IN THE NAME OF THE QUEEN

DECISION

THE HAGUE COURT OF APPEAL

Commercial Division

Case Number : 105.005.369/01
Docket Number (old) : 06/1157
Case/Docket Number District Court: 245392 / HA ZA 05-2016

Decision of the Fifth Civil Chamber of January 27, 2009

the company under foreign law
SAHAJANAND MEDICAL TECHNOLOGIES PVT. LTD.
established in Saiyedpura, Surat, India,
appellant, as also respondent in the conditional cross-appeal,
to be referred to hereinafter as: SMT,
attorney-of-record: mr. P.J.M. von Schmidt auf Altenstadt,
attorneys-at-law: mr. L. Oosting and mr. R.M. van der Velden (Amsterdam),

versus:

1. the company under foreign law
ANGIOTECH PHARMACEUTICALS, INC.
established in Vancouver, Canada,
attorneys-at-law: jhr.mr. R.E.P. de Ranitz (The Hague) and mr. O.P. Swens (Amsterdam)

2. the company under foreign law
BOSTON SCIENTIFIC CORPORATION
established in Natick, Massachusetts, United States of America,
attorney-of-record: mr. E. Grabandt,
attorneys-at-law: mr. R.E. Ebbink and mr. P. Burgers (Amsterdam),

respondents, as also appellants in the (conditional) cross-appeal,
to be referred to hereinafter also as: Angiotech, Boston and jointly: Angiotech et al.

The Proceedings

SMT lodged an appeal by writ of summons of July 13, 2006 from the judgment rendered by the District Court in The Hague between Angiotech et al. as claimants in the principal action as also defendants in the cross-action and SMT, its defendant in the principal action as also claimant in the cross-action of May 3, 2006. While submitting exhibits SMT challenged the judgment with fifteen grounds of appeal. Angiotech et al. contested the grounds of appeal while submitting exhibits, lodged a conditional cross-appeal and two grounds of (cross)appeal. SMT contested the grounds of cross-appeal.

Next the parties had their stands pleaded on the basis of oral pleading notes, SMT by mr. Oosting and mr. Van der Velden aforementioned, Angiotech by jhr.mr. De Ranitz and Boston by mr. Ebbink and mr. Burgers aforementioned. In this SMT filed a document submitting additional exhibits (nos. 23-28) and Angiotech et al. submitted a binder with exhibits (nos. 14-22) whereas no objection was made to any of these documents.
Finally the parties asked for the giving of a decision while submitting their court documents.

Examination in Appeal

1. The facts considered established by the District Court and reproduced in the judgment in 2.1 to 2.12 have not been refuted, and so the Appeal Court will also start from these facts.

2. In the present proceedings Angiotech et al. claimed after reduction and argumentation of claim respectively, a court declaration that SMT infringes directly or indirectly claims 6 and 12 of European patent EP 0.706.376 (hereinafter also "the patent" or the Hunter patent) in the Netherlands and in the other designated countries, as well as – under penalty of civil fines – that SMT to be ordered (both by way of provisional claim and in the main proceedings) to cease the direct or indirect infringement of said claims in the Netherlands and in any of the other designated countries, that SMT to be ordered to desist in the designated countries from using the CE trade authorization or other trade authorizations and/or the sale or advertising of its stents for a period of three years and/or to get back immediately all information and documentation as far as founded on the infringing clinical trials, from all the relevant authorities anywhere in the world, including authorities for the CE authorization of the infringing stents; furthermore they claimed damages to be taxed by the court and/or surrender of profits.
In the cross-action SMT claimed – next to requests to stay the proceedings, at least to hold over the proceedings and call a third party to join the proceedings under Article 118 Dutch Code of Civil Procedure – invalidation of the patent, at least a court declaration that the patent is invalid.
After the District Court had declined jurisdiction as to the claims relating to countries other than the Netherlands, it allowed the claims for the larger part in the principal action, all this as stated in the judgment, and declared SMT inadmissible in its claim aiming at invalidation of the patent in the cross-action, and dismissed the counterclaims as to the rest.

3. Grounds of Appeal 2 to 13 cover the opinion of the District Court in the principal action that the patent is valid, that the Infinnium stent (of SMT) falls under the scope of protection of the patent and that SMT carries out infringing acts at least threatens to carry them out in the Netherlands. Ground of Appeal 14 implies that the District Court wrongfully declared SMT inadmissible in its counterclaim. Ground of Appeal 1 involves that the District Court wrongfully did not examine the validity of all claims of the patent.
The conditional claim has been dismissed by the District Court and is no longer an issue in appeal.

4.1 The dispute concerns European Patent EP 0.706.376 B2 which has been granted according to the short designation (in the authentic English language) for "ANTI-ANGIOGENIC COMPOSITIONS AND METHODS OF USE", which Angiotech

and The University of British Columbia (hereinafter also in singular: Angiotech) are the proprietors of. The PCT application (WO 95/03036) for the patent was filed on July 19, 1994 invoking priority of July 19, 1993 based on the American patent application US 94536. The mention of the grant of the patent EP -0.706.376 B1 was published on June 25, 1997. The patent has been granted for a large number of countries, including the Netherlands.
To the patent an opposition was filed with the European Patent Office (hereinafter also: EPO) by a large number of opponents. The Opposition Division (hereinafter also: OD) revoked the patent by decision of August 11, 2000.
Angiotech has lodged an appeal from this decision with the Technical Board of Appeal of the EPO (hereinafter: TBA) which remitted the case to the Opposition Division by decision of T0890/00 of October 28, 2002. From the interlocutory decision of the OD of April 19, 2005 to maintain EP 0.706.376 B1 in amended form Conor and SMT lodged an appeal with the Technical Board of Appeal. In this SMT and Conor invoked new documents relating to prior art, i.e. D82-D85 (documents SMT) and Exhibits S5 and S6 as well as D53b and D82-D91 (documents Conor, Exhibit S8). The TBA declared Conor and SMT, however, inadmissible in their appeals by decision of T0969/05 of March 14, 2007. This prior art was therefore not taken into consideration, neither by the Opposition Division nor by the Technical Board of Appeal.
The renewed opposition proceedings have been terminated with the final decision of the Opposition Division to grant the patent in amended form of August 8, 2007, also the date of publication of the "New European Patent Specification EP.0.706.376 B2".

4.2. The claims of the patent (B2 version) read as follows:

1. "A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an anti-angiogenic 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.
2. A stent according to claim 1, wherein said polymeric carrier comprises poly (caprolactone).
3. A stent according to claim 1 wherein said polymeric carrier comprises poly(lactic acid).
4. A stent according to claim 1 wherein said polymeric carrier comprise poly(ethylene-vinyl acetate).
5 A stent according to claim 1 wherein said polymeric carrier comprises a copolymer of poly caprolactone and poly lactic acid.
6. A stent according to any one of claims 1 to 5 wherein said stent is a vascular stent.
7. A stent according to any one of Claims 1 to 5 wherein said stent is a biliary stent.
8. A stent according to any one of Claims 1 to 5 wherein said stent is a urethral stent.
9. A stent according to any one of Claims 1 to 5, wherein said stent is a esophageal stent.
10. A stent according to any of the Claims 1 to 5 wherein said stent is a tracheal/bronchial stent.
11. A stent according any of the Claims 1 to 5 for treating narrowing of a body passageway.
12. A stent according to Claim 11 for treating or preventing recurrent stenosis.

5. This concerns a European patent the mention of the grant of which was published in conformity with Article 97, fourth paragraph of the European Patent Convention (hereinafter also: EPC) after April 1, 1995. Under Article 103, paragraph 2 of the Dutch Patent Act 1995 that provided by and by virtue of this Act applies exclusively.

Article 2(2) EPC provides that the European patent has the same legal effects in each of the Contracting States which it has been granted for, and is subject to the same

provisions as a national patent which has been granted in such State save provided otherwise by this convention.

On December 13, 2007 inter alia the Act established on November 29, 2000 in Munich revising the European Patent Convention (EPC) of October 5, 1973, has become effective. Article 7(1) (transitional provision) reads:

> "*The revised version of the Convention shall apply to all European patent applications filed after its entry into force, as well as to all patents granted in respect of such applications. It shall not apply to European patents already granted at the time of its entry into force, or to European patent applications pending at that time, unless otherwise decided by the Administrative Council of the European Patent Organisation*."

On June 28, 2001 the Administrative Council of The European Patent Organisation decided as far as relevant:

"Art. 1
In accordance with Article 7, paragraph 1, second sentence, of The Revision Act, the following transitional provisions shall apply to the amended and new provisions of the European Patent Convention specified below:

Art. 1(1) Articles 14(3) to (6), 51, 52, 53, 54(3) and (4), 61, 67, 68 and 69, the Protocol on the Interpretation of Article 69, and Articles 70, 86, 88, 90, 92, 93, 94, 97, 98, 106, 108, 110, 115, 117, 119 120, 123, 124, 127, 128, 129, 133, 135, 137 and 141 shall apply to European patent applications pending at the time of their entry into force and to European patents already granted at that time. However, Article 54(4) of the version of the Convention in force before that time shall continue to apply to these applications and patents.

Art.1(2) Articles 65, 99, 101, 103, 104, 105a-c and 138 shall apply to European patents already granted at the time of their entry into force and to European patents granted in respect of European patent applications pending at that time.

Article 69 EPC and the Protocol on interpretation of Article 69 have not been substantially changed – apart from adding Article 2 to the Protocol implying that one should take into account in an appropriate manner any element which is equivalent to an element described in the claims – as appears from the explanation.

6.1 According to Angiotech et al. the Infinnium stent infringes, directly or indirectly, claims 6 and 12 of the patent as phrased in the B2 version (see brief concerning reduction of claim, rectification and submission of exhibits, p. 2).

6.2 SMT argues (see statement of reply in the principal action, as also statement of reply in the interim action concerning conditional claims, as also statement of counterclaim, as also brief concerning request to stay the proceedings under Article 83(4) DPA 1995 or holding over under Article 118 DCCP (including exhibits) – while maintaining that argued by it in the first instance – that the Infinnium stent does not infringe the patent for the following reasons:
- a) there is no priority (Article 87 EPC; see par. 6.32-6.35 statement of reply);
- b) nullity of the patent (see in par. 6.23-6.76); by reason of added subject-matter (Article 123(2) EPC, see par. 6.27-6.31); by reason of insufficient disclosure (Article 83 EPC), lack of novelty (Article 54 EPC, par. 6.36) and lack of inventive step (Article 56 EPC, par. 6.37 – 6.76);

-c) the research exemption under Article 53(3) DPA 1995 (see par. 6.1-6.5);
- d) a restricted interpretation of claim 1 of the patent whereat the Infinnium stent falls outside its scope of protection (see par. 6.13-6.22).

7.1 Furthermore SMT claimed nullity of the patent in the cross-action. The District Court declared SMT inadmissible in its invalidation action, because the co-proprietor of the patent was not summoned or called before the court as well. Ground of Appeal 14 challenges this.
In these proceedings SMT did not take the opportunity to call The British Colombia University, co-proprietor of the patent, to join the proceedings under Article 118 DCCP.

7.2 Article 66(2) DPA 1995 provides inter alia which claims can be filed individually by a partner (co-proprietor of a patent). Such claims do not cover any claims aiming at invalidation of a patent in the event that there are multiple proprietors of the patent. Since in these proceedings the co-proprietor, The British Colombia University did not act as claimant also, SMT could have taken the opportunity, also in appeal, to call The British Colombia University under Article 118 DCCP to join the proceedings. Such calling does not require permission of the court. That is why the District Court did not have to deal with the request of SMT for permission to call the co-proprietor of the patent to join the proceedings. Calling did not take place, neither in the first instance, nor in appeal. And so SMT was rightfully declared inadmissible in its claim for invalidation of the patent by the court. As to the alternative (counter)claim for a court declaration that the patent is invalid the following is considered.
SMT did not state sufficient reasons to assume that it has a sufficient interest in obtaining a court declaration of nullity in these proceedings in the cross-action, since it did not involve The British Colombia University in the proceedings as well, nor can it be concluded from its stands what interest it has in this counterclaim vis-à-vis Angiotech, since (moreover) it brings the nullity arguments brought in the cross-action, also in the principal action within the context of its defense (see NethSC June 12, 1987, NJ 1988, 252).
And so ground of appeal 14 fails.

8.1. SMT is of the opinion (ground of appeal 1) that in its examination of the defense of SMT as to nullity of the patent the District Court should have examined all claims and not confined itself to claims 6 and 12.

8.2. This ground of appeal cannot result into annulment. After amendment of claim Angiotech only founded its infringement claim on claims 6 and 12 of the patent. As considered above, SMT is inadmissible in its claim for invalidation of the patent and in the court declaration claimed by it. And so SMT only has an interest within the context of the infringement matter in examination of the validity of claims 6 and 12 (and claims 1 and 11 to the extent that these claims have been incorporated in claims 6 and 12). For this reason discussion of the other claims of the patent is not required.

Re a:
Priority

9.1 SMT contested that in the patent the priority of July 19, 1993 founded on American patent application US 94536 (Exh. 7(a), tab 1) is rightly claimed in the patent.
To that end SMT pleads the following:

- The priority document only discloses two methods (a) and (b) for coating a stent (p. 17, l. 28-32) (...). The description of the Hunter patent discloses five methods (a) to (e) (p. 21, l. 25-35) and moreover gives further examples of method (a).

9.2 In the view of the Appeal Court Article 87(1) EPC provides, to put it briefly, that a (European patent) application and the priority document invoked in it should concern "the same invention". Article 88(3) and (4) EPC make it clear that the priority right is restricted to such elements of the application as comprised in the priority document, whereat not only the claims but the entire disclosure of the priority document should be taken into consideration.

9.3 It is considered that the subject-matter of claims 6 and 12 can be found clearly and completely, or are disclosed in the priority document:

- Claim 6 of the patent refers to claim 1, and so claim 6 should read, written out in full, as follows:

> *"A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an anti-angiogenic 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, wherein said stent is a vascular stent.*

Claim 15 of the priority document involves: "*A stent comprising a generally tubular structure, the surface of which is coated with a composition according to claims 1-12*".
Claim 5 involves: "*A composition comprising (a) taxol; and (b) a polymeric carrier*", such stent may be *"a vascular stent*" as can be concluded from claim 17 of the priority document. According to the description of the priority document (EXAMPLE 2 (p. 32, l. 22-p. 33, l. 36)) taxol is "*an anti-angiogenic factor by the CAM-assay*" (see in particular p. 33, l. 23-25: "*Figure 4 is a bit-map image which shows the CAM after being exposed to taxol. All of the images show a marked reduction in vascularity*."
Thus the priority document fully covers claim 6.

- Claim 12 is dependent upon claim 11, which in its turn refers to claim 1.
Claim 12 would read, written out in full: "*A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an anti-angiogenic 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, for treating narrowing of a body passageway, for treating or preventing recurrent stenosis*."

As considered, claim 15 of the priority document involves "*A stent comprising a generally tubular structure, the surface of which is coated with a composition according to (i.a.) claim 5, comprising (a) taxol; and (b) a polymeric carrier*", in which according to the description of the priority document, "EXAMPLE 2 (p. 32, l. 22-p. 33, line 36) taxol is "*an anti-angiogenic factor by the CAM-assay*" (see in particular p. 33, lines 23-25).

Furthermore the priority document states (p. 3, l. 23-30): "*The major problem with stents, however, is that they do not prevent the ingrowth of tumor or inflammatory material through the interstices of the stent (...) 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*". Furthermore it is stated (p. 5, l. 15-20): "*Within another aspect of the present invention, methods are provided for inhibiting angiogenesis in patients with non-tumorigenic, angiogenesis-dependent diseases, comprising administering a therapeutically effective amount of a composition comprising taxol to a patient with a non-tumorigenic angiogenesis-dependent disease, such that the formation of new blood vessels in inhibited*". Next it is stated (p. 17, l. 11-27): "*A variety of stents may be utilized within the context of the present invention (...) vascular stents* (...). *Representative examples of stents enclose those described in (...) US Patent No. 5,041,126, entitled "Endovascular Stent and Delivery System, all of which are hereby incorporated by reference in their entirety*", and moreover on p. 22, (l. 1-10) "*Within another embodiment of the invention, methods are provided for eliminating vascular obstructions, comprising inserting a vascular stent into a blood vessel (..), 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 recuurent 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). Representative examples of suitable sites include (...) coronary arteries* (...)" (see also p. 24, l. 2-12).

From claim 15 and these text-parts it is clear to the average skilled person with his general technical knowledge that the subject-matter of claim 12 can be found in the priority document. Even the text-part last quoted literally states the words "*treating*" and "*preventing*". Moreover the average skilled person sees in Table I of EXAMPLE 2 (p. 33) that taxol is preferable (above suramine and AIF (Anti-Invasive-Factor)) as anti-angiogenic factor.

9.4 Furthermore the following is considered. The word "coated" in claims 6 and 12 implies according to SMT that these claims are so-called "product-by-process" claims, i.e. claims aimed at a product, a stent, which has been/must have been made using specific methods; according to SMT these claims are therefore restricted to this. Since in the priority document only methods (a) and (b) are disclosed and in the patent methods (c) to (e) have also been added to these methods, SMT believes that the invoked priority document as a whole does not constitute a valid priority, neither for the stent made by using methods (a) and (b), nor for the stent made by using methods (c) to (e).

In the view of the Appeal Court no pointer can be found in the priority document that the methods (a) and (b) stated in it (p. 17, l. 28-32) are necessary to obtain the intended "coating". The average skilled person will therefore understand that these methods serve as example (see text-part p. 17, l. 28-29, "*Stents may be coated (...) in at least two ways (...)*") and that coated has the meaning of "*having been provided with a coating*", and so the stent per se is part of the subject-matter of the priority document (and of the patent), i.e. independent of any method by which the stent has been made. Said priority date therefore was rightfully invoked for the stent per se. Moreover, as considered, methods (a) and (b) are mentioned in the priority documents by way of example. For this subject-matter priority is rightfully invoked.

As to this subject-matter the application is therefore considered to have been filed on July 19, 1993, the day of filing of the American patent application US 94536. This implies for examination of novelty of the application that all that has become available to the public before the priority date, as well as applications of an earlier date which have been deposited for inspection later is considered prior art. In the examination of inventive step of the application only actual prior art is taken into account, i.e. all that was available to the public before the priority date.
As to methods (c) to (e) not found in the priority document but for the first time in the application no priority can be derived from said priority date; said methods were not disclosed but on the date of filing the application.
This means that, if someone else disclosed in the period between the priority date and the date of filing of the application of the patent a method (c) to (e), such method is part of prior art; however the stent made and coated with such method per se is not part of prior art, because this stent has been disclosed after the priority date. This implies that PCT application WO 95/03795 (D62, "Kinsella and Sollott") in which, to put it briefly, a stent with a polymeric carrier and taxol is also disclosed (see in this p. 20, l. 8-15), with a filing date of July 29, 1993, i.e. later than the priority date of July 19, 1993, is not part of prior art as to the stent per se according to the claims of the patent.

Re b;
Added matter

10.1 SMT is of the opinion (Ground of Appeal 2) that claims 4 and 12 of the patent comprise subject-matter which extends beyond the content of the application as filed (see Article 123(2) EPC) and that the patent should be revoked for that reason.

As results from that considered above in 8.2, claim 4 is not an issue and so an opinion on the subject-matter of this claim is not given.
As to claim 12 SMT alleges that the text-part cited in it "*treating or preventing recurrent stenosis*" has not been disclosed in the application as filed.

10.2 As explained above in 9.3 the subject-matter of claim 12 is not literally stated in the priority document, but this subject-matter can easily be derived from this by the average skilled person from the claims and their description.
The application as filed comprises the same text-parts as stated in the priority document: thus claims 17 and 5 of the application are similar to claims 15 and 5 of the priority document. Furthermore EXAMPLE 2 of the priority document can be found as EXAMPLE 2 (in amended form) in the application: Table I has been substituted by the extensive TABLE II, but the anti-angiogenic effect of taxol in the CAM-assay, as appears from TABLE I of the priority document, also appears from TABLE II of the application as filed. Finally the same text-parts as stated above in 9.3 can be found in the application (see p. 3, l. 34-p. 4, l. 10; p. 5, l. 30-35; p. 21, l. 10-24; p. 26, l. 2-12; p. 28, l. 23-33). The text-part which states "*Within another embodiment of the invention, methods are provided for eliminating vascular obstructions, comprising inserting a vascular stent into a blood vessel (...) such that the vascular obstructions is eliminated. Briefly, stents may be placed in a wide array of blood vessels, both arteries and veins, <u>to prevent</u> recurrent stenosis at the site of failed angioplasties, <u>to treat</u> narrowings that would likely fail if treated with angioplasty, and to treat post surgical narrowings (e.g. dialysis graft stenosis). Representative examples of suitable sites include (...) coronary arteries (...)*" (underlining Appeal Court), can be found in the application (see p. 26, l. 2-12). This

text-part is the direct basis of the mention "*treating or preventing recurrent stenosis*" in claim 12 of the patent.
And so the entire subject-matter of claim 12 is founded on the application as filed and so there is no subject-matter in this claim which extends beyond the content of the application as filed.

Sufficiency of disclosure general

11.1 SMT argues that the stent presently laid down in claims 6 and 12 had not yet been "*invented*" on the date of filing/priority date and that the present stent was not the contribution which Angiotech made to the state of the art.
SMT invoked in this respect the decision of the Court of Appeal in the nullity proceedings in the United Kingdom, as far as involving:
"*So the Court (i.e. the Hague District Court) took the view that the patent was in effect a patent by selection – that the patentees had selected the one (or at least one) that would work out of a host of possibles. With great respect I do not agree. This is to read the patent with the hindsight knowledge that taxol stents work. That is just what the skilled person would not know, even by reading the patent (...) Just because taxol is discussed rather more than others is no reason to give the skilled man any reason to suppose it is any more to work in practice than any other anti-angiogenic*."
Furthermore SMT also referred to a text-part in the judgment of Pumfrey J, in which the witness statement of the co-inventor of the patent, Dr. Hunter himself, is referred to:

"*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 this usefulness of stents in prevention of arterial restenosis was just being initiated. A document dated August 1995 reveals that by the 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.*"

11.2 As the Appeal Court understands, SMT alleges that the invention in the patent specification has not been sufficiently disclosed and invokes insufficient disclosure. The Appeal Court considers as follows.

In the description of the patent many, individual inventions have been disclosed. The only invention which the present patent has as subject-matter and which risked to get lost in the giant mass of the application as filed is stated in claim 1 and concerns, briefly, "*the taxol stent*" with in claims 2-12 the preferred embodiments of the stent. The other inventions, which remained as excess subject-matter in the description of the patent have apparently been accommodated in no less than ten divisional applications stated on the cover of the patent.
All these inventions are founded on the idea disclosed in (the priority document and) the application that an anti-angiogenic factor according to the CAM assay, in particular taxol, prevents blood vessel formation and thus undesired tissue growth. This idea is also the basis of the present patent. It is correct that the application does not teach that precisely taxol should be selected. However, the application does make it clear that taxol is preferred (see in particular EXAMPLE II). To characterize over prior art Angiotech confined itself, when "peeling off" the present invention as laid

down in claim 1 (and claims 2-12 dependent upon it), in the prosecution and opposition proceedings in the claims to the stent which is preferred, i.e. the stent having taxol as anti-angiogenic factor. Such procedure in which the applicant retraces to an embodiment forced by the prior art stated in the prosecution is not uncommon (see decision Opposition Division, interlocutory decision of April 19, 2005, p. 7 in par. 42.).
In this case there is good reason for such a "waiver" also seeing the knowable facts of the prosecution file and the documents concerning opposition, appeal and continued opposition. It is also correct that the patent does not specifically regard use of a taxol stent to prevent restenosis. After all, the patent also regards use of the taxol stent in order to prevent undesired tissue ingrowth which is caused by other diseases. However, said use can be derived from the priority document, the application as filed and the patent (see above) and so it can be made into subject-matter of a subclaim, as was done in the present claim 12. Finally it is correct that there is no experimental material available in the patent which shows that already on the priority date of the patent the taxol stent had been made and "worked", i.e. can be successfully used to prevent undesired tissue ingrowth, in particular restenosis.
In the present case the patent granting body apparently assumed that the (taxol) stent according to the patent "works". For the average skilled person who reads in the application (and the patent) the underlying thought that an anti-angiogenic factor according to the CAM assay, in particular taxol, prevents blood vessel formation, it is clear that a stent which eludes such an anti-angiogenic factor, in particular taxol, thus may prevent tissue ingrowth, such as restenosis. The Opposition Division also informed to be convinced that the stent according to the patent effects the claimed result ("works") and the onus of proof to the contrary rested upon the opponents. During the first opposition proceedings Angiotech submitted additional experimental material (see decision Opposition Division of April 19, 2005, p. 10, first paragraph and the letter of Angiotech of June 6, 2000, p. 6, last paragraph), which make the "working" of the claimed stent likely, going back to the filing (priority) date of the application. This is not altered by the fact that methotrexate, an active substance which was even still claimed in the B1 version of the patent and which is still stated in the B2 version (p. 7, l. 4) has a poor score in the CAM assay, as SMT alleged (statement of grounds of appeal, p. 22., in par. 5.12). This only shows that that claimed in the B1 version is much too wide and as to the list of active substances in said version restriction to taxol is required, the only active substance of which it is likely on the basis of the CAM assay results reproduced in EXAMPLE II that upon its release by stent the effect is achieved of inhibiting blood vessel formation and tissue ingrowth, said restriction has been laid down in the B2 version of the patent. Finally, SMT did not make it likely either, for instance by submitting test, that the stent according to the claims of the patent does not "work".
Besides there were already tests, as appears from the examples of the PCT application WO 95/03795 (also called: Kinsella and Sollott (D62)) with priority of July 29, 1993, which is stated in said application (p. 20, l. 21-24): "*The above examples teach taxol's (...) potential beneficial uses (for instance by means of a "drug-impregnated polymer-coated metallic stent") to prevent artery blockage (..).*" And so it is conceivable that in the "first-to-invent" system applicable in the United States of America Kinsella and Sollot could show with these tests that they made the

invention before Hunter et al. (see statement of grounds of appeal 7.83).
Whatever may be of this, in the "first-to-file" system used here there is no sufficient disclosure prejudice.

Novelty

12.1 The PCT application WO 91/12779 (also called: Wolff, D30, Exhibit 8(b) of Angiotech et al.) is chosen as starting-point by the Opposition Division of the EPO. Just like the patent, D30 relates to a stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an anti-angiogenic factor and a polymeric carrier, and wherein said factor is anti-angiogenic in the CAM-assay.
In D30 groups of factors (active substances) are stated, whereat of each group several active substances are stated as examples. In these listings of active substances taxol is not mentioned by name.
Nor is taxol "read into it" in the mind of the average skilled person with his general technical knowledge. D30 focuses on the following: "*There are several types of drugs that interrupt cell replication. Antimitotics (cytotoxic agents) work directly to prevent cell mitosis (replication), whereas antimetabolites prevent deoxyribose nucleic acid (DNA) synthesis, thus preventing replication. The action of the antimitotics and antimetabilites are so similar, they will be grouped into one category. This category will be known as the anti-replicate drugs*" (p. 9, lines 11-19).
With the general technical knowledge of the average skilled person (D82 of SMT, p. 1435 of the 11th edition of The Merck Index 1989 (Exhibit 7 to statement of reply) taxol seems to fit into the series of the "anti-replicate drugs" next listed in Wolff, "Metholtrexate, Azathioprine, Vincristine, Vinblastine, Fluorouracil, Adriamycine, and Mutamycine" (D30, p. 9, l. 20-23). Nevertheless this is not the case, because there are other publications which give almost the same listing as Wolff from which taxol also lacks (see inter alia Jean-Paul R. Herrman et al. "The Search for the Holy Grail? (part 1)" in Drugs 46 (I) 18-52, 1993, in particular p. 46, in par. 3.3.5, in "Cytostatic Agents" (Exhibit 13 with statement of reply in the cross-action, as also brief concerning comment of Angiotech et a.) and see also Rudulf Steiner "Angiostatic activity of anticancer agents in the chick embryo chorioallantoic membrane (CHE-CAM) assay" in Angiogenesis, Key Principles Science-Technology-Medicine (1992), p. 452, Table I (Exhibit 54 of Angiotech et al.) in which "*the most widely used cytotoxic agents*" have been examined, including a.o. vincristine, vinblastine, methotrexate, fluorouracil and doxorubicine, but taxol lacks from this.
By reason of this it cannot be said that in the cited listing in Wolff the antimitotic taxol already known for a long time has been implicitly disclosed. And so the claims of the patent are new in respect of Wolff (D30).

12.2 The latter patent application (Wolff, D30) deposited for inspection on September 5, 1991, in fact only comprises groups of chemical compounds ("drugs") which can interfere in the complicated process of restenosis, as in principle each compound of such a group and in particular a compound literally stated in such groups "is worthwhile trying".
However, D30 does not give any semblance of for instance any experiment with a compound of any group whatsoever and therefore leaves the skilled person completely in the dark as to which direction he should try when selecting an active substance to successfully treat or prevent restenosis. When choosing a starting-point, "*which constitutes the most promising starting point for an obvious development*

leading to the invention" (Guidelines, 2007, C IV-24) it is therefore important for instance that there are guiding experiments (see in this respect also statement of reply as also statement of grounds of appeal in the conditional cross-appeal, in par. 89 and 103).
Of the documents mentioned in the proceedings European patent application EP 0 551 182 A1 (to be also referred to hereinafter as: Morris D32, Exhibit 8(b) of Angiotech et al.) the application of which was timely deposited for inspection on July 14, 1993, regards, just like D30, a stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising a polymeric carrier and a factor to prevent or treat restenosis.
Contrary to D30, however, D32 (see oral pleading notes in appeal of SMT in par. 2.7) does state results of experiments, also of experiments in vivo. As a result of these experiments in this document (see inter alia paragraph [0021, p.6] rapamycine has been selected as anti-restenosis factor:

"The results of the in vitro and in vivo standard test procedures demonstrate that rapamycin and rapamycin in combination with mycophenolic acid are useful in preventing or treating hyperproliferative vascular disease. Specifically, rapamycin is useful in preventing or treating intimal smooth muscle cell hyperplasia, restenosis, and vascular occlusion in a mammal, particularly following either biologically or mechanically mediated vascular injury, or under conditions that would predispose a mammal to suffering such a vascular injury."

In the view of the Appeal Court D32 is therefore closer to the present subject-matter of invention than D30 is. D32 regards the same technical field, has the largest number of features in common with the invention, serves the same goal with already one way to achieve this and provides experimental data *in vivo*. Moreover it can be concluded from the results of the examples in D32 that a stent coated with rapamycine will be effective (oral pleading notes in appeal of SMT, p. 7, in par. 2.7).
The present stent according to the patent is new in respect of D32, because in said application taxol is not explicitly or implicitly disclosed.

Inventive step

13. Claim 12 of the patent includes the word "re(current) stenosis".
Angiotech et al. invoke the Angiotech Technology Primer (Exhibit 2(a), p. 1); this gives the impression that (re)current stenosis is a very broad notion: "*In medicine, a "stenosis" is a narrowing or a partial blockage of a body passageway. For example, tumor or inflammatory material can grow into a body passageway, resulting in a stenosis of the body passageway. A recurrent stenosis ("restenosis") is a renarrowing of a body passageway after it has been opened therapeutically*" (references to notes are left out, AC).
However, from the multitude of documents which both parties invoke the word "restenosis" appears to have only a restricted meaning to the average skilled person, in fact: to put it briefly, a narrowing in a blood vessel wall which has come about by regrowth of tissue of the blood vessel wall through the interstices of the stent as a result of the wound healing process and a possible inflammatory reaction of the (non-carcinogenic) tissue (see statement of grounds of appeal, p. 13 and the Angiotech Technology Primer, p. 3 in 2, third paragraph).
In the patent the word "restenosis" is also used in such a restricted sense, thus the skilled person will understand (see paragraph [0077]).
Upon examining the inventive step of claim 12 below such a restricted meaning will therefore be started from.

14.1 Starting from D32 which also regards restenosis in the (restricted) sense referred to above the objective problem is therefore finding an alternative active substance for the known stent coated with polymer to prevent stenosis.
The question to be answered is whether use of taxol as anti-restenosis factor on a stent with a polymeric carrier is inventive, or not, seeing the entire prior art for any (objective) reason whatever. When answering this question it is not relevant that the inventors of the patent believed that the characteristic of taxol of being anti-angiogenic in the CAM-assay is the basis of the anti-restenosis activity of taxol on the stent coated with polymer. Thus D32 does not state that rapamycine is anti-angiogenic in the CAM-assay and still its use leads to a commercially available and effective stent. And so it can be left out of the discussion whether it was already known in prior art that taxol has anti-angiogenic characteristics, as SMT alleges while citing D81, D53b and D9 and Angiotech contests (note 35 on p. 9, oral pleading notes appeal). Also left out of the discussion can be the allegation of SMT invoking D91 that it was already known in prior art that restenosis is an angiogenesis-dependent disease, as contested by Angiotech (oral pleading notes, appeal in par. 46).

14.2 The introduction of the description of D32 makes it clear that restenosis (called "*hyperproliferative vascular disease*" there) is the result of an extremely complicated cell process (see p. 2, lines 1-43 and see Angiotech Technology Primer, p. 3, third paragraph and statement of grounds of appeal, p. 13, see also D43, W.R.M. Hermans et al, "*Prevention of restenosis after percutaneous transluminal coronary angioplasty: The search for a "magic bullet"*" in American Heart Journal, July 1991, p. 174, Fig. 1). Next the large number of active substances are listed which were tried and did not give the desired result of preventing restenosis (see also the "Holy Grail" article already cited above and the Angiotech Technology Primer, p. 4 in B.1 and p.7 in B.4).
Upon further reading of D32 it will strike the average skilled person that rapamycine which is known inter alia as antibiotic (see D32, p. 3, l. 12-16) has been selected for the hyperantiproliferative characteristics of this active substance (see inter alia p. 3, lines 53-55): "*The effect of rapamycine on hyperproliferative vascular disease was established in an in vitro and in vivo standard pharmacological test procedure that emulates the hyperproliferative effects observed in mammals that are undergoing intimal smooth muscle proliferation and are therefore developing restenosis.*"
And so it can be admitted to SMT (statement of grounds of appeal, p. 14) that the average skilled person will start looking on the basis of this known fact first in the group of known compounds which inhibit proliferation of smooth muscle cells (have an anti-proliferative effect), whereat SMT also referred in substantiation to the Holy Grail article (in par. 3.3): "*Since one of the key features of restenosis is the uncontrolled proliferation of vascular smooth muscle cells, anti-proliferative agents have been considered as an attractive concept*."

14.3 The average skilled person will next, according to SMT, automatically get at taxol, because on the priority date it was commonly known that taxol was a potentially very suitable "anti-proliferative drug", as appears from a large number of documents (oral pleading notes in appeal in par. 2.2), the more so since the article "*The role of cytoplasmic microtubules in regulation of smooth muscle cells*" by S. Katsuda et al (1988) (Exhibit 22 of SMT) states: "*The proliferation of smooth muscle cells in the intima with subsequent accumulation of extracellular connective tissue matrix components is the principal feature of atherosclerosis. Therefore, suppression of their proliferation seems to be important to prevent the progression of the disease*

(...) recent studies have suggested that such an inhibition effect results from the stabilization of microtubules (...) The fact that microtubule stabilization lead to inhibit initiation of DNA synthesis in cultured smooth muscle cells was proved by a series of experiments of taxol, a promoter and stabilizer of microtubules."

14.4 Although it is known from Katsuda that next to dimethylsulfoxide taxol has a microtubuli stabilizing and thus anti-proliferative effect on smooth muscle cells *in vitro*, this is not yet a pointer that taxol can also be successfully used on a drug-eluding stent to fight restenosis, although it is a related disease, different from atherosclerosis (see statement of reply as also statement of grounds of appeal in the cross-appeal, in par. 133).
After all, the document also cited by SMT D20 (Alberts et al, "*Molecular Biology of the Cell*", 2nd Edition (1989) 653 also discusses the microtubuli stabilizing effect of taxol within the context of yet other antimitotic drugs binding to tubuline to be used in cancer therapy, such as colchicine, vinblastine and vincristine, of which compounds it is however, known that they do not, or not on a long term, prevent restenosis, at least not in a systemic administration. Thus the article "*Ineffectiveness of Colchicine for the Prevention of Restenosis After Coronary Angioplasty*" by J.H. O'Keefe et al, JACC June 1992, 1597-1600 (D44):

"*(...) the use of antimitogenic or antineoplastic agents is one of the most promising avenues of exploration in the search for a solution to the complex problem of restenosis. Colchicine is an antimitogenic agent that bind to tubulin, disrupting spindle formation and resulting in the metaphase arrest of cell division. Colchicine has been shown to inhibit (...) muscle cell proliferation (...). In the current study, treatment with oral colchicine that was started at the time of coronary angioplasty had no effect on the subsequent rate of restenosis after angioplasty.* **Conclusions:** *"The use of colchicine, although theoretically promising, proved ineffective in preventing restenosis after coronary angioplasty in the current study.*

This article also states (p. 1598, bottom right):

"*Other neoplastic agents have been used in experimental animal angioplasty models. The hyperplastic smooth muscle cells responsible for the restenotic process are of mesenchymel cell origin (18). The chemotherapeutic agents generally used for tumors arising from mesenchymal cells include methotrexate, vincristine, cyclophosphamide and anthracycline antiobiotic agents. Accordingly, the antineoplastic agents investigated so far in animals have generally been from this group of drugs. Combination therapie with vincristine and actinomycin D has been evaluated in a rabbit aortic model. Short-term therapy resulted in less smooth muscle cell hyperplasia (...). The intermediate and long-term effects of this therapy were not observed in this study.*"

Finally the same article states: *"(...) the use of oral or intramuscular methotrexate or azathioprine did not inhibit intimal proliferation and restenosis*". This finding is confirmed in D26 (David A. Cox et al, "*Effect of local delivery of heparin and methotrexate on neointimal proliferation in stented porcine coronary arteries*" in Coronary Artery Disease, March 1992, 237-248), which shows: "*This preliminary attempt to inhibit neointimal smooth muscle cell proliferation after vascular injury by local delivery of methotrexate and heparin with polymer-coated intracoronary stents was unsuccessful*." (see p. 237) although good results were expected of these compounds by reason of their inhibiting effect on proliferation of smooth muscle cells (see p. 243, right, last paragraph).
In short, by reason of this literature the skilled person will conclude that an anti-

neoplastic active substance, like taxol, of which a proliferation inhibiting effect on smooth muscle cells is already known and which in theory therefore is suitable as anti-restenosis factor does not yet provide a solution when applied on a polymer-coated stent to preventing restenosis in practice.

14.5 SMT is of the opinion that the documents stated above from which it appears according to Angiotech et al. that compounds inhibiting proliferation of smooth muscle cells, like colchicine and vincristine, are not effective (see statement of reply (including exhibits) in par. 6.53-6.61), are irrelevant because they relate to systemic use and other factors (geometry of the stents and/or the type of polymer) instead of the effectiveness of such compounds themselves. Moreover as to these compounds D43 states:
"*Although there is no scientific proof that the tested drugs are effective, many clinician continue prescribing them to prevent restenosis*".
According to SMT there is no basis therefore for the suggestion that said compounds inhibiting proliferation of smooth muscle cells are not effective anti-restenosis factors, when administered locally, for instance on a stent.

14.6 If it is assumed like SMT does, that not only the compound to be selected itself, but also additional factors like dose-dependency, play a part in the effect to be expected, the picture is seen with the studies already carried out in prior art and often contradictory, of a technical field which has been intensively searched for usable anti-proliferative substances to prevent restenosis (see the review articles cited above "The Search for the Holy Grail" and "The Search for a magic bullet") whereas in said technical field it is entirely unpredictable, also by reason of said additional factors, whether a selected, in theory much promising compound has the intended effect, or not. In short, the average skilled person is back to start.

What is more, this type of compounds constitutes a large group, as Angiotech et al. stated while referring to D94, D95 and D96, as not contested by SMT.

14.7 Finally it should also be noted that in D43 (p. 182, at the left, first paragraph) it is stated as to cytostatic compounds, like vincristin, which inhibit proliferation of smooth muscle cells: "*the principle concern with these agents is the potential for serious side effects, because they are capable of damaging of other rapidly dividing cells, for example, those in the gastrointestinal tract, bone marrow, and reproductive system.*" In D44 (p. 1600, last paragraph left) states further in respect of colchicine:
"*Although the use of antineoplastic and antimitotic agents in this application merits further consideration, therapy with higher doses and more potent agents will be limited to some degree by frequent, serious and even life-threatening adverse effects inherent in such regimens*."
As to the "more potent agent", taxol, Angiotech alleged (statement of grounds of appeal, as also statement of reply in the conditional cross-appeal, in par. 105-106) – not contested by SMT – that it was known in 1993 that this agent present toxic characteristics upon systemic administration, including cardiotoxity (patients with heart disorders were excluded form the clinical trials with taxol), allergic reactions, necrosis, neurotoxicity and neutropenia. There was no safety profile of taxol for the longer term in humans, and although taxol had already been known for a long time, taxol had only been authorized recently for only one use, ovary cancer, in the United States of America as drug, as was not sufficiently refuted by SMT.
Although the average skilled person knows in general that upon local delivery, such as through a stent, the problems of systemic administration can be reduced, he will

still be very reluctant to choose taxol and apply this substance on a vascular polymer-coated stent which must be placed in particular near the heart in the coronary artery, where elution of taxol should still cover a longer period to counter restenosis, the ingrowth of non-carcinogenic tissue. This is not altered by the fact that taxol, although already known for a long time, had come more into focus at the time (see statement of grounds of appeal, in par. 4.10).

14.8 By reason of the above (14.1-14.7) the question raised in 14.1 is answered to the negative. The choice of taxol as alternative to rapamycine is not obvious to the average skilled person: there are pointers in prior art which plead both in favor and against the choice of taxol; and so there is no clear directing pointer which leads the skilled person to the choice of taxol.
Moreover one should not forget the unpredictable and not proven in practice beneficial effect associated with the choice of taxol: without the known negative side-effects of taxol known from cancer therapy the claimed polymer-coated taxol stent regulates the natural wound healing process of the (non-carcinogenic) cells of the blood vessel wall, whereat (see Technology Primer, p. 9, last paragraph):

some cell accumulation is desirable because allowing a thin layer of cells to accumulate on the inside of the implanted stent forms a smooth cover, incorporating the device in the vessel wall itself. This thin layer of cells is useful in preventing the complication of thrombosis (blood cells reacting to a foreign object by clotting and blocking the artery). Because paclitaxel can be administered from a stent in doses sufficient to regulate but not completely eliminate cell proliferation, stents coated with paclitaxel afford just the right agent for controlling the accumulation of cells around and inside the stent."

14.9 Within the context of its challenge of the inventive step SMT also invoked the following document which make, in combination with general technical knowledge, other documents or chosen as starting-point, the invention obvious according to SMT.
In that respect the following is considered as to claim 12 of the patent:

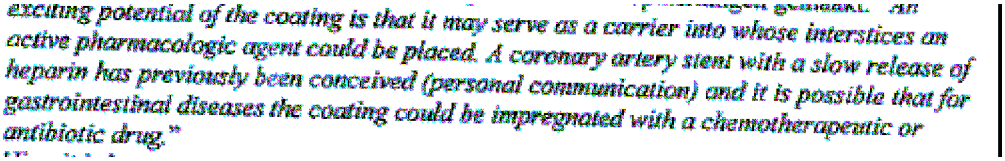
1) PCT application WO 93/11120 (also called: Kopia, (D40)) was timely deposited for inspection on June 3, 1993. The Kopia application regards local delivery of therapeutically active substances by means of complexes which bind the active substance in such sense that it is only released in the desired place and is inactive in bonded (conjugated) form (see inter alia p. 12, l. 29-35 and p. 50, l. 30-p. 6, l. 6). Within this broad context as field of use, treating restenosis is stated next to other uses whereat a large group of active substances is mentioned (p. 5, l. 13-17 and p. 6, l. 27-34):

"In a preferred embodiment, compounds of the invention useful for treatment of post-angioplasty restenosis comprise antiproliferative agents, such as heparin, hirudin, colchicine, vinca alkaloids, taxol and derivatives thereof. (...) Other antiproliferative agents contemplated for use in the practice of the present invention include: angiotensin converting enzyme (ACE) inhibitors, angiopeptin, cyclosporin A, calcium channel blockers, goat-antirabbit platelet derived growth factor antibody, Terbinafine and Trapidil, interferon-gamma and polyanions for binding of cationic growth factors."

In this Kopia further discusses the anti-proliferative characteristics of heparin and colchicine which were known (p. 5, l. 17 – p. 6, l. 6) and indicates in this that two colchicine-conjugates are preferable. When looking in the examples of Kopia to see which active substances Kopia really used in the conjugates claimed by him

(examples 4, 13 and 15) for the treatment of restenosis, then they are colchicine and heparine, but not taxol.
It results from this for the average skilled person that taxol may be usable in theory, it is clearly seen as "second choice".
As forms of administration of the conjugates are mentioned (p. 61, l. 23 et seq.): "*The compounds of invention can be (...) delivered directly to the arterial wall by catheter during an angioplasty procedure. The pharmaceutical preparations of the invention are preferably administered by injection, intrapertioneal infusion, or catheterization. Other modes of administration may also be effective such as oral administration in some cases, or aerosolization.*" Local administration by means of a polymer-coated stent did not come to mind.
As to Kopia the stent according to claim 12 is also considered new and inventive. After all, to the average skilled person it is not obvious to choose precisely taxol, which is considered second choice in Kopia, next abandon the inventive concept of Kopia, local delivery of a taxol conjugate, and choose a local form of administration not mentioned in Kopia in which taxol itself and not the taxol conjugate should be applied to a polymer-coated stent.

2) The article "*A new coated self-expanding metal stent for malignant esophageal strictures*" by David E. Fleischer et al. in Gastrointestinal Endoscopy (1992) 494-496 ("Fleischer" (Exhibit S8 (Conor), D82). It already results from the title of this article that this does not concern a stent to treat or prevent restenosis. This article describes a self-expanding metal stent (SEMS) for malignant esophageal strictures which has been provided with such a silicon top coating that there is no free space in the mesh of the stent. The completely closed coating was intended to prevent tumor ingrowth and to prevent the metal of the stent from being embedded in the tissue in the event that the stent had to be removed.
At the end of the article several additional remarks are made:


exciting potential of the coating is that it may serve as a carrier into whose interstices an active pharmacologic agent could be placed. A coronary artery stent with a slow release of heparin has previously been conceived (personal communication) and it is possible that for gastrointestinal diseases the coating could be impregnated with a chemotherapeutic or antibiotic drug."

It is clear from this to the average skilled person that in this document in case of placing a stent in a coronary artery heparin was chosen and that there is not a single pointer to choose taxol as well. As far as a stent for gastrointestinal diseases is concerned only a general mention is made of the use of a chemotherapeutic or antibiotic.
This document does not give a pointer either in the direction of applying taxol on a polymer-coated stent to prevent restenosis, and so it is not prejudicial to the inventive step of claim 12.

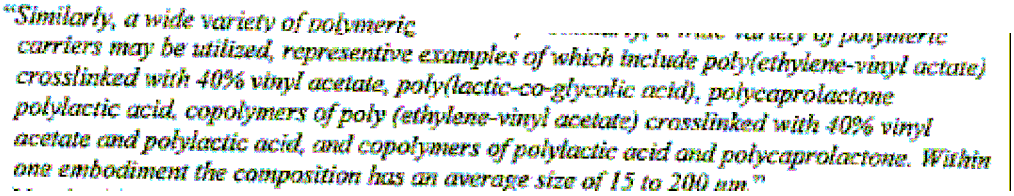
14.10 By reason of the above claim 12 is therefore considered new and inventive, whereat the word restenosis has the restricted sense stated above.

Sufficiency of disclosure polymeric coating

15.1 SMT alleged (statement of grounds of appeal, in par. 7.78-7.82 and oral pleading notes in appeal in par. 8) that the patent is insufficiently disclosed as to its

polymer coating. Finding a polymeric carrier of the stent according to the patent would produce an undue burden for the average skilled person.

15.2 It is already known from Wolff (D30) for instance to coat a stent with a known polymer that is bioabsorbable or biostable. Examples of bioabsorbable polymers are poly-1-lactic acid /poly glycol acid, poly anhydride and polyphosphate ester (see there p. 12, l. 16-30). Of said polymers the biodegradable poly-1-lactide was studied in practice as appears inter alia from the "Holy Grail" article, p. 254, left column. The patent states (p. 3, line 36 et seq.):


"Similarly, a wide variety of polymeric carriers may be utilized, representive examples of which include poly(ethylene-vinyl actate) crosslinked with 40% vinyl acetate, poly(lactic-co-glycolic acid), polycaprolactone polylactic acid, copolymers of poly (ethylene-vinyl acetate) crosslinked with 40% vinyl acetate and polylactic acid, and copolymers of polylactic acid and polycaprolactone. Within one embodiment the composition has an average size of 15 to 200 um."

Example 9 of the patent is specifically aimed at manufacture of the coating of the stent. In these examples polymer-taxol compositions are described in detail as well as how these compositions are applied on the stent. As polymers are stated (p. 23, l. 11-126): polyacprolacton (PCL), the polymer of ethylene vinyl acetate (EVA) and poly(DL)lactic acid (PLA) (see also claims 2-5 of the patent). According to p. 7, l. 42-52 bioabsorbable as well as biostable polymers are suitable. Stated is for instance a polymer of lactic acid and glycol acid which is also already stated in Wolff. With said pointers in example 9 described in detail as starting-point systematic study of these known polymers could result into a suitable polymeric carrier of the patented stent and the patent is sufficiently disclosed to the average skilled person as to such a carrier (see also the decision of the Opposition Division of April 19, 2005, p. 6 l. 30 et seq.).

That in this the polymeric carrier or the residue products of possibly used biodegradable polymers are not toxic goes without saying. For identifying this, according to Angiotech et al. there were already internationally accepted standard norms before the priority (statement of reply as also statement of grounds of appael in the conditional cross-appeal, in par. 162 and 163) as is not contested by SMT. Moreover it is such that systematic study which may take a long time does not prejudice a sufficient disclosure.
Tests in which the effect of such stents are measured, lack. However, SMT did not submit any experimental material which makes it likely that such stents are not effective (at all).
Optimal effect as required for commercially usable stents is not required for sufficient disclosure by the way.
And so the invocation of insufficient disclosure is dismissed.

Industrial aplicability

16. SMT also pointed out that claim 12 is not industrial applicable (statement of grounds of appeal, in par. 7.73-7.77 and oral pleading notes in appeal, in par. 4.3-4.8).

Angiotech et al. referred to T0138/95 (statement of reply as also statement of grounds of appeal in the conditional cross-appeal, note 143 in 154) in which a change of

"claim category" was found permissible of "*A device for the delivering to the blood stream of a patient a therapeutic dose of a polypeptide (...)"* into "*Use of a polypeptide for the manufacture of a device for delivering to the blood stream of a patient a therapeutic dose of the peptide"*(...).

In the view of the Appeal Court the patent does not regard the introduction of a taxol stent in the body of the patient – which cannot be considered industrial application – but the patent regards the use of taxol upon manufacture of a stent, which can be considered an industrial application. Reference is made in this respect to the "claim category" of the claims of D32 (Morris).

The above implies that rephrasing of claim 12 is required to meet the condition of industrial applicability. The Appeal Court considers in this respect that Angiotech (with its co-patentee) is authorized in proceedings concerning the validity of a European patent (under Article 138(3) EPC) to restrict the patent by amending the claims. In the view of the Appeal Court Angiotech also has such right in the present proceedings, in which nullity is purely stated as defense. However, it is required in that case that Angiotech shows that the co-patentee agrees to the suggested rephrasing.

17. The Appeal Court will refer the case to the cause-list in order to allow Angiotech et al. to rephrase claim 12 by brief with due respect of the above (that ruled in par. 16).
In the preliminary view of the Appeal Court SMT does not have an interest by reason of the above in examination of the validity of claim 6 for the infringement matter, if the claim concerning infringing is already allowable as to claim 12, and so a decision on the validity of claim 6 can then be abandoned. In the event that Angiotech believes to have an interest in maintaining claim 6 as grounds for its claims in the principal action it will also be able to state so by brief and it will be requested to rephrase claim 6 upon doing so.
SMT will be allowed to comment on this by brief of reply.

18. The other points of the dispute will be discussed, if necessary, later.

Decision

The Appeal Court

- refers the case to the cause-list session of Tuesday February 26, 2009, for the purposes stated in par. 17 above;
- holds over any further decision.

This decision was rendered by mr. J.C. Fasseur-van Santen, mr. R.A. Grootoonk, mr. S.U. Ottevangers, and pronounced at the public session of January 27, 2009 in the presence of the clerk of the court.

[*signatures]*

[court stamps]