

### Claims

1. A separator for the centrifugal separation of a free-flowing product into different phases or for the centrifugal clarification of a product, having at least the following features:
  - a. a rotatable drum with a lower section and an upper section,
  - b. a means arranged in the drum for the clarification of a product which is to be processed in the centrifugal field,
  - c. one or both of the following parts being of a conical design: the drum upper section and the drum lower section,
  - d. a plurality or all of the following elements consist of plastic or a plastic-composite material:
    - the drum lower section,
    - the drum upper section,
    - the means for clarification,wherein
  - e. the drum comprises a feed system and a discharge system, and the entire drum is designed in a sealed type of construction, and
  - f. at least one discharge channel for a dense product phase is integrated into the drum upper section.
2. The separator as claimed in claim 1, wherein the means for clarification is a plate packet consisting of a stack of separating plates.
3. The separator as claimed in claim 1 or 2, wherein the drum can be rotated by means of a spindle construction which consists of plastic or a plastic-composite material.

4. The separator as claimed in claim 3, wherein the spindle construction is coupled directly to the output shaft of a motor, and wherein the spindle construction has no rotational bearings on its outside circumference.
5. The separator as claimed in one of the preceding claims, wherein all the product-contact regions of the drum consist of plastic.
6. The separator as claimed in claim 1, wherein the drum is enclosed by a housing which consists of plastic.
7. The separator as claimed in claim 4, wherein the entire separator, apart from the motor, consists of plastic.
8. The separator as claimed in one of the preceding claims, wherein the drum lower section is provided directly in one piece with a distribution attachment which has distribution channels for transferring the product to be processed from a feed pipe into the drum interior.
9. The separator as claimed in claim 6, wherein the entire drum, in addition to the feed system and discharge system and possibly a part of the housing, is designed as an exchangeable preassembled module consisting of plastic or a plastic-composite material.
10. The separator as claimed in claim 4, wherein the entire separator, apart from the motor, is designed as an exchangeable preassembled module consisting of plastic or a plastic-composite material.
11. The separator as claimed in claim 4, wherein the motor is flanged directly onto the housing.

12. The separator as claimed in one of the preceding claims,  
wherein the product-contacting sections of the  
discharge system consist of plastic.
- 5 13. The separator as claimed in one of the preceding claims,  
wherein the discharge regions of the discharge system  
are designed as annular channels which open axially  
into annuluses in annular bodies.
- 10 14. The separator as claimed in claim 13, wherein the  
annular bodies consist of plastic or a plastic-  
composite material.
- 15 15. The separator as claimed in one of the preceding claims,  
wherein a drum cover consisting of plastic is mounted  
on the drum upper section.
- 20 16. A use of a separator as claimed in claims 1 to 15 as a  
disposable separator for the one-time processing of a  
product batch.

### Claims

1. A separator for the centrifugal separation of a free-flowing product into different phases or for the centrifugal clarification of a product, having at least the following features:
- a. a rotatable drum with a lower section and an upper section,
  - b. a means arranged in the drum for the clarification of a product which is to be processed in the centrifugal field,
  - c. one or both of the following parts being of a conical design: the drum upper section and the drum lower section,
  - d. ~~one,~~ a plurality or all of the following elements consist of plastic or a plastic-composite material:
    - the drum lower section,
    - the drum upper section,
    - the means for clarification,
- wherein
- e. the drum comprises a feed system and a discharge system, and the entire drum is designed in a sealed type of construction, and
  - ef. at least one discharge channel for a dense product phase is integrated into the drum upper section.
2. The separator as claimed in claim 1, wherein the means for clarification is a plate packet consisting of a stack of separating plates.
3. The separator as claimed in claim 1 or 2, wherein the drum can be rotated by means of a spindle construction which ~~preferably~~ consists of plastic or a plastic-composite material.

4. The separator as claimed in claim 3, wherein the spindle construction is coupled directly to the output shaft of a motor, and ~~in that~~wherein the spindle construction has no rotational bearings on its outside circumference.

~~5. The separator as claimed in one of the preceding claims, wherein the drum comprises a feed system and a discharge system, and wherein the drum is designed in a sealed type of construction.~~

~~6.5.~~ The separator as claimed in one of the preceding claims, wherein all the product-contact regions of the drum consist of plastic.

~~7.6.~~ The separator as claimed in claim ~~5~~1, wherein the drum is enclosed by a housing which ~~preferably~~ consists of plastic.

~~8.7.~~ The separator as claimed in claim 4, wherein the entire separator, apart from the motor, consists of plastic.

~~9.8.~~ The separator as claimed in one of the preceding claims, wherein the drum lower section is provided directly in one piece with a distribution attachment which has distribution channels for transferring the product to be processed from a feed pipe into the drum interior.

~~10.9.~~ The separator as claimed in claim ~~7~~6, wherein the entire drum, in addition to the feed system and discharge system and possibly a part of the housing, is designed as an exchangeable preassembled module consisting of plastic or a plastic-composite material.

~~11.10.~~ The separator as claimed in claim 4, wherein the entire separator, apart from the motor, is designed as

an exchangeable preassembled module consisting of plastic or a plastic-composite material.

5        ~~12.11.~~ The separator as claimed in claim 4, wherein the motor is flanged directly onto the housing.

10        ~~13.12.~~ The separator as claimed in one of the preceding claims, wherein the product-contacting sections of the discharge system ~~preferably~~ consist of plastic.

15        ~~14.13.~~ The separator as claimed in one of the preceding claims, wherein the discharge regions of the discharge system are designed as annular channels which open axially into annuluses in annular bodies.

15        ~~15.14.~~ The separator as claimed in claim ~~1413~~, wherein the annular bodies consist of plastic or a plastic-composite material.

20        ~~16. The separator as claimed in one of the preceding claims, wherein at least one discharge channel for a product phase is integrated into the drum upper section.~~

25        ~~17.15.~~ The separator as claimed in one of the preceding claims, wherein a drum cover consisting of plastic is mounted on the drum upper section.

30        ~~18. A method for operating a separator as claimed in one of the preceding claims, wherein during a clarification process of a product very dense substances are concentrated, and in that the drum, after the processing of a batch, is melted down or is dissolved in an acid or the like, for example, in order to produce the dense substance as a residue of this process.~~

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19.16. A use of a separator as claimed in claims 1 to  
~~17~~15 as a disposable separator for the one-time  
processing of a product batch.

THE PATENTS ACT  
(CHAPTER 221)

IN THE MATTER OF Singapore Patent  
No. 11201408585Y titled "Separator" in  
the name of GEA Mechanical Equipment  
GmbH

IN THE MATTER OF Section 25(5), 83(1)  
and 84(3) of the Patents Act and Rule  
80(3) of the Patents Rules

**STATEMENT OF REASONS FOR PROPOSED AMENDMENT OF PATENT SPECIFICATION**

The Proprietor, GEA Mechanical Equipment GmbH, of Singapore Patent No. 11201408585Y titled "Separator" (hereinafter "the Patent") seeks leave to amend the patent specification.

**A. SUMMARY OF THE PROPOSED AMENDMENTS**

1. Claim 1 is amended to delete the option of "one" from feature d. Claim 1 is further amended to include feature e. which incorporates claim 5 in its entirety and specifies that the entire drum is designed in a seal type of construction.
2. Claim 4 is editorially amended. The term "preferably" is deleted from the claims.
3. Claims 5, 16 and 18 are deleted and subsequent claims are renumbered accordingly.

**B. COMPLIANCE WITH STATUTORY REQUIREMENTS**

4. In *Ship's Equipment Centre Bremen GmbH v Fuji Trading (Singapore) Pte Ltd and others and another suit [2015] SGHC 159* (hereinafter "Ship's Equipment") at [22]-[25], the court affirmed the applicability of not only Section 84(3)(a) and (b) but also the "base-line criteria" in Section 25(5)(b) and (c) of the Patents Act to any post-grant amendment. The present proposed amendments fully comply with these statutory requirements, as discussed in detail below.

**Section 84(3)(a)**

5. The deletion of "one" from feature d. in claim 1 does not add new matter. Page 2, lines 4-6 of the description states that the means for clarification is preferably a separating plate

packet consisting of plastic. Page 2, lines 15-19 of the description states that “some, and preferably even all, of the product-contacting regions of the rotating system consist of plastic or a plastic-composite material, especially the drum lower section and the drum upper section and the plate packet”. Page 10, lines 27-32 and page 11, lines 17-21 offer further similar description. Thus, it is explicitly disclosed that some or all of the drum lower section, drum upper section and means for clarification consist of plastic or plastic-composite material.

6. The inclusion of feature e. into claim 1 does not add new matter. Page 3, lines 23-26 of the description states that “[i]t is advantageous and particularly hygienic in this case if the entire drum, especially also its feed system and its discharge system, is/are designed as a sealed type of construction”. Further, page 10, line 19-21 of the description states that “[t]he feed system and also the discharge system with the at least two discharges, and therefore the entire drum 2, are preferably of a hermetically sealed design”. In other words, feature e. is explicitly disclosed in the description.
7. The deletion of claims 5, 16 and 18 and of the term “preferably”, and the editorial changes to claim 4 are self-explanatory and do not require further discussion.

#### **Section 84(3)(b)**

8. The deletion of “one” from feature d. in claim 1 has the effect of reducing the number of permutations possible from the elements listed in feature (d). More particularly, before the deletion, up to 7 permutations are available from among (i) the drum lower section, (ii) the drum upper section, and (iii) the means for clarification. After the deletion, only 4 of the 7 permutations remain. Thus, it is clear that this change does not extend the scope of protection.
9. It is well-established that an independent claim offers the broadest scope among the claims in the same claim set. That is, the scope of dependent claim 5 is narrower than that of independent claim 1. Thus, the incorporation of claim 5 in its entirety into claim 1 effectively reduces the scope of protection. Specifying “the entire drum” further reduces the scope of protection. More particularly, before the change, not all of the drum is required to be in a sealed type of construction. After the change, all of the drum is required to be in a sealed type of construction. In summary, the inclusion of feature e. into claim 1 does not extend the scope of protection.

10. The changes to claim 4 is editorial in nature as discussed above. The deletion of the term “preferably” has the effect of limiting the scope of the respective claims to the narrower definition. The deletion of claims 16 and 18 further reduces the scope of protection. In particular, the deletion of claim 18 removes the aspect of operating the separator from the scope of protection.
11. In summary, it is submitted that the proposed amendments do not result in the specification disclosing any additional matter or extending the protection conferred by the patent. The proposed amendments therefore comply with the requirements of Section 84(3)(a) and (b).

#### **Section 25(5)(b)**

12. As an initial note, the Patent was granted under the positive-grant system based on a substantive examination report, which has fully considered the requirements of Section 25(5)(b), including terms such as “preferably”. See Chapter 5, Part H of the *Examination Guidelines for Patent Applications at IPO*, April 2015 version.
13. The proposed amendments mainly involve the incorporation of the fully examined claim 5 into claim 1 and the deletion of some of the claims. It follows that these changes continue to meet the requirements of Section 25(5)(b) as noted above. With regards to specifying that the entire drum is designed in a sealed type of construction, it is submitted that this change helps to clarify the feature, as the drum includes multiple parts. For completeness, it is further noted that the deletion of claim 16 helps to remove a redundant claim because its features are already recited in claim 1, while the deletion of the term “preferably” has no negative effect on the clarity of the claim. In other words, the claims as amended are clear and concise.

#### **Section 25(5)(c)**

14. The proposed amendments are fully supported by the description, as discussed in detail in paragraphs 5 and 6 above.
15. In summary, it is submitted that the claims as amended are clear and concise and are supported by the description. Thus, the proposed amendments comply with the requirements of Section 25(5)(b) and (c).

### **C. COMPLIANCE WITH DISCRETIONARY CRITERIA FOR POST-GRANT AMENDMENT**

16. In *Ship's Equipment*, the court followed the approach adopted earlier in *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd and others and other suits (No 2) [2005] SGHC 90* and set out additional assessment criteria in the exercise of its discretion whether to allow a post-grant amendment. The assessment criteria were also applied subsequently in *Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd [2016] SGHC 106* (hereinafter "Warner-Lambert") and *Singapore Shipping Association and Association of Singapore Marine Industries v Hitachi, Ltd. and Mitsubishi Shipbuilding Co., Ltd. [2019] SGIPOS 5* (hereinafter "Singapore Shipping Association"), and formalised in Circular No. 1/2016 from the Registry of Patents. They include:
- i. whether relevant matters are sufficiently disclosed;
  - ii. whether there was any unreasonable delay in seeking amendments; and
  - iii. whether the patentee has gained an unfair advantage obtained by delaying amendments which are known to be needed.

The present proposed amendments fully comply with these discretionary criteria, as discussed in detail below.

#### **Relevant Matters**

17. The Patent is the Singapore national phase of international application number PCT/EP2012/070182. The Patent was granted under the positive-grant system following a local substantive examination based on the International Search Report established by the International Searching Authority, the European Patent Office, in respect of the international application. The application from which the Patent matures was amended twice, on 6 April 2015 before the request for substantive examination was filed and on 15 April 2016 in response to a written opinion issued for the request for substantive examination. A fully positive Examination Report and Notice of Eligibility was issued on 29 July 2016. Subsequently, the grant fee was paid and the patent was granted on 13 September 2016.
18. The full file history is available for public inspection upon a specific request to the Registrar. In addition, the "Patents Open Dossier" system provided by the Registrar makes prosecution documents relating to the Patent publicly available at no cost. The Proprietor therefore submits that it would be unnecessary to provide a detailed

prosecution history of the Patent here, but is willing to provide any documents, except those which are considered privileged, if so required.

19. International application number PCT/EP2012/070182 claims priority of German patent application no. DE 10 2012 105499.1 filed on 25 June 2012. In addition to Singapore, national/regional phase entries were made in Brazil, Canada, China, Europe, India, Japan, Republic of Korea and the United States of America. The European patent that matured from the European regional phase application was validated in a number of countries, including Germany, Switzerland and Lichtenstein, Denmark, Great Britain, and Sweden. For reference, the Proprietor provides a table summarizing the related cases in the same family as the Patent in Annexure A.
20. While different terms are used by the respective patent offices for an official communication containing objection or requiring response, they are generically referred to as “office action” in Annexure A. The Proprietor submits that the detailed office actions, prior art listings, amendments and other official communications, etc. are publicly available through the respective open dossier systems of the different jurisdictions, as also noted by the Registrar in *Singapore Shipping Association* at [32]. Accordingly, such documents can be easily retrievable and are not provided here. Again, the Proprietor is willing to provide copies of any non-privileged documents from the related cases, including a list of all prior art cited in the office actions issued by various patent offices, if so required.
21. The priority German application and the corresponding patent applications in Canada, Japan, Republic of Korea and the United States of America were abandoned by non-action, and the corresponding Indian application is still pending. Thus, no conclusion should be drawn about the relevance of the prior art raised or amendments made, if any, in those applications. In this regard, the Registrar’s comment that “it would, in general, be unreasonable for the Applicants to amend a granted patent in view of pre-grant examination proceedings elsewhere, unless those proceedings had resulted in an allowable claim set” in *Singapore Shipping Association* at [46] is instructive.
22. The corresponding application in China was granted on 12 April 2017 following two rounds of office action and response. In the First Office Action, the Chinese Examiner raised novelty and inventive step objections against the application based on US 2011/319248 A1 (reference D1 in the International Search Report) even though the accompanying search report includes several other documents. In the Second Office

Action, the Chinese Examiner raised inventive step objections against the application based on US 2011/319248 A1 (D1, above) and US 6162163 (reference D4 in the International Search Report). Both D1 and D4 had been fully considered during substantive examination in Singapore, where D1 had been successfully addressed by the amendments and response of 15 April 2016 while D4 had been deemed to belong to general state of the art, that is, not relevant. Accordingly, there were no newly-cited prior art documents that would have warranted an amendment of the claims of the Patent by the Proprietor following the patent grant in China on 12 April 2017.

23. The corresponding European application was also amended twice during the European regional phase, as summarized in Annexure A. The first amendment was made on 2 September 2015 before examination. A First Office Action issued by the European Patent Office cited WO 2012/013654 A2 (D7) and DE 2701624 A1 (D8) in addition to references D1-D6 from the International Search Report, and inventive step objections were raised against claim 1 based on a combination of D1 and D7/ or D1 and D8. The second amendment made on 18 February 2019 was in response to the First Office Action and overcame the asserted combination of D1 and D7/ or D1 and D8. The corresponding European application subsequently proceeded to grant on 21 August 2019. Under European patent practice, a period of 9 months is available for any party to oppose the grant of a European patent. In the case of the corresponding European application, that period would have expired on 21 May 2020. On 19 May 2020, Alfa Laval Corporate AB filed a notice of opposition against the grant of the European patent.
24. In the corresponding Brazil application, the First Office Action that issued includes a search report citing the same references D1-D6 of the International Search Report together with general comments that the application did not meet the relevant requirements. In response, the claims were amended to substantially conform to the claims of the corresponding European patent as granted. The corresponding Brazil application matured to grant on 1 September 2020. Under Brazilian patent practice, a period of 6 months is available for any person having a legitimate interest to oppose the patent grant (also known as administrative nullity proceedings). At this time, that period still has not expired.
25. On 28 August 2020, an application for revocation of the Patent was lodged by Alfa Laval Corporate AB (hereinafter “the revocation applicant”). As noted above and in Annexure A, the same revocation applicant had filed a notice of opposition on 19 May 2020 against the European patent that matured from the corresponding European regional phase

application. The grounds for revocation of the Patent advanced by the revocation applicant are substantially the same as the submissions made in the European notice of opposition, i.e. (a) the invention does not involve an inventive step, and (b) the specification does not disclose the invention clearly and completely for it to be performed by a person skilled in the art. Documents D1-D19 relied upon by the revocation applicant in the application for revocation of the Patent are also the same as documents D1-D19 in the European opposition. A copy of the European notice of opposition is provided as Annexure B. Full documents relating to the opposition procedure are publicly available from the European Patent Office's database.

26. By the present request, the Proprietor seeks to amend the claims of the Patent to bring them substantially into alignment with the claims of the corresponding European patent to the extent possible. A comparison of the claims of the Patent as proposed to be amended and the claims of the corresponding European patent currently on file is provided in Annexure C.

#### **No Undue Delay**

27. It is worth reiterating a major distinction between the Patent and the patents at issue in *Ship's Equipment*, *Warner-Lambert* and *Singapore Shipping Association*, that is, the Patent was substantively examined locally and granted under the positive-grant system which had been adopted in Singapore from 14 February 2014. In the present case, there was independent substantive examination carried out in Singapore. In contrast, the patents at issue in *Ship's Equipment*, *Warner-Lambert* and *Singapore Shipping Association* were granted under various forms of the old self-assessment system where it was common to request grant in Singapore directly based on the examination result from a qualified foreign patent office. For example, in *Singapore Shipping Association*, reliance on a Japanese patent was made for a direct allowance in Singapore.
28. The Patent was granted on 13 September 2016, which is the earliest in its patent family. Following each conclusion of substantive prosecution of a corresponding case, the status of the claims of the Patent vis-à-vis the prior art references asserted in that corresponding case was reviewed. The corresponding Chinese, European and Brazilian patents were granted on 12 April 2017, 21 August 2019 and 1 September 2020 respectively. The substantive prosecution of the Brazilian case has not concluded at this time, since the opposition period has not expired. As submitted above, the objections in the Chinese office actions were based on prior art references already cited in the International Search

Report and fully considered during examination in Singapore. Thus, the Proprietor, based on the review of the relevant information available at the time, was of the view that an amendment of the claims of the Patent was not warranted. Only the corresponding European case encountered objections based on newly-cited references, specifically D7 and D8 as noted above. However, both D7 and D8 were not cited for novelty assessment nor were they primary references, but only cited as secondary references for inventive step assessment. The amendments made in response to the First Office Action of the European case were intended to advance prosecution by providing further distinction over the prior art to overcome the inventive step objections, and not because D7 and D8 presented novelty concerns. In other words, D7 and D8 are not “relevant prior art” in the sense of anticipating the claims of the European case.

29. As the substantive prosecution of a European application can only be considered finally concluded after the end of the opposition period (if the patent is not opposed) or after the end of any opposition proceedings (if the patent is opposed), the corresponding European application could only be conclusively allowed after 21 May 2020 at the earliest provided it was unopposed. The Proprietor would have then carried out a review of the European prosecution matters to ascertain whether any amendments may be required to the Patent. However, in the present case, a notice of opposition had been filed against the European grant by the revocation applicant before the end of the opposition period. As such, the prosecution of the European application has not concluded. A chronology of relevant events is provided below:

| Date           | Event                                                               |
|----------------|---------------------------------------------------------------------|
| 21 August 2019 | Publication of grant of European patent                             |
| 19 May 2020    | Notice of opposition against the grant of the European patent filed |
| 21 May 2020    | Expiration of the opposition period in Europe                       |
| 28 August 2020 | Application for revocation of the Patent lodged in Singapore        |

30. There is no undue delay in the period from 19 May 2020 to 28 August 2020. It was held in *Novartis AG and another v Ranbaxy (Malaysia) Sdn Bhd* [2013] 2 SLR 117 and followed in *Singapore Shipping Association* at [54] that “there was no undue delay on the part of the plaintiff in not amending the Singapore patent in light of prior art, given that they were awaiting the outcome of opposition proceedings before the EPO”. Between 19 May 2020 and 28 August 2020, the Proprietor was facing a similar situation as that quoted above. As mentioned, the Proprietor had been awaiting the outcome of the on-going

European opposition proceedings prior to considering whether any amendments may be required to the Patent. In view of the application for revocation of the Patent being lodged just over 3 months after the notice of opposition was filed against the European patent, the Proprietor is now compelled to proceed with the present amendments in these proceedings notwithstanding that the European opposition proceedings have not concluded. In other words, the Proprietor has acted reasonably and promptly under the circumstances.

### **No Unfair Advantage**

31. In contrast to the conduct of the patentees in ***Ship's Equipment, Warner-Lambert*** and ***Singapore Shipping Association***, the Proprietor has not threatened any parties with infringement proceedings based on the Patent in its un-amended form, nor has the Proprietor attempted to extract a commercial advantage in negotiations with other parties based on the Patent in its un-amended form.

### **Conclusion**

32. Having complied with all the relevant requirements, the Proprietor respectfully requests that the present proposed amendment of the patent specification be allowed.

Dated this 28<sup>th</sup> day of January, 2021

***SPRUSON & FERGUSON***

Patent Attorneys for the Proprietor

SPRUSON & FERGUSON (ASIA) PTE LTD

# **ANNEXURE**

## **A**

### **ANNEXURE A**

| <b>Jurisdiction</b>    | <b>Application number</b> | <b>Status</b>                    | <b>Main prosecution events</b>                                                                                                                                                                                                                                                                               |
|------------------------|---------------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Germany                | DE 10 2012 105499.1       | Abandoned                        | 26 June 2019: Application abandoned by non-action                                                                                                                                                                                                                                                            |
| Brazil                 | BR112014032177            | Granted                          | 5 November 2019: First Office Action issued<br>31 January 2020: Response lodged, including amendment of claims<br>9 June 2020: Examination Report and Notification of Grant issued<br>1 September 2020: Patent granted                                                                                       |
| Canada                 | CA 2875627                | Abandoned                        | 20 September 2018: First Office Action issued<br>15 March 2019: Response lodged, including amendment of claims<br>7 June 2019: Second Office Action issued<br>9 December 2019: Application abandoned by non-action                                                                                           |
| China                  | 201280074251.3            | Granted                          | 7 January 2016: First Office Action issued<br>19 May 2016: Response lodged, including amendment of claims<br>8 July 2016: Second Office Action issued<br>23 November 2016: Response lodged, including amendment of claims<br>23 February 2017: Notification of Grant issued<br>12 April 2017: Patent granted |
| European Patent Office | 12780135.5                | Granted /<br>Under<br>Opposition | 2 September 2015: Voluntary amendment filed<br>8 August 2018: First Office Action issued<br>18 February 2019: Response lodged, including amendment of claims<br>2 April 2019: Notice of Intention to Grant issued<br>25 July 2019: Decision to Grant issued<br>21 August 2019: Publication of grant          |

|                             |                 |           |                                                                                                                                                                                                                 |
|-----------------------------|-----------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             |                 |           | 19 May 2020: Notice of opposition filed by Alfa Laval Corporate AB                                                                                                                                              |
| Japan                       | 2015-518871     | Abandoned | 1 September 2015: Voluntary amendment of description filed<br>20 December 2016: First Office Action issued<br>25 Jul 2017: Application abandoned by non-action                                                  |
| Republic of Korea           | 10-2015-7000871 | Abandoned | 10 July 2017: Voluntary amendment filed<br>24 October 2018: First Office Action issued<br>8 January 2019: Application abandoned by non-action                                                                   |
| United States of<br>America | 14/411,335      | Abandoned | 15 July 2016: First Office Action issued<br>12 January 2017: Response lodged, including amendment of claims<br>3 July 2017: Second Office Action issued<br>22 January 2018: Application abandoned by non-action |
| India                       | 3066/KOLNP/2014 | Pending   | 7 March 2019: First Office Action issued<br>30 August 2019: Response lodged, including amendment of claims                                                                                                      |

# **ANNEXURE**

## **B**

Date: 19 May 2020  
Our Ref: OP 0085-EP



European Patent Office  
80298 Munich  
Germany

**Sent via EPO online filing**

**Alfa Laval Corporate AB**  
Patent Department  
P.O. Box 73  
SE-221 00 LUND  
Sweden

Tel: +4646366500  
Fax: +4646367156

## NOTICE OF OPPOSITION

In accordance with Art. 99 EPC, a notice of opposition is hereby filed against  
EP 2864053 B1.

|                                  |                                                                 |
|----------------------------------|-----------------------------------------------------------------|
| Application Number:              | EP 12780135.5                                                   |
| Publication of Mention of Grant: | 21.08.2019                                                      |
| Patent Proprietor:               | GEA Mechanical Equipment GmbH                                   |
| Title:                           | SEPARATOR                                                       |
| Opponent:                        | Alfa Laval Corporate AB<br>P O Box 73<br>SE-221 00 Lund, Sweden |
| Opponent's Ref.:                 | OP 0085-EP                                                      |

### 1. Requests

Revocation of the above identified Patent in its entirety is hereby requested, in  
accordance with Articles 100(b) and 100(a) EPC, inventive step.

Oral proceedings (Art. 116 EPC) are hereby requested if the Patent cannot be  
revoked on the basis of written submissions.

## **2. Cited Documents and Witness**

Documents D1 – D8 were cited during examination of the preceding application.

Documents D9 – D19 are newly cited documents. Documents D12 – D19 relate to a public prior use.

- D1     US 2011/319248
- D2     EP 0361964
- D3     EP 1685908
- D4     US 6162163
- D5     DE 10333058
- D6     DE 4314440
- D7     WO 2012/013654
- D8     DE 2701624
- D9     US 3126338
- D10    WO 2011/093784
- D11    Extract from Dairy Processing Handbook, 2003, ISBN 6-631-3427-6
- D12    Alfa Laval CF400B leaflet
- D13    Affidavit Mr. Patrik Kagevi
- D14    Quotation CF400B to CJ Biotech (masked)
- D15    AL Internal Order CF400B (masked)
- D16    E-mail to CJBiottech startup meeting CF400B
- D17    Invoice to CJ Biotech CF400B (masked)
- D18    Bill of lading Korea express CF400B
- D19    Extract from Operators Manual CF400B

### **2.1 Witness**

Mr. Patrik Kagevi, Team Leader Biotech, High Sped Separation, at Alfa Laval is offered as a witness for clarifying the public availability of the Culturefuge 400 B before the priority date of the present Patent and the public prior use in the form of

the sale to CJ (Liaocheng) Biotech Co. Ltd. in 2011 and 2012 of one Culturefuge 400 B, D12 – D19.

### **3. Article 100(b) EPC**

Claim 17 of the patent defines a method for operating a separator characterized in that during a clarification process of a product very dense substances are concentrated, and in that the drum, after the processing of a batch, is melted down or is dissolved in an acid or the like, for example, in order to produce the dense substance as a residue of this process.

The patent does not disclose how melting the drum or dissolving the drum in acid would produce the very dense substance. Only paragraphs [0010] and [0023] refer to melting and dissolving in order to arrive at a very dense substance. However, these paragraphs do not disclose more than claim 17.

The skilled person will not be able to perform the method based on the disclosure of the patent since there are numerous aspects of melting or dissolving in acid that will have to be considered in order to produce the very dense substance. What plastic material lends itself for such a method? How is the very dense substance extracted from a molten blob of plastic material? How is it ensured that the very dense substance is not damaged by heat from a melting process or by acid in a dissolving process? How is it ensured that the very dense substance does not mix with molten plastic or with dissolved plastic/acid? What type of very dense substance could be produced by the method? Etc.

Therefore, the patent does not fulfil the requirements of Art. 83 EPC and motivates raising the ground for opposition under Art. 100(b) EPC.

### **4. Article 100(a) EPC**

Claim 1 of the Patent has been phrased and divided into features by the Patentee as follows:

1. A separator for the centrifugal separation of a free-flowing product into different phases or for the centrifugal clarification of a product, having at least the following features:

a. a rotatable drum (2) with a lower section (7) and an upper section (8),

- b. a means arranged in the drum (2) for the clarification of a product which is to be processed in the centrifugal field,
- c. wherein one or both of the following parts are of a conical design: the drum upper section and the drum lower section (8, 7),
- d. wherein a plurality or all of the following elements consist of plastic or a plastic-composite material:
  - the drum lower section (7),
  - the drum upper section (8),
  - the means for clarification,

**characterized in that**

- e. the drum (2) with its feed system and its discharge system, is designed in a sealed type of construction, and
- f. at least one discharge channel for a dense product phase is integrated into the drum upper section (8).

4.1 Inventive Step Art. 56 EPC

4.1.1 D1 US 2011/0319248 and D7 WO 2012/013654 or D8 DE 2701624

The Patent relates to a separator devised for single use in the pharmaceutical industry. For this purpose, at least part of a rotatable drum of the separator consist of plastic or plastic-composite material. Accordingly, after processing a product batch, no cleaning of the drum is required. Instead, the entire drum is replaced with a new drum of the same kind, [0008], [0009].

D1 discloses a disc stack centrifuge (separator) of the same kind as the Patent. A single use portion of the centrifuge, including at least a bowl, an inlet, and fluid outlets, are made from polymers or plastics, [0006], [0008], [0014], [0015], and Fig. 2. D1 was the closest prior art document relied upon during examination of the preceding patent application.

It was concluded during examination that D1 discloses all features of the pre-characterising portion of claim 1. For the sake of completeness, the features of the pre-characterising portion of claim 1 may be found at the following passages/figures of D1:

- a. bowl 4, [0015], Fig. 2;
- b. disc stack 5, [0008], Fig. 2;
- c. upper bowl portion is conical design, Fig. 2;
- d. single use bowl 4 and disc stack 5 of polymeric construction, [0016] (three last lines of page 1), and [0019].

#### 4.1.1.1          Feature e.

D1 also implicitly discloses feature e. of claim 1, that the drum with its feed system and its discharge system is designed in a sealed type of construction. Namely, the fluid inlet and outlet of the centrifuge are fashioned as aseptic connectors, [0009], [0013], [0020], [0021].

At the beginning of paragraph [0020] it is mentioned that “... *the centrifuge is incorporated with or used in conjunction with aseptic (sterile) connectors 10, 20 such that the device may be attached to a process or container without the risk of contamination ...*”. At the end of paragraph [0021] it is further explained that “*Upon combining the two ends of the connector the flow path is generally opened by way of some means such as actuation, use of the membrane barrier and so forth. The fluid flow path is not exposed and therefore remains sterile.*”

Accordingly, the entire single use portion of the centrifuge of D1 is devised in a manner such that it does not risk being contaminated and such that the fluid flow path is sterile. Namely, it would make no sense to provide aseptic connectors to the single use portion unless also the rest of the single use portion is devised in a manner which eliminates the risk of contamination thereof.

Therefore, the bowl 4 with its feed system 8 and its charge system 9 inherently must be designed as a sealed type of construction.

Thus, D1 discloses feature e. of claim 1.

#### 4.1.1.2          Feature f.

Only feature f. is not disclosed in D1. Accordingly, the situation is exactly the same starting from D1 as the closest prior art document as it was during examination of the preceding patent application.

Accordingly, the arguments presented by the Examiner in the Communication under Art. 94(3) EPC dated 08.08.2018 apply:

Der Anspruch 1 **unterscheidet sich** von D1 dadurch, dass in das Trommeloberteil (8) wenigstens ein Ablaufkanal für eine schwere Produktphase integriert ist.

Die mit der vorliegenden Erfindung zu lösende **Aufgabe** kann somit darin gesehen werden, eine konstruktiv einfache Ableitung einer schweren Produktphase zu bewerkstelligen.

Die in Anspruch 1 der vorliegenden Anmeldung vorgeschlagene **Lösung** kann aus folgenden Gründen nicht als erfinderisch angesehen werden (Artikel 52 (1) und 56 EPÜ):

Bei dem unterscheidenden Merkmal handelt es sich nur um eine von mehreren, insbesondere von lediglich zwei häufig verwendeten, naheliegenden Möglichkeiten, die der Fachmann ohne erfinderisches Zutun den Umständen entsprechend auswählen würde, um die gestellte Aufgabe zu lösen.

Dieses Merkmal wurden für denselben Zweck schon bei vielen ähnlichen Separatoren, insbesondere auch bei Separatoren des Anmelders, benutzt;

vgl. dazu Dokument D7, Seite 3, Zeilen 16 - 20, wo beschrieben wird die schwerere Flüssigkeitsphase über einen Scheideteller oder einen Kanal (14) im Trommeldeckel (26) auszutragen oder;

D8, wo auf Seite 4 in der Mitte beschrieben wird, eine schwere Produktphase durch Kanäle (10) im Trommeldeckel (11) abzuleiten.

Es wäre für den Fachmann naheliegend, insbesondere wenn dasselbe Ergebnis erzielt werden soll, dieses Merkmal, welches beim Anmelder selbst hinlänglich bekannt ist und vielfach angewendet wurde, mit entsprechender Wirkung auf einen Separator gemäß dem Dokument D1 anzuwenden und so zu einem Separator gemäß dem Anspruch 1 zu gelangen. Der Gegenstand des Anspruchs 1 beruht somit nicht auf einer erfinderischen Tätigkeit (Artikel 52 (1) und 56 EPÜ).

It might be added that, as discussed above under 4.1.1.1, the inlet 8 and outlet 9 of the D1 centrifuge bowl 4 are provided in a sealed type of construction in order to provide a sterile single use portion of the centrifuge. Accordingly, when integrating the at least one discharge channel for the dense product phase into the drum upper section as taught by each of D7 and D8, the skilled person would also provide the discharge channel for the dense product phase in a sealed type of construction (as defined in feature e.). Otherwise, the sterile requirement of the single use portion of the centrifuge would not be fulfilled.

4.1.2 D1 US 2011/0319248 and D9 US 3126338 (feature f.)

Again, D1 as the closest prior art document discloses all features of the pre-characterising portion of claim 1 as well as feature e. of claim 1, as discussed under 4.1.1.1 above.

Again, based on feature f. being the distinguishing feature over D1, in line with the Communication under Art. 94(3) EPC dated 08.08.2018, the objective technical problem to be solved is to provide a simple structure for conducting a dense product phase out of the separation space of the centrifugal separator.

Feature f. relates to one of a few often-used available well-known options, from which the the skilled person would select without applying inventive activity in order to solve the objective technical problem.

Feature f. has been used in separators of the Patentee for the same purpose. D9 discloses a centrifugal separator with a centrifugal drum 9, 90 comprising outlet channels (outlet flow conduits) 160'' integrated in an upper portion of the drum 9, 90, see Fig.2 and col. 6, lines 42-46.

It should be noted that D9 discloses outlet chamber 16', 160' and outlet channels 16'', 160'' for dense phase that are mechanically hermetically sealed by seals 12, 13, 120, 130, see col. 5, lines 14 – 24, col. 6, lines 42 – 49, and Figs. 1 and 2.

The skilled person would readily apply the outlet channel for the dense product phase (feature f.) of D9 in the separator of D1. In doing so, the skilled person would implement also the mechanical hermetical seals of the outlet channel 16'', 160'' for the dense product phase disclosed in D9, and would arrive at a separator as defined in present claim 1.

Thus, claim 1 does not involve an inventive step over D1 in view of D9.

4.1.3 D1 US 2011/0319248 and D9 US 3126338 (features e. and f.)

If it would be concluded that the D1 centrifuge is not hermetically sealed, and accordingly, starting from D1 as the closest prior art document the distinguishing features of claim 1 would be features e. and f., the effect of these technical features is the prevention of the inside of the bowl from coming into contact with the atmosphere and outside air.

Accordingly, the objective technical problem to be solved may be formulated as providing hygienic conditions in the separation space.

The skilled person would turn to D9 to solve this objective technical problem. D9 is a document relating to a centrifugal drum of a “drum separator”, i.e. a centrifugal separator, and specifically mentions at col. 1, lines 20 – 22 that the centrifugal separator is for material to be centrifugally treated without being exposed to the atmosphere.

D9 discloses feature e., that lower and upper outlet chambers 16', 160', 15', 150' (to which outlet channels 16'', 160'', 15'', 150'' from the centrifugal drum connect) and the inlet chamber 17', 170' (to which inflow conduit 17'', 170'' connect) are mechanically hermetically sealed by seals 11, 12, 13, 110, 120, 130, see col. 4, line 75 – col. 5, line 34, and col. 6, lines 29 – 52, and Figs. 1 and 2. Also, in a general manner, col. 1, lines 16 – 22 mention that the centrifugal drum of the separator is hermetically sealed.

In order to provide hygienic conditions in the separation space, the skilled person would apply the hermetic seals as taught by D9 in the centrifuge of D1. Moreover, in order to provide the sealed hygienic environment in the separation space, the skilled person would implement the integrated discharge channels 16'', 160'' for the dense product phase (feature f.) as disclosed in D9 in the centrifuge of D1.

In the latter context, it should be noted that the discharge ports 6 of the D1 centrifuge according to one alternative are arranged for continuous discharge of the dense product phase (“solids” in D1), see page 2 middle of paragraph [0018]. Thus, also the D1 centrifuge would require the hermetically sealed outlet channel 16'', 160'' disclosed in D9 in order to provide the continuous discharge of the dense product phase in a hermetically sealed version of the D1 separator drum.

Accordingly, in order to solve the above stated problem, the skilled person would provide the mechanical seals and the outlet channel for the dense product phase according to features e. and f. as taught by D9 in the centrifuge/separator of D1.

Thus, claim 1 does not involve an inventive step over D1 in view of D9.

It may be noted in a comparison between Fig. 2 of D9 and the upper portion of Fig. 1 of the present Patent, that both rely on substantially identical sealing solutions with delimiting inlet and outlet chambers provided by radial seals between rotating parts of the separator drum and a stationary upper part of the separator.

#### 4.1.4 D1 US 2011/0319248 and D10 WO 2011/093784 (feature f.)

Starting from D1 as the closest prior art document, it discloses all features of the pre-characterising portion of claim 1 as well as feature e., feed and discharge system in a sealed type of construction, as discussed under 4.1.1.1 above.

Based on feature f. being the distinguishing feature over D1, the objective technical problem to be solved is to provide a structurally simple solution for conducting a dense product phase out of the separation space of a centrifugal separator.

Feature f. relates to one of a few often-used available well-known options, from which the skilled person would select without applying inventive activity in order to solve the objective technical problem.

D10 discloses a system comprising a hermetic centrifugal separator 1 with a rotor, separator bowl 19, delimiting a separation chamber 20, see page 1, lines 6 – 8; page 5, lines 8 – 10; page 7, line 23 – page 8, line 9; and Fig. 4. The separator bowl 19 comprises heavy component outlet pipes 21, which according to one alternative are “... arranged ... in ... the interior wall of said upper part of the separator bowl”, and which lead to a heavy component outlet channel 5 (feature f.), see page 7, line 32 – page 8, line 6; and Fig. 4.

The skilled person would find D10 in his search to solve the above stated problem since it relates to the field of centrifugal separators, the same field as D1. The outlet pipes 21 of D10 provide a structurally simple solution for conducting a dense product phase out of the separation space, to be implemented directly in the bowl 4 of the separator of D1.

Thus, claim 1 does not involve an inventive step over D1 in view of D10.

#### 4.1.5 D1 US 2011/0319248 and D10 WO 2011/093784 (features e. and f.)

If it would be concluded that the D1 centrifuge is not hermetically sealed, the features distinguishing claim 1 over D1 would be features e. and f. The effect of these features is the prevention of the inside of the bowl from coming into contact with the atmosphere and outside air.

Accordingly, the objective technical problem to be solved may be formulated as providing hygienic conditions in the separation space.

The skilled person would turn to D10 to solve this objective technical problem. As mentioned above under 4.1.4, D10 discloses a system comprising a hermetic centrifugal separator 1. The skilled person is aware of the hygienic properties provided by a hermetic centrifugal separator and would accordingly, consider applying technical solutions disclosed in D10 in the separator of D1.

Since the D10 centrifugal separator 1 is a hermetic separator, its inlet and outlets are hermetically sealed. That is, the centrifugal separator is of “*a sealed type of construction*”, as defined in feature e.

In order to provide hygienic conditions in the separation space, the skilled person would apply the hermetic seals as taught by D10. Moreover, in order to provide the sealed hygienic environment in the separation space, the skilled person would exchange the discharge ports 6 of the D1 separator with heavy component outlet pipes 21 (feature f.) as disclosed at page 7, lines 29 – 32 of D10.

Thus, claim 1 does not involve an inventive step over D1 in view of D10.

#### 4.1.6 D1 US 2011/0319248 and D11 Dairy Processing Handbook

Again, starting from D1 as the closest prior art document, which according to one line of argumentation discloses all features of the pre-characterising portion of claim 1 as well as feature e., see 4.1.1.1, 4.1.2, 4.1.4 above, or according to a different line of argumentation discloses all features of the pre-characterising portion of claim 1, see 4.1.3, 4.1.5 above.

D11 is a handbook related to dairy processing published by TetraPak in 2003. D11 discusses many aspects of milk processing, the milk itself, the equipment used, and the produced products. Under section 6.2 Centrifugal separators are discussed, see “Contents” (Index). On pages 103 - 107 the general principles of centrifugal separation and the continuous centrifugal separation of milk are discussed. From page 107 basic design of centrifugal separators is discussed starting with semi-open design and continuing at page 108 with hermetic design. With respect to the hermetic design, it is mentioned that the bowl of a hermetic separator is completely filled with milk and that there is no air in its centre.

For instance, Fig. 6.2.27 discloses a semi-open separator and Fig. 6.2.28 discloses a hermetic separator. In Fig. 6.2.29 the air column of the semi-open/separating discs separator is shown and that there is no such air column in the hermetic separator.

The skilled person, knows that a hermetic separator without any air in it during operation, comprises mechanical seals between stationary and a rotating parts of the centrifugal separator. Also, from the figures showing hermetic separators is clear that the hermetic separators are provided with mechanical seal at their upper ends in connection with the outlets for cream and skim milk.

Further, at page 119, D11 discloses a so-called Bactofuge ®. The Bactofuge is a centrifugal separator utilised inter alia in a process for separating micro-organisms, such as heat resistant spores, from milk. The Bactofuge is available as a two-phase Bactofuge shown in Fig. 6.2.43 for continuous discharge of bactofugate (dense phase). From Fig. 6.2.43 it is clear that the Bactofuge is a hermetic separator. It is explained in the fifth paragraph at page 119 that the two phase Bactofuge has two outlets: one for continuous discharge of bacteria (dense phase) via a special top disc and one for bacteria reduced phase (light phase).

#### 4.1.6.1 Feature f.

According to the first line of argumentation, according to which only feature f. is the distinguishing feature, the skilled person starting from D1 as the closest prior art document would solve the objective technical problem of providing a structurally simple solution for conducting a dense product phase out of the separation space of the centrifugal separator.

It is well-known that a centrifugal separator is one of the main equipment utilised in milk processing. Thus, the skilled person would consider the disclosure of D11. Moreover, the skilled person understands that the hygienic requirements applicable during the processing of milk would lend aspects of a centrifugal separator for the treatment of milk applicable in the centrifugal separator of D1. Studying D11, the particular application of the Bactofuge for the separation of microorganisms, would prompt the skilled person due to its relationship with biopharmaceuticals and biotechnology, i.e. the applicable field of the D1 separator, see paragraph [0017] of D1.

Thus, the skilled person would readily apply the special top disc of the Bactofuge disclosed in D11 and lead the dense phase intimately along the drum upper section out of the separator in the separator of D1 (feature f.). In doing so, the skilled person would also implement the mechanical hermetical seals of the outlet channel for the

dense product phase of the Bactofuge and would arrive at a separator as defined in present claim 1.

Accordingly, claim 1 does not involve an inventive step over D1 in view of D11.

#### 4.1.6.2 Features e. and f.

According to the second line of argumentation, wherein features e. and f. are the distinguishing features, the skilled person starting from D1 as the closest prior art document would solve the objective technical problem of proving hygienic conditions in the separation space.

It is well-known that a centrifugal separator is one of the main equipment utilised in milk processing. Thus, the skilled person would consider the disclosure of D11. Moreover, the skilled person understands that the hygienic requirements applicable during the processing of milk would lend aspects of a centrifugal separator for the treatment of milk applicable in the centrifugal separator of D1.

In order to provide hygienic conditions in the separation space, the skilled person would apply the hermetic seals of the Bactofuge disclosed in D11 (feature e.). Moreover, in order to provide the sealed hygienic environment in the separation space, the skilled person would exchange the discharge ports 6 of the D1 separator with the special top disc of the Bactofuge disclosed in D11 and lead the dense phase intimately along the drum upper section out of the separator (feature f.).

Thus, claim 1 does not involve an inventive step over D1 in view of D11.

#### 4.1.7 Alfa Laval Culturefuge 400B + D1 US 2011/0319248 ([0017])

D12, D14, and D19 disclose an Alfa Laval Culturefuge 400 B (CF400B). The Culturefuge is a centrifugal separator constructed according to the same principles as the Bactofuge, i.e. a hermetically sealed separator provided with a top disc forming channels for the heavy/dense phase to be discharged intimately along the upper portion of the separator drum discussed above under 4.1.6.

The Culturefuge was publicly known at the priority date of the present Patent. For instance, D14 – D18 form evidence of a sale of one CF400B, see further below under 4.1.7.1.

The Culturefuge is targeted at the biotech industry especially for the separation of a liquids comprising shear sensitive particles. In order to be usable in the biotech industry, the Culturefuge is constructed to be sterilized, D12, page 1; D14, page 6.

The Culturefuge comprises features a. – c., e. and f of present claim 1. Features a. – c. are clearly shown in the cross sectional bowl drawings at page 2 of D12, at page 5 of D14, and at pages 29, 36, and 41 of D19.

Feature e. is provided by the Culturefuge being referred to as a hermetic centrifuge, in D12, D14 e.g. page 4, and D19 e.g. page 29. Also, the cross sectional drawings at page 2 of D12 and at page 5 of D14 disclose at its upper end mechanical seals between rotating parts and stationary parts of the Culturefuge. The mechanical hermetical seals are discussed at pages 28 and 29 of D19.

Feature f. is disclosed e.g. in the cross sectional drawing at page 2 of D12 and in the first paragraph in the left-hand column at page 2, *“The heavy phase particles leave the role of over the top disc (5) and are taken out by ...”*. D14 refers to separated cells being *“pressed out over the top disc as a heavy phase”*, page 5, 3<sup>rd</sup> paragraph. D19 page 41 also mentions the heavy phase and its traveling along the top disc of the separator.

Accordingly, the differentiating feature of present claim 1 is feature c., that at least two of the drum lower section, the drum upper section, and the means for clarification are made from plastic material.

This feature provides for the drum of the separator to be devised for single use, i.e. to be disposed of after separation of e.g. one product batch.

The objective technical problem may thus formulated as how to adapt the Culturefuge to single use.

D1 provides a solution to this problem, the invention of D1 is to use polymers and plastics as materials for single use centrifuges. The single use components are primarily comprised of the fluid contact areas including the inlet, fluid outlet, and fluid contact surfaces where separation takes place, see [0014], [0015]. In the disclosed embodiments, the entire bowl 4 and the disc stack 5 are made out of a polymeric composition, [0019].

Thus, the skilled person, applying the teaching of D1 to the Culturefuge, would manufacture at least its separator drum and separation discs from a plastic material.

Moreover, D1 discloses at paragraph [0017] that the invention of D1 “*may incorporate any type of centrifuge used in biopharmaceutical, biotechnology or related industries and may be a disc stack centrifuge ...*”. Accordingly, D1 supports the modification of available centrifuges used in the biotech industry (such as the Culturefuge) to incorporate single use plastic material parts.

Thus, claim 1 lacks an inventive step over the Culturefuge in view of D1.

#### 4.1.7.1 Public Availability of Culturefuge 400 B

As testified by Mr. Kagevi in D13, D12 is a leaflet that was publicly available in 2011. The leaflet was supplied to potential Alfa Laval clients within the biotech industry.

Mr. Kagevi is also offered as a witness to clarify any matter with respect to the public availability of the CF400B, see 2.1 above.

D14 – D18 provide proof of sale of one Culturefuge 400 B (CF400B) centrifugal separator to the Chinese company CJ(Liaocheng) Biotech Co. Ltd. The sales price has been masked in D14, D15, and D17.

D14, dated 7 June 2011, is a so-called Quotation, an offer for sale, of one CF400B to the Chinese company CJ(Liaocheng) Biotech Co. Ltd. D14 was sent to CJ Biotech in China from the Alfa Laval Korean Market Company. From the Quotation the construction of the CF400B separator, at least with respect to features a. – c., e., and f. is known, as explained above under 4.1.7.

In response thereto CJ ordered one CF400B, see D15 dated June 16 2011, Alfa Laval internal order form quoting Customer order No. FRM-1106-372-KR-YZ, CF400B, and CJ(Liaocheng) Biotech Co. Ltd.

In October 2011 a start-up meeting relating to the CF400B was conducted between staff at Alfa Laval, inter alia Mr. Kagevi, and staff at the client CJ Biotech. An e-mail including Minutes of Meeting, D16, was sent as follow-up to the client, see the two addresses ending with @cj.net.

An invoice for the CF400B, D17, was sent to the client in March 2012 stating the order No. FRM-1106-372-KR-YZ.

D18 is the receipt from the transport company Korea Express for loading the CF400B in Gothenburg to be shipped to CJ Biotech in China. D18 quotes the loading date 29<sup>th</sup> of April 2012 and the order No. FRM-1106-372-KR-YZ.

D19 is an extract of the Operators Manual for the CF400B copyright 14 July 2010. The Operators Manual is supplied together with the CF400B to clients buying the CF400B, such as e.g. CJ Biotech.

### 5. Dependent Claims

Since it at present is not possible to foresee which claim amendments the Patentee might consider, it is not possible to present detailed arguments against all possible amendments. Therefore, in the following we point to relevant sections of documents disclosing the features of the dependent claims. Also, reference is in some instance made to the common general knowledge of the skilled person.

Detailed inventive step arguments will be presented in the event that the Patentee would file amended claims.

#### 5.1 Claim 2

*2. The separator as claimed in claim 1, characterized in that the means for clarification is a plate packet (2) consisting of a stack of separating plates (20').*

Each of the listed documents below explicitly discloses a separation discs/plates and/or a disc stack with separation discs/plates.

D1 – Disc stack 5; [0031]; Figs. 1 – 4, 7

D2 – Separator discs 278, 280, 282; paragraph bridging cols. 8 and 9; Figs. 7 - 10

D3 – Cone 71; [0026]; Figs. 15, 16

D4 – Fig. 1 (downwardly angled lines without reference numbers)

D7 – Teller 7, Tellerpaket 6; page 6; Fig. 2

D8 – Tellereinsatz 4; page 4, 3rd paragraph; Figure

D9 – Fig. 2 (discs shown at lower end without reference numbers)

D11 – Conical discs, mentioned at last paragraph of page 104, shown in numerous figures of D11, e.g. Figs. 6.2.15, 6.2.43

#### 5.2 Claim 3

*3. The separator as claimed in claim 1 or 2, characterized in that the drum (2) can be rotated by means of a spindle construction (3).*

Each of the listed documents below explicitly discloses a separator comprising a spindle.

D1 – Rotor 7; [0016]; Figs. 1 – 4, 7

D2 – Drive shaft 66; col. 4, lines 28 - 32; Fig. 1

D4 – Fig. 1 (shown without reference number at lower end of the figure)

D6 – Antriebsspindel 4; Figs. 1 - 4

D7 – Fig. 2 (shown without reference number at lower end of the figure)

D8 – Figure (shown without reference number at lower end of the figure)

D9 – Shaft ; col. 4, lines 17 – 20; Fig. 1

D11 – Bowl spindle 17, shown in numerous figures of D11, e.g. Figs. 6.2.26

#### 5.3 Claim 4

*4. The separator as claimed in claim 3, characterized in that the spindle construction (3) consists of a plastic or a plastic-composite material.*

Depending on the type and construction of a single-use centrifugal separator, also a spindle thereof may be made exchangeable and thus, from plastic material. Choosing a plastic material for the spindle lies within the common general knowledge of the skilled person and can thus, not involve an inventive step.

#### 5.4 Claim 5

*5. The separator as claimed in one of the preceding claims 3 or 4, characterized in that the spindle construction (3) is coupled directly to the output shaft (5) of a motor (4) and in that the spindle construction (3) has no rotational bearings on its outside circumference.*

A suspension solution wherein the rotatable drum is supported and journaled by the driving motor is disclosed in:

D1 – Fig. 7

D6 – Claim 1; Figs. 1 - 4

### 5.5 Claim 6

*6. The separator as claimed in one of the preceding claims, characterized in that all the product-contact regions of the drum (2) consist of plastic.*

D1 – [0014] and [0015] disclose that single use components are primarily comprised by the fluid contact areas of the device. Appropriate materials for single use are polymers and plastics. The last sentence of [0022] mentions an entirely disposable polymeric flow path.

D2 – [0059] discloses that the bowl member and the discs may be made from a plastic material.

D3 – [0006] mentions a molded plastic and welded plastic designs of the rotor shell, and that it provides an incinerable product. [0012] mentions that centrifuge comprises five injection molded plastic components including the cone-stack.

D5 – [0019] mentions a centrifuge 4 made entirely from plastic material.

### 5.6 Claim 7

*7. The separator as claimed in one of the preceding claims, characterized in that the drum (2) is enclosed by a housing (1).*

Each one of D1, D2, D5 – D7, D9 and D11 explicitly discloses a housing enclosing a rotor/drum of a separator, see the figures of each of D1, D2, D5 – D7, D9 and D11.

### 5.7 Claim 8

*8. The separator as claimed in one of the preceding claims, characterized in that the entire separator, apart from the motor (4), consists of plastic.*

D2 – [0059] discloses that the bowl member, the housing and the discs may be made from a plastic material.

Moreover, depending on the type and construction of a single-use centrifugal separator, a smaller or a larger portion thereof may be made exchangeable and thus, from plastic material. Electing to manufacture the entire separator from a plastic material therefore, lies within the common general knowledge of the skilled person and cannot involve an inventive step.

#### 5.8 Claim 9

*9. The separator as claimed in one of the preceding claims, characterized in that the drum lower section (7) is provided directly in one piece with a distribution attachment (11) which has distribution channels (13) for transferring the product to be processed from a feed pipe (13) into the drum interior (15).*

D2 – [0059] discloses that the bowl member, the housing and the discs may be made from a plastic material. Looking at Fig. 1 it may be concluded that the separator is of an upside-down construction with an apex of the conical discs pointing downwardly instead of upwardly. Accordingly, the part of the D2 separator corresponding to the “drum lower section” is the (upper) bowl member 140, which deeming from Fig. 1 appear to include vertical channels integrated therein.

Thus, the part of the D2 separator correspond to a drum lower section of a more traditional separator design appears from Fig. 1 to be constructed in one piece with a distributor, comprising distribution channels.

#### 5.9 Claim 10

*10. The separator as claimed in one of the preceding claims, characterized in that the entire drum (2), in addition to the feed system and discharge system and possibly a part of the housing, is designed as an exchangeable preassembled module consisting of plastic or a plastic-composite material.*

D1 – [0014] and [0015] disclose that single use components are primarily comprised by the fluid contact areas of the device. Appropriate materials for single use are polymers and plastics. [0022] specifically discusses an embodiment wherein a single use centrifuge is pre-connected ... by way of tubing, flow path components or connectors. An entirely disposable polymeric flow path is mentioned.

#### 5.10 Claim 11

*11. The separator as claimed in one of the preceding claims, characterized in that the entire separator, apart from the motor (4), is designed as an exchangeable preassembled module consisting of plastic or a plastic-composite material.*

D1 – [0014] and [0015] disclose that single use components are primarily comprised by the fluid contact areas of the device. Appropriate materials for single use are polymers and plastics. [0022] specifically discusses an embodiment wherein a single use centrifuge is pre-connected ... by way of tubing, flow path components or connectors. An entirely disposable polymeric flow path is mentioned.

D2 – col. 13, lines 25 - 31 discloses that the bowl member, the housing and the discs may be made from a plastic material.

Moreover, depending on the type and construction of a single-use centrifugal separator, a smaller or a larger portion thereof may be made exchangeable and thus, from plastic material. Electing to manufacture the entire separator from a plastic material therefore, lies within the common general knowledge of the skilled person and cannot involve an inventive step.

#### 5.11 Claim 12

*12. The separator as claimed in one of the preceding claims, characterized in that the motor (4) is flanged directly onto the housing (1).*

D6 discloses a separator wherein the electric drive motor is directly connected to the housing.

#### 5.12 Claim 13

*13. The separator as claimed in one of the preceding claims, characterized in that the product-contacting sections of the discharge system consist of plastic.*

D1 – [0022] discusses an embodiment wherein a single use centrifuge is pre-connected ... by way of tubing, flow path components or connectors. An entirely disposable polymeric flow path is mentioned.

#### 5.13 Claim 14

*14. The separator as claimed in one of the preceding claims, characterized in that the discharge regions of the discharge system are designed as annular channels which open axially into annuluses (28, 29) in annular bodies (30, 31).*

D9 discloses that lower and upper outlet chambers 16', 160', 15', 150' are formed by chamber means 10', 100', see col. 4, line 43 – col. 5, line 34 and col. 6, lines 29 – col. 7, line 10; and Figs. 1 and 2.

#### 5.14 Claim 15

*15. The separator as claimed in claim 15 [?], characterized in that the annular bodies (30, 31) consist of plastic or a plastic-composite material.*

In a single use separator as the one disclosed in D1 it is obvious to the skilled person that inlet and outlet portions of the separator, which obviously come into contact with the product, are also exchangeable and thus, made from plastic material.

#### 5.15 Claim 16

*16. The separator as claimed in one of the preceding claims, characterized in that a drum cover (27) consisting of plastic is mounted on the drum upper section.*

The chamber means 10', 100' of D9, see above under 4.1.13, correspond to a "drum cover". Depending on the type and construction of a single-use centrifugal separator, a smaller or a larger portion thereof may be made exchangeable and thus, from plastic material. Electing to manufacture a "drum cover" from a plastic material lies within the common general knowledge of the skilled person and cannot involve an inventive step.

#### 5.16 Claim 17

*17. A method for operating a separator as claimed in one of the preceding claims, characterized in that during a clarification process of a product very dense substances are concentrated, and in that the drum, after the processing of a batch, is melted down or is dissolved in an acid or the like, for example, in order to produce the dense substance as a residue of this process.*

D3 - [0006] disclose incineration of rotor and cone-stack

D5 - [0019] disclose incineration of housing 1, bearings, and centrifuge 4 made from plastic material.

**6. Conclusion**

For the above reasons, revocation of the opposed patent is motivated.

Yours sincerely,

Filip von Friesendorff  
European Patent Attorney

Association Alfa Laval Attorneys No. 578

Encls. D1 – D19

# **ANNEXURE**

## **C**

### **ANNEXURE C**

| <b>Claim in the Patent<br/>(SG11201408585Y) as<br/>proposed to be amended</b> | <b>Claim in the European<br/>patent (EP284053B1)<br/>as granted</b> | <b>Remark</b>                                                                                                                                    |
|-------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 1                                                                             | 1                                                                   | Substantially the same, except that claim 1 of the Patent additionally recites “entire” in respect of the construction of the drum in feature e. |
| 2                                                                             | 2                                                                   | Substantially the same                                                                                                                           |
| 3                                                                             | 4                                                                   | Substantially the same; claim 4 of the European patent includes all of the features of its claim 3                                               |
| 4                                                                             | 5                                                                   | Substantially the same                                                                                                                           |
| 5                                                                             | 6                                                                   | Substantially the same                                                                                                                           |
| 6                                                                             | 7                                                                   | Claim 6 of the Patent recites that the housing consists of plastic, while claim 7 of the European patent does not                                |
| 7                                                                             | 8                                                                   | Substantially the same, except that claim 7 of the Patent depends on claim 4 only to provide antecedent for “the motor”                          |
| 8                                                                             | 9                                                                   | Substantially the same                                                                                                                           |
| 9                                                                             | 10                                                                  | Substantially the same, except that claim 9 of the Patent depends on claim 6 only to provide antecedent for “the housing”                        |
| 10                                                                            | 11                                                                  | Substantially the same, except that claim 10 of the Patent depends on claim 4 only to provide antecedent for “the motor”                         |
| 11                                                                            | 12                                                                  | Substantially the same, except that claim 11 of the Patent depends on claim 4 only to provide antecedent for “the motor”                         |
| 12                                                                            | 13                                                                  | Substantially the same                                                                                                                           |
| 13                                                                            | 14                                                                  | Substantially the same                                                                                                                           |
| 14                                                                            | 15                                                                  | Substantially the same                                                                                                                           |
| 15                                                                            | 16                                                                  | Substantially the same                                                                                                                           |
| 16                                                                            | -                                                                   | Claim 16 of the Patent is not present in the European patent                                                                                     |
| -                                                                             | 17                                                                  | Claim 17 of the European patent is not present in the Patent                                                                                     |