Judgment

DISTRICT COURT OF THE HAGUE

Civil-law sector

Case number / docket number: 313328 / KG ZA 08-777

Judgment in interlocutory proceedings of 28 August 2008

In the matter of

ABBOTT CARDIOVASCULAR SYSTEMS INC.,
having its registered office in Santa Clara, California, United States of America,
plaintiff,
local counsel: C.J.J.C. van Nispen,
attorneys: C.J.J.C. van Nispen and Mr. S.C. Dack of the Hague, barrister,
registered pursuant to section 16h Counsel act,

versus

1. **MEDTRONIC B.V.,** a private company with limited liability,
2. **MEDTRONIC TRADING NL B.V.,** a private company with limited liability,
3. **B.V. MEDTRONIC FSC,** a private company with limited liability,
   all of them having their registered office in Heerlen,

defendants,
local counsel: P.J.M. von Schmidt auf Altenstadt,
attorneys: J.J. Allen and Ch. Gielen of Amsterdam.

The parties will hereinafter (including in the operative part) also be referred to as Abbott and Medtronic.

1. The course of the proceedings

1.1. The course of the proceedings is evidence by:

- the writ of summons of 18 June 2008;
- exhibits 1-12 submitted on the part of Abbott by letter of 27 June 2008, received at the court registry on 30 June 2008;
- exhibits 1-32 submitted on the part of Medtronic by letter of 24 July 2008, received at the court registry on 25 July 2008;
- exhibit 33 submitted on the part of Medtronic by letter of 24 July 2008, received at the court registry on 25 July 2008;
- fax by Mr. Allen of 31 July 2008, - received at the court registry on 1 August 2008, containing a request to extend the time of 45 minutes allocated to each of the parties to conduct their oral pleading to 90 minutes in the first session;
- Mr. Dack's reply thereto by fax of 1 August 2008;
- Gielen's fax of 1 August 2008, containing further details regarding the request for an extension of the time allocated to the parties to plead their cases, plus a statement of defence;
- e-mail addressed to the parties by the provisional measures judge, dated 4 August 2008, stating that the initial time allocated to each of the parties to plead their cases has been set at 60 minutes for the first session and at 30 minutes for the second session;
- Van Nispen's letter of 1 August 2008, received at the court registry on 4 August 2008, containing the confidential exhibit 13 as well as the exhibits 14-28;
- Mr. Dack's e-mail of 5 August 2008, in compliance with a request to forward a legible copy of Abbott's exhibit 23;
- Van Nispen's letter of 6 August 2008, containing the exhibits 29A and 29B and the exhibits 30A-30C (also sent by e-mail);
- the break-down of the costs of the proceedings submitted by e-mail on 6 August 2008 and 7 August 2008 respectively by Abbott (€ 125,463.45, plus an amount of € 2,102.75 in disbursements) and Medtronic (€ 95,031.67) respectively;
- the oral hearing of the case on 7 August 2008;
- notes of oral pleading Van Nispen and Mr. Dack;

- notes of oral pleading Mr. Allen and Gielen, with the deleted paragraphs 110-116, 151-161, 171-187 and 192-217, which were not read out in court;
- mr. Allen's additional notes of oral pleading;
- the illustration submitted at the hearing by Medtronic and certified by the provisional measures judge;
- the record of the oral hearing.

Part of the hearing took place in closed chambers. Accordingly it was decided at the hearing by the provisional measures judge pursuant to article 29 (1) (b) Code of Civil Procedure, that the persons mentioned in the record of the hearing who attended the confidential part are not permitted to disclose any information to third parties regarding the contents of the confidential exhibit 13 on the part of Abbott.

1.2. Finally a date was set for judgment to be rendered.

2. The facts

2.1. Abbott is the owner of the European patent with number 1 068 842 (hereinafter: the patent or EP 842), regarding "Expandable stents". The patent was granted on 18 June 2008 following an application to that effect of 27 October 1992 (application number 00122970.7), priority being claimed on 28 October 1991 on the basis of US 783,558. The patent is a divisional of EP-A-0 734 699, which in its turn is a divisional of the parent application EP-A-0-540 290 – meanwhile revoked by the Technical Board of Appeal (see ground 2.7.). The patent expires on 26 October 2012.

2.2. Claim 1 of the patent as granted reads as follows in the original English text:

> 1. A longitudinally flexible stent (10) comprising a plurality of cylindrically shaped elements (12), the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition and having, in the unexpanded condition, an axial length which is less than their diameter, the cylindrically shaped elements (12) being generally aligned on a common longitudinal axis such that, other than at an end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions, each of said cylindrically shaped elements (12) being interconnected to one of said adjacent cylindrically shaped elements (12) by three or four or more interconnecting elements (13) disposed at locations circumferentially displaced from the locations at which said cylindrically shaped element (12) is interconnected to the other of said adjacent cylindrically shaped elements (12), said cylindrically shaped elements (12) having a

serpentine circumferential undulating pattern of peaks and valleys which is out of phase with the undulating pattern of each of said adjacent cylindrically shaped elements (12) such that flexibility is provided along the length of the stent (10) and about its longitudinal axis.

2.3. In the official Dutch translation the claim reads as follows:

1. Overlangs flexibele stent (10) die bestaat uit een hoeveelheid cilindrische elementen (12), waarbij de cilindrische elementen (12) in de radiale richting onafhankelijk rekbaar zijn vanuit een ongeëxpandeerde toestand naar een ongeëxpandeerde toestand en in de ongeëxpandeerde toestand een axiale lengte hebben die kleiner is dan de diameter ervan, waarbij de cilindrische elementen (12) doorgaans gealigneerd zijn op een gemeenschappelijke lengteas zodanig, dat, anders dan aan het eind van de stent (10), elk cilindrisch element (12) twee aangrenzende cilindrische elementen (12) ruimtelijk gepositioneerd in tegengestelde axiale richtingen heft, waarbij elk van genoemde cilindrische elementen (12) met een van genoemde aangrenzende cilindrische elementen (12) is verbonden door drie of vier of meer verbindingselementen (13) die zijn gesitueerd op locaties die over de omtrek versprongen liggen van locaties waarop genoemd cilindrisch element (12) is verbonden met het andere van genoemde aangrenzende cilindrische elementen (12), waarbij genoemde cilindrische elementen (12) een slangvormig over de omtrek lopend golfpatroon van pieken en dalen hebben dat uit fase is met het golfpatroon van elk van genoemde aangrenzende cilindrische elementen (12) zodanig dat flexibiliteit langs de lengte van de stent (10) en om de langsas ervan wordt verschaft

2.4. Following objections raised by Medtronic against the original Dutch translation, Abbott on 5 August 2008 filed an amended translation of the patent with the Netherlands Patent Office (Octrooicentrum Nederland). The translation of claim 1 now reads as follows (changes highlighted in bold):

1. Overlangs flexibele stent (10) **omvattende** [*comprising, translator*] een hoeveelheid cilindrische elementen (12), waarbij de cilindrische elementen (12) in de radiale richting onafhankelijk **expandeerbaar** [*expandable, translator*] zijn vanuit een ongeëxpandeerde toestand naar een ongeëxpandeerde toestand en in de ongeëxpandeerde toestand een axiale lengte hebben die kleiner is dan de diameter ervan, waarbij de cilindrische elementen (12) doorgaans gealigneerd zijn op een gemeenschappelijke lengteas zodanig, dat, anders dan aan het eind van de stent (10), elk cilindrisch element (12) twee aangrenzende cilindrische elementen (12) ruimtelijk gepositioneerd in tegengestelde axiale richtingen heeft, waarbij elk van genoemde cilindrische elementen (12) met een van genoemde aangrenzende cilindrische elementen (12) is verbonden door drie of vier of meer verbindingselementen (13) die zijn gesitueerd op locaties die over de omtrek versprongen liggen van locaties waarop genoemd cilindrisch element (12) is verbonden met het andere van genoemde aangrenzende cilindrische elementen (12), waarbij genoemde cilindrische elementen (12) een slangvormig over de

omtrek lopend golfpatroon van pieken en dalen hebben dat uit fase is met het golfpatroon van elk van genoemde aangrenzende cilindrische elementen (12) zodanig dat flexibiliteit langs de lengte van de stent (10) en om de langsas ervan wordt verschaft.

2.5. Broken down Stripped down to its individual features claim 1 of EP 842 as granted reads as follows:

(i) a longitudinally flexible stent (10)
(ii) comprising a plurality of cylindrically shaped elements (12),
(iii) the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition
(iv) and having, in the unexpanded condition, an axial length which is less than their diameter,
(v) the cylindrically shaped elements (12) being generally aligned on a common longitudinal axis such that, other than at an end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions
(vi) each of said cylindrically shaped elements (12) being interconnected to one of said cylindrically shaped elements (12) by three or four or more interconnecting elements (13)
(vii) disposed at locations circumferentially displaced from the locations at which said cylindrically shaped element (12) is interconnected to the other of said adjacent cylindrically shaped elements (12).
(viii) said cylindrically shaped elements (12) having a serpentine circumferential undulating pattern of peaks and valleys
(ix) which is out of phase with the undulating pattern of each of said adjacent cylindrically shaped elements (12)
(x) such that flexibility is provided along the length of the stent (10) and about its longitudinal axis.

And in the amended Dutch translation:

(i) Overlangs flexibele stent (10)
(ii) **omvattende** een hoeveelheid cilindrische elementen (12),
(iii) waarbij de cilindrische elementen (12) in de radiale richting onafhankelijk **expandeerbaar** zijn vanuit een ongeëxpandeerde toestand naar een ongeëxpandeerde toestand
(iv) en in de ongeëxpandeerde toestand een axiale lengte hebben die kleiner is dan de diameter ervan,

(v) waarbij de cilindrische elementen (12) doorgaans gealigneerd zijn op een gemeenschappelijke lengteas zodanig, dat, anders dan aan het eind van de stent (10), elk cilindrisch element (12) twee aangrenzende cilindrische elementen (12) ruimtelijk gepositioneerd in tegengestelde axiale richtingen heeft,

(vi) waarbij elk van genoemde cilindrische elementen (12) met een van genoemde aangrenzende cilindrische elementen (12) is verbonden door drie of vier of meer verbindingselementen (13)

(vii) die zijn gesitueerd op locaties die over de omtrek versprongen liggen van locaties waarop genoemd cilindrisch element (12) is verbonden met het andere van genoemde aangrenzende cilindrische elementen (12),

(viii) waarbij genoemde cilindrische elementen (12) een slangvormig over de omtrek lopend golfpatroon van pieken en dalen hebben

(ix) dat uit fase is met het golfpatroon van elk van genoemde aangrenzende cilindrische elementen (12)

(x) zodanig dat flexibiliteit langs de lengte van de stent (10) en om de langsas ervan wordt verschaft.

2.6. With the patent are ten figures. Of these only figure 10 shows a stent having the features of claim 1, judging by its description. The figure is illustrated below:

[Figure 10 EP 842]

2.7. On 27 October 1992 a European application was filed, based on the American priority document US 180,193. In response to this application, published as EP-A-0-540 290, EP 0 540 290 B1 was granted, one of the dates on which this took place being 28 January 1998. This patent was subsequently revoked by the Opposition Department. The appeal filed against this decision by Abbott was unsuccessful. The Technical Board of Appeal in its decision of 1 July 2003 upheld the decision by the Opposition Department (T 1196/00). To that end it was held as follows by the Board, to the extent relevant

4. Inventive step

4.1 Document D6 [EP-A1-0 364 787, hereinafter: Schatz] represents the closest prior art and the starting point of the invention since it discloses a plurality of longitudinal flexible stents each formed from an elongated tubular member within the meaning of the contested patent. The structure consists in rectangular slots deformable upon expansion (cf. Figures 1A, 1B) so as to confer radial rigidity to the stents in order to

retain their expanded configuration and to resist radial collapse (column 7, lines 15 to 23). When the stents are connected together by interconnecting elements 100 (Figures 7 and 8) the stent as a whole exhibits improved flexibility in order to negotiate the curves within the vascular system in any direction (column 5, lines 20 to 24 and column 14, lines 27 to 38).

More specifically, following the terminology of claim 1 in suit, document D6 discloses in combination a delivery catheter having an expandable member and a longitudinally flexible stent slidably mounted on said expandable member (Figures 3 and 4). The stent comprises (Figure 7) a plurality of cylindrically shaped elements 70 which are independently expandable in the radial direction and which are connected to one another by interconnecting elements 100, so as to be generally aligned on a common longitudinal axis. Each cylindrically shaped element is spaced from an adjacent one in opposite axial directions and the interconnecting adjacent cylindrical elements, i.e. placed on both sides of an intermediate cylindrical element, are circumferentially displaced, i.e. radially offset in relation to each other (cf. column 13, lines 41 to 49 and column 14, lines 4 to 9).
The subject-matter of claim 1 differs from the disclosure of document D6 only in that the cylindrically shaped elements, when mounted on the delivery catheter in an unexpanded condition, have an axial length which is less than their diameter.

4.2 The technical problem underlying the present patent (cf. column 1, lines 31 to 41) is to provide a stent having satisfying radial rigidity to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery. The solution is provided by a stent having all the claimed features in combination since each of them contributes for a part to the rigidity and the flexibility of the stent as a whole.

Document D6 proposes a stent having the required characteristics and comprising all the features as claimed, except for the distinguishing feature mentioned previously. However, even if said feature is regarded as sufficiently supported in the meaning that it is implicitly referred to and comprised within the content of the application as filed, as is held in section 2 above, there is no support in the description that the length-to-diameter ratio assists in improving the stent flexibility in tortuous passageways or its radial rigidity to hold open a body lumen. The only passage of interest in the description (column 2, lines 18 to 21 is confined to mention a preference for the claimed ratio without indicating any purpose or effect, however. It has to be concluded therefrom that said only distinctive feature with respect to document D6 is of minor technical relevance and results from a mere dimensional optimalisation falling within the normal competence of a person skilled in the art, as also suggested

by document D6 (column 8, lines 14 to 19) where it is stated that the length of the stent (graft) can be made longer or shorter as desired.

Document D11 [hereinafter: Radiology[1]] equally suggests to use a plurality of stents interconnected by struts, each stent being formed from a wire bent into a zig-zag configuration and having a length which is less than its diameter (cf. page 665, passage bridging middle and right columns), although no particular requirement was made as to the rigidity or the flexibility of the stent.

4.3 In consequence of the above considerations, the subject-matter of claim 1 according to the main request does not involve an inventive step vis-à-vis document D6. Therefore, the requirements of Article 52(1) in connection with Article 56 EPC are not met.

5. Auxiliary request

Claim 1 according to the auxiliary request differs from the main request by the incorporation of the feature according to which the cylindrical shaped elements are 'formed of structural members in an undulating pattern, the undulating pattern being flat in transverse cross-section'. The flat, rectangular cross-section results from the stent being formed from an elongated tubular member of thin uniform thickness. This allows for efficient holding of the artery in an opened and expanded state without damage and without interference with the blood flow through the artery (cf. patent, column 15, lines 48 to 56).

A similar result is achieved by the stent disclosed in document D6 which is also formed from an elongated and thin tubular member having a uniform thickness and being flat and rectangular in cross-section (cf. Figure 2: column 7, lines 28 to 31 and column 8, lines 34 to 48). According to D6, the cylindrically shaped elements are made of a plurality of slots arranged in a staggered relationship (Figure 1A), which are deformable upon expansion into s diamond or hexagonal configuration (Figure 1B). The resulting meshed closed structure is supposed to be more rigid radially than the opened structure according to the invention, made of a plurality of elements in an undulating pattern.

However, document D2 [EP-A2-0 421 729, hereinafter: Wolff, Provisional Measures Judge) discloses a succession of cylindrical stent elements made of a number of wire segments welded together in a zig-zag configuration around the circumference and

[1] Heputic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents. Shigeru Furui et al, Radiology 1990, pp. 665-670.

then connected by flexible hinges to provide additional flexibility and better accessibility to arteries having curved portions (Figure 5). Further, the interconnecting hinges are radially offset (Figure 4) and the stent is mounted on a delivery guide-catheter in a compressed state (Figure 8). Although D2 is not specifically concerned with a circumferential undulating pattern or serpentine in the exact embodiment as shown on Figures 4 and 5 of the contested patent, the Board considers that the opened zig-zag structure used in document D2 is practically equivalent in terms of radial expansion and rigidity and represents a particular form of an undulating pattern within the general meaning of an alternating configuration.
Therefore, the subject-matter of claim 1 according to the auxiliary request derives in an obvious manner from a combination of the teachings of documents D6 and D2. A direct suggestion in this respect is to be seen in the fact that both documents are concerned with stents providing, though at different degrees, radial retention and longitudinal flexibility by combining elements which are functionally equivalent. If, as submitted by the appellant, the invention resides in the combination of all its features with the purpose to optimize rigidity and flexibility, the same is true for the cited documents. The requirements of Article 56 EPC, are, therefore, not met.

2.8. However, Abbot had filed an application for two more divisionals. EP 0 807 424 B2 was granted in respect of the first divisional – following a decision of the Technical Board of Appeal of 8 July 2004 in T 1000/02 on the basis of the second auxiliary request. The present EP 842 was granted on 18 June 2008 in respect of the other divisional.

2.9. The difference between EP 0 807 424 B2 and EP 842 is that the former patent in claim 1 contains the element that the stent is "*formed from a single piece of tubing (21)*", whereas EP 842 does not contain such an element.

2.10 The Technical Board of Appeal held as follows in T 1000/02, to the extent relevant:

2.2 Inventive step

2.2.1 D 1 [Schatz] is considered to represent the most relevant prior art and discloses (se in particular Figure 7) a longitudinally flexible stent comprising a plurality of cylindrically shaped elements (71), having an undulating (wavelike) patterns of peaks and valleys (pattern of the axial end of the elements (71) being independently expandable in the radial direction from an unexpanded condition to an expanded condition (compare Figures 1a and 1b) and being generally aligned on a common longitudinal axis such that, other than at an end of the stent, each cylindrically shaped element (71) has two adjacent cylindrical shaped elements (71) spaced in opposite axial directions (see Figure

7), the undulating pattern of each of said cylindrically shaped elements (71) being out of phase with the undulating pattern of each of said adjacent cylindrically shaped elements (71) and each of said adjacent cylindrically shaped elements (71) being interconnected to one of said adjacent cylindrically shaped elements (71) at a location circumferentially displaced from the location at which said cylindrically shaped element (71) is interconnected to the other of said adjacent cylindrically shaped elements (71) (see Figure 7).

2.2.2 Contrary to the assertion of the appellant. D1 discloses elements having an undulating pattern. Certainly, the best mode of carrying out the invention (as disclosed in the figures of the patent in suit) comprises elements whose overall form is an undulating pattern. However, the wording chosen for claim 1 is not restricted to such an embodiment. It also covers elements whose contour only is in the form of a wave. Furthermore, the expression ‘ undulating pattern’ does not necessarily mean ‘ having a gentle profile’, in particular since also the embodiments shown in the figures of the patent in suit have sharply rising and falling vertical parts (see Figures 4, 5 and 10).

2.2.3 Starting from D1, the object underlying the patent in suit may be regarded as to improve the longitudinal flexibility of the stent, see patent specification, column 1, section 0007. This object is achieved by the distinguishing feature of claim 1, according to which the elements have, in the unexpanded condition, an axial length which is less than their diameter.

This increases the number of elements per unity and correspondingly the number of deformable junction between the elements, thereby attaining a higher deformability.

2.2.4 The person skilled in the field, facing the problem of increasing the flexibility of the stent, will certainly consider shortening the length of the elements, since it is evident that such measure will increase the number of junctions per unity of length of the stent and therefore will result in an improvement of the longitudinal flexibility.
The appellant’s argument that the person skilled in the art would not consider to shorten the elements shown in D1 so that, in the unexpanded condition, their axial length was less than their diameter, is not convincing. D1 itself does not exclude such a shortening of the length of the elements. On the contrary, according to D1, the length of each element (graft) can be made longer or shorter as desired (see column 8, lines 14 to 19). Moreover, since the opinion of the author of D1 that a stent of the type disclosed in D1 could not be shortened to the extent defined in claim 1 is not sufficient to prove that there was a prejudice against the use of such elements in a stent according to D1, there was no reason which could prevent the person skilled in the art from shortening the elements of the stent disclosed in D1 in order to improve their flexibility.

This measure is even more obvious since it is known in the field of stents, see D3 [US-A-4 994 071, hereinafter: MacGregor, Provisional Measures Judge]. Since D3 suggest the use of a stent made of their elements forming undulating patterns each having a length shorter than their diameter, and since the person skilled in the art recognizes that the use of such elements improves the flexibility of a multilink stent, it was obvious for him to shorten the elements shown in D1 according to the teaching of D3.

Therefore, in the light of the teaching of D1 and D3, the subject-matter of claim 1 of the main request does not involve an inventive step.

(…)

4. Second auxiliary request

(…)

4.2 Inventive step

4.2.1 With respect to claim 1 of the second auxiliary request, D1 is still considered to represent the most relevant state of the art.
Starting from D1 and under consideration of the features of claim 1 of the second auxiliary request: the object to be achieved is to be seen in improving the flexibility and in maintaining a sufficient strength of the stent (see sections 005 and 007 of the patent specification).

This object is achieved by a stent comprising the features according to which

(a) the elements have in unexpanded condition an axial length less than their diameter.

(b) the cylindrically shaped elements are interconnected each other by three or four or more interconnecting elements.

(c) the undulating pattern of the cylindrically shaped elements is a serpentine circumferential undulating pattern, and

(d) each serpentine pattern is out of phase with the corresponding pattern of the adjacent element such that flexibility is provided along the length of the stent send about its longitudinal axis.

4.2.2 D1 itself does not disclose any of the features (a) to (d). In particular D1 does not disclose cylindrical elements having a serpentine circumferential undulating pattern.

Serpentine is a term which narrows the scope of the term undulating and requires that the shape of the undulating pattern is snake-like, or, in other words, that the pattern is free of any edges. As the appellant convincingly explained, the provision of elements having such a pattern results in a further improvement of the flexibility of the stent, since they are more flexible than elements having a pattern as shown in D1, D2 [EP-A-O 335 341, hereinafter: Palmaz-Schatz], D3 [MacGregor] and D5 [Wolff], in particular when the interconnecting elements are arranged in the peaks and valleys of the serpentine undulating pattern.

4.2.3 The board is convinced that the replacement of the undulating pattern shown in D1 by a serpentine undulating pattern according to the feature c) is not obvious. It is true that the provision of elements having a serpentine undulating pattern is known from D4 [Radiology], and that the person skilled in the art could use this pattern in the elements of D1. However, it is not likely that he would select such serpentine undulating pattern for the elements of D1. When the person skilled in the art decides to replace the elements of D1 by elements which, in their unexpanded condition, have an axial length less than their diameter (feature a), he would maintain the undulating pattern shown in D1, which essentially corresponds to the undulating pattern of the elements shown in D3. However, there is no reason to replace this pattern by the serpentine undulating pattern disclosed in D4, in particular since D4 does not suggest to use such a pattern for improving the flexibility of a stent, and since the elements of D4 have a relatively high length-diameter ratio in the unexpanded condition.

Therefore, the board concludes that the provision of a serpentine undulating pattern according to the feature (c), in particular in combination with features (a), (b) and (d), in a stent according to D1 is not obvious.

Therefore, the subject-matter of claim 1 and claim 7 (which includes all features of claim 1) of the second auxiliary request involves an inventive step.

2.11. Medtronic is active in the manufacture, trading and distribution of all types of medical equipment. Among the products offered on the Dutch market are three different types of stents, which are architecturally identical. They are the Medtronic Driver stent, the Endeavor Drug Eluting stent and the Endeavor Resolute Drug Eluting stent. Below are illustrations of the Medtronic Driver stent and the Endeavor Drug Eluting stent:

two illustrations

The stents will hereinafter collectively be referred to as: the Driver stents

2.12. Abbot has initiated accelerated proceedings on the merits before this court. Oral pleadings in the matter have been scheduled for 6 February 2009.

2.13. On 4 August 2008 Medtronic has filed an opposition against the granting of the patent (submitted on 5 August 2008 according to the on-line register at www.epoline.org), thereby requesting an accelerated hearing of the case.

2.14. As successors in title Abbott and Medtronic are the "heirs" to legal proceedings started before the United States District Court for the District of Delaware (hereinafter: Delaware District Court) in 1998 between Advanced Cardiovascular Systems Inc. and Guidant Sales Corp. (hereinafter: ACS) on the one side and AVE Galway Limited (hereinafter: AVE) on the other side. In 1999 AVE was taken over by Medtronic Inc., whereas Abbott took over ACS in 2006. By its unanimous jury verdict of 18 February 2005 it was ruled by the Delaware District Court that a specific ("bare metal") stent produced by what is now Medtronic infringes US 5,514,154, US 6,066,167, US 6,066,168 and US 6,432,133 ("the U.S. Lau Patents") owned by ACS. Medtronic has appealed against the decision of 18 February 2005. However, due to a number of motions that are still pending, the appeal has not yet been heard by the court. On 29 March 2007 the request filed by Medtronic to reverse or review the decision of 18 February 2005 ("motion" for a "retrial") was dismissed. On 29 June 2007 Abbott filed a motion with the Delaware District Court for an injunction against the trading of the Medtronic Driver stent and the Medtronic Endeavor, all this further to an alleged infringement of an American patent related to EP 842.

2.15. On 9 May 2002, four years before Abbott took over ACS and its patent portfolio, Abbott and Medtronic entered into a "Supply and License Agreement" (hereinafter: the agreement), under which Medtronic was granted a license to certain of Abbott's intellectual property rights regarding "drug and coating technology" to be used in the manufacture of a "drug eluting stent". The agreement (submitted by Medtronic as exhibit 28) among other things provides for the fact that Medtronic will not be attacked on the basis of certain patents of which Abbott was the owner at that time (Article 14.1.a). Pursuant to Article 15.18 (b) the non-attack clause does not concern "*Later Acquired Intellectual Property*"

2.16. In reply to Abbott's motion for an injunction, Medtronic invoked the agreement, arguing that the said agreement entitled it to certain rights under the Lau patents. As the agreement contained an arbitration clause, the dispute was submitted to an arbitrator appointed by the joint parties. On 26 February 2008 it was among other things held by the arbitrator that

Medtronic had not acquired any explicit or implicit license regarding the Endeavor stent under the U.S. Lau patents. Under the agreement this is a binding award.

3. The dispute

3.1. Briefly put Abbott alleges that by trading the Driver stents of all sizes and with a diameter (in expanded condition) of 4.0 mm or more and the 9 mm stents with a diameter of 3.5 mm, Medtronic is infringing EP 842 in the Netherlands. For that reason Abbott – briefly put – seeks a patent infringement injunction plus a penalty of € 100,000 per day, with an order against Medtronic to pay the full costs of the proceedings pursuant to article 1010h Code of Civil Procedure

3.2. Medtronic has filed a reasoned defence. The parties' arguments will be discussed in greater detail below, to the extent relevant.

4. The examination of the dispute

Jurisdiction

4.1. Since Abbott has argued that Medtronic is infringing its patent right in the Netherlands, the provisional measures judge of this court has jurisdiction to hear the claims pursuant to section 80 (2) of the Patents Act (Rijksoctrooiwet) 1995 (hereinafter: Patents Act 1995).

Urgency

4.2. The urgency required for these proceedings follows from the alleged continuous infringement of Abbott's patent. This is not outweighed by the personal and financial interests as alleged by Medtronic.

Validity

4.3. In these proceedings Medtronic is extensively targeting the validity of the patent. It has argued that the patent is invalid on account of a large number of validity objections, including added subject matter, invalid priority claim, lack of novelty, lack of inventive step and failure to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. As an invalid patent cannot be infringed, the validity of the patent will first of all be discussed (on a provisional basis).

Added subject matter

4.4. Medtronic has raised various added-matter objections in. its statement of defence, submitted prior to the oral hearing of the case. To this Abbott has replied in writing with its exhibit 30A, also prior to the oral hearing.

4.5. When examining the objections raised with respect to added subject matter, the following should be noted. Pursuant to article 123 (2) of the Convention on the Grant of European Patents (European Patent Convention – hereinafter: EPC) a patent application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. According to established case law this implies that it will have to be examined (see also Guidelines for Examination in the European Patent Office – December 2007, Part C, Chapter VI, no. 5.3.1.) if the subject matter of the application as a whole is by adding, changing or deleting, changed to such a degree that the person skilled in the art is provided with information which he cannot directly and unambiguously infer from what has been explicitly and implicitly disclosed in the application. The rationale of article 123 (2) EPC is to prevent an applicant from improving his position by adding matter that has not been disclosed in the original application, as this would give him an unjustified advantage and might be harmful to the legal certainty of third parties relying on the contents of the original application (see G1/93, OJ 8/1994.541). The court will take this criterion as a starting point.

Figure 10 as basis

4.6. Medtronic has first of all argued that the information provided in paragraph [0017] of the patent to the effect that figure 10 is the only embodiment of a stent according to claim 1 represents added subject matter, as this information was not included in the original application. This argument is dismissed because, as has been rightly argued by Abbott, it merely aims to clarify the fact that, given the limitations applied to the claim during the granting procedure, of all the figures figure 10 is the only figure falling within the scope of protection of the claim, being the figure which clearly shows that the cylindrically shaped elements are serpentine-shaped and are out of phase. It has furthermore been argued by Medtronic that figure 10 is incapable of providing a basis for at least the features iii, iv, v, vi and x, since these cannot be visually inferred from the said figure. This argument is dismissed as well, because in the court’s provisional view Medtronic wrongly assumes that figure 10 is supposed to contain the full details of claim 1. Its arguments are furthermore based on the incorrect assumption that figure 10 could be the only basis for the combination of the features

mentioned in claim 1.

4.7. Secondly – and following from the aforementioned objection – Medtronic has argued that claim 1 is a combination of elements, referred to as “a random collection”, which were not presented as interrelated elements in the original application, as a result of which the person skilled in the art would have no reason to select the specific combination of features referred to in claim 1. According to Medtronic this denotes added subject matter. In the court’s provisional view this objection is unfounded too. The description of the application as originally filed (EP 1 068 842 A2) provides details of a number of specific aspects of the stents claimed in that place, including the shape of the cylindrical element, details regarding the inter-connecting elements (column 3, lines 9-12) and the undulating pattern of peaks and valleys on the cylindrical elements (column 2, lines 28-31). During the granting procedure it is customary for the scope of protection of the originally-filed claim to be limited (for example in the light of documents of the state of the art quoted by the examiner), by reverting to the combinations discussed in the description.

4.8. The objections contained in 24 of the statement of defence are not conclusive. To the extent that they mean to say that there is not supposed to be a basis for feature x (*such that flexibility is provided along the length of the stent (10) and about its longitudinal axis)* it should be noted that, as has been rightly argued by Abbott, such basis is to be found in column 2, lines 11-14. To the extent that it is to be understood from Medtronic’s arguments that essential elements are missing in the claim regarding this feature, it should be noted that this is not a 123 (2) objection, but in fact an objection pursuant to article 84 EPC, which, however, is not a ground for invalidity.

4.9. The argument that the elements contained in claim 1 would lead to a shortening has been challenged by Abbott, whereas Medtronic has subsequently failed to substantiate this in greater detail, so that this argument will be disregarded. For the rest the court fails to see how this argument relates to the subject of added subject matter.

4.10. It is incorrect to state that the person skilled in the art would not find an indication for the specific choice of “*three, four or more inter-connecting elements*” Contrary to what is supposed by Medtronic, it is not required that the basis for this can consist in figure 10 or claim 9 only. In that respect Abbott has rightly referred to column 6, lines 26-35of the application filed, where this feature is disclosed (*FIG. 10 illustrates a stent of the present invention wherein three interconnecting elements 13 are disposed between radially expandable cylindrical elements. The interconnecting elements 13 are distributed radially*

around the circumference of the stent at a 120 degree spacing. Disposing four or more interconnecting elements between adjacent cylindrical elements 12 will generally give rise to the same considerations above for two and three interconnecting elements'). The same applies to the requirement recurring in feature vi that "*each of said adjacent cylindrically shaped elements (12)*" is interconnected "*to one of said adjacent cylindrically shaped elements (12)*". This feature is for example disclosed in:

> EP 842 A2, column 1, line 57 continued in column 2, line 3: "*Interconnecting elements or struts extending between adjacent elements (…)*";
> Column 2, lines 56-57: "*The elongated elements which interconnect adjacent cylindrical elements (…)*";
>
> Column 3, lines 14-18: "*The number and the location of elements interconnecting adjacent elements (…)*";
>
> Column 4, lines 38-42: "*the stent generally comprises a plurality of radially expendable cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements";*
>
> Column 6 lines 4-6: *"(…) to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially expendable cylindrical elements*".

4.11. Subsequently Medtronic has also argued that the use of the word "*generally*" in the above-quoted passage would imply that the effect which is ascribed to the two or three interconnecting elements, does not necessarily occur with every stent design. However, this interpretation of the word "*generally*" appears far-fetched and it is difficult to see what conclusion Medtronic wants to draw from this line of arguing. To the extent that it means to say that the person skilled in the art would find no indication for the specific choice of "*three, four or more interconnecting elements*", it should be repeated here that this combination has sufficient basis in the original application.

4.12. The argument that the person skilled in the art would understand from figure 10 that there would be one interconnecting element between the adjacent cylindrical elements only is not accepted by the court. As is rightly argued by Abbott, Medtronic fails to appreciate in that respect that the figure represents part of the drawing only. For now the court fails to see the relevance of this argument within the context of added material.

Axial length versus diameter

4.13. Thirdly Medtronic has argued that there is no basis for feature iv ("and having, in the unexpanded condition, an axial length which is less than their diameter"). This is incorrect, however. The basis is to be found in the original claim 3 of the application filed, for in that claim a stent is disclosed "*wherein the cylindrically shaped elements (12) in an unexpanded condition have a length less than the diameter thereof*". Figure 10 not providing a basis for this feature is irrelevant in that respect.

Flexibility

4.14. Fourthly it has been argued by Medtronic that the original application lacks a basis for feature x ("such that flexibility is provided along the length of the stent (10) and about its longitudinal axis"). This argument is incorrect. Abbott has referred to various sources in the application filed where the provision of flexibility is emphasised. See for example:

> Column 1, lines 37-43: '*What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily expanded and yet have the mechanical strength to hold open the body lumen into which it expanded. The present invention satisfies this need.';*
>
> Column 1, lines 44-50: '*The present invention is directed to an expandable stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein';*
>
> Column 2, lines 3-14: '*The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall, but not so close as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but which is still very stiff in the radial direction in order to resist collapse';*
>
> Column 3, lines 14-17: '*The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition';*
>
> Column 3, lines 22-24: '*Generally, the greater the longitudinal flexibility of the stent, the easier and the more safely it can be delivered to the implantation site*'.

Subsequent claims

4.15. The 123 (2) objections raised by Medtronic by statement of defence in the matter of the subsequent claims 4, 5 and 7 require no discussion within the context of these interlocutory proceedings, as at the hearing Abbot has indicated in reply to a question to that effect that it now relies on claim 1 of the patent only.

Subject matter added to the description

4.16. According to Medtronic the rectification of '*a coated 9.1 mm (4 inch) length of (…) tubing*' into '*a coated 10.1 mm (4 inch) length of (…) tubing*' represents added subject matter. This argument is dismissed, as it is highly likely, as has been argued by Abbott, that this was an error permitted under rule 88 EPC old (rule 139 new), for the original phrasing in the parent application EP 0 540 290 A2, in which document all that was used was the non-SI unit 'inch', also contained the value 4 inch (column 8, line 28), which indicated to the person skilled in the art that the term 4 inch was correct in the application filed, and that 9.1 mm represented an error.

4.17. As discussed above, the addition of information in paragraph [0017] of EP 842 does not represent added subject matter.

4.18. The argument that the deletion of figure 7 and the non-deletion of figures 1-6 and 8-10 represents added subject matter is also dismissed. Without further substantiation, which has not been provided, the court fails to see how deleting a figure may result in matter being added. The fact that the figures other than figure 10 have not been deleted cannot be construed as such, not even when viewed in the light of the explicit information provided in paragraph [0017].

4.19. Medtronic has furthermore indicated that EP 842 is not in full based on the parent application EP 0 540 290. In that respect it has argued that in paragraph [0029] of EP 842 (being the separate application that was filed) an Anorad value of FR=10 is given, whereas the patent application mentions an Anorad value of FR=20. This objection is dismissed, as it seems likely that this is a matter of a typing error, which may easily be corrected pursuant to rule 139 EPC in the course of the opposition proceedings currently pending.

4.20. The argument that line 10 of page 16 of EP 0 540 290 is believed to have been missing in the original application is dismissed. Abbott after all has submitted as exhibit 30C the original

page 16 of the patent application as filed, which shows that the words of line 10 were indeed included in the patent application, albeit in the wrong place. However, it was indicated by means of a hand-written note where the line should have been inserted. It seems likely that this too was a rectification of an evident error.

4.21. Finally it has been argued by Medtronic that the value of the current in paragraph [0036] of 0.06 to 2.3 amps/cm² is believed to represent added subject matter, as the parent application mentions a scope of 0.4 to 1.5 amps/in². However, as has also been stated by Medtronic itself, this is unmistakably an arithmetical error. The court fails to see why this error might not be easily corrected in the opposition proceedings. The person skilled in the art, when reading the patent application, would after all understand that the value specified in that place is the correct one.

Conclusion added subject matter

4.22. In the court's provisional view the features of claim 1 as granted are to be inferred '*directly and unambiguously*' from the original patent application. Moreover, the combination of the original features as claimed in claim 1 is not such that the conclusion will have to be drawn that the invention in respect of which protection is sought extends beyond the content of the original application. In the court's provisional view there is no question either of subject matter having been added to the description.

Invalid priority

4.23. Medtronic has furthermore argued that the priority claim of EP 842 is invalid.

Not a first application

4.24. According to Medtronic the priority document of EP 842 (US 783,558) is not a first application within the meaning of article 87 (1) EPC. To that end it has argued that EP 0 505 686 A1 claims the priority of US 647,464, which last-mentioned application was filed on 28 January 1991, being an earlier date than the claimed priority date of 28 October 1991. According to Medtronic the figures 4-7 of US 647,464, relating to a '*Stent delivery system*' show a stent which is '*virtually identical*' to the one shown in the figures 1-3 of the priority application on which EP 842 is based. From this Medtronic draws the conclusion that according to claim 1 (and 7 – but this claim will not be discussed, since Abbott has indicated, following a question on the matter, that in these interlocutory proceedings it wants to rely on claim 1 only) the invention had already been disclosed.

4.25. In the court's provisional view this attack fails. The figures 4-7 of US 647,464 represent a stent in which each of the '*cylindrically shaped elements*' is interconnected to an adjacent element by means of one '*interconnecting element*'. Nowhere in this publication is there any disclosure or suggestion to the effect that the cylindrical elements should contain '*three or for or more*' interconnecting elements. The invention according to claim EP 842 has therefore not been disclosed in US 647,464, so that, contrary to what is argued by Medtronic, EP 842 is in fact a first application within the meaning of article 87 (1) EPC and has duly been entitled to priority as of 28 October 1991. In that respect it is not conclusive that, as has furthermore been argued by Medtronic, the number of '*interconnecting elements*' is an artificial feature without any relevant technical effect, and for that reason should not be considered in the examination of the question whether the priority application is in fact the first application. This argument may be relevant in examining the level of inventiveness of the device according to EP 842, but should be disregarded within the context of the question whether a valid priority claim has occurred.

Not the same invention

4.26. According to Medtronic the priority claim is believed to be invalid because the subject matter of claim 1 of EP 842 is not the same invention as the one made in the priority application. To that end it has argued that in the description of the priority application it is stated that

> The elongated elements which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements.

whereas, still according to Medtronic, this feature, despite the use of the word '*should*', is absent in the claims pertaining to EP 842. For that reason too Medtronic believes that the priority claim is invalid.

4.27. In the court's provisional view this argument does not hold. The basic test for determining whether a specific claim is entitled to the date of a priority document is, as far as the requirement of the same invention is concerned, the same as the test for determining whether a patent satisfies the requirements of article 123 (2) EPC. In other words: in order for an entitlement to the first date to be valid, the matter of the claim must be '*directly and unambiguously derivable from the disclosure of the invention in the priority document, also taking into account any features implicit to a person skilled in the art in what is expressly mentioned in the document*' (see G 2/98, OJ 10/2001, 413). If this standard is assumed, the court comes to the conclusion that the average person skilled in the art can directly and

unambiguously derive the invention as claimed in claim 1 of EP 842 from the priority document. The above-quoted passage has identically been included in the description of the patent as granted (column 2, line 56, continued in column 3, lines 1 and 2). Without any further explanation, which has not been provided, the court for now fails to see why, in order for making a valid claim to the priority of US 783,558, the subject matter of claim 1 should at any price contain the feature that the interconnecting elements have '*a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements.*' By and large the use of the word '*should*' in the priority application in any case is not sufficient for that purpose

Lack of novelty

EP-A-0 505 686 (Lau Stent Delivery System)

4.28. According to Medtronic this patent application anticipates the subject matter claimed in claim 1 of EP 842, on the one hand for reason of the invalid priority claim, and on the other hand pursuant to article 54 (3) EPC. As it has already been held earlier that EP 842 is duly entitled to the priority of US 783, 558, the lack of novelty argument based on the first reason has to fail. EP-A-0 505 686, which application was published after the priority date and the filing of EP 842, pursuant to article 54 (3) is comprised in the state of the art, fictitious or otherwise, and for that reason is relevant only within the context of determining the novelty of the invention. With reference to ground 4.25 it should be noted that this publication does not anticipate the matter claimed in EP 842, as the figures contained therein do not disclose the feature that each of the '*cylindrically shaped elements*' is interconnected to the adjacent element by '*three or four or more interconnecting elements*'.

FR-A-1 602 513 (NRD)

4.29. Abbott has objected to the failure to submit a Dutch translation of this document and for that reason has requested not to consider it. This request is dismissed. Although it has to be granted to Abbott, that submitting a Dutch translation of a foreign-language (including English) publication, or prior art publication, will in principle facilitate the examination of the disclosures contained therein (see also the Accelerated Regime for Patent Matters: a document written in a language other than Dutch or English may not get the envisaged attention), it will not be left out of account for that reason. To that must be added that French is one of the three official European patent languages, and those engaged in patent law, including specialized patent attorneys, may be expected to have a command of that language, or at least to

understand a document written in that official language.

4.30. It has been argued by Medtronic that FR-A-1 602 513 (NRD) anticipates the patent. This French patent application (hereinafter: NRD), concerning '*Dilataleurs chirurgicaux et, en particulier, dilateur oesophagien*' dates back to 5 August 1968 and therefore constitutes state of the art for EP 842. The document describes a surgical dilator (dilating instrument), specifically for use in the oesophagus during surgery. Other uses are also mentioned, including vaginal use. The relevant figures of NRD are as follows:

[Figures numbered 1, 4 and 7]

4.31. When examining the matter it is stated first and foremost that a measure is not novel if all its relevant features are explicitly or implicitly disclosed directly and unambiguously in one single source comprised in the state of the art to a person skilled in the art, making use of his general expertise.

4.32. Using this criterion as the standard, the provisional measures judge for now takes the view that NRD does not impair the novelty of EP 842. In particular it must be noted that NRD does not disclose the feature (i) that a '*longitudinally flexible stent*' is required. It so happens that a dilator is not a stent. It is a far larger device than a stent, while its purpose is not to remain behind inside the body. For now the court therefore fails to see how the dilator can remain in an expanded position following expansion, which is the very purpose of the stent. This seems to be confirmed by the fact that according to figure 4 of NRD, which is referred to in particular by Medtronic, the dilator is not made of metal, as is the stent, but of a synthetic or some other plastic material or rubber (see page 2 of the description, lines 38-39: '*La figure 4 représente encore une autre forme de l'armature 1 qui est constituée par un simple moulage de nylon ou autre matière plastique ou de caoutchouc.*' Feature (iii) is not disclosed either. Given the fact that the cylindrical elements, if at all distinguishable, are on all peaks and valleys interconnected with adjacent elements, the court fails to see that those elements are independently radially expandable, as required by the patent. A radial force exerted on one cylindrical element will unmistakably have an effect on the adjacent elements, given the way in which they are interconnected. The fact that figures 7 and 8 show a tapering dilator does not change all this.

4.33. Apart from all this it should be noted that the provisional measures judge does not even offer its opinion on the question, whether there would at all be reason for the average person skilled in the art to inspect the dilator according to NRD. The invention according to EP 842 concerns

an expandable stent which is relatively flexible along its longitudinal axis '*to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein'*. The dilator according to NRD should at least be suitable for that purpose. However, given its size it is not. It will therefore have to be assumed that the average person skilled in the art would not take notice of the dilator disclosed in NRD, for reason of being too remote. But even if this were different, the person skilled in the art would not be capable of making the dilator according to NRD suitable for a '*longitudinally flexible stent*' to be used in blood vessels or arteries, without making major adaptations thereto, in other words: without '*undue burden*'. For this reason too it cannot be held that NRD anticipates EP 842.

Lack of inventive step

Irie

4.34. In the matter of the alleged lack of inventive step Medtronic has in the first place invoked an article published by Irie et al. (hereinafter: Irie), in Radiology in 1991[2] well before the priority date, which last-mentioned fact has not been challenged.

4.35. The Irie article concerns the problem of different types of metallic stents being incapable of being relocated, after having been inserted into a lumen. Irie describes a solution to this problem. To that end use is made of adjusted Gianturco stents, in such a manner that these are '*relocatable*' and '*retrievable*'. The original Gianturco metallic cylindrical elements have for that purpose been fitted with '*wire struts*' and '*monafilament line*' (or put irreverently: fishing wire). To types of stent are disclosed, one fitted with '*long struts*' and one fitted with '*short struts*'. The stents made of 0.012 and 0.0114 inch stainless steel wire are 1.5 cm in diameter and 1.5 cm long. Stents made of 0.018 are 2.5 cm in diameter and 2.5 cm long. The article describes that all the stents have been successfully inserted, '*retrieved*' and '*relocated*' in a silicone vascular model and the IVC (*inferior vena cava* – i.e. the lower hollow artery) of five dogs.

4.36. If the terminology of the patent is observed, Irie, contrary to what has been argued by Abbott (see under 81 notes of oral pleading Van Nispen and Mr. Dack) discloses in an expanded position a longitudinally flexible stent, which means that feature (i) ('*a longitudinally flexible stent (10)*') has been satisfied. It is true that in column 1 on page 577 it is said with respect to

[2] Relocatable Gianturco Expandable Metallic Stents. Toshiyuki Irie et al., Radiology 1991: 178: pp. 575-578.

the long strut design also disclosed in Irie that '*this design will not expand in a curved stricture unless strong expansive force is used, which can cause undesirable stress on the wall of the stricture*'. However, immediately afterwards it is said that '*in curved strictures the more flexible tandem stent design with short struts can be used*'. This is not the same as the quotation contained in the notes of oral pleading, where it is said that "*the more flexible tandem*' *[i.e. not interconnected] short stent can be used*". Contrary to what Abbott wrongly suggests, this is not a matter of individual stents placed in tandem, but cylindrical elements that have been interconnected by means of struts.

4.37. Irie also discloses '*a plurality of cylindrically shaped elements (12)*'. Figure 2b (see below)

[Figure 2b]

demonstrates that the stent pictured there consists of various zig-zag elements, which are cylindrically shaped when viewed circumferentially (see figure 2b). This means that feature (ii) is also disclosed.

4.38. The '*cylindrically shaped elements*' are '*generally aligned on a common longitudinal axis such that, other than at an end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions*'. This means that feature (v) has also been disclosed, for it is clear that the zig-zag elements, other than at the ends of the stent, always have two adjacent zig-zag elements, spaced in opposite axial directions.

4.39. Also disclosed is feature (i) which requires that the undulating pattern of the cylindrically shaped elements is out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements, albeit that, as will be demonstrated hereinafter, there is no serpentine circumferential undulating pattern of peaks and valleys within the meaning of the patent.

4.40. Finally it would seem that, in view of what has been held above in ground 4.36, feature (x) has also been satisfied, which sets the following requirement: '*such that flexibility is provided along the length of the stent (10) and about its longitudinal axis*'.

4.41. However, in the court's provisional view the specific question will have to be answered if Irie is a better starting point for examining the inventive step of the matter claimed in EP 842 than the Schatz application, as assumed by the Technical Board of Appeal in the aforementioned

cases (see ground 2.7 and 2.10). It is true that the attention of the average person skilled in the art will have been drawn towards the parallel developments of the Gianturco stent, but the specific question is whether he would have regarded Irie as the closest prior art, since Irie concerns self-expanding stents and not – as is the case with Schatz – balloon-expandable stents. To that must be added that, as has been argued by Abbott at the hearing without being challenged, Gianturco stents have never been applied in practice towards the use in coronary blood vessels, so that, for that reason too, it would be less obvious for the person skilled in the art to take Irie as a starting point. It is doubtful, to say the least, if the reply thereto could be that Irie has a '*similar purpose or effect as the invention*' (c.f. Guidelines, C-IV 11, 7.1). If, however, Medtronic's argument were accepted to the effect that Irie qualifies as the 'most promising springboard', the following should be noted.

4.42. the features (iii), (iv), (vi), (vii) and (viii) are not disclosed. The subject matter of claim 1 of EP 842 therefore differs from Irie's disclosure in the following respects:

(iii) *'the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition'*

Figure 2b, the stent with the 'short-strut design', shows that, other than at the ends of the stent, the zig-zag elements are on all peaks and valleys interconnected to the adjacent zig-zag elements by means of short struts. The court fails to see how these cylindrical elements might independently expand in a radial direction. For example, the situation pictured in figure 7 of the Gianturco US 4,580,568 patent (see below),

[Figure 7]

where two stents are side by side (and therefore independently) in series inserted in the narrow part of the vessel, as a result of which the one Z-stent will radially expand more than the other, will according to Irie be out of the question.

(iv) '*and having, in the unexpanded condition, an axial length which is less than their diameter*,

This feature is not disclosed. Figure 4c Irie (pictured below – and not, as argued by Abbott, figure 5c, which concerns a long-strut)

[Illustration of stent]

shows that the lengths of the cylindrically shaped elements in an unexpanded condition exceed their diameters. This is also described by Irie in the Radiology article, for example on page 1, column 1, final paragraph, continued on page 2, first column, as far as the second paragraph. Stents are referred to of 0.012 and 0.014 inch wire, which are 1.5 cm in diameter as well as 1.5 cm long as well as stents of 0.018 inch wire, 2.5 cm in diameter and 2.5 cm long. In terms of the patent this concerns L = D instead of L < D. In the court's provisional view this feature, contrary to what has been argued by Medtronic, must be included when assessing inventive step, as it seems likely that this feature, in any case in the combination with the other features, contributes towards the longitudinal flexibility.

(vi) *'each of said cylindrically shaped elements (12) interconnected to one of said cylindrically shaped elements (12) by three or four or more interconnecting elements (13)'.*

Although figure 2b clearly shows that the cylindrical elements are on all peaks and valleys interconnected to each other by short struts, the feature '*three or four or more '* nevertheless for now appears to be something different from a connection by 'all connecting elements', in which last-mentioned case after all the feature (vii), to be mentioned below, cannot have been satisfied either, so that feature vi is not disclosed either.

(vii) *'disposed at locations circumferentially displaced from the locations at which said cylindrically shaped element (12) is interconnected to the other of said adjacent cylindrically shaped elements (12').*

As appears from figure 2b above, and was already discussed earlier, the zig-zag elements on all peaks and valleys are connected to each other by means of short struts. Moreover there is no question of displacement (radially offset) of the places where the cylindrically shaped elements are connected to each other, as required by feature (vii).

(viii) '*said cylindrically shaped elements (12) having a serpentine circumferential undulating pattern of peaks and valleys*'

The patent provides no definition of a '*serpentine undulating pattern*'. The parties' views as to how this is to be interpreted are different. Medtronic has referred to a definition of the noun as appearing in Webster's dictionary of 1913, where, after the definitions '*resembling a serpent; having the shape or qualities of a serpent; subtle, winding or turning one way and the other,*

like a moving serpent; anfractuous', the terms '*meandering, sinuous and zig-zag*' are also used. This causes Medtronic to draw the conclusion that the zig-zag pattern too as disclosed by Irie represents a '*serpentine undulating pattern*' – as used in the terminology of the patent. Abbott on the other hand refers to the adjective as it appears in the most recent edition of Webster's dictionary, where these last-mentioned terms do not appear. The provisional measures judge takes the view, and to that extent has regard to what has been held on the matter by the Technical board in T 1000/02 (see ground 2.10), that serpentine is a term which narrows down the extent of the term '*undulating*' and requires the shape of the undulating pattern to be '*snake-like*', or, in other words, '*that the pattern is free of any edges*'. Contrary to what has been held by the Technical Board, the court for now takes the view that it cannot be said of the Gianturco stent, as disclosed in Radiology, that it has a '*serpentine undulating pattern*'. It unmistakably has a zig-zag pattern, showing edges, albeit that these have been rounded off slightly. However, a pattern of that kind cannot be put on a par with a '*snake-like* ' pattern, which is '*free of edges*'. The stent disclosed in Radiology compares with the stent as included in Irie's article. For the same reason the court takes the provisional; view that the stent disclosed in Irie has no '*serpentine undulating pattern*'. The stent disclosed there has to be qualified as a Z- (zig-zag) stent. This means that feature viii is not disclosed either.

4.43. Assuming Irie to be the closest prior art, the patent therefore distinguishes itself by the following characteristics:

(iii) *' the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition'*

(iv) *'and having, in the unexpanded condition, an axial length which is less than their diameter'*

(vi) *'each of said cylindrically shaped elements (12) interconnected to one of said cylindrically shaped elements (12) by three or four or more interconnecting elements (13)'*

(vii) *'disposed at locations circumferentially displaced from the locations at which said cylindrically shaped element (12) is interconnected to the other of said adjacent cylindrically shaped elements (12)'*

(viii) *'said cylindrically shaped elements (12) having a serpentine circumferential undulating pattern of peaks and valleys'*

4.44. Taking Irie as the starting point and having regard to the features listed in claim 1 of EP 842, the objective technical problem underlying the patent is the presence of the quality of radial rigidity ('still very stiff'), required to keep open a body lumen, while at the same time

maintaining the longitudinal flexibility of the stent for the purpose of facilitating inserting/positioning that same stent. The solution is offered by a stent that includes the combined features (iii), (iv), (vii) and (viii) of the patent, since each of these in part contribute towards the rigidity and the flexibility of the stent in its entirety.

4.45. Irie discloses none of the features (iii), (iv), (vi), (vii) or (viii). None of the prior art referred to by Medtronic, viz. Schatz, Palmaz-Schatz, Wolff, Hillstead and Boneau (Pinchuk is left out of account because it has not been argued by Medtronic) disclose all of these features independently. Only Schatz discloses the features of independent expansion in the radial direction (feature iii) and the connecting elements (vii) being 'displaced'. Wolf merely discloses this last-mentioned feature.

4.46. In the court's provisional view the average person skilled in the art, assuming Irie as the most promising springboard and faced with the technical objective problem, having in mind the features disclosed by Schatz and Wolff, could not arrive at the solution according to EP 842 without inventive effort, let alone that the document would contain pointers that might induce the person skilled in the art to want to arrive at the invention. Irie in particular does not contain any pointer for the purpose of replacing the pattern of cylindrical elements in Irie by a '*serpentine circumferential undulating pattern of peaks and valleys*'. On the contrary, given the fact that Irie teaches that original Gianturco stents require adjusting and have to be fitted with wire struts and monofilament line, the person skilled in the art, if anything, would be drawn away from the invention.

4.47. This means that in the court's provisional view Irie does not prejudice the level of inventiveness of EP 842.

Boneau

4.48. In the matter of the alleged lack of inventive step Medtronic has also invoked European patent application EP 0 417 928 A1, filed on 224 august 1990, claiming priority as of 24 August 1989 on the basis of US 398,180 (hereinafter: Boneau).

4.49. Boneau concerns a balloon-expandable '*Endovascular support device*' for the treatment of chronic restenosis or other vascular narrowing, together with a method '*for delivering a plurality of such devices to an affected area of a vessel*'. The stent has been illustrated below in its expanded form.

[Figure 1]

4.50. The documents describes a number of problems with prior art stents, including the fact that every stent has its own percentage of thrombosis, restenosis and tissue in-growth, and stent inserting difficulties. Moreover a number of stents do not adjust smoothly to the shape of the vessel. It is furthermore pointed out that the relatively great length of the prior art stents makes it difficult to treat tortuous vessels, while resisting the successful insertion of a number of such stents. The description mentions that the invention '*substantially reduces the complications and overcomes the limitations of prior art devices*' The device according to the invention for that purpose has a '*very low mass which is capable of being delivered to the affected area by means of a slightly modified conventional balloon catheter similar to that used in a standard balloon angioplasty procedure*'.

4.51. Following the terminology of the patent, Boneau discloses only one feature of EP 842, viz. '*a longitudinally flexible stent*' (feature i).

4.52. There is no question of a '*plurality of cylindrically shaped elements*' (feature ii). Medtronic does suggest that this is so, but the relevant passages quoted from the description (column 4, lines 14-20) merely concern the claimed method '*which permits a plurality of such devices to be implanted commensurate with the length of the lesion under treatment*'. This unmistakably concerns individual, non-connected stents, which are successively positioned side by side in the place where the narrowing occurs.

4.53. For this reason there can be no '*plurality of cylindrically shaped elements*' either, being '*independently expandable*' in the radial direction (feature iii).

4.54. Feature iv is not disclosed either ('*and having, in the unexpanded condition, an axial length which is less than their diameter*'). Medtronic has pointed at a passage in the description speaking of the minimum length of the stent (column 6, lines 17-40) and from this draws the conclusion that the feature L<D is disclosed in that place. The court does not follow Medtronic in this respect. The passage in question reads as follows:

> Typical cardiovascular vessels into which the stent 10 might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding stents may range from one millimetre to two centimetres in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters has been performed with good success outside the

United States and testing on animals is also going on.

This passage adequately shows, particularly by the use of the word 'vessels', that the diameters specified there, i.e. 1.5 millimeters to 5 millimeters, relate to the diameter of the vessel. Due to the link that is subsequently made with the stents ('*corresponding vessels*') the lengths described there cannot in fairness be interpreted as denoting anything other than the length of those stents in their expanded condition. This means that the diameters and lengths mentioned in the passage teaches nothing of the diameters and lengths of the stent in the unexpanded condition, so that feature iv is not disclosed.

4.55. Due to the absence of '*a plurality of cylindrically shaped elements*' in Boneau, the features v ('*two adjacent cylindrically shaped elements (12) spaced in opposite axial directions*'), vi ('*three or four or more interconnecting elements'), vii ('disposed at locations circumferentially displaced')and ix ('*out of phase*')* are not disclosed either.

4.56. Boneau does not disclose feature viii either ('*serpentine circumferential undulating pattern'*). The stent according to Boneau after all has a zig-zag shape, in respect of which it has already been held hereinbefore that it cannot be put on a par with a '*serpentine undulating pattern*'.

4.57. Due to the absence of all the features contained in EP 842 with the exception of feature (i), feature (x) is not disclosed either ('*such that flexibility is provided along the length of the stent (10) and about its longitudinal axis*').

4.58. Under those circumstances a problem-solution approach will be meaningless. It is not very likely that the average person skilled in the art, assuming Boneau as the closest prior art, and given the disclosure of only one feature contained in that document, familiar moreover with the feature, disclosed in Schatz, of the independent expansion in the radial direction (feature iii) and the fact that in Schatz and Wolf the interconnecting elements are 'displaced' (feature vii), could without inventive effort arrive at the invention according to EP 842.

Hillstead

4.59. At the hearing it has been argued by Medtronic that US 4,856,516 (hereinafter: Hillstead), filed on 9 January 1989 and granted on 15 August of that same year, also prejudices the inventive step of patent EP 842. Although this is discussed in detail in the memorandum of oral pleading (paragraphs 188-191) and in the deleted paragraphs (192-217), Medtronic at the hearing due to lack of time was unable to properly substantiate this allegation. It did not go

beyond the mere argument that the invention according to EP 842 would on the basis of Hillstead have been obvious to the average person skilled in the art. Since Abbott has not been able to submit a proper reply thereto, due to the absence of a reasoned explanation on the part of Medtronic, Hillstead will not be considered within the context of these interlocutory proceedings.

Insufficient disclosure

Claim 1 – inadmissible 'limitation by the result'

4.60. It has been alleged by Medtronic that the patent is incapable of being reproduced, due to the fact that the description contains no clues whatsoever that might enable the average person skilled in the art to determine when the limitation claimed in feature (x) ('such that flexibility is provided along the length of the stent (10) and about its longitudinal axis') is met. This argument is dismissed because in the court's provisional view the person skilled in the art, reading the description and the claims, will without 'undue burden' be able to carry out the invention. The term 'such that' in feature (x) implies that the desired flexibility is achieved if the preceding features a-ix are carried out. The problem which Medtronic in fact has with the aforementioned feature is more an objection of clarity within the meaning of article 84 EPC, which, however, does not constitute a ground for invalidity.

Claim 1 – no specific disclosure of the stent structure

4.61. Following up on the previous argument Medtronic has furthermore argued that the claim and the description of EP 842 do not teach the person skilled in the art how he may arrive at the claimed flexibility and radial rigidity. This argument is dismissed as well, since, in the court's provisional view, it is unlikely to be correct.

4.62. With respect to the '*interconnecting elements*' it should be noted that the patent indicates sufficiently clearly that the number is '*three, four or more*', while the description goes on to state that '*preferably, all of the interconnecting elements of a stent rejoined at either the peaks or the valleys of the undulating structure of the cylindrical elements which form the stent*'. The above is not altered by the fact that the description furthermore states that the number and the location of the interconnecting elements may vary. The same applies to what has been denoted by Medtronic as '*variable*', '*circumferential positions of the interconnecting elements*', (further down – under f (see 43 memorandum of oral pleading Medtronic) also referred to as: '*relative positions of the undulating pattern in the cylindrical elements*'). The fact that the

description indicates that '*various configurations for the placement of interconnecting elements are possible*' and that '*several examples are illustrated schematically in FIGS 7-10*', is to be understood in the light of the above as a hint to the person skilled in the art that he has some degree of discretion in the positioning of the interconnecting elements. In that respect it should be remembered that the description clearly indicates that figure 10 is the only figure that shows a stent, or part thereof, that meets the features claimed in claim 1 (column 3, lines 53-55). In that respect too it will definitely not be impossible for the for the person skilled in the art to carry out the invention.

4.63. The objection raised by Medtronic to the effect that the description teaches that the '*properties of the stent 10 may also be varied by alteration of the undulating pattern of the cylindrical elements 12*' requires no discussion, since Medtronic itself indicates (footnote 14 in its memorandum of oral pleading) that the passage in question does not re-appear in the patent as granted. For the sake of completeness it is noted that the description (column 2, lines 34-39) shows that that the cross section of the undulating component' is relatively narrow, and preferably has an '*aspect ratio*' of 2:1 to 0.5:1, whereas a 1:1 ratio is referred to as '*particularly suitable*'. This provides the person skilled in the art with sufficient clues to determine the width of the 'undulating components'.

4.64. As to the '*undulations in the undulating pattern of the cylindrical elements*' and the possible variation therein, it should be noted that this too will not confuse the person skilled in the art, for his professional expertise will ensure that he is familiar with the average diameter of a blood vessel, or coronary blood vessel, while the patent furthermore teaches him that the cylindrical elements in the unexpanded condition have an axial length which is less than their diameter. Given those limitations, the person skilled in the art will be perfectly able, perhaps by making use of a certain degree of trial and error, to establish the number of '*undulations*' as well as their amplitude.

4.65. The last objection raised by Medtronic argues that the patent cannot be carried out, because the distance between the cylindrical elements is described too vaguely ('*close but not too close*'). The court does not accept this objection either. From the conclusion, and viewed in the light of the description and the drawing, it will be sufficiently clear to the person skilled in the art that the cylindrical elements, as taught by the description (column 2, lines 9-13), have to be positioned sufficiently close to each other '*so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall*', but then again not so close as to reduce the longitudinal flexibility. Again it should be noted that the person skilled in the

art may be expected to rely on a certain degree of trial and error.

4.66. In the court's provisional view the objections as to the inability to carry out the invention have been wrongly raised.

Conclusion

4.67. The provisional conclusion will be that in these proceedings the validity of EP 842 will for now have to be assumed. In view of this it will now be examined if, as argued by Abbott, Medtronic's Driver stents are infringing the patent.

Infringement?

4.68. When examining the infringement claims, it should first and foremost be stated that under article 69 of the EPC and the corresponding section 53 (2) of the Patents Act 1995, the scope of protection of a patent granted in the Netherlands is determined (since the entering into effect on 13 December 2007 of the EPC 2000) by the terms of the claims, with the description and the drawings being used to interpret the claims. For the purpose of this criterion the Protocol to article 69 should be considered. According to the Protocol article 69 should be interpreted as defining a position between the extremes of a strict, literal meaning of the wording used in the claims and the interpretation where the claims serve only as a guideline for determining the scope of protection, contemplating what the inventor has wanted to protect in the eyes of the average person skilled in the art. According to Supreme Court 13 January 1995, LJN ZC1609, Ciba Geigy/Oté Optics as understood in Supreme Court 7 September 2007, LJN BA3522, Lely/Delaval this interpretation means that the essence of an invention - or in other words: the invention idea underlying the words of the claims - is a point of view , whilst on the other hand there is the literal text of the claims. In that respect the court will also have to decide whether the outcome of the court's examination does adequate justice to the legal certainty for third parties – in which respect lack of clarity for the average person skilled in the art, who seeks to determine the scope of the protection offered by the patent, in principle works to the detriment of the patent owner, while the court just as much needs to consider a reasonable degree of protection for the patent owner. According to the Protocol equivalents should also be included in this consideration.

4.69. Not in dispute is the fact that Medtronic's Driver stents, with the lengths and diameters specified in ground 3.1, all of them meet the features i and ii, iv, v, vii, viii, ix and x of claim 1 of EP 842.

4.70. However, Medtronic takes the view that its stents do not infringe EP 842, as they do not satisfy feature vi (‘*each of said cylindrically shaped elements (12) being interconnected to one of said cylindrically shaped elements (12) by three or four or more interconnecting elements*’). Following from the above Medtronic furthermore argues that feature iii (‘*the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition*’). The court holds as follows with respect thereto.

No interconnecting elements?

4.71. Medtronic has first of all argued that the average person skilled in the art will in every-day speech interpret the term ‘interconnecting elements’ as a separate part or component of the stent. This argument cannot succeed, because a person skilled in the art will always first consider the claims of the patent, in order to understand what is meant by a specific term used in the patent (the patent owner is his own lexicographer). If the claims provide the person skilled in the art with insufficient clues, he will then use the description and the drawings for their interpretation.

4.72. In the court’s provisional view the average person skilled in the art, even after having studied the claims, if necessary with the help of the description and the drawings, will not interpret the feature ‘*interconnecting elements*’ in the sense that such by all means concerns a separate part or component. It is true that Medtronic has argued that the description among other things mentions ‘*interconnecting elements*’ or ‘*struts*’ (column 2, lines 4-5), but the conclusion it draws from this, viz. that these two terms are denoted as synonymous, cannot conclusively be derived from this passage. It is to be assumed that the person skilled in the art will interpret the use of the two separate terms as meaning that the cylindrical elements may be connected to each other by struts, but that this does not have to be so. It will be clear to him that a simple connection between the cylindrical elements may also suffice.

4.73. the court does accept Medtronic’s view that the patent requires that the ‘*interconnecting elements*’ extend between the adjacent cylindrical elements. This view is after all supported by the passage already quoted above, which mentions ‘*extend between adjacent cylindrically elements*’. Medtronic has furthermore rightly highlighted the passage in the description where the ‘*interconnecting elements*’ are denoted as ‘*elongated elements*’. From these two sources the person skilled in the art will understand that the ‘*interconnecting elements*’ extend between the cylindrical elements.

4.74. Medtronic has argued that the cylindrical elements of the Driver stents are connected by means of autogenous fusion-welding, in which process use is made of a laser. Medtronic takes the view that, given the use of the term '*elongated*', it is incorrect to regard a fusion weld ass an '*interconnecting element*'.

4.75. However, with Abbott the court takes the view that a fusion weld can be regarded as an '*interconnecting element*' within the meaning of the patent for the following reasons.

4.76. Abbott has submitted a copy of a photomicrogram by way of an exhibit (DTX-150A from the American proceedings – see ground 2.14) showing the side of the weld. The copy in question has been pictured bottom-left. The illustration on the right (which Medtronic invokes, an of which Abbott claims that it is an S7 stent, not a point of discussion in the present case) is a picture that was taken after two cylindrical elements had been welded from the opposite side: the picture has been taken as if someone is looking out from inside the stent.

2 pictures

These pictures, specifically the DTX-150A, demonstrate that an interconnecting element is present, which has been formed by the weld, extending between the two cylindrical elements. It is clearly visible, notably in the places where the top of the curves bend away, that the weld has caused material to gather between the cylindrical elements, which material was not present before the welding.

4.77. This theory is supported by the technical report submitted by Abbott and written by Dr. Gary Schneiderman, Ph.D., particularly in the drawing contained therein, which have been copied from Medtronic's own user instructions and design specifications regarding its Driver stents. The design specification of the Large Vessel Driver stent has been represented below:

Various figures

The bottom left-hand drawing clearly shows that the interconnecting elements are explicitly represented by black squares. This conclusion alone is in sharp contrast with Medtronic's allegation that no interconnecting elements, separate or other wise, are present. Even more important, however, is the top right-hand drawing. The interconnecting element between the second and the third cylindrical element (seen from the left) is denoted as '*detail*' by Medtronic. '*Detail A'* is highlighted in the top left-hand corner. In so doing Medtronic itself

indicates that the minimum length and width of the element are 0.002 x 0.006 inches.

4.78. At the hearing Medtronic has confirmed in reply to a question that the weld extends between the cylindrical elements and that it has its own dimension. Under those circumstances it cannot be maintained that the fusion weld used in the stent of Medtronic, does not qualify as an 'interconnecting element' within the meaning of the patent. This means that in the court's provisional view the requirements of feature vi are met, by way of equivalence, if not in the literal sense, since the weld in the Medtronic Driver stents essentially performs the same function, essentially in the same manner and essentially with the same result.

4.79. Abbott having failed to raise the issue of equivalent infringement, and this issue not having been addressed for that reason, as argued by Medtronic, is a line of arguing not adopted by the court for now. To that end it should be noted that Abbott has argued that the Driver stents re covered by the scope of protection provided by EP 842. As pointed out hereinbefore in ground 4.68, the court, when determining the scope of protection of a patent, has to take proper account of equivalent elements, in any case since the entry into effect of EPC 2000 as of 13 December 2007 ('*due account shall be taken of any element which is equivalent to an element specified in the claims*'), as a result of which he will be able to include such elements in his examination of the case.

No individually expandable elements?

4.80. A second non-infringement argument raised by Medtronic states that the weld has created an extremely rigid connection, such that if one of the cylindrical elements is expanded, this will always have an impact on at least the element immediately next to the element in question.

4.81. This argument is contested by studies performed and described in the aforementioned report of Dr. Schneiderman.

Photograph

Dr. Schneiderman writes as follows in his report:

> '*the study objective was to observe whether or not the cylindrical elements of Medtronic's Driver stents are 'independently expandable' such that the stent may be expanded to a shape other than cylindrical (e.g. including a tapered shape) to facilitate implantation in a variety of lumen shapes.*'

In the study use was made of a Medtronic Driver stent of 4.0 x 30 mm. After the stent had been removed from the packaging, it was inflated to the nominal pressure of 9 ATM. Subsequently the air was let out of the balloon and the stent was removed. Subsequently a separate 4.5 mm. balloon catheter was partly inserted in the stent, in such a way that about half the length of the stent would continue to expand, once the balloon had been inflated. After the expansion the air was let out of the second balloon again. Finally a third 5.0 mm balloon catheter was also inserted in the stent in order to further expand the part that had already been expanded by the 4.5 balloon. In the process the expanded stent was observed and photographed under light microscopy.

4.82. The results as represented above show that the right-hand side of the stent has been expanded to a diameter of about 4 mm., whereas the left-hand side of the stent has been expanded to a larger diameter of around 5 mm. Between these two sides the stent shows a tapered diameter, running from 4 mm. to 5 mm. Dr. Schneiderman draws the following conclusion:

> '*The results of this study show that the cylindrical elements of the tested Medtronic Driver stent are independently expandable at least because the stent may be expanded to a shape other than cylindrical to facilitate implantation in a variety of lumen shapes, including a lumen containing a tapered shape.*'

4.83. Dr. Schneiderman furthermore observes that there are no clear differences in the structures of the 4.0 x 30 mm stent and the other lengths of the 4.0 mm Driver stents. For that reason he considers it likely that at least all 4.0 mm Driver stents have cylindrical elements capable of being expanded independently. As the general structure and the connecting pattern of the 3.5 x 9 mm Driver stent is identical to that of the 4.0 mm Driver stent, Schneiderman also considers it likely that those cylindrical elements too are capable of being expanded independently.

4.84. Medtronic has not challenged the results of Dr. Schneiderman's study, so that for that reason the provisional measures judge for now considers it likely that the of the Driver stents are all of them capable of being expanded independently. This means that these stents are also in conformity with feature iii of claim 1 of EP 842.

Conclusion infringement

4.85. The conclusion is that in the court's provisional view Medtronic is infringing EP 842.

Forfeiture of rights/abuse of rights?

4.86. To the extent that it were held that Medtronic infringes claim 1 of EP 842, which, as discussed earlier, in the court's provisional view is the case, Medtronic has by way of defence argued that Abbott has forfeited its rights, or at least is abusing its powers. This argument has been substantiated by Medtronic in the sense that it alleges that Abbott's attitude towards Medtronic had given rise to the legitimate expectation that the Lau patents would not become an issue.

4.87. Abbott has contested Medtronic's arguments with reasons. In that respect it has pointed out that the agreement concerns a supply and license agreement for the drug rapamycin and the phosphoryl choline coating, which may be applied to a drug eluting stent. According to Abbott the license does not concern the stent itself. With respect thereto Abbott has referred to the arbitrator's binding award (see ground 2.16). Abbott has furthermore contested having raised the legitimate expectation that it would not attack Medtronic on the basis of EP 842.

4.88. Given Abbott's reasoned challenge it is up to Medtronic in principle to furnish proof for its allegation. However, within the context of these proceedings there will be no time to do so, so that it will be disregarded by the court, being considered insufficiently likely by the court in its provisional view. It will be up to the judge in the proceedings on the merits already pending before this court if necessary to examine this allegation on its merits.

Penalty

4.89. The penalties to be imposed will be subject to judicial mitigation, all this as stated in the operative part.

Costs

4.90. As the party found against Medtronic will be ordered to pay the reasonable and proportionate costs of these proceedings pursuant to article 1019h Code of Civil Procedure. Since the reasonableness and proportionality of the costs incurred on the part of Abbott have not been disputed by Medtronic, they will be estimated at the amount claimed in accordance with the specification, i.e. € 125,463.45 plus € 2,102.75 in disbursements.

Security

4.91. The security demanded by Medtronic in the amount of € 15,000,000 annually is rejected, as the court fails to see the alleged interest in such relief. Abbott has argued, without being contradicted by Medtronic, that it is a FORTUNE 100 company, which means that there need be no doubts about its ability to pay damages if ordered to do so, while there is no reason either to presume that it would not comply with such an order, should it be imposed by a Dutch court.

5. Decision

The provisional measures judge

5.1. orders Medtronic, severally, with immediate effect after service of this judgment to cease infringing EP 1 068 842 B1 in the Netherlands, in particular through manufacturing, using, marketing, reselling, leasing delivering or otherwise trading in or for the benefit of its business, or through offering, importing or stocking for any third parties such stents as conform to the elements of claim 1 of the patent, this on pain of a penalty of € 100,000 per day;

5.2. decides that the penalty will be subject to judicial mitigation, to the extent that enforcement would by the standards of reasonableness and fairness be unacceptable, considering the extent to which the judgment has been complied with, the seriousness of the violation and the degree of blame to be apportioned to Medtronic;

5.3. orders Medtronic, jointly and severally, such that payment by one party will discharge the other, to pay to Abbott the reasonable and proportionate costs of the proceedings, estimated at the until the date of this judgment at € 125,463.45 plus € 2,102.75 in disbursements.

5.4. declares this judgment provisionally enforceable to this extent;

5.5. dismisses all other applications;

5.6. sets the term referred to in article 1019i Code of Civil Procedure at six months, to be calculated from the date of this decision.

This judgment was rendered by J. Th. Van Walderveen and pronounced in open court on 28 August 2008.