Patents and plausibility

Paul England*

Grand enterprise

Perhaps in as little as five years from now the grand enterprise of converging patent law across the contracting Member States of the Unified Patent Court (UPC) should be well underway. When it is, one case may stand out from the authorities in England and Wales as having done more to make United Kingdom patent law compatible with the Technical Boards of Appeal (TBAs) of the European Patent Office (EPO) than any other. The extent to which British law has encompassed the principles in this case is shown by the cases in Table 1 and has become most apparent in the recent Court of Appeal decision in Regeneron Pharma, Inc & Bayer Pharma AG v Genentech Inc. 1 This appeal, concerns the infringement and validity of EP(UK) 1 238 986, which claimed human vascular endothelial growth factor (hVEGF) antagonists for the treatment of non-cancerous (non-neoplastic) diseases characterized by excessive blood vessel growth (angiogenesis). Bayer wanted to sell the VEGF-Trap product, developed by Regeneron, for age-related macular degeneration, but Floyd J upheld the patent which, he said, covered VEGF-Trap.

On appeal, it was argued that the claim that VEGF antagonists would be useful for preventing angiogenesis in the treatment of all non-neoplastic diseases was not plausible. Accordingly, it was submitted, for those diseases where it is not plausible, the patent could not solve any technical problem. Thus, if no technical problem is solved; there can be no invention. This argument was advanced as part of the appellants’ obviousness case. However, Kitchin LJ—as Floyd J had done at first instance—decided to treat the issue as an insufficiency argument:

[Floyd J] considered this argument covers the same ground as that raised by the insufficiency allegation and he dealt with it under that heading. I agree and shall do the same.

What is going on here? How can an argument put forward as part of an obviousness case be considered under the heading of insufficiency? The answer is the case alluded to above. It is AgrEvo/Triazole sulphonamides (T 939/92) 2 and the principle to which it gives rise: patentability requires a plausible technical contribution. This article traces the emergence of AgrEvo in British patent law to attempt to explain what is happening and its significance.

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This article

- The AgrEvo authority, as read in the light of the language of Johns Hopkins, crystallizes the principle that, to be patentable, claims must make a technical contribution which is at least plausible. In the European Patent Office (EPO), AgrEvo concerns obviousness and this is the context in which it first appears in the English authorities, in Conor Medsystems. Since then, plausibility of technical contribution has spread in application in English cases to selection inventions, industrial applicability and insufficiency.

- In five years, the requirement to provide a plausible technical contribution has in effect become a common denominator, or base-line, of patentability in English patent law. This is a widespread realignment of English principles with the case law of the Technical Board of Appeal (TBA). In the area of obviousness, lack of plausibility is also effectively an independent ground of attack that, if successful, by-passes the need to address obviousness in the orthodox manner. Similarly, a claim may now be held insufficient without the need to consider whether performing its disclosure requires an undue burden.

- The quick and widespread introduction of the EPO mindset that AgrEvo has brought with it may prove to be a matter of lasting importance as the project to converge patent law in the Unified Patent Court (UPC) begins.

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1 Regeneron Pharma, Inc & Bayer Pharma AG v Genentech Inc [2013] EWCA Civ 93 (joined actions), on appeal from Floyd J.
Origins

AgrEvo

AgrEvo concerns a product claim for a class of chemical compounds for use as herbicides. On appeal, the TBA held the patent sufficient because it was established that all of these compounds could be made. However, the TBA held that the patent was invalid for obviousness. It did so, first, on the finding that there was nothing inventive in making the compounds. Accordingly, such invention as there is must lie in the finding that the compounds have herbicidal properties. Secondly, the problem for the patentee was that the description contained nothing to justify the assertion that all the compounds claimed were herbicidal.\textsuperscript{3} The TBA held that there must be a technical effect (in this case, herbicidal properties), and this must not be ‘inherently unlikely’ in substantially all the compounds. Instead, it must be ‘reasonably predictable’, ‘fairly assumed’ or ‘credible’. Without a technical contribution, the technical problem of the prior art—identified for the purpose of the problem/solution approach—had not been solved and there could be no invention. The patent was invalid for obviousness.

Johns Hopkins

AgrEvo did not use the word ‘plausibility’ but, a decade later, in Factor-9/Johns Hopkins (T 1329/04),\textsuperscript{4} the threshold for demonstrating a technical contribution was reiterated and expressed in slightly different terms:

Johns Hopkins concerns the validity of claims to growth differentiating factor-9 (GDF-9), in particular polynucleotides encoding polypeptides having GDF-9 activity. The technical problem addressed by the patent application is the identification of a further member of the TGF-\beta superfamily, a group of polypeptide factors that regulate differentiation processes during embryogenesis. In the patent application, functions of members of the TGF-\beta superfamily are attributed to GDF-9 on the basis of amino acid sequence homology with the superfamily, but without any technical evidence of equivalent function. The question before the TBA in Johns Hopkins was how much weight could be given to these speculations when assessing inventive step according to the approach of AgrEvo described above. The TBA concluded:

The application does not sufficiently identify this factor as a member of this family ie that there is not enough evidence in the application to make at least plausible that a solution was found to the problem that was purportedly solved. [emphasis added]

The requirement in AgrEvo that the patent specification provides a ‘reasonably predictable’, ‘fairly assumed’ or ‘credible’ basis for the technical contribution in a class of compounds is thus, in Johns Hopkins, expressed as the need for the technical contribution to be ‘at least plausible’. It is the language of plausibility that has largely, though not exclusively, stuck.

Inventive step

The first time AgrEvo was applied at appeal level in the United Kingdom was in the House of Lords in Conor Medsystems Inc v Angiotech Pharma, Inc.\textsuperscript{5,6} The patent in suit in Conor Medsystems concerns stent technology used in the treatment of angiogenesis (is the excessive growth of small blood vessels that causes arteries to become constricted or ‘stenosed’). This condition can result in angina and heart failure. The problem can be alleviated to a certain extent by stents—small, tubular wire cages that are pushed into the blocked artery to hold it open. However, stents cannot prevent the further growth of tissue and associated blood vessels by angiogenesis in and around the structure of the stent itself. This growth causes further closing of the arteries—a problem called restenosis.

To solve the restenosis problem, Angiotech’s patent claimed the use of a stent covered in an anti-angiogenic factor, in particular taxol: one of a number of known drugs at the priority date of the patent that could prevent cell division and thus angiogenesis. Importantly, the patent did not contain any proof that the stent coated with taxol would actually work to treat restenosis. Conor thus sought revocation of the patent on the basis that it was obvious in the light of prior art, disclosing a drug-eluting stent for local delivery of ‘anti-replicate’ drugs that might reduce restenosis. At first instance,
Pumfrey J revoked the patent as obvious. This decision was upheld on appeal, where Jacob LJ stated:

Just to name one ‘other’ anti-replicate which, on the information given in the patent, is no more and no less likely to be found to work in practice is not to make an invention.

Given the lack of evidence in the patent that taxol would work, both Pumfrey J and the Court of Appeal said that the correct obviousness question to ask is whether it is obvious that taxol might work in the stent, not whether it would work. On appeal to the House of Lords, the argument was put along the same lines: because the patent did not show that taxol would actually work in reducing restenosis, it was nothing more than an idea that taxol might work—and ideas, as such, cannot form the basis of an invention. The Lords agreed that a patent must not be granted for an idea which is mere speculation, unsupported by any disclosure in the specification. However, that was not the case here: the claim did contain support for a claim to a taxol-coated stent to treat or prevent restenosis, even if there was no actual evidence of it having done so. Angiotech were therefore entitled to have the obviousness of the patent addressed on the assumption that taxol would work, providing that it was plausible. Having reviewed AgrEvo and Johns Hopkins, Lord Hoffmann said:

... I agree that the description, though offering a theory (its anti-angiogenic properties) as to why taxol would prevent restenosis, did not offer any evidence that this would turn out to be true. If it has not turned out to be true, the patent would have been insufficient. But there is in my opinion no reason as a matter of principle why, if a specification passes the threshold test of disclosing enough to make the invention plausible, the question of obviousness should be subject to a different test according to the amount of evidence which the patentee presents to justify a conclusion that his patent will work.

Lord Hoffmann thus resolves obviousness into a two stage process: (i) determine that the claimed invention is plausible; then (ii) determine whether that invention as claimed is obvious (according to the established approaches in UK law).

Selection inventions

The next appellate case to apply AgrEvo was Dr Reddy’s Laboratories (UK) v Eli Lilly & Co. The Court of Appeal had to decide whether Eli Lilly’s patent claiming the single compound olanzapine (Figure 1) was valid over a prior art specification claiming a novel class of thienobenzodiazepines. This class of compounds was disclosed in the prior art by means of a Markush formula (Figure 2).

Substituting all the options for R, R, Q and T given in the specification of the prior art document, the Markush formula in Figure 2 was estimated to cover some 10 compounds, including olanzapine. However, olanzapine was nowhere identified specifically in the earlier patent. The question thus arose as to whether the disclosure of olanzapine generically, in the Markush formula, anticipated the Eli Lilly patent for olanzapine alone.

Until Dr Reddy’s, the leading British case on selection inventions had been Du Pont’s Patent, decided by the House of Lords under the rules on ‘selection patents’ formulated in pre-1977 law (which applied before the implementation of the European Patent Convention (EPC) into English law by the Patents Act 1977). Dr Reddy’s thus provided the first occasion for the Court of Appeal to adjust the British approach to selection inventions post-1977. This new approach was described by Jacob LJ:

So I think the better approach is to see what the EPO Boards do when a patented product or class of products falls within a greater class. They deploy the objection of obviousness where the patentee has in truth made no real technical advance. (para 40)

The EPO jurisprudence is founded firmly around a fundamental question: has the patentee made a novel non-obvious technical advance and provided sufficient justification for it to be credible? That is the basis of all the reasoning—see eg [2.4.2] of AgrEvo. A ‘selection’ (by which I mean the later
In order to be patentable a selection of compounds must not be arbitrary. It must instead be justified by a hitherto unknown ‘technical advance’. This selection must also be ‘credible’ across the selected compounds. By reference to AgrEvo, it is submitted, these words are synonymous with ‘technical contribution’ and ‘plausible’ respectively.

Industrial applicability

Two years after Dr Reddy’s, the issue of plausibility and technical contribution again arose at appeal level, in Human Genome Sciences Inc (HGS) v Eli Lilly & Co. This case concerned a patent disclosing the amino acid and coding nucleotide sequence for a polypeptide called Neutrokine-α (a member of the tumour necrosis factor (TNF) superligand family). HGS’s scientists had determined the nucleotide sequence for the gene coding for Neutrokine-α and its amino acid sequence using a computational biological technique called bioinformatics: this meant that they had no experimental evidence of activity. They could only make assumptions about Neutrokine-α activity based on shared sequence homology with other members of the same superfamily. On this basis, Eli Lilly argued that the patent was invalid because it did not disclose an invention capable of industrial application and submitted that the identity of any receptor was unknown, as was any disease which the polypeptide might treat.

At issue were the industrial applicability requirements of Article 57 EPC, as well as the requirement of the Biotechnology Directive that the industrial application of a gene sequence be disclosed in the patent application. Given the dearth of British authorities on the application of Article 57 EPC, the case reached the Supreme Court which reviewed the TBA cases were reviewed, including Johns Hopkins:

- on its familiar problem/solution approach, and described ‘the problem to be solved . . . as isolating a further member of the TGF-β superfamily’, whose established members it described as ‘[having] influence on a wide variety of differentiation processes such as adipogenesis, myogenesis etc’. The Board went on to say that the patent’s claimed solution was the nucleotide sequence encoding for the claimed polypeptide, and described the issue as being ‘[w]hether or not the problem . . . has been plausibly solved’.12

In HGS Lord Neuberger summarized the TBA’s approach to Article 57 in relation to biological material, setting out a number of points of general principle. These included the need for the patent to disclose a ‘practical application’ and a ‘concrete benefit’ that is derivable from the description. But, he said, these must not be merely speculative. Instead — and this is at the heart of the ruling — the claimed use must be ‘reasonably credible’, an ‘educated guess’ or ‘plausible’. Lord Hope supports the plausibility threshold in reflecting on the decision of the Court of Appeal that was being reversed:

I think that there are indications in these passages that the standard which Jacob LJ was setting for susceptibility to industrial application was a more exacting one than that used by the TBA. He appears to have been looking for a description that showed that a particular use for the product had actually been demonstrated rather than that the product had plausibly been shown to be ‘usable’.

Insufficiency

A review of insufficiency brings the history of AgrEvo, technical contribution and plausibility in English law back to the Regeneron case discussed in the introduction. At first instance, Floyd J described the relevant element of the claimants’ obviousness case in Regeneron as follows:

The claimants also advance an obviousness case along the lines permitted by the decision of the Technical Board of Appeal in the Agrevo case: T 929/92. In substance they say that the claim that VEGF antagonists would be useful for preventing angiogenesis in the treatment of all non-neoplastic diseases was not plausible. Accordingly, in respect of those diseases for which it is implausible, the patent does not solve any technical problem. Indeed, they say that in fact the claim extends to diseases such as atherosclerosis for which the treatment would not work.13

As noted in the introduction, Kitchin LJ decided to treat AgrEvo as an insufficiency argument. In doing so, he first reiterated the accepted principles that apply to an insufficiency assessment, which include the following:

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12 Johns Hopkins, above, n 4.
13 Regeneron, above, n 1.
the scope of the monopoly, as defined in the claims, must correspond to the technical contribution the patentee has made to the art;

it is permissible to define an invention using general terms provided the patent discloses a principle of general application in the sense that it can reasonably be expected the invention will work with anything falling within the scope of these terms.

He added that it must be possible to make a reasonable prediction that the invention will work with substantially everything falling within the scope of the claim, or

... put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible.

If it is possible to make this prediction, the claim in question will not fail for insufficiency simply because it has not been demonstrated the invention works in every case. If it is not possible to make this prediction, said Kitchin LJ, or if it is shown that it is wrong, the scope of the monopoly will exceed the technical contribution the patentee made to the art and there will be insufficiency. Further:

It may also be invalid for obviousness, there being no invention in simply providing a class of products or methods which have no technically useful properties or purpose.

What the judge refers to here is the Agrevo/Johns Hopkins obviousness test: which is serving as a threshold of both obviousness and insufficiency.

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<th>Table 1</th>
<th>British cases referring to Agrevo and/or Johns Hopkins</th>
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<td>Case</td>
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<td>Raychem Corp.’s Patents [1998] RPC 31 (12 June 1997)</td>
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<td>Monsanto Company and Others v Merck &amp; Co Inc and Another [2000] RPC 709 (4 February 2000)</td>
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<td>Conor Medsystems Incorporated v Angiotech Pharmaceuticals Inc and Others [2008] UKHL 49 (9 July 2008)</td>
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<td>Novartis AG and Another v Johnson &amp; Johnson Medical Ltd and Another [2009] EWHC 1671 (Pat) (10 July 2009)</td>
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<td>Human Genome Sciences Inc v Eli Lilly and Company [2011] UKSC 51 (2 November 2011)</td>
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<td>Novartis AG v Generics (UK) Limited (trading as Mylan) [2012] EWCACiv 1623 (12 December 2012)</td>
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<td>Samsung Electronics Co Limited v Apple Retail UK Limited and Another [2013] EWHC 468 (Pat) (7 March 2013)</td>
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<td>Eli Lilly and Company v Janssen Alzheimer Immunotherapy [2013] EWHC 1737 (Pat) (25 June 2013)</td>
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A two-step approach to obviousness and sufficiency

In the light of Regeneron and the other cases discussed above, what is the status of plausibility in the assessment of obviousness and insufficiency, and other areas of
patent law? In the case of insufficiency and obviousness, the answer simply appears to be that the plausibility test adds a first, threshold, step that needs to be passed. As regards obviousness, this is clear from Lord Hoffmann’s application of the plausibility threshold to the invention of taxol-coated stents as a first step before going on to consider other obviousness criteria, in *Conor Medsystems*. In the context of insufficiency, a two-step approach is also adopted by Arnold J in *Eli Lilly v Alzheimer Immunotherapy*14 (see further below), in which he addresses plausibility as a first step in assessing insufficiency:

The first stage is to determine whether the disclosure of the Patent, read in the light of the common general knowledge of the skilled team, makes it plausible that the invention will work across the scope of the claim. If the disclosure does make it plausible, the second stage is to consider whether the later evidence establishes that in fact the invention cannot be performed across the scope of the claim without undue burden.

As a threshold test, the plausibility requirement does not remove the need to apply the traditional four-step, structured approach to obviousness set out in *Windsurfing*15 as modified by *Pozzoli*16 and any of the sub-tests that may additionally assist in determining whether an invention is obvious, for example, whether it is obvious-to-try or a workshop variation. This is manifest in *Conor Medsystems*, where Lord Hoffmann goes on to consider obviousness by reference to the conventional obvious to try approach, once plausibility has been established. Furthermore, as regards industrial applicability and selection inventions, the requirement of a plausible technical contribution is effectively the only step. As such, a plausible technical contribution is established as a threshold requirement, or ‘baseline’ of patentability, across these areas. This threshold is important because, if a claim fails to show a plausible technical contribution, it will be invalid without the need for further enquiry (see further below).

Figure 3 illustrates schematically the plausibility threshold across the areas of patentability discussed.

**Technical contribution and inventive concept**

In the TBA, the identification of the technical contribution is part and parcel of examining the inventive step, according to the problem/solution approach. As the reasoning in *AgrEvo* makes clear, if there is no technical contribution there can be no invention. This comes as a shock to practitioners in the UK where the courts do not largely restrict themselves to the problem/solution approach in the same way as the EPO, and do not have the same technical contribution-focused mind set. Instead, they tend to address the idea of inventive concept. But is

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14 *Eli Lilly v Alzheimer Immunotherapy* [2013] EWHC 1737 (Pat).
16 *Pozzoli Spa v BDMO Spa and another* [2007] EWCA Civ 588, which is (1) (a) identify the notional person skilled in the art, (b) identify the relevant common general knowledge of that person; (2) identify the inventive concept of the claim in question or if that cannot readily be done, construe it; (3) identify what, if any, differences exist between the matter cited as forming part of the ‘state of the art’ and the inventive concept of the claim or the claim as construed; (4) viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?
there a difference? The answer is that there is a difference:

We know from, for example, the TBA in Fuel Oils/Exxon\(^{17}\) that the inventive concept and the technical contribution must be co-extensive across the claim:

... the claims must be supported by the description, in other words it is the definition of the invention in the claims that needs support. In the Board's judgment, this requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified...

The claimed invention must be enabled across its breadth, and the claim scope must correspond to the technical contribution. This is also expressed in AgrEvo:

... it has for long been a generally accepted legal principle that the extent of the patent monopoly should correspond to and be justified by the technical contribution to the art\(^{18}\).

However, AgrEvo continues by adding that the invention must also extend across the claim scope:

Now, whereas... this general legal principle was applied in relation to the extent of the patent protection that was justified by reference to the requirements of Articles 83 and 84 EPC, the same legal principle also governs the decision that is required to be made under Article 56 EPC, for everything falling within a valid claim has to be inventive. If this is not the case, the claim must be amended so as to exclude obvious subject-matter in order to justify the monopoly...

In most cases, therefore, technical contribution and inventive concept may appear to refer essentially to the same thing. However, this is not quite the case, as is explained in Generics (UK) Limited and others v H Lundbeck A/S\(^{20}\) in the House of Lords. Lundbeck was concerned with a claim to the (+) enantiomer compound called escitalopram even though escitalopram was held to be an obvious ‘known desideratum’ and the claim was inventive because the process for making it is inventive. However, escitalopram was worthy of patent protection per se: since it was now possible to make it for the first time, the invention made a technical contribution. In coming to this decision, the Lords thus drew a distinction between the invention (the method of making escitalopram) and the technical contribution—escitalopram itself. Said Lord Walker:

During the oral argument before your Lordships there was some discussion of whether ‘inventive concept’ means the same as ‘technical contribution to the art.’ Neither expression is a statutory term of art. Lord Hoffmann used both expressions several times in his opinion in Biogen, ... Mr Thorley QC submitted in his reply that the two expressions (as used in Lord Hoffmann’s opinion) are synonymous.

I do not think that this is quite right. The expressions are certainly connected, but I do not think it is helpful (either in considering Lord Hoffmann’s opinion, or generally) to treat them as having precisely the same meaning. ‘Inventive concept’ is concerned with the identification of the core (or kernel, or essence) of the invention—the idea or principle, of more or less general application\(^{21}\) which entitles the inventor’s achievement to be called inventive. The invention’s technical contribution to the art is concerned with the evaluation of its inventive concept—how far forward has it carried the state of the art? The inventive concept and the technical contribution may command equal respect but that will not always be the case.

Although it is difficult to picture, what Lord Walker appears to say is that a patentable invention has two aspects: a connective notion or idea (the inventive concept) and a tangible manifestation, or product, of that idea (the technical contribution). That there are two aspects is evident from the fact that they are not always to be found in exactly the same place, as Lundbeck illustrates. In Lundbeck, the invention is in the method, found in the patent description, and the technical contribution is in the product, found in the patent claims. Other cases, such as HGS, illustrate that the technical contribution may instead be found in the purpose of the sequences, as described in the description.

A patent requires both aspects, which is why the presence of both must be tested. AgrEvo and Johns Hopkins tell us to look for the technical contribution and ask whether it is plausible. Once the technical contribution has been established, it must still be tested for inventive step/non-obviousness. This is why the traditional obviousness assessment is required as a second step. The technical contribution must also be sufficient, which is why this must also be tested as a second step. However, it is submitted that the fact that technical contribution has appeared as a first stage in both, is not really a reflection of the fact that it shares any particular relationship with those headings of validity. Technical contribution is
actually better thought of as an independent requirement of patentability in itself, which is dealt with at the same time as one or other of those considerations as a matter of convenience. It just happens to be convenient to deal with technical contribution together with obviousness in the EPO, because of the problem/solution approach. UK law is not steeped in this approach and so it should not be surprising that the plausibility of the technical contribution should be dealt with, on occasion, under the sufficiency heading.

Once the plausible technical contribution step had been introduced into English law by the House of Lords, the way was been opened for the courts to explore the application of the concept freely and quickly, including those other areas of TBA law in which it is found such as industrial applicability and selection inventions. There is no reason of principle why it should not be asked whether there is a plausible technical contribution during a discussion of novelty, other than the likelihood that this would cause considerable confusion.

Plausibility and post-dated evidence

The swift proliferation of the plausible technical contribution enquiry into English law has practical implications too, particularly regarding evidence:

The role of post-published evidence in a plausibility finding is reviewed by the Court of Appeal in Generics (UK) Limited t/a Mylan v Yeda Research and Development Co Ltd.22 Starting from the proposition that, in general, evidence may be deployed if it is relevant to a matter properly in issue between the parties, Floyd LJ provides a list of reasons why, under Article 56, it is relevant to ask whether the alleged technical contribution has been made. These reasons include the principle that the problem/solution approach to assessing obviousness under Article 56 encapsulates and promotes the need for the patentee’s monopoly to be justified by a contribution to the art:

It would be a surprising result if the effect of applying this approach was that a monopoly could be justified by reference to an alleged contribution which could be demonstrated not to exist in fact.

Therefore, while evidence that is relied on to show that the invention was an obvious step for the skilled person to take must be evidence that was available to the skilled person at the time, demonstrating that there is a technical contribution is a different, underlying question:

... in order to determine whether an invention is obvious at the priority date one needs to decide an anterior, and purely factual question: what is the invention?

The Court of Appeal does not deal with the similar question of whether post-priority evidence is admissible to attack a technical contribution in the context of insufficiency. However, Arnold J had addressed this question in Eli Lilly v Alzheimer Immunotherapy only days before. Eli Lilly concerns Janssen’s patent EP (UK) 1 994 937 for the prevention and treatment of amyloidogenic disease (a cause of Alzheimer’s disease). Eli Lilly sought an order for revocation of the patent and also a declaration of non-infringement regarding their pharmaceutical compositions comprising the antibody solanezumab; in phase III testing at the time. The patent was attacked on the grounds of added matter, lack of novelty, obviousness and insufficiency. The issue of plausibility was, as in Regeneron, argued before him under the head of obviousness, but it was again dealt with by the judge as a matter of sufficiency.

On this ground, Arnold J found the patent invalid. He held that, although post-dated evidence cannot be used to support a finding of sufficiency for a patent that is implausible as at the priority date,23 it is well established that it is permissible for a party attacking the validity of a patent to rely on post-priority evidence to attack sufficiency. The judge derives support for this from Kitchin LJ in Regeneron: ‘if it is shown the prediction is wrong and the invention does not work with substantially all the products or methods falling within the scope of the claim then ... the claim will be insufficient’.

The effect is that a claim that is found implausible at the priority date may not be rescued using post-priority evidence. But, a claim that is found plausible at the priority date may not be rescued using post-priority evidence (see Table 2). The effect of these decisions is again to distinguish plausibility as a separate ground of attack to obviousness and insufficiency, but it also means that parties now need to consider whether they can be assisted in an implausibility attack by post-dated evidence, a consideration that has implications for disclosure outside the four year window.

All-conquering AgrEvo

The AgrEvo authority, as read in the light of the language of Johns Hopkins, crystallizes the principle that, to be patentable, claims must make a technical contribution
which is at least plausible. In a class claim, the technical contribution must be plausible across substantially all the claim. In the EPO, these authorities concern obviousness assessments: if a claim to a technical problem is not plausible, the claim is obvious. It is in this context that the case first has an impact to a significant degree in the British authorities, in *Conor Medsystems*. Since then, the issue of plausibility of the technical contribution has spread in application to selection inventions and insufficiency at Court of Appeal level and to industrial applicability in the Supreme Court.

In five years, the requirement to provide a plausible technical contribution has in effect become a common denominator, or base-line, of patentability in the patent law of the UK. This is significant, because the application of the plausibility threshold in this way is not merely a new way of expressing what the law was already perceived to be. It has instead caused a widespread realignment of UK principles with the case law of the TBA. This is most evident in the area of industrial applicability and selection inventions. The threshold of industrial applicability may actually have been lowered as a result, and a new test is now applied to the patentability of claims that select from previously disclosed classes.

In the area of obviousness, lack of plausibility is effectively an independent ground of attack that, if successful, completely by-passes the need to address obviousness in the orthodox manner. Similarly, a claim may be held insufficient without the need to consider whether performing its disclosure requires an undue burden. It could be said that none of this is actually new: the requirement of technical contribution is merely another name for the requirement of industrial applicability, but by another name. However, this would be to ignore the bigger picture: the *AgrEvo* authority is rooted in the problem/solution mindset. Its widespread application, with an increased focus on technical contribution, must inevitably bring a TBA mindset with it. It is the quick and widespread introduction of this mindset that may prove to be the lasting matter of importance as the impact of the UPC unfolds—English patent law has very quickly become a lot more accommodating to the approaches of the EPO.

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**Table 2 Application of post-dated evidence in obviousness and insufficiency assessments**

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<th>Obviousness</th>
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26 To the extent, as least, that the Supreme Court found the claims in question to have the requisite industrial applicability when the Court of Appeal and Patents Court had not.