Statement of Defence and Counterclaim for Revocation

AIJA – Mock Trial 2016

Statement of Defence (cf. Rules 23, 24 of the UPC Rules of Procedure ["UPC RP"] and **Counterclaim for Revocation** (cf. Rule 25 UPC RP) to the Unified Patent Court, Munich Local Division

I. Parties

1 **Defendant**: OMYHEART GmbH, with a registered office at [address], Germany, represented by Neilan and Stauber; authorized to accept service:

- **Jevan Neilan** c/o Mason Hayes & Curran, South Bank House, Barrow Street, Dublin 4; jneilan@mhc.ie
- **Demian Stauber** c/o Rentsch Partner AG, Fraumünsterstrasse 9, 8001 Zurich; stauber@rentschpartner.ch

2 **Claimant**: PLAQUAWAY BV, with a registered office at [address], Netherlands, represented by Abbott, Mayer & Kobler; authorized to accept service:

- **Paul Abbott** c/o Arnold & Porter (UK) LLP, Tower 42, 25 Old Broad Street, London EC2n 1HQ; paul.abbott@aporter.com
- **Hans Mayer** c/o Knobbe, Martens, Olson & Bear, LLP, 10100 Santa Monica Boulevard, Suite 1600, Los Angeles, CA 90067 310-551-450; hans.mayer@knobbe.com
- **Michael Kobler** c/o Bardehle Pagenberg Partnerschaft mbB, Prinzregentenplatz 7, 80765 München; michael.kobler@bardehle.de

3 **Defendant for the Revocation Action**: PLAQUAWAY, Inc., Washington DC, AB 11000, USA

Contents

II. Requests

(1) Claimant's requests as contained in the Statement of Claim be denied.

(2) The European Patent EP 1 123 123 B2 be fully revoked.

(3) Legal costs shall be borne by Claimant and the Defendant to the Counterclaim (Article 69 of the Agreement).

III. Standing to sue

4 Defendant is entitled to file the present revocation action by way of counterclaim against the proprietor of the patent in dispute (Rule 25(2) UPC RP).

5 Claimant's standing to sue is not disputed.

IV. Amount in dispute for the Counterclaim

6 Defendant estimates the value in dispute for this case (including its counterclaim) to amount to EUR 100 million (Rule 25(1)(f) UPC RP).

V. Competent UPC division

7 The jurisdiction of the Munich Local Division, Germany, is undisputed. The same court is competent for the revocation action filed by way of a counterclaim (Article 33(3) of the Agreement on a Unified Patent Court of 19 February 2013 (the "Agreement").

VI. Summary of the reasoning of the statement of defence and the revocation action

8 Claimant's claim chart (Exhibit C3) is acceptable. However, Claimant has not provided any proper claim construction, let alone a determination of the relevant person skilled in the art. The lack of substantive reasoning on Claimant's side requires Defendant to address issues partially on a high-level only. Defendant reserves the right to respond to Claimant's new allegations should such come up in the further course of the proceedings.

9 Defendant will, in the following, demonstrate that the Patent-in-suit is neither novel nor inventive over the prior art. In particular, the invention as described in the Patent-in-suit is anticipated by the PCT Application WO 00/30468, which contains all elements claimed in the Patent-in-suit (Exhibit D1 or "Grey").

10 Should the Court – contrary to Defendant's view – consider the Patent-in-suit valid, Defendant will also demonstrate (even though Claimant has not yet alleged equivalent infringement) that neither literal nor equivalent infringement are given.

11 It is correct that the Patent-in-suit relates to prosthetic stents having helical elements. It is also correct that advantages of the stent of the invention of the patent include *inter alia* relatively uniform stent-to-vessel ratios when expanded (cf. [0006] of the Patent-in-suit). It is *disputed* that the Accused stent seeks to achieve the same advantages by utilizing the technical features protected by the Patent-in-suit, as will be explained in more detail hereinafter. The Accused stent does not contain helical segments. Further, in the Accused stent, not all of the cylindrical elements contain circumferential segments with either three linear portions/two curved portions or five linear portions/four curved portions. Moreover, the cylindrical elements in the main body are partially connected by more than two connecting elements. Accordingly, there is no literal infringement.

12 There is also no equivalent infringement. This in particular because the Accused stent is a non-inventive variant of the prior art.

VII. Defendants reasoning for the revocation action

A. Lack of novelty

13 The Patent-in-suit is not novel (Article 52(1) and 54 EPC). All elements of the Patent-in-suit are disclosed in PCT Application WO 00/3046.

14 The Patent-in-suit claims priority from US223344 filed on 11 December 2000. PCT Application WO 00/30468 (Exhibit D1) was published on 2 June 2000 and is thus prior art under Article 54(2) of the EPC.

15 If Claimant's claim construction were correct, which it is not, the only differences between the stent disclosed in Fig. 4 of Exhibit D1 and the Patent-in-suit would be the following:

- two connectors instead of four.

- two connectors should be 180° apart.
- the pattern of the first and second circumferential segments (3-5-3-5 linear portions).

16 These elements are disclosed in other parts of D1, as is demonstrated in the table below.

17 Defendant reserves the right to elaborate on why elements derived from different parts of Exhibit D1 may be considered for assessing novelty in this particular case.

18 Defendant sees the person skilled in the art as a bio engineer with some years of experience and a rather general know-how of a broad range of subjects, such as heat transfer, kinetics, biocatalysts, biomechanics, bioinformatics, separation and purification processes, bioreactor design, surface science, fluid mechanics, thermodynamics, and polymer science.

Element No.	**'123 Patent, Claim 1**	**D1: WO 00/30468**
1	A balloon expandable stent comprising a main body (11), wherein the main body has a generally cylindrical shape and a cylindrical axis (5)	Claim and Fig. 4
2.1	and, when the stent is unexpanded, the main body comprises a plurality of expandable helical segments (30, 40	Fig. 4 (and Fig. 5)
2.2	wherein the main body further comprises a plurality of main body cylindrical elements (100) having collinear cylindrical axes, wherein the main body cylindrical elements (100) are adjacent one another and attached to one another by the helical segments (30, 40),	Fig. 4 (and Fig. 1, 4, 5)
3	each main body cylindrical element (100) having a circumference (110) that is substantially identical to that of an adjacent cylindrical element, and comprising a plurality of expandable circumferential segments (50, 60) positioned between consecutive connecting elements (250) which connect said cylindrical element to an adjacent cylindrical element,	Fig. 4 (and Fig. 3, 5)
4	wherein the circumferential segments (50, 60) are joined together by portions of the helical segments (30, 40) to form the cylindrical elements (l00), wherein the plurality of circumferential segments (50, 60) comprise a majority of the circumference (110) of each cylindrical element (100),	Fig. 4 (and Fig. 3, 5)
5	**characterized in that** the cylindrical elements (100) comprise first circumferential segments (50) alternating with second circumferential segments (60),	Fig. 4 (and Fig. 3, 5)
6	**in that** said second circumferential segments resemble a generally S-shaped structure, having three linear portions connected to each other by two curved portions,	Fig. 4 (and Fig. 1, 2, 3, 5)
7	**in that** said first circumferential segments have five linear	Fig. 1

	portions connected to each other by four curved portions,	
8	**in that** adjacent cylindrical elements are connected to one another by two connecting elements (250),	Claim 2, [0018], [0025], [0028], (Fig. 2)
9	**in that** second circumferential segments (60) of adjacent cylindrical elements are joined together by connecting elements to form one of two first expandable helical segments (30, 40),	Fig. 4 (and Fig. 1, 3)
10	**in that** first circumferential segments (50) of adjacent cylindrical elements are joined together by connecting elements to form one of two second expandable helical segments (200,210),	Fig. 4 (and Fig. 1, 3)
11	**in that** said first expandable helical segments (30, 40) are generally parallel one to another and 180 degrees apart,	Fig. 4 (and Fig. 1, 3)
12	**and in that** said second expandable helical segments (200, 210) are generally parallel one to another and 180 degrees apart.	Fig. 4 (and Fig. 1, 3)

19 As may be seen from the above chart, all elements of the Patent-in-suit are present in Exhibit D1 if the claim construction of Claimant with regard to the helical segments were correct (which is disputed, see below). Therefore, the Patent-in-suit lacks novelty if it were to be construed according to Claimant's interpretation.

B. Lack of inventive step

20 Further, should the court find that one of the other elements were not present, the Patent-in-suit should be revoked for lack of inventive step (Article 56 EPC).

21 Starting from Fig. 4 of Exhibit D1, the problem to be solved by the Patent-in-suit would be to increase the flexibility of the stent, which is achieved by the two connectors. The same is achieved by the two connectors and thus the helixes being separated by 180° along the circumferential element (Priority Application, Exhibit C2, at p. 8). The view taken by the opposition division, that the problem to be solved is to avoid foreshortening when the stent is expanded, is incorrect because this is not what is achieved by the use of fewer connecting elements.

22 Since the solution is already provided in the same document D1 (cf. page 3, [0018] and [0025] and [0028]), and in claim 2, which the person skilled in the art would obviously consider for seeking solutions to the problem, the person skilled in the art would almost inevitably arrive at the solution contained in the Patent-in-suit. Further, it was well known to the skilled person that positioning the two helices at an angle of 180° along the circumferential element would increase flexibil-

ity and provide radial strength since the principle of cantilever spring pairs has been part of the general knowledge for decades.

23 Against this background and as confirmed by Professor Black at p. 3 of Exhibit D3, the use of two (Exhibit D1, Fig. 2) instead of four connectors (Exhibit D1, Fig. 4) is not inventive. The skilled person would have known that the use of two connectors makes the stent more flexible, which is the solution provided by the Patent-in-suit for the problem to be solved. Further, the skilled person would easily have found the way of arranging two connectors in a stent having 16 linear portions: There are only two realistic options (the 7-1-7-1 variant, or the 5-3-5-3 variant, in which the digits indicate the number of linear portions between the successive connectors an each side) (cf. Exhibit D3 at p. 3). Necessarily, if the helical segments shall be achieved, this leads to a solution in which the connectors are 180° apart. Such solution would also have been readily available to the person skilled in the art since it has long been known that this leads to a cantilever spring pair, which would of course have been considered as well by the skilled person.

24 To sum up: Given the prior art disclosed in Exhibit D1 and reading this in light of common general knowledge, this Court should find that the Patent-in-suit lacks, and did lack at the time of filing, the necessary elements for a patentable invention.

C. Invalidity for added subject matter if Claimant's claim construction were true

25 If Claimant's construction of elements 11 and 12 (180°) were correct, which it is not, the patent would have to be declared invalid for added subject matter (Article 123(2) EPC). There is no disclosure that the segments should be 180° out of phase in the originally filed application.

VIII. Defendants reasoning for the lack of infringement

A. No literal infringement

1. The Accused stent does not have the claimed alternating circumferential segments

26 First, the Accused stent is not covered by the Patent-in-suit because it does not have the claimed alternating circumferential segments. According to Claim 1 of the Patent-in-suit, the main body (11) of the patent comprises a plurality of main body cylindrical elements (100), which in turn consist of first circumferential segments (50) and second circumferential segments (60). Such first circumferential segments have five linear portions connected to each other by four curved portions and such second circumferential segments resemble a generally S-shaped structure, having three linear portions connected by two curved portions.

27 Whilst there is no such limitation in the description of the Patent-in-suit, the wording of the claim is clear. The wording of the claim is supported by the figures (see for instance figures 2 and 3 of the Patent-in-suit) and is unambiguous.

28 Accordingly, one of the core facets to the design and description of the patented stent is the first and second circumferential segments, which alternate and make up the cylindrical elements to form the main body of the patented stent. This form of alternating segments is only partially present in the Accused stent.

29 Claimant has chosen to omit a relevant part of the main body of the Accused stent when addressing these elements in its claim chart (Exhibit C3). As may easily be inferred from Defendant's illustration submitted as Exhibit D2, the Accused stent contains three cylindrical elements (out of a total of seven), which do not contain segments consisting of five linear portions connected to each other by four curved portions or segments having three linear portions connected by two curved portions. Rather, there are segments having four linear portions (first cylindrical element), alternating segments with one or three linear portions (second cylindrical element), and alternating segments with four, three and one linear portion (third cylindrical element) (see for instance the parts highlighted by red rectangles in Exhibit D2). Furthermore, there is no clear and distinct alternation of circumferential elements in the Accused Stent (addressed further and in more detail, below).

30 Already for this reason, the Court may not find a literal infringement.

2. The Accused stent does not (only) have the two connecting elements no. 250

31 It is evident that the accused stent has portions of its main body with more than two connecting elements present (see for instance the connectors highlighted by red arrows in Exhibit D2). Therefore, the court may not find a literal infringement.

3. The Accused stent does not have the claimed helical character (elements no. 30, 40)

32 Furthermore, the Accused stent is not covered by the Patent-in-suit because it does not have the claimed helical character.

33 The Accused stent is clearly a ring-and-connector stent, something that is highlighted by expert, Professor Blair Black (cf. Exhibit D3). Ring-and-connector stents are just that – stents comprised of two principal elements: rings and connectors. As a result of this simple fact, the only alternation existing in each circumferential band-like element (or "ring") is the intervals and frequency of which a connector is seen to join two parallel circumferential elements. The Defendant would, in particular, refer to Figures 1 and 3 of Exhibit D1. Furthermore, Exhibit D1 describes the claim in the prior art as having "*adjacent first and second band-like elements … connected with two or more interconnecting elements*" (p.5).

34 Exhibit D1 describes the construction of a stent similar to the design of Accused stent, stating "*[i]n another embodiment, the inventive stent is comprised of band-like elements of a single wavelength, interconnected by interconnecting elements*." (0020 at p.4)

35 In contrast, Professor Black further states that "*[h]elical segments contain elements that travel helically round the stent and exhibit the mechanical properties of helixes*". He adds "*it was well known at the time – as it is today – that … artificial paths having a helical direction can be drawn along the wire pattern of nearly every stent around*". (Exhibit D3 at p. 1)

36 The Claimant has sought to artificially construct unnatural so-called "helixes" in the ring-and-connector structure of the Accused stent. One can, however, equally adopt a similar approach to, in particular, Figures 1 and 3 in Exhibit D1 or any other similar design. By simply separating each circumferential element into artificial segments where a "connector" meets the "ring", one can seek to interpret a "helix"-like design from the angular pattern that is interpreted as emerging. However, this is not the case in reality. As explained by Professor Black, one can attempt to draw a helix on any ring-and-connector stent, such as those depicted in the prior art in Exhibit D1 but such "helixes" are not a helix by function or by design.

37 The Defendant would direct the court to Exhibit D2, based on Exhibit C3. Exhibit D2 depicts Figure 3 from Exhibit D1 and demonstrates that the comparison carried out by the Claimant between the Accused stent and the description of the Patent-in-suit can equally be transposed to designs from Exhibit D1, which forms the prior art and which is a ring-and-connector stent.

38 Additionally, it is important to consider the structure of and properties displayed by both the Patent-in-suit and the Accused stent in the expanded and in-body form, as opposed to merely considering the designs in unexpanded, flat planar form. The Accused stent is unlikely to provide or display a helical nature and an equivalent degree of helical strength when compared with the Patent-in-suit in a similar state.

39 Moreover, the Accused stent does not have the uniform stent-to-vessel ratio that is achieved by helical segments. The priority application of the Patent-in-suit (Exhibit D4), the Patent-in-suit (Exhibit C1) at [0004] and Professor Black confirm that the so-called stent-to-vessel ratio is crucial. In the words of the priority application, the "*stent-to-vessel-ratio refers to the degree to which the vessel is supported by the stent in its expanded state*" (Exhibit D4, at p. 2). It is exactly the problem the invention of the Patent-in-suit tries to solve [0006]. Professor Black explains that the helical properties include primarily a generally uniform 'stent-to-vessel' ratio along the length of the stent, "*and the coupling of the radial stiffness and longitudinal flexibility design requirements"*. However, as may easily be concluded from the shape of the connectors in the Accused stent, they are expanded in longitudinal direction in expanded state of the stent. This is confirmed by Professor Black (cf. p.2 Exhibit D3). Hence, the Accused stent contains a substantial region in between each of the circumferential elements in which the stent-to-vessel ratio is low (highlighted in blue in Exhibit D2). This is exactly what the patented invention tries to overcome through the use of the helical segments.

B. No infringement under the doctrine of equivalents

40 Claimant has refrained from asserting equivalent infringement. Such would be disputed, should Claimant try to invoke this principle in the further course of the proceedings. In particular, under

the three Schneidmesser or Catnic/Improver-Questions, the Accused stent is not infringing: (a) it does not have the same technical effect, as explained above; (b) even if it had, a skilled person would not have thought that such effect could be achieved by a main body containing different segments and (c) finally, in light of the wording of the claim requiring two connecting elements, whilst the description is broader, the person skilled in the art would have concluded that this was a deliberate choice by the patent owner. In any event, to the extent one might find some similarities between the Patent-in-suit and the Accused stent, the latter is certainly closer in similarities and structure to the prior art depicted in Exhibit D1 than it is to the former (cf. BGH – Dyglicidverbindung, BGH, 13.09.2011 - X ZR 69/10).

41 Moreover, if the court should find that there was an equivalent infringement in principle, the Defendant invokes the defence arising from *Gillette Safety Razor v Anglo Trading Case* (1913) and *Formstein* (BGH, 29.04.1986 - X ZR 28/85) based on the fact that Accused stent is a non-inventive variant of the prior art stent technology disclosed in Exhibit D1. According to case law, practising the prior art cannot be held to infringe a later patent. Thus, it is simply the question of whether the Accused stent has modified the design(s) disclosed in Grey in such a manner that it is not sufficient to be deemed inventive.

42 It is clear that the Accused stent follows the designs disclosed in Exhibit D1, particularly in, as further described below, the design depicted at Fig. 3. In particular, the band-like elements and connectors, evident from the depictions in the prior art, are demonstrated and envisaged by the designs in Exhibit D1.

43 The claim in Exhibit D1 specifically addresses the matter of non-inventive variants of the designs and descriptions contained therein. In particular, p.5 of Exhibit D1 states that:

> "*[t]hese examples and this description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto."* (at 0029)

44 Given Exhibit D1 clearly and specifically envisages "*alterations*" and "*variations"* of the designs disclosed within the document, the Defendant will show that the Accused stent is merely a non-inventive variant of the prior art.

45 In many respects, Fig. 3 of Exhibit D1 closely mirrors the design of the Accused stent:

46 First, the cylindrical elements in both Fig. 3 and the Accused stent are similarly designed. In particular, in Fig. 3, the waves making up the cylindrical elements, which form the 'rings' of the stent, are uniform in amplitude and almost identical in frequency to that in the Accused Stent (cf. [0024]). In this respect, the design of the wavelength of the Accused stent aligns with the design comprising prior art depicted in Fig. 3.

47 Furthermore, like the Accused stent, Fig. 3 in Exhibit D1 displays similar connectors. Aligning with the design of the Accused Stent, the connectors depicted in Fig. 3 are angular, are parallel to one

another and alternate in pitch connecting between the peaks and troughs in the waves of different cylindrical elements (described further at 0024).

48 Finally, while Fig. 3 depicts the use of 3 such connectors, the use of two connectors, as seen in the Accused stent, is present in Fig. 2 of Exhibit D1. As already highlighted above in various instances, Exhibit D1 specifically envisages the use of at least two interconnecting elements and it would be known to the skilled person that removing a connector would increase flexibility (cf. p.3 Exhibit D3.

49 Given the similarities between the Accused stent and the designs depicted in Exhibit D1, and in light of the fact that the prior art in question specifically notes that potential for variations and combinations to be used within the bounds of the prior art, the court may find the Accused stent is merely a non-inventive variant of the prior art.

50 Based on the above, the court may find that there is no infringement of the Patent-in-suit.

IX. List of exhibits

Referred to in this Statement of defence (no need of translation):

- **Exhibit D1** (PCT Application WO 00/30468 [already on file])
- **Exhibit D2** (Chart addressing Claimant's arguments re helical segments)
- **Exhibit D3** (Expert statement of Professor Blair Black [already on file])
- **Exhibit D4** (Priority Application of Patent-in-suit [already on file])
- **Exhibit D5** (certificate of transfer of Court fees in the amount of EUR xxx) for the revocation action [not included]

DISCLAIMER