Legal & Regulatory Update

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NOTES FROM THE EU

Court of Justice of the European Union to decide again on the patentability of embryonic stem cells

In its decision of 17 December 2009, the German Federal Court of Justice referred several questions regarding the patentability of embryonic stem cells to the Court of Justice of the European Union (formerly the European Court of Justice).

By way of background, a German scientist had a German patent protecting isolated and purified neural precursor cells, methods for their generation from embryonic stem cells and the use of the neural precursor cells to treat neural defects.

Greenpeace filed a complaint against this patent and requested it to be declared invalid due to violation of public order to the extent that the patent covers precursor cells, which are obtained from human embryonic stem cells.

The German Federal Patent Court upheld this complaint for the most part. The patentee appealed this decision to the German Federal Court of Justice. The German Federal Court of Justice stayed the proceedings and referred several questions to the Court of Justice of the European Union.

The German Federal Court of Justice arrived at the conclusion that the decision on the nullity action depended on whether the alleged invention is excluded from patent protection pursuant to the German Patent Act to the extent that precursor cells are concerned which are obtained from embryonic stem cells. The German Patent Act *inter alia* excludes from patent protection the use of human embryos for industrial or commercial purposes. This again depends on the interpretation of the European Directive 98/44/EC (Biotechnological Inventions Directive), which has been implemented into national law by means of this rule of exclusion.

Pursuant to the opinion of the German Federal Court of Justice, it is particularly relevant in these proceedings what 'human embryos' are within the meaning of the Directive. It is in particular relevant whether embryonic stem cells, which are obtained from embryos at the blastocystic stage, are to be regarded as 'embryos' as such stem cells do not have the ability to develop into a complete individual by that stage. Also, the question arises whether at least the blastocysts themselves, from which such stem cells are extracted, have to be regarded as human embryos within the meaning of the Directive. The decisive factor for this is whether the term 'embryo' covers all development stages of human life starting from the fertilisation of the egg cell, or whether a fertilised egg cell has to be regarded as an 'embryo' within the meaning of the Directive only when it reaches a later stage of development.

Furthermore, the German Federal Court of Justice felt it important to consider at what point one would talk about 'use for industrial or commercial purposes' for the purposes of the Directive and in particular whether any commercial utilisation, including use for research purposes, should be covered.

Finally, the German Federal Court of Justice is faced with the issue whether a 'use of embryos' within the meaning of the Directive requires the use of the embryos itself to be part of the technical teaching

claimed in the patent. This is relevant for the question of whether the exclusion rule also applies if the use of human embryos is not a part of the patent claim, but is a necessary requirement for it.

In this regard the European Patent Office (EPO) decided a short while ago in connection with the so-called 'WARF' patent that patent protection for products, which at the date of application could only be produced by a method that inevitably involves destroying human embryos, is excluded.

It remains to be seen whether the Court of Justice of the European Union will assume a similarly restrictive approach or whether it applies a broader interpretation to the exclusion of patentability of human embryos.

New block exemption for vertical agreements, such as distribution agreements

On 20 April 2010, the European Commission published its new block exemption regulation and guidelines for vertical agreements which will replace the existing regulation and the guidelines on 1 June 2010. The new rules will remain in force for 12 years, expiring on 31 May 2022. The proposed changes will have an effect on the legal treatment of vertical agreements in the EU.

The distribution rules in context

Article 101(1) of the Treaty on the Functioning of the European Union (TFEU) prohibits agreements, decisions of associations of undertakings and concerted practices that have as their object or effect the prevention, restriction or distortion of competition. Under Article 101(2) TFEU all such agreements are void. Article 101(3) TFEU provides that agreements, which meet specified criteria, may be exempt from the prohibition. A block exemption regulation defines a category of agreements that will normally meet these criteria for exemption. The current block exemption that covers vertical agreements (such as distribution agreements) is Regulation 2790/1999, which expires on 31 May 2010. (Existing agreements covered by the current block exemption will in any event continue such benefit under a transitional provision, until 31 May 2011).

How will the new rules affect distribution agreements?

It is expected that more distribution agreements will need individual examination but the changes mean more flexibility for designing the distribution system you want. However more in-depth analysis is needed to take advantage of the changes.

One of the Commission's themes in modernising these rules has been the greater importance of e-commerce/online sales as compared to the situation ten years ago. This is particularly important for products such as luxury goods. Another theme is to allow for potentially more lenient treatment of certain practices categorised as 'hardcore' restraints of competition, for example, resale price maintenance. Table 1 summarises the main changes and their effects.

European commission publishes updated clinical trials guidance

On 30 March 2010, the European Commission published updated guidance in relation to clinical trials.

The documents updated included the 'Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial' to the Clinical Trials Directive (2001/20/EC)[1] – this is the third version of this guidance document. The Commission has also updated 'The Guidance documents applying to clinical trials – Question & Answers Document' which is now the fifth version, and 'Annex VI to Guidance for the conduct of GCP inspections – Record keeping and archiving of documents'.

All of these revised documents are now available in Volume 10 of Eudralex on the European Commission's website.

Table 1: New block exemption for vertical agreements

Changes	*Summary*
Market shares	The 30 per cent market share threshold will in future apply to all parties to the agreement, that is, typically both the supplier and the buyer. By including this additional market share threshold for the buyer, the Commission has taken into account that some buyers on their own may have market power, which potentially has a negative effect on competition. Effect: fewer agreements will benefit directly from the block exemption leaving greater legal uncertainty for those that are subject to an individual analysis.
Resale price maintenance (RPM)	RPM will continue to be treated as a 'hardcore' (that is, serious) restriction, but the Commission accepts in its guidelines that in some cases RPM may lead to efficiencies (for example, when the manufacturer introduces a new product and where the RPM is supplier driven). Possible examples given are the following: use of RPM during the introductory period to induce distributors to take the manufacturer's interest in promoting the product into account; and a coordinated short term low price campaign in a franchise network; and use of RPM in a retail network to fund additional pre-sale services. Subject to demonstrating consumer benefits, such arguments may justify application of the exception under article 101(3) TFEU. Effect: this is a very important change of approach that may allow suppliers greater flexibility in operating a distribution system. However, it is necessary to tread carefully before (implicitly or explicitly) imposing RPM.
Selective distribution systems – I	The guidelines make clear that, under the block exemption the supplier may require quality standards for the use of the internet site to resell its goods, just as the supplier may require quality standards for a shop; for selling by catalogue or for advertising and promotion in general. The supplier may for instance require its distributors to have one or more bricks-and-mortar shops or showrooms as a condition for becoming a member of its distribution system. Effect: manufacturers may choose distributors on the basis of quality standards for presenting their products, whether online or otherwise. Hence, brand owners of luxury goods may refuse a distributor if it has no brick-and-mortar shop or showroom.
Selective distribution systems – II	As regards restrictions of sales by members of a selective distribution system to unauthorised distributors, on territories reserved by the supplier to operate the system whereas in Regulation 2790/1999 such focus was not included. Effect: no unlimited restriction on active or passive sales by the members of a selective distribution system to unauthorised distributors. It is only allowed if it relates to the territory where such selective distribution system is operated or to a territory, which has been reserved by the supplier to operate that system. Please note that the guidelines explain 'the territory reserved by the supplier to operate that system' as any territory where the system is operated or where the supplier does not yet sell the contract products. Therefore, the addition of the territories reserved by the supplier to operate the selective distribution system, will most likely not lead to any significant changes although the wording may indicate otherwise.
Online sales	Sales over the internet are in most instances categorised as permissible passive sales, which cannot be restricted, irrespective of the language used on the website. The guidelines have become much more explicit about online sales, making it clear that it would, for example, be an illegal restriction of passive sales to introduce automatic re-routing of customers to the manufacturer's or another distributor's website or to provide for termination of purchases if credit card data reveal that the customer is based outside the distributor's territory. Effect: the new block exemption and guidelines codify the Commission's strict approach, which is intended to safeguard online (passive) sales, particularly cross-border sales. Parties will therefore need to be careful in developing their policies as regards sales over the Internet.
Upfront access payments	Fees paid by distributors to obtain access to a supplier's distribution network may, in many cases, as explained in the guidelines, be covered by the block exemption, subject to the market share thresholds. Effect: this is a new category of agreements that are explicitly described as within the scope of the block exemption.
Category management	Agreements where a supplier takes responsibility for marketing a particular category of products sold by the distributor (including products of competing suppliers) will be covered by the block exemption, subject to the market share thresholds. Effect: this is a new category of agreements that are explicitly described as within the scope of the block exemption and is particularly important in the food and beverage sector. The rules may bring substantial opportunities for businesses who are contemplating moving into new markets, introducing new products or otherwise reshaping their reseller arrangements.

Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial.

The first revision of the 'Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial' was published in April 2004[2], and revision 2 followed in October 2005.[3]

The new version 3 therefore comes after a period of over four years and is a substantial rewrite of revision 2. This was required due to changes to the regulatory framework for pharmaceuticals and clinical trials in the European Union arising mainly as a consequence of the paediatrics legislation and the legislation on advanced therapies. This version of the guidance now helpfully lists what it does not apply to, that is it does not apply to medical devices, cosmetic products and food. In addition to the definitions in Directive 2001/20/EC, it also refers to other guidance documents for 'valuable additional definitions', so cannot be read in isolation. It also defines the Member State where the clinical trial is to be performed as 'Member State concerned'.

In terms of procedural aspects, there is now detail e.g. the time-lines for the Member State concerned to consider a request for authorisation of a clinical trial (as rapidly as possible and may not exceed 60 calendar days), and time-lines to be followed when an application is not considered valid.

The layout of the guidance has been completely updated with clearer labelling of the paragraphs, and has been expanded with increased direct reference to the relevant Articles in Directive 2001/20/EC.

Notification of amendment is only required if it is a 'substantial amendment', and the guidance now has sections headed 'the notion of "amendment"' and 'the notion of "substantial"' and gives examples of substantial amendments in relation to assessment by the national competent authorities of the Member State concerned (not the Ethics Committee, which is subject to separate guidance).

The summary tables which were at the end of version 2 of the guidance of the different national variations in requirements have been removed, which may indicate an increased level of harmonisation of requirements in the different Member States.

In line with these changes, the European Commission has also published a revised version of the clinical trials application form, which will become applicable in the course of the first half of 2010. It has been published on the website in advance to allow stakeholders time for preparation. A precise date for when the new version of the clinical trials form becomes applicable will be published on the Commission website soon.

CJEU holds that national public health authorities of Member States may lawfully offer incentives to doctors to prescribe certain medicines in preference to others

In its judgment of 22 April 2010 the Court of Justice of the European Union (CJEU, formerly the ECJ) rejected the recommendation of Advocate-General Jaaskinen, on 11 February 2010 in Case C-62/09, *The Queen, on the Application of the ABPI* v. *MHRA,* and held that Article 94(1) of Directive 2001/83/EC as amended (the Community Code relating to medicinal products), did not render unlawful financial incentive schemes implemented by the national public health authorities of Member States, such as that in issue here, that provided an incentive to doctors to prescribe certain medicines in preference to others in the same therapeutic class.

Article 94(1) provides that 'Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are

inexpensive and relevant to the practice of medicine or pharmacy' The ABPI had argued that Article 94(1) applied not only to commercial operators but also to the activities of Member States in organising and delivering health services and medical care, and that the incentive scheme in issue (operated by the English National Health Service, and which encouraged the use of a different, but cheaper medicinal product within the same therapeutic class) constituted 'promotion' within the meaning of the Article. The Advocate General had agreed with the ABPI and considered that Article 4(3) of the same Directive, which recognised the right of Member States to set prices for medicinal products or to decide on their inclusion in the scope of national health insurance schemes, did not provide Member States with a generalised exemption from the application of Article 94(1).

The CJEU disagreed, limiting the application of the Article to commercial promotion, and moreover held that Article 168(7) of the Treaty on the Functioning of the European Union (TFEU, formerly Article 152(7) TEC) preserved to Member States the right to organise their social security systems and in particular measures intended to govern the consumption of pharmaceutical products. It did however observe that by virtue of Directive 89/105/EEC such schemes should be transparent, based on objective criteria and not discriminate between national medicinal products and these from other Member States.

Life sciences patent litigation in the United Kingdom – A summary of calendar year 2009

2009 was an exceptionally active year in the English Patents Court, and this is reflected in the large number of cases at first instance in the life sciences sector concerning patent infringement and/or validity and in which judgment was given (Table 2). Five out of the 12 patents whose validity was attacked (another was not challenged as it had previously survived such attack in other proceedings) survived such challenge. Allegations of infringement succeeded in four out of the eight cases where this was in issue. However, in no case where both validity and infringement were in issue was the patent found both valid and infringed, with the result that in only three cases, where one or the other was not in issue, can the patentee have been said to have succeeded.

Three out of the six life sciences decisions of the English Patents Court in 2008 were the subject of appeals in 2009, and the other two appeals were from two of the first instance decisions in 2009 listed above (Table 3).

There are no pending appeals in any of these matters to what is now the Supreme Court.

UK Court of Appeal Judgment in *Eli Lilly* v. *Human Genome Sciences*

In its unanimous judgment delivered by Lord Justice Jacob on 9 February 2010, the Court of Appeal upheld the finding in the Patents Court by Mr Justice Kitchin that the UK designation of Human Genome Sciences (HGS) EP 0,939,804 ('the Patent') is invalid on the grounds of lack of industrial applicability. The judgment is noteworthy not only because of its importance to bioinformatics companies but also because its conclusion is the opposite of that reached by the EPO Technical Board of Appeal (TBA) on the same patent a few months earlier. Because of this, Lord Justice Jacob's judgment addresses at some length not only the substantive question of industrial applicability, but also key differences in approach between the English Courts and the EPO.

The Patent discloses the nucleotide and amino acid sequences of a novel member of tissue necrosis factor (TNF) ligand superfamily (a class of proteins which mediate in the immune response and the function each of which is the subject of much investigation), which HGS calls Neutrokine-α. By analysing the nucleotide sequence of a cDNA clone

Table 2: Summary of 2009 life science patent litigation

Date	*Parties*	*Subject matter*	*Judge*	*Infringed?*	*Valid?*
9/1/2009	*Corevalve Inc* v. *Edwards Lifesciences AG and anr*	Artificial heart valve EP 0 592 410	Prescott QC	No	Yes
16/1/2009	*Actavis UK Ltd* v. *Novartis AG*	Sustained release fluvastatin formulation EP 0 948 320	Warren J	Not applicable	No – All claims as to which independent validity asserted obvious (Upheld on appeal in 2010)
23/1/2009	*Laboratoires Almirall SA* v. *Boehringer Ingelheim International GmbH*	Combination aclidinium and B2 agonists EP 1 651 270 GB 2 419 819	HHJ Fysh	Not applicable	No × 2 – All claims obvious, claim 20 of 819 invalid as method of medical treatment
12/2/2009	*Ratiopharm (UK) Ltd* v. *Alza Corp and anr;* *Alza Corp and anr* v. *Sandoz Ltd*	Transdermal patches for administering fentanyl EP 1 381 352	Kitchin J	Yes	No – All claims anticipated (which could have been overcome by amendment) and obvious
03/3/2009	*Novartis AG* v. *Dexcel-Pharma*	Cyclosporin Formulation GB 2 222 770[4]	Arnold J	Yes	Not applicable
27/3/2009	*Scinopharm Taiwan Ltd* v. *Eli Lilly & Co*	Gemcitabine Process EP 0 577 303	Kitchin J	Not applicable	Yes
01/5/2009	*Wake Forest University and ors* v. *Smith & Nephew plc and anr*	Apparatus for promoting wound healing EP 0 620 720	Wyand QC	Yes – claims 1, 2, 4, 9, 13, 15, 16, 17, and 19	Partially, and subject to amendment – claims 1, 2 and 15 anticipated, claims 8, 9, 13 and 17 obvious (All claims held invalid on appeal in 2009)
15/5/2009	*Leo Pharma A/S and anr* v. *Sandoz Limited*	Crystalline hydrate of calcipotriol EP 0 679 154	Floyd J	Conceded	Yes (Upheld on appeal in 2009)
12/6/2009	*Edwards Lifesciences AG* v. *Cook Biotech Inc*	Artificial Heart Valve EP 1 255 510	Kitchin J	No	No – all claims obvious
16/6/2009	*Tate & Lyle Technology Ltd* v. *Roquette Freres*	Use of maltotritol to control the crystal structure of maltitol EP 0 905 138	Lewison J	Not applicable	No – only claim to have survived EPO opposition anticipated and to mere discovery
10/7/2009	*Novartis AG & anr* v. *Johnson & Johnson Medical Limited & anr*	Contact lens EP 0 819 258	Kitchin J	Yes – claims 8 & 11	No – all claims insufficient
29/7/2009	*Zeno Corporation & ors* v. *BSM-Bionic Solutions Management GmBH & anr*	Medical device EP 1 231 875	Lewison J	No	Yes
31/7/2009	*Occlutech GmbH* v. *AGA Medical Corp & anr*	Medical device	Mann J	No	Yes
28/8/2009	*Mölnlycke Health Care AB* v. *Wake Forest University and anr*	Apparatus for promoting wound healing EP 0 620 720[5]	Kitchin J	Not applicable	No – obvious, and protection extended
20/11/2009	*Teva* v. *Merck*	Ophthalmic formulations of timolol and dorzolamide for the treatment of glaucoma EP 0 509 752	Floyd J	Not applicable	No – obvious

Table 3: Summary of appeal in 2009

Date	*Parties*	*Subject matter*	*Judge upheld?*	*Infringed?*	*Valid?*
1/4/2009	*Napp Pharmaceutical Holdings Ltd* v. *Ratiopharm GmbH* *Napp Pharmaceutical Holdings Ltd* v. *Sandoz Ltd*	Pharmaceutical formulation – Oxycodone EP 0722730 B EP 1258246 B	No	Yes × 2, reversing judge	Yes × 2
2/7/2009	*Generics (UK) Ltd* v. *Daiichi Pharmaceutical Company & anr*	Pharmaceutical – Levofloxacin EP 0206283 & SPC	Yes	Not applicable	Yes
31/7/2009	*Wake Forest University and ors* v. *Smith & Nephew plc and anr*	Apparatus for promoting wound healing EP 0 620 720	Yes as to anticipation of claim 1, no as to obviousness of claims 4, 16 and 19	Not applicable	No, reversing judge on obviousness
17/11/2009	*Leo Pharma A/S and anr* v. *Sandoz Limited*	Crystalline hydrate of calcipotriol EP 0 679 154	Yes	Not applicable	Yes
18/12/2009	*Dr Reddy's Laboratories (UK) Limited* v. *Eli Lilly & Company*	Pharmaceutical – Olanzapine EP 0 454 436 B	Yes	Not applicable	Yes

using bioinformatics (sequence homology and comparison algorithms), HGS identified the sequence as corresponding to a new TNF ligand. Eli Lilly opposed the grant of the Patent in the European Patent Office and sought revocation of the UK designation in the Patents Court. In the Patents Court, Mr Justice Kitchin held on 31 July 2008 that the Patent is invalid on the grounds of lack of industrial applicability (Article 57 European Patent Convention) as well as lack of inventive step (Article 56 EPC) since each of the claimed inventions failed to make any technical contribution (as followed logically from the finding of lack of industrial applicability). The EPO Opposition Division held on 3 December 2008 that the Patent should be revoked on the grounds of extension of subject matter (Article 123(2) EPC) and lack of inventive step (Article 56 EPC).

Given the fact that the appeal from the EPO Opposition Division to the TBA could also dispose of the appeal from the Patents Court, the Court of Appeal was keen to ensure that the appeal to the TBA be dealt with before the hearing of the appeal pending before it. Because of this the Court of Appeal sought, and was accorded, acceleration of the appeal to the TBA. Both the decision of the TBA and the judgment of the Court of Appeal refer to this cooperation.

In the appeal to the TBA, HGS put forward slightly amended claims in their main request, limiting claim 1 to an 'isolated' polynucleotide (selected from a more limited group of sequences than in the Patent as granted) which encodes a Neutrokine-α polypeptide. Similar amendments were made to the claims covering recombinant vectors and to antibodies that bind to Neutrokine-α polypeptides. The TBA reviewed the disclosure of the Patent and previous decisions of the TBA in relation to Article 57 EPC. The TBA noted that the parties accepted that Neutrokine-α had been correctly identified as a new member of the TNF ligand superfamily in the Patent and that the key question was *whether this in itself suffices to suggest a practical way to exploit the claimed invention which is centred on Neutrokine-α, thereby providing 'an immediate concrete benefit'* in accordance with TBA decision T 898/05 (*Zymogenetics*). The TBA noted in particular a statement in the Patent that '*(l)ike other members of TNF*

family, Neutrokine-α exhibits activity on leukocytes including for example monocytes, lymphocytes and neutrophils. For this reason Neutrokine-α is active in directing the proliferation, differentiation and migration of these cell types'. The TBA decided that this information should not be taken as a mere theoretical or hypothetical assumption because *it is plausible and, secondly, there is ample post-published evidence on file confirming both the presence of Neutrokine-α on activated T-cells and its ability to co-stimulate T-cell proliferation (cf inter alia* Tables 1 and 2 *of the second declaration of Dr Kelsoe III …)*. This, together with other considerations, led the TBA to conclude that the Patent *provides a concrete technical basis for the skilled person to recognise a practical exploitation of the claimed invention in industry* and accordingly that the Patent fulfils the requirements of Article 57 EPC. In relation to the objections by Eli Lilly under (Article 123(2) EPC) and (Article 56 EPC), the TBA reversed the decision of the Opposition Division, thereby upholding the Patent and remitting it to the Opposition Division on the basis of the amended claims.

The English Court of Appeal, which heard the appeal just under 2 months after the hearing before the TBA, dealt only with the questions arising under Article 57 EPC as these were (as it turned out) dispositive of the appeal. As indicated above, because of the difference in its conclusion from that of the TBA, the Court was at pains to explain the differences in procedure in the English Courts and the EPO, mentioning differences in approaches to evidence and the final nature of Court proceedings in contrast to the 'administrative' nature of EPO proceedings. The Court also commended the cooperation between the Court and the EPO that led to the TBA decision being made available before the English appeal.

In his judgment, Lord Justice Jacob reviewed essentially the same disclosures in the Patent and the same TBA decisions relating to Article 57 EPC as the TBA. Although the same 'plausibility' test was applied to each of the postulated uses of Neutrokine-α (some of which as noted earlier by Mr Justice Kitchin contradicted others), Lord Justice Jacob concluded on the evidence before him (note that this included evidence given at first instance under cross-examination) that although the postulated uses were 'plausible' this was *miles away from being able to say that any particular use was plausible in the sense of being taken, by the reader, to be reasonably so. In reality one was faced with a research program to see which, if any, of the possible uses of the Neutrokine-α or its antagonists was real.*

Importantly, and as noted by Lord Justice Jacob, the Court did not consider any of the 'post-published evidence' put forward by HGS before the TBA. He said '*(i)t is surely axiomatic that whatever the standard for susceptibility to industrial application may be, the information about it must be in the patent (supplemented if necessary by the common general knowledge of the time). Otherwise you could satisfy the Art. 57 requirement by just identifying a compound in the patent and finding a use for it later. That would contravene, for example Art. 5(3) of the* [Biotechnological Inventions] *Directive* [which requires the industrial application of a gene sequence to be disclosed]. *You cannot have a patent for an invention when only years later you or someone else finds out what it is for. The same principle as applied in Johns Hopkins* [T 1329/04] *concerning obviousness must apply also to Art. 57*'. For this reason the Court did not consider the post-published Kelsoe evidence that so clearly influenced the TBA – in particular Table 1 of Kelsoe identified seven post-published scientific publications that confirm that Neutrokine-α is expressed in activated T-cells and Table 2 identified nine publications that confirmed that Neutrokine-α co-stimulates T-cells.

The decisions of the TBA and Court of Appeal, apart from reflecting differences in procedure, also perhaps reflect differences of legal approach: The TBA regarded the post-published scientific literature identified in the Kelsoe declaration as *confirmatory* of the postulated uses in the Patent whereas the Court of Appeal considered that such evidence

was not relevant at all. Second, the Court of Appeal appears to have applied the same standard of disclosure to Article 57 as that which applies to obviousness under Article 56, whereas the TBA is quite clear that the standard of disclosure required under Article 57 is the same as that which applies to sufficiency under Article 83. It remains to be seen whether the English case will go to the Supreme Court.

NOTES

1. Official Journal 2010/C 82/01-82/19 (30.03.2010).
2. ENTR/CT 1 Revision 1 April 2004.
3. ENTR/F2/BL D. (2003) CT 1 Revision 2 October 2005.
4. Previously in issue in *Novartis AG* v. *Ivax Pharmaceuticals UK Ltd* [2006] EWHC 2506, [2007] EWCA Civ 971.
5. Previously in issue in *Wake Forest University and ors* v. *Smith & Nephew plc and anr* [2009] EWHC 908, [2009] EWCA Civ 848.