JUDGMENT

THE HAGUE DISTRICT COURT

Civil Law Division

Case Number / Docket Number: 245392 / HA ZA 05-2016

Judgment of 3 May 2006 (by anticipation)

in the case of

1. the company under foreign law
   ANTIOTECH PHARMACEUTICALS INC.,
   established in Vancouver, Canada,
2. the company under foreign law
   BOSTON SCIENTIFIC CORPORATION,
   established in Natick, Massachusetts, United States of America,

claimants in the principal action,
defendants in the cross-action,
attorney-of-record mr. W. Taekema,
attorneys-at-law claimant in 1 mr. R.E.P. de Ranitz in the Hague and mr. O.P. Swens in Amsterdam,
attorney-at-law claimant in 2 mr. R.E. Ebbink in Amsterdam,

versus

the company under foreign law
SAHAJANAND MEDICAL TECHNOLOGIES PVT. LTD.,
established in Saiyedpura, Surat, India,
defendant in the principal action,
claimant in the cross-action,
attorney-of-record mr. P.J.M. von Schmidt auf Altenstadt,
attorneys-at-law mr. L. Oosting and mr. K.A.J. Bisschop in Amsterdam.

The parties will be referred to hereinafter as Angiotech et al. and Sahajanand.

1. The Proceedings

1.1. The course of the proceedings appears from:
- the interim judgment of 31 August 2005 and the documents cited in it;
- the statement of reply in the principal action, also entailing statement of reply in the interim action concerning conditional claims, as also statement of counterclaim, as also brief requesting stay of the proceedings under Article 83(4) ROW 1995 or else under Article 28 Brussels Regulation, as also request to call a third party to join the proceedings under Article 118 Rv (including exhibits),
- the statement of reply in the cross-action, as also brief concerning comment,
- the interim statement concerning conditional claims of Angiotech et al.,
- the brief concerning decrease of claim (in the principal action), rectification and submission of exhibits,

- two briefs concerning submission of additional exhibits of Sahajanand,
- the oral pleading notes of mr. De Ranitz, mr. Ebbink and mr. Swens,
- the oral pleading notes of mr. Oosting and mr. Bisschop.

1.2. Finally judgment was set on 10 May 2006.

2. The Facts

In the principal action and in the cross-action

2.1. Angiotech Pharmaceuticals Inc. is active in the field of drug-eluting medical devices and biomaterial. Boston Scientific is active in the field of medical devices. The companies cooperate in the field of paclitaxel-eluting stents. Angiotech Pharmaceuticals Inc. is the owner of European Patent 0706376 (hereinafter the patent or EP 376) together with the University of British Columbia (hereinafter UBC). Boston Scientific Corporation is licensee in the field of cardiovascular medicine under EP 376.

2.2. EP 376 was granted on 25 June 1997 for anti-angiogenic compounds and uses and invokes priority of the American patent application US 94536 which was filed on 19 July 1993. The following countries have been designated: Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, Great Britain, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, the Netherlands, Portugal and Sweden. The patent was validated in all these countries.

2.3. The claims of EP 376 as granted on 25 June 1997 read as follows in the authentic English language:

> 1. A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an antiangiogenic factor and a polymeric carrier.
> 2. A stent according to claim 1 wherein said anti-angiogenic factor is a chemotherapeutic agent.
> 3. A stent according to claim 1 wherein said anti-angiogenic factor is selected from the group consisting of estramustine and methotrexate.
> 4. A stent acccording to claim 1 wherein said anti-angiogenic factor is taxol, or an analogue or derivative thereof.
> 5. A stent according to any one of claims 1 to 4 wherein said polymeric carrier comprises poly (caprolactone).
> 6. A stent according to any one of claims 1 to 4 wherein said polymeric carrier comprises poly (lactic acid).
> 7. A stent according to any one of claims 1 to 4 wherein said polymeric carrier comprises poly (ethylenevinyl acetate).
> 8. A stent according to any one of claims 1 to 4 wherein said polymeric carrier comprises a copolymer of poly caprolactone and poly lactic acid.
> 9. A stent according to any one of claims 1 to 8 wherein said stent is a vascular stent.
> …
> 14. A stent according to any one of Claims 1 to 8 for treating narrowing of a body passageway.
> 15. A stent according to Claim 14 for treating or preventing recurrent stenosis.
> 16. Use of a composition comprising an anti-angiogenic factor for the manufacture

> of a medicament for treating arthritis.
> 17. Use according to Claim 16 wherein said anti-angiogenic factor is taxol, or an analogue or derivative thereof.
> …
> 25. Use of a composition comprising an anti-angiogenic factor and a polymeric carrier for coating a stent according to anyone of claims 1-15.
> 26. Use of taxol, or an analogue or derivative thereof for the manufacture of a medicament for anti-angiogenesis.

The patent originally comprised 29 claims.

2.4. Initially opposition proceedings were instituted against the patent by (1) Schering AG, (2) Focal Inc., (3) Inflow Dynamics (the opposition was withdrawn afterwards), (4) STS Biopolymers Inc. (the opposition was withdrawn afterwards) and (5) Biocompatibles (later Abbott Vascular Devices Limited). By decision of 11 August 2000 the Opposition Division of the European Patent Office (EPO) revoked the patent under Art. 102(1) EPC.

2.5. From this decision an appeal was lodged on 5 September 2000. In these proceedings a new main request was filed on 21 December 2000. Seen the fact that the product claims in the new main request had not been examined by the Opposition Division in the opposition proceedings and did not serve as ground of the decision to revoke the patent, the Technical Board of Appeal used its power under Art. 111(1) European Patent Convention (EPC) to refer the case back to the Opposition Division for further examination.

2.6. On 24 January 2005 after holding a full formal hearing attended by the remaining opponents, the Opposition Division decided orally that the claims of the (amended) auxiliary request met all conditions of the EPC. The written decision of the Opposition Division with the content of the oral decision of 24 January 2005, was issued on 19 April 2005.

2.7. The text of claims 1, 6 and 12 of EP 376 read at present as follows:

> 1. A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an antiangiogenic factor and a polymeric carrier, the factor being anti-angiogenic by the CAM assay, and wherein said anti-angiogenic factor is taxol, or an analogue or derivative thereof.
> 6. A stent according to any one of claims 1 to 5 wherein said stent is a vascular stent.
> 12. A stent according to claim 11 for treating or preventing recurrent stenosis.

The original claims 2 to 4 and 16 to 29 have been deleted, the other claims have been renumbered and adapted to the new phrasing of claim 1. A translation into Dutch or a printed version of the new claims is not available yet.

2.8. None of the opponents lodged an appeal from this decision of the Opposition Division of the EPO. Nor did the patentees lodge an appeal. Conor Medsystems Inc., (hereinafter Conor) and Sahajanand nevertheless sent a letter with a request for

intervention/appeal to the EPO on 28 April and 17 June 2005 respectively.

2.9. Sahajand is a manufacturer of stents for coronary arteries located in India. It produces among others a drug-eluting stent under the name of Infinnium, which contains as a drug paclitaxel, the generic name of taxol. At the request of Sahajanand Prof.Dr. P.W.J.C. Serruys carried out a clinical trial, named SIMPLE 2, at the Erasmus Universiteit in Rotterdam. This trial was completed in 2005.

2.10. On 18 November 2005 the examining Technical Board of Appeal of the EPO sent a provisional opinion to Conor and Sahajanand implying, in short, that their intervention/appeal was inadmissible with reference to Articles 105 and 107 EPC, as well as to case-law of the Enlarged Board of Appeal (G3/04, G4/91 and in particular G1/94). As reason for this it was stated that no opposition proceedings were pending anymore (for none of the parties had lodged an appeal) when Conor and Sahajanand tried to intervene, or lodge an appeal respectively.

2.11. To Sahajanand a CE-marking was granted for the Infinnium stent by the Norwegian body Det Norske Veritas having number 2005-OSL-MDD-0413 on 5 December 2005.

2.12. The English High Court invalidated the English part of EP 376 by judgment of 24 February 2006 on the ground of not being inventive (judgment of Pumfrey J, Case No: HC05C00376, Conor v. Angiotech – UBC, see website www.hmcourts-service.gov.uk).

3. The Dispute

3.1. Angiotech et al. claim (summarized and after decrease and increase of claim respectively) a declaratory ruling that Sahajanand infringes, directly or indirectly, claims 6 and 12 of EP 376 in the Netherlands and in the other designated countries, as well as an injunction (both provisionally and in the case in chief) not to infringe said claims in the Netherlands and in any of the other designated countries, including additional claims, including a moratorium of three years to be imposed by reason of use of unlawfully obtained research data in the Netherlands for the purposes of the application for a CE-marking, including damages to be determined by the court and/or an account of profit and costs.

3.2. Angiotech et al. found (summarizing) these claims on the allegation that Sahajanand infringes inside and outside the Netherlands, because with the Infinnium stent a clinical trial was and is carried out by a company, called Cardialysis, established in Rotterdam, and/or in the laboratory of Prof. Patrick Serruys in Rotterdam and that in any case it imported 16 stents into the Netherlands for these purposes, whereas moreover there is threat of infringement inter alia because a CE-marking has been granted to Sahajanand, it indicated to wish to enter the market in Europe with the Infinnium stent and statements in the Dutch language have also been included on the packaging.

3.3. Sahajanand pleads a reasoned defense, alleging that there is no infringement because on the one hand the research of Serruys allegedly can be covered by the research exemption, there is no threat of acts in the Netherlands and moreover its stent does

not fall under the scope of protection of the patent, whereas on the other hand the patent can be considered to be invalid, because it lacks the required novelty and inventive step seen the prior art submitted by Sahajanand (also to the EPO and by Conor), as well as that it contains added matter.

3.4. In the cross-action Sahajanand claims that the District Court allows it to call UBC to join the proceedings, for being co-patentee, and furthermore that the District Court invalidates the patent (as the District Court understands exclusively for the Netherlands), at least declares that the patent is invalid. Angiotech et al. plead a reasoned defense.

4. The Examination

Cross-border Jurisdiction

4.1 In the interim judgment this court already ruled that it only has jurisdiction as to the Netherlands, which opinion the court maintains, and so in the following only the claims and allegations as far as they regard infringement and/or unlawful acts in the Netherlands will be discussed. This goes just as much for the conditional claim, once more cross-border, filed after said interim judgment.

Introduction

4.2 Before getting at the examination of the defense pleas the court will first give a (short) introduction of the technology at hand (derived from the explanation of the parties).

4.3 Stenting is a non-surgical procedure which, if combined with balloon angioplasty, is used to dilate constricted body-passageways. Stenting is for instance combined with balloon angioplasty to treat coronary artery disorders, such as atherosclerosis (see illustration 1 below): a partially blocked coronary artery can be dilated by using a stent and balloon angioplasty.

4.4 Stents have the shape of an expandable tubular mesh frame, usually made of metal, such as stainless steel, cobalt chromium, tantalium, platinum, nitinol (a very elastic alloy of nickel and titanium), or other materials such as plastics. Upon being installed in a constricted blood vessel (Ill. 1a) an ordinary (i.e. non drug-eluting stent) can improve the inflow of blood to the heart for some time. During the process of balloon angioplasty, a non-expandable stent is placed around a non-inflated balloon and delivered to the artery (Ill. 1b). When next placing the stent/balloon combination in the place of constriction of the artery the balloon is inflated in order to expand the stent and the surrounding artery. By pressing the wall of the artery and staying open, the stent prevents the artery from falling back into its originally constricted state. After use, the balloon is deflated and removed while the stent stays permanently in its place and keeps the passage open (Ill. 1d).

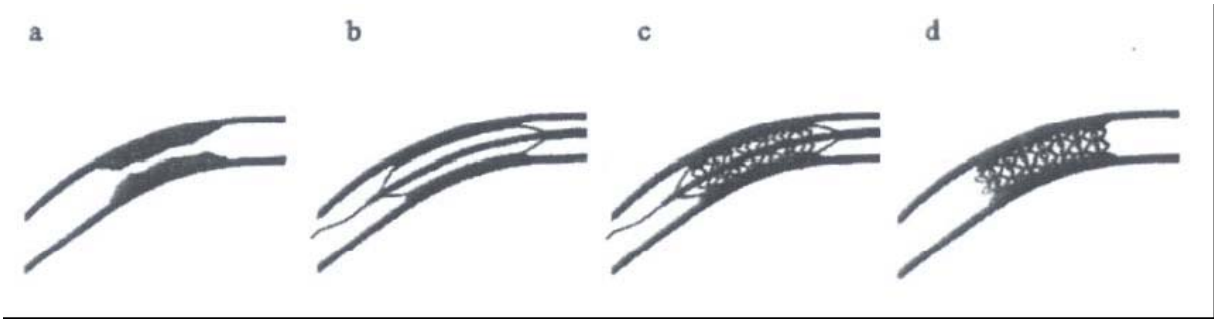

Illustration 1. Use of a stent upon arterial balloon angioplasty: a. artery with plaque; b. balloon before expansion in angioplasty procedure; c. stent procedure; d. result after stent procedure. Source: www.bostonscientific.com

4.5 A problem with uncovered (metal) stents is, however, that they do not prevent material from growing into the interstices of the stent (restenosis). When this material reaches the inside of the stent and jeopardizes the stent lumen, this may lead to blockage of the body-passageway in which the stent has been installed, again. Moreover the presence of a stent in the body may entail that reactive or inflammatory tissue (e.g. blood vessels, fibroblasts or leukocytes) enter the stent lumen, resulting into partial or full closure of the stent and the artery. Restenosis occurs in about 20-45 percent of the uncovered metal stent implants.

4.6 For the sake of a better understanding of the case the court will also give a description of the notions of ‘anti-angiogenic’, ‘anti-mitotic’ and ‘anti-proliferative’ which play an important part in the arguments of the parties. In this the definitions of Angiotech et al. will be adhered to, because as such they have not been refuted with sufficient reasons. Anti-angiogenic are substances which inhibit blood vessel growth. Anti-proliferative substances inhibit the increase of the number of cells in a more general sense and an anti-mitotic substance inhibits cell mitosis (and thus the growth of new cells). See for all this inter alia statement of reply in the cross-action, no. 69.

In the principal Action

Validity

4.7. Being the farthest reaching defense the court will first discuss the objections raised to the validity of the invoked claims 6 and 12 of the patent.

Added Matter

4.8. The arguments of Sahajanand which relate to matter allegedly added to claim 4 can be left out of the discussion here, because Sahajanand is not accused of infringement of said claim.

4.9. As to claim 12 Sahajanand has argued that one cannot conclude the occurrence of restenosis from the original application, and so the subject-matter of said claim relating to this would be impermissible. The court considers that the prevention of restenosis most definitely is stated in the application (and in the priority document US 94536), see p. 26, l. 7-11 (p. 22, l. 5-9 of US 94536):

Briefly, stents may be placed in a wide array of blood vessels, both arteries and veins, to prevent recurrent stenosis at the site of failed angioplasties, to treat narrowings that would likely fail if treated with angioplasty, and to treat post surgical narrowings (e.g., dialysis graft stenosis).

The light which Sahajanand sees between preventing restenosis in general and after an angioplasty intervention in particular the court does not see, and has not been made sufficiently understandable. The same goes for the difference alleged by Sahajanand between the word "prevent" from said text and "treat and prevent", taking into account that it appears from the entire description (see for instance the first paragraph about the "Technical Field" in both the priority document and the application) that it concerns treatment of angiogenesis-dependent disorders, including therefore restenosis. In the following (as to the inventive step this argument will come up again) it should therefore be assumed that it is sufficiently clear to the average skilled person that the invention of the patent (also) regards prevention (and treatment) of restenosis.

Novelty/priority

4.10.1. Next Sahajanand took the stand that the patent wrongly invokes the priority of US 94536, because the latter document only discloses two manners of coating of the stent, whereas the original application for the patent also added three more:

…(c) by interweaving anti-angiogenic composition coated thread (or the polymer itself formed into a thread) into the stent structure, (d) by inserting the stent into a sleeve or mesh which is comprised of or coated with an antiangiogenic composition, or (e) constructing the stent itself with an antiangiogenic composition.(p. 21, r. 31-35)

4.11. Hypothetically assuming that this explanation of possible ways of coating of the stent, entail impermissible added matter in respect of the priority documents, the court agrees with the opinion of the Opposition Division of the EPO on this point. After all, in that case it should be assumed that only for these embodiments c, d and e of the stent there is no valid priority, whereas this opinion would, however, not result in invalidity, because Angiotech et al. alleged without being contested that these embodiments were not described in the only prior art document considered relevant by Sahajanand, i.e. D62. Contrary to what Sahajanand apparently argues, it is certainly possible that in an application in which several variants are claimed, different relevant dates for defining prior art apply to the different variants, i.e. embodiment variants which do enjoy priority and other variants which can only fall back on the date of application (or sometimes on another priority date), see G 3/93 of 16 August 1994. In the present case there is an "OR" claim (three alternative stents are added to both types of coated stents of the priority document) and not an "AND" claim in the sense of jur.gr. 6.5-6.7 of G 2/98 of 31 May 2001:

6.5 According to the memorandum,in evaluating whether there is any justification for claiming multiple priorities for one and the same claim of an application, a distinction has to be made between the following situations:
(i) "AND"-claim

(ii) "OR"-claim
6.6 As regards the "AND"-claim (point 6.5(i) supra), it is held in the memorandum that where a first priority document discloses a feature A, and a second priority document discloses a feature B for use together with feature A, "then a claim directed to A+B cannot enjoy a partial priority from the first priority date, because the invention A+B was disclosed only at the date of the second priority document". From this it clearly follows that, according to the legislator, multiple priorities cannot be claimed for an "AND"-claim. Hence, the application of the so-called "umbrella"- theory (according to which the feature A in the claim directed to A+B would enjoy a partial priority from the first priority date, with the result that the feature A could under no circumstances become state of the art in relation to the claimed invention A+B) is to be disregarded. Besides, the application of the "umbrella"-theory would manifestly be at variance with Article 88(4) EPC.
6.7 As regards the "OR"-claim (point 6.5(ii) supra), it is held in the memorandum that where a first prioritydocument discloses a feature A, and a second priority document discloses a feature B for use as an alternative to feature A, then a claim directed to A or B can enjoy the first priority for part A of the claim and the second priority for part B of the claim. It is further suggested that these two priorities may also be claimed for a claim directed to C, if the feature C, either in the form of a generic term or formula, or otherwise, encompasses feature A as well as feature B. The use of a generic term or formula in a claim for which multiple priorities are claimed in accordance with Article 88(2), second sentence, EPC is perfectly acceptable under Articles 87(1) and 88(3) EPC, provided that it gives rise to the claiming of a limited number of clearly defined alternative subject-matters.

And so the patent is new and rightly invokes priority for variants a and b. For completeness' sake it is also considered that D62 can be seen as fictive prior art (*post published – translator*) seen its late publication (for variants c-e) and thus cannot be taken into account for the inventive step of any variant a-e to be discussed in the following.

Inventive Step

4.12. Furthermore Sahajanand contested the level of inventiveness of the patent, more specifically of claims 6 and 12. On this the following is considered.

4.13. According to the patent (which text-part the Opposition Division of the EPO also referred to in its decision cited in 2.6) the following problem is at its basis:

> *…The major problem with stents, however, is that they do not prevent ingrowth of tumor inflammatory material through the interstices of the stent. If this material reaches the inside of a stent and compromises the stent lumen, it may result in blockage of the body passageway into which it has been inserted. In addition, presence of a stent in the body may induce reactive or inflammatory tissue (e.g. blood vessels, fibroblasts, white blood cells) to enter the stent lumen, resulting in partial or complete closure of the stent.* (p.3, r. 17-21).

According to claims 6 and 12 as maintained at present the patent suggests, to put it briefly, use of taxol as medicine for a drug-eluting stent which is known as such (for instance from D30). According to the patentee the invention lies in the use of specifically the taxol-stent, by which said problem of renewed ingrowth of body-material would be solved.

4.14. Sahajanand also argued that the patent does not so much regard prevention of restenosis, but use upon ingrowth of tumors and infections, because in the description of the patent (as originally granted) restenosis as such was not specifically mentioned (oral pleading notes no. 1.4). This is not correct. As already considered above in respect of added matter, prevention of restenosis is most definitely mentioned in the patent, see p. 12, l. 33-38 (said passage being almost identical to be found in the application and in the priority document, see above in jur.gr. 4.9):

> *Within another embodiment of the invention, methods are provided for eliminating vascular obstructions, comprising inserting a vascular stent into a blood vessel, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition as described above, such that the vascular obstruction is eliminated. Briefly, stents may be placed in a wide array of blood vessels, both arteries and veins, to prevent recurrent stenosis at the site of failed angioplasties, to treat narrowings that would likely fail if treated with angioplasty, and to treat post surgical narrowings (e.g., dialysis graft stenosis).*

And so it is sufficiently obvious to the average skilled person that the invention of the patent (also) regards prevention of restenosis.

4.15. Sahajanand also argued that neither the patent nor the original documents teach, or provide any experimental data in that respect, that and why precisely the taxol-stent would solve said problem of restenosis. Although it is said in the patent that taxol has an anti-angiogenic effect (in the so-called CAM assay, see example 2) and furthermore that a stent can be coated with a taxol containing polymer, (the priority document or the original application of) the patent lacks any pointer for the skilled person that it be precisely taxol which produces a favorable effect on preventing restenosis. On the contrary, both in the priority document, the original application, as well as the patent as (originally) granted, a considerable number of anti-angiogenic medicines are listed which could be applied to the stent, and although taxol figures among them it also lists heparin and methotraxate for example. As to the latter two medicines it is clear that they are not suitable for use in a drug-eluting stent, whereas that is certainly uncertain for the other ones. Which of the medicines must be selected from the long list is information which did not become available but after filing of the (priority) application, which should thus not be taken into account in the examination of the inventive step. And so it is incorrect to claim the finding of taxol for a drug-eluting stent which prevents restenosis as invention. This is not the contribution which the patent made to the state of the art, still according to Sahajanand.

4.16. This defense is also left aside. Contrary to that argued by Sahajanand the patent (as well as the original application and the priority document) teaches most certainly that

precisely taxol should be used to prevent restenosis. This results sufficiently clear from claims 5, 15, 17, 26 and 28 of the patent as originally granted, each individually but more so seen in interrelation. From the priority document the preference for taxol could also clearly be concluded, witness claims 5 and 17 and 26 but in particular 28. All this is even emphasized by the quote of p. 12, l. 33-38 of the patent (corresponding with p. 22, l. 1-9 of the priority document) included above in jur.gr. 4.14, read in conjunction with the following text-part (p. 4, l. 6-14 of the patent, corresponding with p. 5, l. 15-28 priority document):

> *A method of angiogenesis inhibition is disclosed, comprising administering a therapeutically effective amount of a composition comprising taxol to a patient with a nontumorigenic angiogenesis-dependent disease, such that the formation of new blood vessels is inhibited. (…)*
> *Methods are disclosed for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with a composition comprising taxol, such that the passageway is expanded.*

The first mentioned, previously cited text-part teaches that with a vascular stent provided with an anti-angiogenic factor, restenosis can be prevented and treated, whereas the latter just cited text-part shows that in non-tumorgenous, but angiogenesis-dependent disorders, a stent provided with taxol should be used. Thus these text-parts jointly teach the use of taxol in a vascular stent to prevent restenosis.

4.17. Moreover in example 2 of the patent taxol scores high in the so-called CAM assay, by which the anti-angiogenic effect in vivo is tested on chicken embryos (better than for instance suramine and anti-invasive factor, see example 2B of the priority document). In this a further pointer is to be found for the skilled person that the patent gave a clear preference for using taxol specifically.

4.18. And so seen the fact that the average skilled person would understand from the patent as originally granted (the priority document or the application respectively) that according to the patentee it is advantageous to use taxol (with a polymeric carrier) on a drug-eluting vascular stent to prevent restenosis after an angioplasty intervention, it is not required in the view of the court that experimental data concerning such use of taxol stents in humans and the actual prevention of restenosis be included in the patent to further substantiate this. This would only be otherwise if there be doubt as to whether this advantage is indeed achieved with the taxol stent, which Sahajanand did not allege, however. Nor is it relevant that the inventors of the patent apparently did not yet test in practice a taxol stent for prevention of restenosis upon an angioplasty intervention, as appeared in the English proceedings (see jur.gr. 2.12):

> *"28. To this extent, therefore, I conclude that the disclosure is indeed speculative. The reason was provided by Dr Hunter's evidence. At the priority date, the Patentees had neither made nor tested any taxol-eluting stent for the prevention of restenosis in percutaneous transluminal coronary angioplasty. By December 1994, work had been done on the use of coated stents for the purpose of treating cancerous blockages, but the evaluation of*

the usefulness of stents in prevention of arterial restenosis was just being initiated. A document dated August 1995 reveals that by that date no in vivo studies had been performed, and it appears from the evidence that the first such studies were performed somewhat later than this."

It is sufficient that by applying the teaching of the patent the claimed advantage can be effected, and so use of a taxol stent to prevent restenosis after an angioplasty intervention can be considered to be the contribution to the state of the art ("technical contribution").

4.19. Next the court will verify with the problem-solution method whether use of a taxol stent to prevent restenosis after an angioplasty intervention was obvious, or not, seen the state of the art. According to the problem-solution method the following steps can be distinguished:

(i) determining the closest prior art,

(ii) establishing the objective technical problem to be solved, and

(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

(i) Closest prior art

4.20. The parties debated on the question of which document should be considered to be the closest prior art. Like the Opposition Division and Angiotech et al. the court assumes that Wolff (WO 91/12779, published on 5 September 1991, D30) comes closest to the patent. Wolff suggests use of a drug-eluting stent to prevent restenosis, whereat the drug has been applied to the stent in a polymeric carrier. The only difference with the patent, as far as relevant at present, is that Wolff does not disclose the use of taxol specifically. D3, D4 and D32 are more or less equal to D30 and also disclose a drug-eluting stent. D82 is less close to the patent, because this document does not principally deal with a drug-eluting stent but only mentions it casually. Whatever may be the case, no explicit disclosure of taxol to be used as drug for a drug-eluting stent can be found in prior art, and so this should be considered a significant difference.

(ii) Objective technical problem

4.21. In comparison with Wolff in which taxol is not disclosed, the invention is based on the objective technical problem of finding a drug for a drug-eluting stent to allow prevention of restenosis. The court does not believe it is correct to define the problem as finding an alternative drug, because Wolff does not disclose that the medicines suggested in it (inter alia the anti-replicate medicines methotrexate, azathiprine, vincristine, vinblastine, fluorouracil, adriamycine and mutamycine are specifically mentioned) actually help to prevent restenosis. On the contrary, it has meanwhile become known that the medicines specifically stated by Wolff do not act in preventing restenosis. However, even if considering the problem nevertheless to be the finding of an alternative for the medicines specifically suggested in Wolff, this would not have altered the opinion to be given below.

(iii) was the invention obvious?

4.22. Next the question has to be answered whether the use of taxol to prevent restenosis on a drug-eluting stent was obvious, starting from Wolff. The court answers this question in the negative, to which end the following is considered.

4.23. After having found that restenosis must be prevented by inhibiting proliferation (growth) of smooth muscle cells (p. 7, l. 19-20) Wolff mentions some five hypotheses of how to stop restenosis in a biochemical manner and explains this (p. 7, l. 25-p.8, l. 7):

> *1. Reduce the adhesion and aggregation of the platelets at the arterial injury site.*
> *2. Block the expression of the growth factors and their receptors.*
> *3. Develop competitive antagonists of the above growth factors.*
> *4. Interfere with the receptor signaling in the responsive cell.*
> *5. Find a "natural" inhibitor of smooth muscle proliferation.*
> *Item #1 is directly related to the formation of thrombus, a major problem with all types of angioplasty procedures. Items #2, #3, and #4 are closely related. They deal with blocking restenosis during the massive cell migration and replication cycle. Unlike item #1, these items address the growth factors that are produced from sources other than platelets. Item #5 is listed to address the question, why don't the 50-80% of the people who don't restenose, restenose. There may be some type of natural inhibitor that these people produce that stops the proliferation of smooth muscle cells.*

Next examples are given in Wolff of these five categories. As to medicines which might be suitable to inhibit cell replication Wolff mentions anti-mitotic medicines which prevent cell mitosis and anti-metabolites which prevent DNA synthesis and ranges them in the group of anti-replicate medicines (p. 9, l. 11-18).

4.24. Sahajanand has in the first place alleged that the average skilled person with general technical knowledge of the manual of D20 (Molecular Biology of the cell) and the Merck Index (D82) respectively will already read taxol to be comprised in Wolff, at least will immediately think of it. In fact it can be concluded from D20 that next to colchicine, colcemide, nocadazole, vinblastine and vinchristine, taxol is considered to be an anti-mitotic medicine which binds to microtubuli which have come about during mitosis. The same results from the Merck Index.

4.25. The court considers that D20 and the Merck Index do not add anything more or else to Wolff than that taxol is also a possible alternative medicine to apply to the stent. However, for there to be an insufficient level of inventiveness the average skilled person should be induced according to settled case-law to use taxol. This means that with the expectance that it (might) prevent restenosis he would have chosen taxol as a result of the pointers in the state of the art. However, one should take into account in this that the average skilled person may be expected to carry out some (routine) research work to optimize known art, and so a selection from a rather limited group of medicines – assuming that the testing of these medicines as such do not involve any special problems for the skilled person or that there is overcoming a prejudice – may produce insufficient level of inventiveness, even if such selection produces an

optimum result.[1]

4.26. However, it cannot be retrieved from Wolff alone, nor combined with D20 or the Merck Index why the average skilled person would precisely choose taxol. It is relevant in this that Angiotech et al. alleged without being disputed that the "notion of "anti-replicate" encompasses hundreds of structurally and functionally different compounds having in common only the general function of preventing or hindering of cell replication by diverse modes of action" (statement of reply in the cross-action, no. 77). This is supported by the statement of Prof. De Scheerder (Exh. 23 Angiotech et al., nos. 67 and 68), which indicates that proliferatives are "an extremely broad class of structurally diverse agents that inhibit proliferation by a wide variety of mechanisms" and even that "more than a hundred different antimitotics were known by 1993". As said before, although one may expect the skilled person to carry out some (routine) research work to optimize the art from Wolff, but seen this considerable number of possible anti-replicate substances it would go too far to deny the finding of taxol any inventive level by reason thereof.

4.27. Furthermore it has meanwhile become known that among the multitude of studied substances so far only taxol and rapamycin have been successfully applied to a stent to prevent restenosis, and so it is legitimate to conclude that the selection of taxol from this large group did not produce an expectable optimal effect, but rather a precisely surprising effect: contrary to the other medicines proposed by Wolff and D20/Merck Index for a stent, the taxol-stent precisely does have an effect on prevention of restenosis. The situation at hand can therefore very well be compared so far with the example of the Guidelines of the EPO, Part C, Annex to Chapter IV, ex. 3.2 (ii), which example is considered to be inventive:

> *(II) the invention consists in selecting particular chemical compounds or compositions (including alloys) from a broad field, such compounds or compositions having unexpected advantages.*
> *Example: In the example of a substituted chemical compound given at (iv) under 3.1 above, the invention again resides in the selection of the substituent radical "R" from the total field of possibilities defined in the prior disclosure. In this case, however, not only does the selection embrace a particular area of the possible field, and result in compounds that can be shown to possess advantageous properties (see IV, 9.11 and VI, 5.3.5) but there are no indications which would lead the person skilled in the art to this particular selection rather than any other in order to achieve the advantageous properties.* (emphasis added*).*

As said before, no indication whatsoever appeared to choose precisely taxol and not one of the other ones from the group of anti-replicate or anti-proliferate medicines.

[1] To that extent the court differs form the opinion of the English court stated in jur.gr. 2.12 which invalidated the patent for lack of inventive step by reason of a different application of law/right. IN fact the English court examined – to put it briefly – the question of whether the average skilled person would consider to try taxol (see in particular jur.gr. 65 of said decision) and next answered it in the positive. Contrary to the court, the English court did not get to the question of whether there was a reason, or not, to choose precisely taxol from the suggested alternative of the state of the art.

4.28. Moreover Sahajanand wrongfully assumes that Wolff would disclose the use of specific anti-replicate substances for the stent. The mere reference on p. 7, l. 19-20 of Wolff (see jur.gr. 4.23 above) that proliferation of the smooth muscle cells must be stopped in order to prevent restenosis does not make sufficiently obvious and unambiguous the choice of Wolff advocated by Sahajanand for anti-proliferative (anti-replicate respectively, let alone anti-mitotic) medicines. The subsequent text in Wolff precisely gives pointers again to use anti-coagulant medicines and anti-platelet medicines and does not show at all any explicit preference for anti-replicates. Claim 3 of Wolff also claims again precisely the large group of "anti-platelet drugs, anticoagulant drugs, anti-inflammatory drugs, antimetabolite drugs and combinations of said drugs". All this makes it clear that Wolff rather states wide categories of medicines and only makes several specific suggestions as to which type of medicine to be used, but in fact leaves the actual choice up to the reader. D20 and the Merck Index add at most to the teaching that taxol is also part of this group of medicines, but do not render the choice of specifically taxol obvious.

4.29. Nor does Kopia (D40), combined with Wolff, specifically suggest use of taxol for the stent. Just like D20 and/or the Merck Index Kopia in fact only adds new possible substances to the large group of medicines of Wolff. Kopia might stress more clearly than Wolff does, the use of anti-proliferatives to prevent restenosis (p. 50, l. 13-17), but only mentions taxol as example. Taxol is mentioned next to heparin, hirudine, colchicin and vincal kaloids, but also next to "angiotensin converting enzyme (ACE) inhibitors, angiopeptin, cyclosporin A, calcium blockers, goat-antirabbit platelet derived growth factor antibody, Terbinafine and Trapidil, interferon-gamma and polyanions for binding of cationic growth factors."(see p. 51, l. 28-34). A specific suggestion to use taxol in particular is not found by the skilled person in Kopia. On the contrary in said paragraph Kopia focuses in particular on colchicin. Not even mentioning that Kopia concerns local administration through inter alia catheterization (not through stents) of conjugates of the medicines with liposomes or virosomes stated in it, which the patent does not regard, and so it remains to be seen whether the average skilled person would get to the combination with Kopia.

4.30. Nor do the documents mentioned also by Sahajanand in this respect (D21, D81, D90, D53, D10 or D38) induce the skilled person to use precisely taxol. No pointers to the taxol stent can be derived from this. These documents give in particular information about the anti-proliferative action of taxol, and this even in systemic and not in local administration, and so they do not actually teach more than do D20, the Merck Index or D40, said documents already having been discussed above. In none of these documents a link is established between taxol and the prevention of restenosis. D53, which document regards treatment of cancer, adds anti-angiogenic action to the known anti-proliferative and anti-replicate action of taxol, as well as that this medicine may have an anti-tumor effect in this way, but this document also mentions taxol in one breath with other (new) cytotoxic substances, such as camptothecins and biologic agents, allegedly having an anti-angiogenic effect, and so once more it concerns a selection from a group of substances without any distinct pointer to taxol. Moreover in the reading of Sahajanand no actual distinction can be made between anti-angiogenic and anti-proliferative action (save an incidental medicine which specifically only inhibits angiogenesis, which taxol is not able to, see nos. 6.11 and 6.12 by reply) and so in this view it cannot be understood either that information about an anti-angiogenic effect of the substances stated in D53 (including taxol) adds anything to the already

known anti-proliferative action of taxol. Reversely, if the view of Angiotech et al. is followed that there is most definitely a difference between anti-angiogenic and anti-proliferative action of a medicine, and that in this also lies the key to the solution of the patent, Sahajanand did not make it clear how the advantage of an anti-angiogenic effect on prevention of restenosis should have been known to the average skilled person on the priority date, and so it cannot be understood how information about the anti-angiogenic effect of taxol would have put him on the track of using this medicine. D30 and D40 do not give such information. Finally D85 is not part of the state of the art and for this reason cannot prejudice the inventive step.

4.31. The mere fact that taxol might have been (also on the priority date) a rather known anti-proliferative medicine which was in the public eye for that reason, does not effect that there is a sufficient technically relevant pointer to taxol. This would be different, if in respect of such being known Sahajanand had alleged while stating sufficient reasons and proven – which it did not – that taxol would have been studied without any restriction as the first or one of the first ones of said group of hundreds of anti-proliferatives/anti-replicates by the skilled person. Nor did this appear sufficiently clear otherwise, bearing in mind in the first place that taxol was not mentioned as example by Wolff, nor by Wolff in his continuation-in-part application, filed five months following the priority date and three years following the submission of D30, was claimed (Exh. 20 Angiotech et al.).

4.32. By reason of the above the allegation of Angiotech et al. that there be a prejudice to the use of taxol in respect with (inter alia) cardio-toxicity and other reported side-effects of this medicine no longer has to be discussed.

Conclusion validity defenses

4.33. The invoked claims of the patent are new, inventive and do not include any added matter. A stay pending the opposition/appeal procedure instituted by Conor and Sahajanand with the EPO is not considered called for, because if not unlikely it is at the least rather uncertain whether said procedure will result into examination of the merits seen inter alia the provisional judgment of the EPO and the case-law of the Enlarged Board of Appeal cited in it (in particular G1/94, see jur.gr. 2.10). In this it is important that the court is convinced of the validity of – in any case – the invoked claims 6 and 12. And so the validity defenses fail, and thus the court gets to the question of whether these claims are also infringed, at least whether a threat thereof can be assumed sufficient to legitimate an infringement injunction.

Threat of infringement

4.34. The court considers that there is a serious threat of infringement, whereas the following is considered in support of this. In the first place the allegation of Sahajanand that the Infinnium stent would not fall under the scope of protection of said claims of the patent, is left aside for the following reasons.

4.35. Upon examining whether there is (literal) infringement it is a priori that when interpreting the claims of a patent specification, also in the light of the description and drawings, one should identify what according to the skilled person reading this, is essential to the invention the protection of which is claimed – to put it differently:

what the inventive thought is underlying the words of these claims – in order to avoid an interpretation exclusively founded on the literal meaning of the wording and therefore possibly too restricted (or needlessly broad) for a reasonable protection of the patentee. However, the court called to interpret the claims of the patent specification will also have to examine whether the results of his examination sufficiently respect legal certainty for third parties. The latter point of view may justify a restrictive interpretation more in line with the wording of the claims in the sense that lack of clarity for the average skilled person who wants to define the limits of the protection offered by the patent, should not be to the disadvantage of the patentee (see NethSC 12 November 2004, NJ 2004, 674, Impro v. Liko and NethSC 13 January 1995, NJ 1995, 391 Ciba Geigy v. Oté Optics).

4.36. When applying said criterion it is clear that the Infinnium stent falls under the protection of the invoked claims. Contrary to that alleged by Sahajanand the court does not find it relevant that the Infinnium stent has not only been provided with two polymeric carrier layers in which taxol has been included, but also with an outer layer without any anti-angiogenic factor. After all, by applying the first two layers the inventive thought of the patent is used without any doubt, i.e. to coat a stent with taxol in a polymeric carrier to prevent restenosis. This does not change by the argument of Sahajanand that the term “coated” of the claims would imply that the outside would always be provided with coating with a polymeric carrier and taxol. Although it can be read in the description that it should concern a stent “having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition as described above” the court cannot see that the average skilled person would really doubt when having this text in front of him that a stent which has been provided with a coating as such but is also covered with a polymeric layer not containing taxol, would not meet the invoked claims of the patent in a literal sense. Even let alone that one cannot conclude from said text that the outer layer of the whole should not contain an anti-angiogenic factor, but rather that the surface of the initially bare stent (for this is what “structure” in said text-part refers to) has been provided with such a layer, as is the case in the Infinnium stent.

4.37. Nor does the court follow Sahajanand in its argument that the patent would not regard a stent provided with a coating which has been applied in several steps. Nowhere in the patent can such a restriction be read, whereas the invoked claims moreover regard a product claim and not a process claim, and so it is not important by which process the alleged infringer achieved the product. Nor is there a product-by-process claim, seeing that Angiotech et al. alleged rightly that the phrase starting with the word “coated” should be considered to be an adjective phrase in the sense of “provided with a coat” describing a state (a physical/structural feature respectively) and not an action. Had the latter been intended, then it would have been more logical to use a present participle. The court even does not take into account that Angiotech et al. alleged without being refuted that the claim was not written either in the product-by-process layout common for this (“product obtained by the process of…”).

4.38. Sahajanand furthermore took the stand that there is no threat that with the Infinnium stent any act reserved to the patentee be carried out. This defense is also left aside, because a sufficiently serious threat that Sahajanand will enter the market with the Infinnium stent inter alia in the Netherlands results from the following circumstances.

4.39. In the first place it is important that a CE-marking has been granted to Sahajanand for the Infinnium stent by which in principle it can also enter the market in the Netherlands. Furthermore the court perceived at the session that the box in which the Infinnium stent purchased by Angiotech et al. (outside the Netherlands by-the-way) was packaged also includes instructions in the Dutch language (next to German, Spanish, Italian and Norwegian). It was not alleged that this text was affixed on the box with the mere aim of the clinical trial SIMPLE 2 held in the Netherlands, nor has this become likely otherwise. It is relevant to this that on the same box also instructions are stated in languages where neither the SIMPLE 1 nor SIMPLE 2 trial took place (they were India, Brasilia and the Netherlands, see p. 16 of Exhibit 26 Angiotech et al.) , whereas it has not been alleged that in all these countries a different trial took place: Italy, Spain and the German-speaking countries do belong to the designated countries of the patent. And so it is likely that all these languages were affixed on the box in order to enter the market with the stent in the countries in question, including the Netherlands. Furthermore it is indicative that in a press-release issued by Sahajanand on 2 December 2005 states that it obtained the CE-marking and that this "will allow the indigenously produced stent to be marketed in European countries…". The press-release also mentions that without the CE-marking "certain products like stents cannot be sold in the 15 member states of the European Union and Norway, Iceland and Liechtenstein". And so it can be concluded from this press-release that at present Sahajanand wishes to enter the market in Europe with said stent. The fact that in several European countries there is no patent protection and the allegation of Sahajand that it is allowed to enter the market there, does not alter the above sufficiently.

4.40. Furthermore it is considered – bearing in mind the claimed determination of damage – that Angiotech et al. rightly submitted that the supply of stents by Sahajanand to Prof. Serruys within the context of the SIMPLE 2 clinical trial, whereat in any case Sahajanand also acknowledges that 16 stents were implanted here in this country, constituted infringement of the patent rights of Angiotech et al. The District Court finds that it has not become sufficiently clear that this trial had a purely scientific purpose and could take advantage of the legal research exemption for that reason. The following is considered in this respect.

4.41. The SIMPLE 2 trial, sponsored by Sahajanand, was held in the same period in which the application for the CE-marking was filed (2004). Sahajanand on which the duty to state facts and the onus of proof rests, did not allege with sufficient reasons that this trial – thus held right before the market launch – would exclusively concern research into an improved stent, because it allegedly has been provided with three coatings, and as a result a more moderate release of taxol could take place and thus prevent complications (answer no. 6.5). Sahajanand did not give this allegation any scientific substantiation (for instance by means of a party expert opinion), were it even of a speculative nature. Moreover the polymeric carrier of the patent also provides some form of delayed release of taxol. Furthermore it is important that the trial did not concern so much the development of an improved stent but the gathering of data on "safety, efficacy and applicability" of the stent (opinon of Serruys of 14 February 2006, Exh. 12 of Sahajanand). Serruys does not say anything in his statement about any improvement studied by him. This is the more conclusive, since Prof. Gambhir alleges in his presentation of the results of the SIMPLE 1 trial that the efficacy of the Infinnium stent is "comparable to other DES (Drug-Eluting Stents, court) in Real

World Lesions"(Exh. 10 D of Angiotech et al., p. 47). Nor does he refer to any (aspired) improvement in comparison with the existing taxol-stents concerning the prevention of complications. This becomes even more clear at the presentation by the same Gambhir of the results of both the SIMPLE 1 and SIMPLE 2 trials on 21 October 2005: "The overall MACE of 1.9% is comparable with Similar Paclitaxel Eluting Stents" and "QCA at 6 Months Reveals that the Late Loss with Infinnium Stent is Almost Similar to the Observations in TAXUS II & VI Trials" (Exh. 26 of Angiotech et al., p. 41). In this state of affairs one cannot come to the conclusion that the trial of Serruys concerned an actual aspired improvement of the patented stent. It does not concern research in the sense of the scientific research exemption, but (pre-marketing) tests.

4.42. Nor did Sahajanand allege to wish to take out a license under the patent, as may already appear from its stand in these proceedings, and so this purpose cannot be stated as justification for having the stents studied by Serruys. Both parties further indicated that the research of Serruys is highly appreciated in the world and can be considered authoritative, and so – also in the light of the threatening entry of Sahajanand on the market with the Infinnium stent – it can reasonably be assumed that with the results of this trial in its possession Sahajanand wants to increase acceptance of the stent, since it comes from a country which is not really known as a producer of stents. Research with this purpose is not covered by the research exemption.

4.43. This case differs from the Kirin Amgen v. Boehringer case, contrary to that also alleged by Sahajanand (see in particular jur.gr. 31 and 32 of the Hague Appeal Court 3 February 1994, knowable from NethSC 21 April 1995, NJ 1996, 462) in the sense that it was assumed there that the research aimed at a purpose effecting the purport of the Patent Act, i.e. looking for a second (and subsequent) use of the studied medicine. Such second use is not the case with the Infinnium stent.

4.44. To the extent that Angiotech et al. also wanted to state that any act of Cardialysis within the context of the SIMPLE 1 trial would produce the act restricted to the patentee, they did not sufficiently substantiate this. At the time Cardialysis apparently only played a coordinating part and analyzed photographs, whereat it did however not appear that within this context any stent was brought on Dutch territory.

Conclusion in the principal action

4.45. Sahajanand's Infinnium stent falls under the scope of protection of claims 6 and 12 of the patent, whereas the invalidity defenses challenging this do not hold. Sahajanand's import and supply for the sake of the SIMPLE 2 trial constituted infringement of the patent rights of Angiotech et al. Furthermore there is a threat of infringement, and so the court declaration and the injunction are allowable. Which purpose the moratorium of three years also claimed might serve is not immediately clear, but assuming that this should become effective after expiry of the patent protection the court considers that it has not become sufficiently clear in the present proceedings that the results of any infringing act in this country (more specifically of the SIMPLE 2 trial) were used for the grant of the CE-marking, let alone that is has become sufficiently clear that without these results no CE-marking would have been granted. On the latter point it should be borne in mind that is has been established that for only 16 patients of the total of 385 (282 in SIMPLE 1 and 103 in SIMPLE 2) there were infringing acts here, whereas it

has not become clear that and why the results concerning the other 369 patients – if used – were not sufficient to obtain a CE-marking. Nor can it be understood which purpose an injunction to use the data of the SIMPLE 2 trial in advertising or in sale might serve, seeing that in the Netherlands the stents are no longer allowed to be sold or offered as a result of the general infringement injunction to be allowed in 1 and the injunction concerning such data would only regard the Netherlands as a result of the jurisdiction judgment.

4.46. Furthermore Angiotech et al. did not allege with sufficient reasons why the injunction should also cover branches or subsidiaries of Sahajanand, which are after all not a party to these present proceedings, or in which way Sahajanand threatens to indirectly infringe the patent, and so all this will be dismissed.

4.47. It has become sufficiently likely that it is possible that Angiotech et al. incurred some damage as a result of the established patent infringement, which may be assessed on the basis of the profits generated thereby by Sahajanand. The claim for damages to be determined by the court is therefore open to allowance. The court further considers – with reference to NethSC 14 April 2000, NJ 2000, 489 – that damages and account of profit cannot accumulate unlimitedly. No more than a sum equaling the highest of the total sums claimed for the account of profit and damages respectively consisting of loss of license fees can be allowed. And so Angiotech et al. are allowed to choose the highest one of these two items claimed after the damage has been determined. Accumulation of account of profit and any other items of loss (depreciation of patent right and for instance extrajudicial costs) is possible. For an order to give a bank guarantee of EUR 10 million the court does not see a reason, since it has not been made likely that the damage will amount to such a sum.

4.48. The claimed civil fine will be moderated to EUR 10,000.—for each stent or day, at the discretion of Angiotech et al. The conditional claim does not come up, because at present a final judgment can be given. To the extent that the conditional claim also concerns cross-border measures, the court finds itself out of jurisdiction – as already considered above. The court does not see any reason not to declare the claims enforceable notwithstanding appeal save for the court declaration.

4.49. Being the party found to be at fault in the principal action Sahajanand will be ordered to pay the costs of the proceedings. The costs on the part of Angiotech et al. are assessed at:

- writ of summons	EUR	71.93	
- court fees		244.00	
- fees attorney-of-record		1,152.00	(3.0 points x rate EUR 384.00)
Total	EUR	1,467.93	

In the cross-action

4.50. Since not both patentees are party to the proceedings, Sahajanand has to be declared inadmissible, according to settled case-law, in its claim for invalidation of the patent. It could and should have called UBC to join the proceedings under Art. 118 Rv. (or claim invalidity of the patent not in the cross-action but in a separate action against both patentees). Although Sahajanand already acknowledged the possibility and need to call up this party, it attached the incorrect conclusion to this that it had to address a petition to the court. After all, no permission of the court is required for calling a third party to the proceedings under Article 118 Rv.

4.51. The claimed court declaration that the patent is invalid has to fail by reason of that considered in the principal action in respect of the validity defenses and is dismissed as to the rest for lack of sufficient interest.

4.52. Being the party also found to be at fault in the cross-action Sahajanand will be ordered to pay the costs of the proceedings. The costs on the part of Angiotech et al. are assessed at:

- fees attorney-of-record		576,00 (3.0 points X factor 0.5 x rate EUR 384.00)
Total	EUR	576.00

5. The Decision

The Court

In the principal action:

5.1 declares that Sahajanand directly infringes claims 6 and 12 of EP 0 706 376 in the Netherlands, more in particular by selling, marketing and delivering – as well as importing, offering, or keeping in stock for these purposes – its paclitaxel-eluting stents in the Netherlands;

5.2 orders Sahajanand to immediately cease and desist the direct infringement of claims 6 and 12 of EP 0 706 376 in the Netherlands, more in particular by selling, marketing and delivering – as well as importing, offering, or keeping in stock for these purposes – its paclitaxel-eluting stents in the Netherlands;

5.3 orders Sahajanand to pay to Angiotech c.s. a penalty sum to a total of EURO 10.000 per stent or – to the choice of Angiotech c.s. – for each day that Sahajanand does not fully complies with the aforementioned orders;

5.4 orders Sahajanand to pay Angiotech a full indemnification of damages, to be established in a so-called subsequent separate procedure for determining damage, and/or surrender of profits, obtained with or with the aid of the infringing stents;

5.5 orders Sahajanand to pay the costs, to this date at the side of Angiotech estimated at EUR 1.467,93;

5.6 declares this judgment enforceable notwithstanding appeal, with the exception of the declaratory judgment (5.1)

5.7 dismisses any further or other claims

In the cross-action

5.8 declares Sahajanand inadmissible in its claim in as far as it concern the invalidation of EP 0 706 376 for the Netherlands;

5.9 dismisses the claim for the remainder;

5.10 orders Sahajanand to pay the costs of the proceedings, at the side of Angiotech estimated to this date at EUR. 576,-;

5.11 declares this judgment in the cross action enforceable notwithstanding appeal as regards the order to pay the costs of the proceedings;

This judgment has been issued by mr. J.W. du Pon, mr. G.R.B. van Peursem and mr. E.F. Brinkman and pronounced in public on 3 May 2006.