxial Temno™ and Tru-Cut™ soft tissue CNB product line trademarks and brands owned by BD. A non-exhaustive list is included at **Appendix 2** to the Commitments. A non-exhaustive list of BD's current soft tissue CNB product line is included at **Appendix 3** to the Commitments.

(e) **Other intangible assets**: The Divestment Business will also include:

(i) Any contracts exclusively or predominantly related to BD's soft tissue CNB product line or pipeline projects (or are otherwise necessary to operate the Divestment Business and to develop the pipeline projects) entered into by BD prior to Closing.

(ii) In order to confer the benefit of such contracts to the Purchaser, BD will use its commercially reasonable efforts to transfer (in whole or in part) any sales, sourcing, supply and distribution agreements to the extent they relate exclusively or predominantly to the manufacture and/or commercialization of BD's soft tissue CNB product line or pipeline projects (or are otherwise necessary to operate the Divestment Business and to develop the pipeline projects). A non-exhaustive list of shared contracts is included at **Appendix 4** to the Commitments.

(iii) All licenses, permits and authorizations issued by any governmental organization (including, where applicable, the CE mark) specifically identified by reference to a schedule, to the extent transferable under applicable legal requirements and Purchaser and its affiliates do not own substantially similar licenses, permits and authorizations.

(f) **Patent and Know-How License:** The Divestment Business will also include an "unblocking license", a perpetual, royalty-free, sub-licensable, worldwide license under BD's retained patents and trade secrets, confidential know-how, confidential customer data, or other confidential information and other intellectual property to the extent necessary to own and operate BD's soft tissue CNB product line and pipeline projects, as it was operated immediately prior to the Closing, or to the extent they are used (but not exclusively or predominantly) in the Divestment Business or pipeline projects immediately prior to Closing. Confidential know-how as used in this paragraph (f) includes all information, reports, clinical trials results, design history files, regulatory documentation, clinical data, prototypes and all documentation related to [the pipeline products].

4. At the option of the Purchaser, the Divestment Business will include one or more Key Personnel, [Confidential] identified in **Appendix 5** to the Commitments.

5. **Contract Manufacturing Agreement**. A transitional contract manufacturing agreement ("**CMA**") for a period of up to [Confidential], entered into by BD and the Purchaser for the supply of the BD soft tissue CNB products. Prices will be at actual cost incurred to provide the relevant products, including the cost of direct labor and direct material used and percentage allocation of overhead that has been agreed with the Purchaser in the sale and purchase agreement to be approved by the Commission pursuant to paragraph 18 of the Commitments.

6. For a period of up to [Confidential], BD will provide the Purchaser with transition services [related to business support functions]. BD will further provide the Purchaser with [capability building services]. BD will also provide the Purchaser with transition services for a period of up to [Confidential] with respect to contracts in the Divestment Business for which contract consents and/or governmental approvals are needed but not obtained prior to Closing. Purchaser can also work to obtain its own contracts or governmental approvals (to the extent it does not already have them) during this period.

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