ANGIOTECH: A TALE OF TWO JURISDICTIONS

CAMILLA SMITH AND SHELLEY BLYTHE
Associates, Intellectual Property Group, Arnold & Porter (UK) LLP, London

In January 2007, decisions were handed down by two of Europe's highly regarded forums for patent disputes: the Court of Appeal in England and the Hague District Court. The decisions relate to the same companies and the same patent and yet they conflict with each other. On the one hand, the English court found that the patent was invalid and on the other, the Hague District Court found that the patent was at least partially valid and infringed.

Such conflicting decisions might be considered surprising, given that they relate to the same 'European' patent, and in this article we consider the differences in the approach used by the courts and how this ultimately led to the differing conclusions.

The decisions address a number of different issues including, for example, the use of arguments relating to commercial success in the English courts and the application of the exemption to patent infringement for clinical trials in the Dutch decisions. However, the focus of this article is the different conclusions drawn by the courts with respect to the issue of obviousness, in a case where no prior art anticipating the invention was found.

Background to the Dispute

Angiotech Pharmaceuticals, Inc. is the proprietor of European Patent EP 0706376 ('Patent') which has a priority date of 19 July 1993. The patent is entitled 'Anti-angiogenic compositions and methods of use', but the disputes mainly related to one particular aspect of the patent related to the use of a 'stent' coated in taxol, for the treatment of recurrent stenosis. Angiotech exclusively licensed the patent to Boston Scientific who had commercialised a product 'Taxus' which, since being placed on the market, has achieved a good level of success.

Whilst two decisions relating to the case were handed down in January 2007, in fact, the patent had already been the subject of two earlier decisions, one in England and one in the Hague District Court and it had already been opposed by a number of companies in the European Patent Office.

The English decisions were a High Court (first instance) and Court of Appeal decision between Angiotech and Conor Medsystems, Inc ('Conor'): Conor made a pre-emptive strike for revocation of the patent. The patent was held to be invalid by the English High Court and Court of Appeal because the inventive step claimed in the patent was held to be obvious to the person skilled in the art.

By contrast, the two Dutch decisions partially upheld the patent as a selection patent, and as a consequence Angiotech was successful in infringement claims against Sahajanand Medical Technologies PVT Ltd ('SMT') and also against Conor.

Technology

Coronary heart disease has a high morbidity rate in Europe and across the world. One of its main causes is the narrowing of the arteries. Historically, treatment for narrowing (or closure) of the arteries has included the use of a balloon-type device to physically widen the arteries: angioplasty. An improvement to angioplasty was the advent of stents: devices which fit around the 'balloon' and are subsequently left in the artery following the angioplasts to give support and hold the artery open. However, a common problem with angioplasts was the subsequent gradual closure of the lumen of the artery (restenosis).

Much research was done into restenosis and it became a well-known theory that it was caused, not necessarily only by the physical movement to close the artery by the 'failure' of the devices, but also by the body's own mechanism for healing: cell division. This was considered to occur because injuries are inflicted on the arteries by the insertion of the balloon and stent device. The injury would cause a healing process and proliferation of cells could reblock the artery, regardless of the devices present to hold it open.

The invention in the patent was aimed at the prevention of this cell regrowth by the use of a substance to prevent the multiplication of the cells: taxol.

Relevant Claims

In both the English and Dutch courts, the dispute focused on claim 12, as the claim being allegedly infringed by SMT and Conor, as they too produced taxol-eluting stents for the treatment of recurrent stenosis. Claim 12 must be read with claims 1, 6, 11 and 12, as set out below.

Claim 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 derivative thereof.

Claim 6:

A stent according to ... claim 1 wherein said stent is a vascular stent.

Claim 11:

A stent according to claim 1 ... for the treating of narrowing of a body passageway.

Claim 12:

A stent according to claim 11 for treating or preventing recurrent stenosis.

Key Differences between the Courts

In all the judgments the courts primarily concerned themselves with whether the patent, in particular claim 12, was obvious. In so doing the courts:

- used different tests: *Windsurfing*[1] in the English courts and the problem-solution methods in the Dutch courts;
- came to different decisions on what the patent contributed to the art; and
- consequently came to different conclusions about whether the pleaded prior art rendered the patent obvious.

One of the key differences between the judgments was the answer reached by the courts to the question: is it sufficient for the purposes of proving obviousness to show that taxol is an *obvious candidate* for testing on a drug-eluting stent in addition to the material specifically identified in the prior art, or is it necessary to show that taxol is an obvious, or *the obvious*, *material to use* in a drug-eluting stent for administration to human beings? Put another way,

> *Is the patent vulnerable only if it can be shown that the skilled person would have an expectation of success sufficient to induce him to incorporate taxol in a drug-eluting stent, or is it sufficient that without any expectation of success he would test or screen taxol?*[2]

The English High Court considered that the patent would be obvious if the skilled man would consider it obvious to test taxol incorporated in a stent with a view to seeing whether it works to prevent restenosis and whether it is safe.

The Dutch Courts, by contrast, treating the patent as a selection patent, proceeded on the basis that it was necessary to show that the skilled man would consider that taxol was the obvious material to use in a drug-eluting stent for administration to humans in the treatment and prevention of restenosis. As such, they looked for specific direction to the use of taxol to render the patent invalid. They did not find such specific direction.

Tests Applied For Assessment of Obviousness

The European Patent Convention states that '*An invention shall be considered as involving an inventive step, having regard to the state of the art, it is not obvious to the person skilled in the art*'.[3]

The English and Dutch courts have developed and continue to use separate, more detailed, tests for the consideration of obviousness. It does not seem that these different tests were the sole cause of the different outcome of these cases in the English and Dutch courts, but it is important to understand what tests were applied.

The English Courts

The English courts used the *Windsurfing* test which contains four steps:

- to identify the inventive concept;
- to assume the mantle of the normally skilled, but unimaginative, addressee in the art at the relevant date and to impute to him what was common general knowledge in the art in question;
- to identify what, if any, differences exist between matters cited as being 'known or used' and the alleged invention; and
- to decide whether those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.

1) *Windsurfing International v Tabur Marine* [1985] RPC 59.

2) A question asked by Pumfrey J in the High Court in England.

3) Article 56 EPC.

The Dutch Courts

By contrast, the Dutch courts applied the 'problem-solution' method of identifying whether the invention was obvious,[4] which is a three-step approach as follows:

- determine the 'closest prior art';
- establish the 'objective technical problem' to be solved; and
- consider 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.

Inventive Concept of the Patent

One of the first key differences between the approaches of the two courts can be illustrated by an assessment of what was found to be the inventive concept contained in the patent. Whether or not there was an invention described in the patent at all, and what that invention was, were both in dispute.

The English courts found that the inventive concept (over and above anything found in the prior art) was the use of taxol in a drug-eluting stent. On the other hand, the Dutch courts considered that the inventive concept was, in fact, the use of taxol on a drug-eluting stent for the prevention of restenosis.

This difference arose largely because of the courts' assessment of what the patent actually teaches by way of inclusions within the specification and claims. The courts reached different conclusions here too.

In considering what the patent added to the state of the art, the English court accepted a list of deficiencies in the patent put forward by Conor (and agreed to under cross-examination by one of Angiotech's experts), namely that the patent:[5]

- contained no data as to the efficacy of any of the compounds disclosed;
- did not address the question whether any of the compounds disclosed inhibited the proliferation of smooth muscle cells (believed to be the main mechanism of restenosis);
- did not deal with possible side-effects in otherwise healthy tissue;
- did not address the question of dosage;
- did not address the length of time for which a taxol-containing product should remain in the location in question.

The fact that a compound was anti-angiogenic was not of any assistance in concluding whether or not the compound would actually work to inhibit the proliferation of smooth muscle cells.

This led the English court to conclude that the patent was, in fact, a speculative disclosure by the patentee and that at the priority date, the patentee had neither made nor tested any taxol-eluting stent for the prevention of restenosis. As a consequence, the English court accepted only that the patent disclosed the use of taxol in a drug-eluting stent and that taxol was one of many possibilities disclosed.

The Dutch courts, on the other hand, dismissed this submission and found that the invention set out in the patent was fully supported and clearly indicated the inventive concept, that is, '*the specific unambiguous choice to use the taxol-stent*'.[6] The Dutch courts stated that the patent did, in fact, teach '*precisely*' that taxol should be used to prevent restenosis. In particular, they pointed to certain assays described in the patent which showed the strength of anti-angiogenic activity and were referred to in other claims. The Dutch courts stated that these assays would give the skilled person a clear preference for using taxol specifically.

The Dutch court concluded that the skilled man would understand that the patent held the use of taxol to be advantageous, and so use of a taxol stent to prevent restenosis after an angioplasty intervention could be considered to be the contribution to the state of the art.[7]

4) Derived from Rule 27 EPC.

5) Paragraphs 27 and 28 of the first instance hearing of *Conor v Angiotech* in the English courts.

6) Paragraph 4.17 of the Hague Court decision in *Conor v Angiotech*.

7) These conclusions of what was disclosed in the patent related to the question of determining the inventive step/objective technical problem to be solved for the purpose of obviousness, that is, what was the patent's contribution to the state of the art. This is to be distinguished from consideration of whether the patents disclosed sufficient information to enable the skilled reader to perform the work described. In other words, the courts were considering what was disclosed regarding *why* the skilled men would want to make and use the stents described in the patent, rather than *how* the skilled men would go about making and using the stents.

In the Dutch court the sufficiency of disclosure arguments related to the description 'analogue or derivative' and the lack of detail on what polymers should be used. There was no attempt in relation to sufficiency, to indicate that there was inadequate disclosure in relation to the use of taxol or its action in preventing restenosis.

Common General Knowledge

On the evidence put to the English court it was held that that common general knowledge at the priority date of the patent consisted of the following:[8]

- Bare metal stents were available for use with balloon angioplasty in the treatment of atherosclerosis. There were problems with the deliverability of stents in coronary arteries;
- Restenosis was known to occur as a result of both balloon angioplasty and stenting;
- Restenosis was known to be caused by (*inter alia*) the proliferation of smooth muscle cells;
- Research was known to be directed (*inter alia*) into local delivery of anti-proliferative drugs;
- One form of delivery being contemplated was in the form of a drug-eluting stent. Dosage levels of drugs to be used on drug-eluting stents were of orders of magnitude lower than those used for systemic administration; and
- The concept of using a polymer coating on the stent as a vehicle for drug delivery was well known.

In Conor the Dutch court accepted that the following were known:

- drug eluting stents;
- the anti-tumor activity of taxol;
- the use of stents in obstructions of body-passage ways by tumors;
- the use of a stent eluting chemo-therapeutic agents.[9]

The Dutch court considered that what was known in the art was sufficient to invalidate claim 1, hence the limitation of the inventive concept discussed above which focuses on the treatment of restenosis with the taxol stent. The English assessment of common general knowledge was based on a single review article[10] which does not appear to have been discussed in detail during the Dutch proceedings.

Person Skilled in the Art

In the English court, the parties agreed that the persons skilled in the art in relation to assessing obviousness should be a team engaged in research aimed at treating or preventing restenosis after angioplasty, such team to include an interventional cardiologist and someone familiar with drugs for treating cancer.

When assessing the attributes of the skilled person, Pumfrey J cautioned against the use of hindsight when assessing obviousness and emphasised that it is '*essential to try to reflect, to the extent that the evidence permits, the actual ordinary skills of the real-life contemporaries of the skilled man at the priority date*'.

The Dutch Approach

The Dutch court did not spend significant time considering the attributes of the skilled addressee and therefore it is not possible to ascertain, for the purposes of this analysis, who they were addressing the patent to. However, it is to be assumed that they would have been imputed with the knowledge discussed above.

Closest Prior Art

Both the English and Dutch approaches to obviousness require an assessment of what is contained in the closest piece of prior art presented. On the one hand, the English courts considered the differences between the prior art and the inventive concept as determined by the court. On the other hand, the Dutch courts consider the prior art alongside the objective technical problem to be solved.

Both the English and Dutch courts considered the closest prior art to be the 'Wolff' patent WO 91/12779, which was published about two years before the priority date. Both courts considered additional pieces of prior art, but for the purposes of this assessment we focus on the assessment applied to the Wolff prior art (and to a lesser extent mosaicing of Wolff with other prior art as submitted in the Dutch court).

Wolff discusses intravascular stents. Its invention relates to methods of lessening restenosis, and to prostheses for delivering drugs to treat said restenosis. These prostheses can be biostable with at least one drug diffused out of the biostable materials. It refers to suitable drugs stating '*The drugs in the prosthesis may be of any type which would be useful in treating the lumen. In order to prevent restenosis in blood vessels, migration and subsequent proliferation of smooth muscle cells must be checked.*' Wolff mentions several types of drugs which interrupt cell replication including antimitotics, which interrupt cell division and anti-replicate drugs. Conor and SMT alleged that the person

8) Paragraph 54 of the High Court judgment.

9) See paragraphs 4.8 to 4.9, *Conor v Angiotech*, The Hague District Court.

10) Herman and others, 'Pharmacological Approaches to the Prevention of Restenosis following Angioplasty – The search for the Holy Grail?' Drug (1993) Vol 46, No 1, pp 173–179.

skilled in the art would have considered taxol as an anti-replicate drug. The Wolff patent does not, however, specifically disclose the use of taxol. In fact, Wolff does not specifically mention any drug that works rather suggests drugs and drug types that might work.

The English Court

Conor argued in the English case that it was '*sufficient for the purposes of invalidating the claims of the Patent in suit that the interventional cardiologist, in consultation with someone of skill and experience in the field of anti-mitotic drugs of one sort or another, would see paclitaxel [taxol] as worth experimentation.*'

Angiotech argued that the properties of taxol, namely its toxic character, were such that the skilled person would not think that taxol was suitable for local administration in a drug-eluting stent.

The English courts having found that drug-eluting stents formed part of common general knowledge, also considered that the Wolff patent disclosed:

- the idea of a drug-eluting stent, the purpose of this being to achieve local delivery of the drug;
- the fact that very little of drug would be needed because of local delivery;
- that such a stent might be useful to deal with restenosis;
- that the kind of drug which might be used is an 'anti-replicate'; and
- that 'anti-replicate drugs *include among others* Methotrexate, Azathioprine, VinBlastine, Fluororacil, Adrianmycin and Mutamycin (Court of Appeal's emphasis).

The court held that a difference between the Patent and Wolff was the use of an 'anti-proliferative' (either an anti-mitotic or an anti-metabolite) and a wide variety of metabolites, whereas the patent disclosed an 'anti-angiogenic', a wide variety of examples and specifically mentions taxol. However, the court considered that the use of the term 'anti-proliferative' had, for these purposes, the same meaning as the patent's 'anti-angiogenic'. As such both Wolff and the patent taught the use of 'anti-mitotics' and, consequently, the specification of taxol in the patent was not sufficiently inventive to warrant a patent, particularly as taxol '*would naturally occur*' to the skilled addressee.

The English court considered that it would not matter that the team of skilled addressees would not know whether taxol would have any better prospect of working than another anti-mitotic, because all Angiotech had done was '*name taxol as a suitable drug along with many others*': Wolff had already invited the skilled reader to consider other anti-mitotic drugs.

Angiotech arguments against the use of taxol because of its toxic effects were dismissed because it was considered that Wolff taught that such small amounts were needed that toxicity would have not been considered an issue to the skilled man.

This position was summarised by the English court as follows:

> *... it is essential to remember that the objection of obviousness is available even when the invention is not anticipated.*[11] *This proposition may be trite, but it is important to guard against the suggestion that lack of anticipation is in itself an indication of non-obviousness in the technically objective sense. It is not.*[12]

Also, the court stated that:

> *Inventions may be obvious even though the art missed them ... It is absurd to suggest that everything objectively obvious at the priority date should have been done or contemplated either then or at any time thereafter. Patents should not be granted for things that have been obvious for a long time.*[13]

If Angiotech had shown in some way why taxol was different, or better, or one of only a few anti-proliferatives that would work, the situation would have been different as the '*contribution to human knowledge would then be of value*' and the English court may have considered the position differently. However, as the patent was considered by the English court to lack this information, it was held to be invalid. In particular, it was noted that the patent referred to substances which have since been shown to be ineffective, although '*it is clear that the patentee did not know that*' at the priority date. This also counted against the patentee for the purposes of the view of the English courts.

Other prior art was put before the English court, including Kopia,[14] which proposed a drug delivery method for the purpose of (among other things) delivering taxol to the site of post-angioplasty restenosis. Like the patent, Kopia gives no detailed information which enables the reader to satisfy himself that taxol will either work or satisfy any safety

11) No prior art in this case was found to anticipate the patent.

12) Paragraph 37 of the High Court judgment, Pumfrey J.

13) Paragraph 37 of the High Court judgment, Pumfrey J.

14) PCT Application number WO 93/11120.

requirements. However, the fact that Kopia describes taxol as '*one among many anti-proliferatives capable of being delivered by its novel method of delivery to an angioplasty site*' was considered to be enough to make it obvious to test taxol to see if it works.

The Dutch Court

In contrast, the Dutch court chose to use a 'patent by selection' approach in assessing obviousness. In so doing, the Dutch court disregarded the lack of evidence in the patent for making such a selection, as discussed above, and considered that the disclosure and specific direction to the use of taxol is sufficient for the skilled man to understand that the use of taxol was advantageous.

The Dutch court accepted that Wolff states that the proliferation of smooth muscle cells must be stopped in order to prevent restenosis, but said that Wolff does not specifically, in a '*sufficiently obvious and unambiguous manner*' state that 'anti-proliferatives', such as taxol, should be used.

The Dutch court pointed to the fact that Wolff makes 'five hypotheses' as to how restenosis could be stopped, including use of an inhibitor of smooth muscle proliferation. Wolff also suggests five different categories of medicines including anti-mitotic medicines and the broad range of anti-replicate medicines. The Dutch court held that the notion of 'anti-replicate' in this sense '*encompasses hundreds of structurally and functionally different compounds*.'

The Dutch court stated that the test to show obviousness applied was to show that there was an '*insufficient level of inventiveness the average skilled person should be induced to use taxol*'. It concluded that there had not been a sufficiently clear pointer to taxol in Wolff to the use of taxol and therefore the patent was inventive.

The Dutch court accepted that there would be a certain level of experimentation expected, but stated that where there were such a large number of possibilities to chose from that it was not obvious in this case to choose taxol for such experiments and there was no specific direction to taxol. Making reference to the EPO guidelines[15] which confirm this approach to their view, they held the selection of taxol to be inventive.

Evidence relating to Kopia (as discussed above for the English court) was put to the Dutch court. The Dutch court was encouraged to consider the combination of Wolff and Kopia together, in the light of the common general knowledge. Kopia mentions taxol as an example as one of a number of antiproliferatives which are to be delivered through, for example, catheters and not through stents.

In these circumstances, the Dutch courts held that Kopia, combined with Wolff, did not '*specifically*' suggest use of taxol in a stent and instead Kopia only added new substances to the already large group of potential substances. The courts also doubted whether the documents would ever have been read together.

To summarise, there were a number of reasons the Dutch courts did not consider that the patent was obvious:

- Wolff suggests a number of possible retenosis treatments;
- Wolff suggest a number of different types of drugs including antiproliferatives;
- Wolff does not mention taxol by name; and
- Suggestions elsewhere (by way of example) that taxol might be used to treat retenosis, are not sufficient to suggest use on a stent and are not something that would naturally be read with Wolff as the closest prior art.

The Dutch court considered also that the success of taxol compared to a number of other possibilities was surprising and sufficient to contribute to patentability by way of a selection patent.

Relying on the Supreme Court judgment in *Spiro/Flamco*[16] the Dutch courts held claim 1 invalid but upheld claim 12. They sought to balance of legal requirements for patentability on the one hand and the legitimate interests of third parties on the other.

Other Arguments Raised

Obvious to Try

This concept came into English law in the *Johns-Manville* case where there was an old, known process and the patent was for the use of a new agent in this known process. It has since been used on occasion to test for the obviousness of a patent.

The patent in the *Johns-Manville* case was held obvious as the new agent was '*well worth trying out*', with the court holding that the skilled man would '*assess the likelihood of success as sufficient to warrant actual trial*'.[17] Both English and US courts have since taken into account the fact that all research

15) EPO Part C, Annex to Chapter IV ex 3.2 (ii) (Not obvious and consequently inventive selection among a number of known possibilities).

16) NJ1998, 2

17) [1967] RPC 479.

is not undertaken in '*complete blindness*'[18] and that there will be a semblance of a chance of success. Consequently, the English test was limited to encompass the fact that the '*mere possible inclusion of something within a research programme on the basis you will find out more and something might turn up is not enough. … The obvious to try test really only works where it is more or less self-evident that what is being tested ought to work*.'[19]

For the purposes of this case, the obvious to try test would only have been appropriate if it has been considered that it was more or less self-evident that including taxol in a drug-eluting stent ought to help prevent restenosis by ingrowth of cells. The English court considered that this was not an appropriate test here because the patent had not in any way demonstrated that taxol actually works to prevent restenosis and so has not, in fact, been put to the test.

Given the Dutch court's 'selection patent' approach to this case, similar issues did not arise.

Likelihood of Success

Angiotech submitted that an expectation of success is a relevant factor in assessing the question of obviousness. The English court agreed with this as a broad proposition, but then asked: success in what? What was the skilled man's 'definite object in view'?[20] Angiotech submitted that the 'definite object in view' was the treatment or prevention of restenosis and argued that the perceived chances of any one of the different avenues of research would have provided a 'successful result'[21] was relevant.

This argument was rejected by the English court on the grounds that, as discussed above, although the specification provides directions to make a stent, it provides no data or other material suggesting that such a stent is in fact suitable for the treatment of restenosis. Consequently, in the view of the English courts, success in preventing restenosis was not a relevant consideration when assessing the obviousness of constructing such a stent upon which is a coating loaded with taxol and optimally other active ingredients as well.

As a result, the English court held that in this case obviousness would be established if, on balance, the evidence showed that the skilled man would consider taxol to be worth testing to see what its properties were.

In contrast, the Dutch courts concentrated on whether the skilled man would have chosen to use taxol, out of the 'vast array' of possible anti-proliferatives, in a drug-eluting stent. The court considered it particularly important that of all the substances listed in the prior art, only taxol and rapamycin had proved effective in drug-eluting stents in the prevention of restenosis.

The Dutch courts concluded that taxol, contrary to the other medicines suggested in the prior art, does have an unexpected effect in helping prevent restenosis. The use of taxol in this way was held to be not obvious.

Commercial Success

This was also raised by Angiotech in the English courts to try to overcome arguments of obviousness in respect of the patent, but it failed. It was accepted that to an extent the need for a stent which prevents restenosis was something that at the priority date of the patents was a 'long felt want'. However, on this occasion the commercial success of the resultant product did not mean that it was an idea worthy of patent protection. The judgment in the English High Court contains a detailed analysis of commercial success as a defence to claims of obviousness.[22] The failure here, though, was in most part due to the fact that this was not considered to be a simple invention which 'sprung' on to the market; rather it was the first past the post in what had been accepted as a complex problem for some time.

Conclusion

The courts in the different jurisdictions came to different conclusions but the reasons for this may not be related entirely to the different jurisdictions.

The primary difference appears to be the courts' decisions on what the patent teaches. The Dutch courts concluded that the patent was the only document which precisely specified the use of taxol in a drug eluting stent for the treatment and prevention of restenosis. Consequently, to invalidate the patent the Dutch courts required a precise pointer in the prior art to use taxol in this way. As none of the prior art, in combination with the common general knowledge contained this precise pointer, the patent was held to be non-obvious.

In coming to this conclusion, the Dutch courts decided that the patent was a patent by selection and that Angiotech had selected taxol out of a host of possible substances. The English courts, and the Court of Appeal in particular, disagreed with this patent by selection approach. They

18) *Tomlinson's Appn* (1966) 363 F 2d 298.

19) *Gobain v Fusion Provida* [2005] EWCA Civ 177.

20) Goff LJ in *Hickman v Andrews* [1983] RPC 147 at 189.

21) *Lilly Icos LLC v Pfizer Ltd* [2002] EWCA Civ 1.

22) The leading case in this area being *Haberman v Jackel International* [1999] FSR 683.

believed this approach to be based on the hindsight knowledge that taxol stents actually work. The English Court of Appeal stated that

> *… this is just what the skilled man would not know, even by reading the patent … The patent proposes many things … 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 likely to work in practice than any other anti-angiogenic.*

The English court assessed the patent based on the difference between the closest prior art and the inventive step and found that the disclosures in the patent were not, in fact, inventive. The English courts concluded that the use of anti-proliferatives in drug-eluting stents for the treatment of restenosis was known from a combination of the prior art and common general knowledge. The English courts' view, as a result of the lack of supporting evidence, was that the teaching in the patent was simply to specify a well-known anti-proliferative, taxol, to be used in this manner. Consequently '*the patent adds nothing to the knowledge of the skilled man. So the patentee has done nothing by his disclosure to deserve a monopoly*', and it was held that the patent was obvious.

In coming to their decision, the English courts considered scenarios where a monopoly might make sense, such as when an old or obvious idea takes a lot of work, expense and time to develop and turn into something practical and successful. The court noted that without the incentive of a monopoly people may not do that work or spend the time and money. However, the English court stated that it is not the court's job '*to uphold any claim to monopoly for an idea which requires investment and risk to bring to market*'. The court's job was to uphold monopolies only '*for ideas which are new, non-obvious and enabled*'.

It is understood that the SMT decision is under appeal in the Netherlands. We await this judgment to see if the Dutch Appeal Court will continue with the Dutch patent by selection method, or follow the English courts' approach.