

UK patents review

2004

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The Courts continue to seek a balance between a literal and functional interpretation of claims in accordance with the Protocol. Whilst purposive construction continues to be applied, the Courts will seek to limit claims to that which a skilled reader would be “reasonably confident” was intended by the patentee.

Construction and infringement



If our law has reached the stage where experiments and extensive expert evidence is admissible to aid in construing patents, then it suggests that something has gone wrong.

Laddie J, Merck v Generics (UK)



Scope of claim not based upon inventive contribution made – skilled reader must be “reasonably confident” variant falls within its scope.

The case of *Merck v Generics (UK)* provides a comprehensive review of the rules of construction and the Protocol Questions and Improver Questions - see also the case of *Pharmacia v Merck* reported in our UK Patents Reviews 2001 and 2002. Commenting upon the extensive experiments carried out for the purposes of determining the sole issue of construction, Laddie J expressed alarm both at the conduct of the litigation (see below) and the approach to determining construction adopted by the Courts - “one can stand back and think how Courts construe other documents, such as contracts, deeds and wills. It is doubtful that in any of them would it be appropriate to have expert evidence of the breadth and complexity of the evidence served here. A patent is a document written by the patentee for publication to the world at large and is designed not only to set out clearly what the invention is but to describe the monopoly sought in unambiguous terms. It is supposed to be comprehensible to members of the relevant trade simply on reading. If our law has reached the stage where experiments and extensive expert evidence is admissible to aid in construing patents, then it suggests that something has gone wrong”.

The case concerned Merck’s patented process for the production of alendronate for the treatment of osteoporosis. The Defendant also employed a process for the production of alendronate that differed in many respects from the patented process. The Claimant argued that the differences were immaterial variants that clearly were intended to be covered by the patent and thus infringed.

The Judge re-visited the fundamental principles of the drafting of patent specifications and claims - "the drafting of a specification and claim has to be considered against the background that no-one is forced to apply for a patent or to seek as wide protection as possible. The patentee can be taken to be aware of the fact that there is always a balance to be achieved between width of protection and validity. It is up to the patentee to choose the level of risk he wishes to run". A patentee can choose language as wide or as narrow as he likes and this was stated to be particularly easy when scientific language is employed. For the patent system to work fairly, the reader of the patent must be able to understand clearly the limits of the prohibited field. He should not need to carry out experiments to determine the width of the monopoly and Laddie J directed that in future actions the Court's informed consent to such experiments be obtained in advance (see below).

The Protocol on Interpretation of Article 69 of the Convention requires that a balance be struck combining "fair protection for the patentee" and "a reasonable degree of certainty for third parties". The Claimant submitted that the requirement for fairness meant that the Court should give as much protection as it felt was justified having regard to the inventive contribution made by the patentee. This submission was rejected - "the Courts are not a branch of social services whose job it is to help the infirm or the unwise and the Protocol does not require them to be so. There is no cannon of construction which would justify the Courts in granting a patentee more protection than that which, objectively assessed, he indicated he wanted. Indeed, to do so would not be "fair" to the patentee. It could expose them to a greater risk of invalidity than he was prepared to shoulder". Laddie J stated that the monopoly of a patent should only cover those embodiments which the skilled reader would conclude, with "reasonable confidence", the inventor wanted to cover.

Laddie J considered that the approach of "reasonable confidence" was consistent with the Improver Questions and proceeded to analyse the same. The First Improver Question, whether the variant had a

material effect on the way the invention worked, was generally not in dispute. The Second Improver Question required a different test to the test of obviousness to invalidate a patent over published prior art. To invalidate a patent one merely needed to demonstrate that the skilled reader of the prior art found the prospects of achieving the desired results sufficiently encouraging to warrant trying it out. When one was attempting to broaden the patent monopoly to cover variants which were not within the contextual meaning of the claims, however, a higher degree of confidence of success must be involved - "the reader must have little or no doubt that the variant will, not may, work in the same way to produce the same results". The Third Improver Question would be answered using the approach of "reasonable confidence" mentioned above.

On the facts, the Defendant's process was found not to infringe whether following the direct route of the Protocol Questions or the structured approach of the Improver Questions.

Defence under section 60(5)(d) of the Patents Act 1977 that ship temporarily in jurisdiction not dependent on frequency of visits

Section 60(5)(d) of the Patents Act 1977 provides that a patent is not infringed by the use of otherwise infringing products on ships that have "temporarily" or accidentally entered the internal or territorial waters of the United Kingdom. The Court of Appeal has upheld the first instance decision in *Stena Rederi v Irish Ferries*, confirming that a defence to patent infringement based upon section 60(5)(d) of the Patents Act 1977 does not depend upon the frequency of the visits. The Defendant operated a ferry (the "*Jonathan Swift*") which sailed between Dublin and Holyhead. The Defendant's vessel was found to comprise a super structure falling within the scope of Stena's claims. Irish Ferries asserted that they did

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It is up to the patentee to choose the level of risk he wishes to run.

Laddie J, Merck v Generics (UK)

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Whether a vessel visits temporarily cannot in this context depend on frequency.

Munby J, Stena Rederi v Irish Ferries



not infringe the patent by virtue of section 60(5)(d) of the Patents Act 1977. Stena argued that this defence was not available to Irish Ferries by virtue of the regularity and frequency of the visits of the *Jonathan Swift* to the United Kingdom. The Court of Appeal held that the word “temporarily” should be construed as “transient” or “for a limited period of time” and whether a vessel visited the United Kingdom temporarily could not depend on frequency. Accordingly, there was no infringement.

A device “for” a process is a device “suitable for” that process and capable of working as such for a significant part of its operation

The case of *Rockwater v Coflexip* was noteworthy for a number of reasons. In the first place, Laddie J reversed an earlier finding of validity of the patent-in-suit given by himself in the case of *Coflexip v Stolt* (- see our UK Patents Review 2001 and below). In addition, a number of interesting points on construction arose.

The case concerned alleged infringement by Rockwater of Coflexip’s patent for the laying of flexible pipes and conduits on the seabed. The patent required “a tensioning means comprising the last means for guiding the flexible conduit” on board the ship. Laddie J proceeded to construe a number of these terms in order to assess the issue of infringement.

The word “comprising” was mandatory and did not equate to “capable of comprising”. The word “means”, one of the most frequently used in patent specifications, was not limited, but was used to encompass anything capable of carrying out a specified function. It thus covered any structure for guiding a flexible pipe. The term “guiding” required an element of lateral force. Laddie J cited an example discussed during the trial “if a man and woman walked down a straight road while holding hands, neither is guiding the other. If the man gently pushes the woman in a different direction, he is

guiding her. He is applying a lateral force to ensure that she takes another direction. As Mr. Miller argues, if a pipe is hanging vertically in water and it passes through a hole in a plate, it is not, *in that condition*, being guided by the edge of the plate. Furthermore, if the pipe just touches the edge of the plate but there is no lateral force applied by the one to the other, again, *in that condition*, the pipe is not being guided. On the other hand, if the edge of the plate applies force to the side of the pipe so as to alter its direction, *in that condition* it is guiding”.

Perhaps of the most interest, however, was the Judge’s construction of the term “for”. Whilst at first instance in the case of *Coflexip v Stolt*, Laddie J had held that a “device for operating a process” meant “a device which was operating the process”. The Court of Appeal in that case disagreed with Laddie J’s interpretation and the Judge had the opportunity to follow the Court of Appeal’s construction in the present case. A means “for” guiding was thus interpreted as being a means “suitable for” guiding, and which was capable of working for a “significant” part of its operation. This is consistent with the case of *Lilly v Pfizer* (see our UK Patents Review 2001) where it was held that an apparatus “suitable” for a purpose, must be capable of being effective for that purpose.

Thus there appears to be a distinction between “product by process” claims and “product for process” claims. In the former, the process features are limiting - thus a product produced by a different process would not be infringing (see *Kirin Amgen v Roche* in our UK Patents Review 2003). On the other hand, with “product for process” claims, the process features are not limiting, subject to the conditions stated above. This is also consistent with the decisions in 2003 of *Vericore v Vetrephearm* and *SmithKline Beecham v Apotex*. In the latter case, Pumfrey J commented “that part of the claim introduced by the word “for” is merely a statement of the effect of operating the claimed process (i.e. that the process is suitable for attaining the specified result) and is descriptive rather than limiting. Such phrases rarely, if ever, operate as limitations upon the claim, and cannot normally add novelty except in the case of “Swiss-form” claims”.

Purposive construction continues to be applied

Purposive construction in accordance with the Protocol continues to be applied in the English Courts. For example, in the case of *SEB v De'Longhi*, the Court of Appeal upheld the Judge at the first instance's construction of the term "closed". The patent-in-suit, directed to deep-fat fryers, required the air filled space between the vessel and the skirt to be closed to prevent the escape of hot air. The Court of Appeal could not find fault with the Judge's approach to the question of construction of the term, which needed to be construed in its context and having regard to the function which it is intended to perform - "the word "closed" is used in the claim to distinguish the prior art and to prevent the risk of burning. Both sides accept that it does not connote that there should be hermetic sealing. We are of the opinion that the Judge was right in para 27 of the Judgment to answer the question "how closed?" with the answer "closed enough practically to prevent connection between the skirt and the vessel and the consequence escape of hot air, with the associated risk of burning". We believe that as a practical matter third parties are left in no uncertainty".

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The word "for" is merely a statement of the effect of operating the claimed process and is descriptive rather than limiting.

*Pumfrey J, SmithKline
Beecham v Apotex*

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In the light of seemingly conflicting decisions last year, there is still uncertainty regarding the level of experimentation a skilled reader may employ in departing from the teaching of the cited prior art, and yet still anticipate the patent.

Patentability and validity



The patent system does not confer monopolies on those who develop obvious or old products.

Jacob J, Teva v Instituto Gentili & Merck



Dosing regimes unpatentable as methods of medical treatment

In our UK Patents Review 2001 we reported the Court of Appeal decision in *Bristol-Myers Squibb v Baker Norton*. In that case it was held that the patent for a dosing regime, whilst disguised as a second medical use claim by being drafted in “Swiss form”, was unpatentable as a method of treatment under section 4(2) of the Patents Act 1977.

Similar considerations arose in 2003 in the case of *Teva v Instituto Gentili & Merck*. The patent-in-suit related to the use of alendronate for inhibiting bone resorption for treating osteoporosis. The use of alendronate for inhibition of bone resorption was known in the art and the claim, drafted in Swiss form, required administration of alendronate “in a unit dosage form which comprises about 70mg of alendronic acid or a pharmaceutically acceptable salt thereof, or alendronic acid active weight basis, according to a continuous schedule having a dosing interval of once-weekly”. The invention derived from the knowledge that patients receiving a dose of 70mg once a week would suffer less gastrointestinal adverse events than patients receiving 10mg once a day.

Jacob J expressed his reluctance at being bound by the decision in *Bristol-Myers Squibb v Baker Norton* and the necessary finding of invalidity therefore since the patent was directed to a method of medical treatment incapable of industrial application pursuant to section 4(2) of the Patents Act 1977. The Judge stated “I accordingly hold both patents invalid. I do so with some regret. Merck have only had a few years’ exclusive exploitation of alendronate. They must surely have had to make a very considerable investment and incurred considerable risk in bringing it to market and mankind is better off as a result. But the patent system does not confer monopolies on those who develop obvious or old products, even if they have never been exploited. A workable system for that might be a good idea, particularly in medicine and analogous fields”.

The Court of Appeal later in the year upheld Jacob J’s judgment for the same reasons although noted that the patentee had reserved the right to contend elsewhere that the decision in *Bristol-Myers Squibb v Baker Norton* had been wrongly decided.

Less risk of a Court failing to adopt the mantle of the skilled person when assessing obviousness from common general knowledge

In an assessment of obviousness, the Court will frequently adopt the guidance set out in the case of *Windsurfing v Tabur Marine*. The second step in the *Windsurfing* approach requires that the Court adopt the mantle of the skilled addressee of the patent-in-suit. In appealing the first instance decision in the case of *SEB v De'Longhi*, the applicant argued that the Judge had failed to adopt the mantle of the skilled addressee and cited the relevant paragraph of the judgment, "when obviousness in the light of the common general knowledge is concerned, the risks of failing to look at the problem through the eyes of the skilled person are perhaps diminished. There is no clearly defined starting point in the sense of a single publication". Counsel for the Respondent submitted that these remarks were merely judicial comment that the Court may be less likely to fail to remember to look at the problem through the eyes of the skilled person in a case where the Court is looking to see if the invention is obvious in the light of the common general knowledge. The Court of Appeal agreed with these submissions and dismissed the appeal finding that the Judge had followed the *Windsurfing* approach, including the second step, in any event.

Test for novelty not whether two inventors have "in substance" reached the same invention

In the case of *Synthon v SmithKline Beecham*, the Court of Appeal gave consideration to the test for novelty and the requirement that there be an "enabling disclosure" in the cited prior art

to anticipate a patent as derived from the authoritative cases of *General Tire, Union Carbide, Hills v Evans* and *Asahi Kasei*. The Court of Appeal in particular considered "the amount of deviation allowed by the skilled reader" in departing from the teaching of the prior art whilst still anticipating the patent.

The patent in-suit related to a pharmaceutical product (referred to as PMS) and a process for producing the same in crystalline form. Synthon started proceedings seeking revocation of the patent asserting it lacked novelty over their unpublished patent application. Section 2(3) of the Patents Act 1977 provides that unpublished patent applications may form part of the state of the art for the purposes of an attack based on lack of novelty – such unpublished applications may not, however, form the basis of an attack for lack of inventive step (see section 3 of the Patents Act 1977). Synthon's unpublished application related to a very wide range of compounds, including PMS. The only mention of PMS in crystalline form, however, was in one example in the application. Experiments in the case demonstrated that the example was not repeatable so as to obtain crystalline PMS of the form claimed in SmithKline Beecham's patent.

At first instance, Jacob J held that two inventors had disclosed the same invention at the same level of generality and that the patent was therefore lacking novelty. SmithKline Beecham appealed.

The Court of Appeal allowed the appeal. The Court stated that the Judge had incorrectly applied the law on novelty – "the test is not whether the two inventors have in substance reached the same invention. The comparison is between the claimed invention and the disclosure to decide whether in fact, not in substance, the disclosure makes the claimed invention available to the public". The Judge was wrong to take "a broad view" of the disclosed content of the earlier application and to consider the issue at a level of generality that entailed ignoring "the slightest of differences" between the cited prior art and the patent in-suit. There was



When obviousness in the light of the common general knowledge is concerned, the risks of failing to look at the problem through the eyes of the skilled person are perhaps diminished.

Pumfrey J, SEB v De' Longhi



no room for a different approach to novelty in Section 2(3) cases to Section 2(1) cases and there was therefore no legal basis for the Judge's conclusion.

The test for novelty is well established in case law including the requirement set out in *General Tire* for "clear and unmistakable directions". The crucial question is not whether the skilled reader would expect success from a modification to the process disclosed – rather there is a need for a clear and unmistakable disclosure in the prior art. On the facts the Synthon application provided no such clear and unmistakable directions to make PMS in the form claimed in the patent. The general teaching of the Synthon application did not mention PMS and it was only one of a number of compounds that were described by reference to formulae. The only specific reference was in an example that was unable to be repeated and that produced a different form of PMS. The first instance decision was thus set aside and the claim for revocation dismissed.

Use of ordinary skill in solving known problem without undue effort – the boundary between novelty, inventive step and sufficiency

The case of *Synthon v SmithKline Beecham* referred to above does not, however, entirely accord with the decision in *SmithKline Beecham v Apotex*, which also considered the test for novelty, on the grounds of the invention being an "inevitable result" of following the instructions in the prior art.

Pumfrey J stated that he considered the case of *Synthon v SmithKline Beecham* to be merely a particular application of the general principles of *General Tire* and not to establish any novel proposition. This perhaps explains why the two cases do not sit happily together. Pumfrey J cited the Court of Appeal decision in *SmithKline Beecham v BASF* which rejected the

contention that the test for anticipation by a document in "inevitable result" cases was the same test as the "enabling disclosure" test for establishing sufficiency.

In cases where a skilled man is set a particular problem, such as repeating an experiment, and where this could be done in a number of ways, often one particular solution claimed in a patent will be alleged to be both anticipated and obvious. In *SmithKline Beecham v Apotex*, the Court stated that when considering such cases where the objections lie on the boundary between obviousness and anticipation, and where some of the solutions to the problem fell within the scope of the claim, then the claim should be held to be invalid. On the one hand the claim would be obvious – not as a whole, but rather in the particular techniques employed to perform the experiment. In addition, however, the claim may be anticipated, depending upon the level of experimentation required. In considering the level of experimentation that a skilled reader could perform whilst still anticipating the patent, the Court of Appeal in the *BASF* decision had commented that the alterations in that case had gone further than replication by a skilled addressee of the disclosure in the prior art example using his "ordinary skills". There were also no "clear and unmistakable directions" as required by *General Tire*. Pumfrey J inferred from the *BASF* decision of Aldous LJ that had the alterations not gone "further than replication by a skilled addressee of the disclosure in example 1 using his ordinary skills" that there would have been anticipation.

Accordingly if, and it appears only if, one is dealing with a case where the skilled man is told what he is aiming for, and if in aiming for that objective he adjusts experimental conditions in a manner contemplated by the specification and with the normal exercise of skill and without undue effort, such adjustments are permissible and the specification will be an enabling disclosure and anticipate.

Supplementary Protection Certificates for combination drug therapies are only available if the combination is protected by a basic product patent in force.

Supplementary Protection Certificates

Combinations required to be protected by a basic product patent

It is possible in certain circumstances in effect to extend the duration of patent protection for a medicinal product for a period of up to 5 years by applying for a supplementary protection certificate (SPC). The aim of an SPC is to compensate the patent owner for the time lost, in terms of patent protection, in conducting lengthy clinical trials and obtaining a marketing authorisation. The SPC takes effect on the expiry of the basic product patent and may be granted for a patented active ingredient or under certain circumstances a mixture of active ingredients (combination therapy).

In the case of *Takeda v Comptroller General of the Patent Office*, the Court rejected an application for an SPC for a combination drug therapy where only a basic product patent covering one active ingredient existed.

Takeda owned two patents for the compound lansoprazole for use in the treatment of upper gastrointestinal tract infections. Takeda also had a product licence for lansoprazole, when used in combination with certain antibiotics. Takeda applied to the Patent Office for an SPC covering the combination of lansoprazole and an antibiotic compound. The Patent Office refused to grant the SPC and Takeda appealed the decision. The Court affirmed the Patent Office refusal to grant the SPC. Article 3(a) of the SPC Regulation (EEC/1768/92) specified that the product had to be protected by a basic patent in force, whereas, even though the combination therapy would infringe the patent, the Takeda patents only covered the lansoprazole element of the combination. Jacob J stated “the so called “combination” of lansoprazole and an antibiotic would only infringe because of the presence of the lansoprazole. In truth, the combination is not as such “protected by a basic patent in force”. What is protected is only the lansoprazole element of that combination. It is sleight-of-hand to say that the combination is protected by the patent. The sleight-of-hand is exposed when one realises that any patent in Mr Alexander’s sense protects the product of the patent with anything else in the world. But the patent is not of course for any such “combination”.”

The case demonstrates that combination therapies will not be granted an SPC, unless an underlying patent exists for the combination itself.

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It is sleight-of-hand to say that the combination is protected by the patent.

Jacob J, Takeda v Comptroller General of the Patent Office

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The Courts are taking steps to manage cases actively to limit unnecessary costs and delay. The new “streamlined procedure” will be a tool frequently imposed upon parties to achieve these objectives. Parties will no longer be allowed to litigate in a “bubble”.

Procedure and evidence



Whatever the position may have been in the past, it is no longer the case that the parties and their lawyers have a free hand to conduct an action as they like.

Laddie J, Merck v Generics (UK)



Not possible to compel Patent Office to disclose information not within its records

Peter Prescott QC's judgment in the case of *Haberman v Comptroller General of the Patent Office* begins “this is a very unusual case”. It is also a very unusual, and rather emotive, judgment. The case concerns an application by Mrs Haberman under section 118 of the Patents Act 1977 for an order that the Patent Office be compelled to disclose information not within its records.

Mrs Haberman was the well-known inventor of a baby-feeding cup. She applied for an initial UK patent on 8 April 1991 and, having developed the invention further in the following twelve months, sought to “regenerate her priority date” by abandoning the first application and making a further application on 7 April 1992. It is a requirement of the Paris Convention (Article 4) that the earlier application be abandoned before the filing of the second application. The case arose because there was no evidence of the precise date on which Mrs Haberman's first application was abandoned and such information was not contained in the Patent Office's records.

Whilst the Judge considered that the evidence suggested the application had been abandoned prior to the filing of the second application, he could not compel the Patent Office to disclose information that was not within its records under section 118 of the Patents Act 1977. Section 118 was not a procedure to enable a party to compel the Patent Office to “ascertain” facts - it was rather a procedure to require the Patent Office to “give” information in its possession.

Peter Prescott QC expressed some regret at this state of affairs - “it would be fairly obvious that I have a great deal of sympathy for Mrs Haberman. Her predicament is a disgrace. If I could help her, I would. But I cannot bend the law”. Earlier the Judge, quoting Robert Burns, stated “if we - the international patents system - were granted the gift to see ourselves through the eyes of a Mrs Mandy Haberman, what might we learn? Would we be pleased with ourselves? Going by this case, I do not think so. I am bound to say that Mrs Haberman would seem to have every right to complain”. The Judge also showed empathy with the pressures upon patent attorneys - “it is in the nature of the

profession of patent attorney that he/she lives against a constant background of crucial dates which must not be missed. To miss even one is a nightmare. (For that reason I am glad that I did not choose that branch of the profession). Thus, in my experience, all firms of patent attorneys have standard procedures to try to ensure that it does not happen...that record staff are empowered to badger anyone, even the Senior Partner, is because the alternative is even worse - at best, constant anxiety and the loss of sleep. That is the reality of the situation."

Experiments on *Catnic*-type questions of construction not allowed without Court's permission in advance

Earlier in this UK Patents Review we report Laddie J's considerations of the rules of construction in the decision of *Merck v Generics (UK)*. In the case Laddie J also gave strong guidance on the appropriate conduct of litigation when dealing with issues of construction.

In the first place he directed that, in future, no experiments should be conducted going to *Catnic*-type questions of construction unless the Court has given informed permission for them in advance.

Laddie J expressed concern at the number of experiments and volume of evidence submitted by both parties on a simple issue of construction in a matter that had been ordered to come on as a speedy trial. Noting that the cost of patent litigation has been a source of concern in this jurisdiction for many years, Laddie J commented that the fact that it is not the Court's task to intervene in relation to the question of fees did not relieve it of its duty to control the way in which litigation was conducted. "If our system allows parties to leave no stone unturned in the course of litigation, it is not really a surprise that they do so, particularly when the stakes are high, and even if some of the stones which they turn are no bigger

than grains of sand. Whatever the position may have been in the past, it is no longer the case that the parties and their lawyers have a free hand to conduct an action as they like. Under CPR 1.2 the Court "must" seek to give effect to the overriding objective". Laddie J made it clear that the Court should not allow the parties to conduct the litigation in a "bubble" where the only considerations are what the parties and their lawyers want. Rather, the Court will in future use its case management powers, including the possibility of imposing the new streamlined procedure, to control carefully the conduct of litigation.

Inflexible expert witnesses are less persuasive

There was substantial criticism of the expert witnesses in the case of *SmithKline Beecham v Apotex*. One expert for the Claimant, whilst describing himself as "an independent consultant" in fact only consulted for the Claimant's lawyers in respect of the pharmaceutical product that was the subject of the litigation. Accordingly he was considered to be "loyal" to the Claimant and not willing to be "entirely dispassionate" between the parties – this was considered to be a serious fault in an expert witness. One expert for the Defendant was also alleged to have been a "hired gun". Whilst the expert frequently gave evidence on behalf of the Defendant, he was not shown to always say what the Defendant wanted him to say and was not "in Apotex's pocket".

Generally, however, all of the experts were from time to time partisan and argumentative and "insufficiently flexible" to be willing to adjust their views so far as necessary to accommodate sound criticism of those views. Their evidence, when effectively acting as advocates rather than experts, was less persuasive to the Court.

The Judge also expressed surprise at the lack of evidence regarding the alleged infringing process. Samples at all stages of the process would have been of considerably more assistance to the Court than a great deal of speculation by experts which formed a substantial part of the evidence.

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It is in the nature of the profession of patent attorney that he/she lives against a constant background of crucial dates which must not be missed. To miss even one is a nightmare.

*Peter Prescott QC,
Haberman v Comptroller
General of the Patent Office*

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Second bite of the cherry successful – twice!

In the case of *Rockwater v Coflexip* (see above) it was unusual that the Judge reversed an earlier finding on validity of the same patent in a different case. In the case of *Coflexip v Stolt* Laddie J had found Coflexip's patent for the laying of flexible pipes and conduits on the seabed not to be invalid for obviousness and anticipation. This finding was upheld on appeal. On a subsequent action for revocation of the same patent, however, Rockwater were successful in invalidating the patent for obviousness and anticipation. Parties are usually very reluctant to challenge the validity of a patent a second time because of the risk of being ordered to pay costs on an indemnity basis. Rockwater was able to invalidate the patent by virtue of identifying a new prior art document that had not been submitted in the case of *Coflexip v Stolt*.

As a result of the decision in *Rockwater v Coflexip*, Stolt, the unsuccessful party in the earlier action, sought a stay of the enquiry as to damages asserting "it would be monstrous if they have to pay an enormous sum in respect of a violation of a wholly non-existent right". Whilst Jacob J felt this proposition had a lot to be said for it, he did not consider that it was right. In particular he held that Stolt were bound by the rule of cause of action estoppel and cited the "formidable" authority of *Poulton v Adjustable Cover*. Notwithstanding Stolt's arguments, this authority still

stood and Stolt were required to pay damages. Jacob J noted that there were also policy considerations supporting this view. Otherwise, if a Defendant, having finally lost a patent action, knew that an application for successful revocation by another might get him off the hook of damages, he would have every motive for digging up better prior art and encouraging another to attack the patent. Of interest, it was noted that both parties agreed that the injunction against Stolt would not continue in force, although Jacob J stated that he was not entirely clear why, since if contempt for breach of injunction proceedings were brought, he did not see why the Defendant could say "but there is no patent" to that charge but not in the claim for damages. He did not consider the matter further.

Similar considerations also applied in the case of *SmithKline Beecham v Apotex*. The patent in-suit, relating to SmithKline Beecham's pharmaceutical product, paroxetine hydrochloride anhydrate, had previously been the subject of a revocation action by BASF AG in which Pumfrey J had held a number of claims of the patent to be invalid, but two particular claims to be valid. This decision was upheld by the Court of Appeal last year. In the *Apotex* case, Pumfrey J again came to consider the validity of the patent and considered the impact of his earlier decision and the judgement of the Court of Appeal in the *BASF* action. Pumfrey J stated that neither the evidence nor the judgement in the *BASF* action was admissible in the present action save on questions of construction, being issues of law. It must be

remembered that construction of documents is not the end of the question and that their disclosure is a question of fact upon which evidence is admissible. While Pumfrey J had come to a particular view on the evidence in the *BASF* action he had to put this out of his mind for the purposes of the *Apotex* action and to base his findings upon the evidence advanced by the parties in that case. Pumfrey J concluded that the evidence in the *Apotex* case justified his departure from his conclusion in the *BASF* case. He thus found the claims of the patent to be invalid for anticipation and obviousness (see above) and not infringed.

On a separate application SmithKline Beecham sought to use in the *Apotex* litigation documents that had been disclosed to it by *BASF* in that litigation. Since the judge in both cases was the same, in the interests of justice, the Court of Appeal held that the documents should be allowed to be used in the *Apotex* proceedings in confidence.

“It would be monstrous if they have to pay an enormous sum in respect of a violation of a wholly non-existent right. Stolt's unsuccessful submission, *Coflexip v Stolt*”

”

We are likely to see more applications for interim injunctive relief and fewer appeals on issues of anticipation or obviousness in the future as a result of guidance from the Courts last year.

Remedies

Clarification on causation of damages awaited

On an enquiry as to damages, the question can arise as to the lost profits to which the successful patentee is rightfully entitled. The issue of causation in such cases is unclear and remains unclear notwithstanding the Court of Appeal decision in *Coflexip v Stolt*. Pending the enquiry as to damages, Stolt successfully argued that Coflexip should replead their case indicating how and why the use of the invention by Stolt was causative of the loss in respect of each of 15 contracts that had been awarded to Stolt. Coflexip appealed this decision and sought a ruling from the Court of Appeal that the relevant test for causation was the “but for” test – that is, that the Defendant had been shown to infringe their patent and that, but for those infringing acts, the relevant contracts would have been awarded to them. Stolt argued that the “but for” test was not sufficient to determine causation. Coflexip would also need to prove that the contracts had been awarded to Stolt as a result of their use of the infringing process – they too sought a determination from the Court of Appeal. The Court declined, however, to resolve the issue of causation pending clarification of the background facts of the case. Both parties’ views on the law of causation were arguable and it was inappropriate to resolve such issues at an interlocutory stage without a final determination of the facts – “save in a case where the loss claimed clearly failed the “but for” test, issues of this kind do not generally lend themselves to resolution at an interlocutory stage”.

In the case of *SmithKline Beecham v Apotex*, the issue of causation of damages was also considered. On this occasion, the Court of Appeal stated that a patentee was entitled to recover damages for loss caused by the infringement provided that they were not too remote and that the normal considerations (as set out in *Gerber v Lectra*) would apply. There was no general proposition that damage caused by infringement would be too remote and unrecoverable unless the damage was a loss of sales in goods falling within the ambit of the claim of the patent. In the case the anhydrate and hemihydrate were for all practicable purposes interchangeable and it was reasonably arguable that the damage caused to the sales of one by the sales of the other would not be too remote.

Prospects of obtaining interim injunctions in patent proceedings improve

Interim injunctions in patent proceedings in recent years have been comparatively rare. Following the cases of *SmithKline Beecham v Apotex* and *Wyeth v Alparma* last year, the prospects of obtaining interim injunctions in such actions appear, however, to have dramatically



Save in a case where the loss claimed clearly failed the “but for” test, issues of this kind do not generally lend themselves to resolution at an interlocutory stage.

Kay LJ, Coflexip v Stolt



improved, particularly for pharmaceutical companies seeking to prevent early generic entry into the market.

The case of *SmithKline Beecham v Apotex* related to SmithKline Beecham's patent for crystalline paroxetine hydrochloride, its preparation and its use as a therapeutic agent, particularly relating to its anhydrous form. SmithKline Beecham sell a different form (the hemihydrate) as a pharmaceutical under the name Seroxat. The same patent has been the subject of much litigation in this jurisdiction and elsewhere. In this particular case SmithKline Beecham applied for an interim injunction to restrain the alleged infringing activity of the Defendant.

At first instance, an interim injunction was granted and a number of arguments raised by the Defendant were dismissed (see our UK Patents Review 2003). Thus interim injunctions could be granted notwithstanding that amendment proceedings were pending, the patentee was not exploiting the product claimed in the patent and notwithstanding the fact that damages might be unavailable to the respondent.

The Court of Appeal last year upheld the first instance decision on similar grounds. In particular, the Court of Appeal held that the Court's jurisdiction to grant interlocutory injunctions is not limited (including by section 63 of the Patents Act 1977). A final injunction would normally be granted in cases where damages after amendment would not be recoverable by the applicant, and there was no principle that would preclude an interlocutory injunction from being granted in similar circumstances. Whilst it would be unusual to grant an

interlocutory injunction if no damages could be recovered by the respondent, there was no principle why a Court should not grant such an injunction.

The Court of Appeal also supported the Judge's considerations in weighing up the balance of convenience. He had been entitled to have in mind that the Defendants could have cleared the way before them by seeking revocation of the patent or seeking a declaration of non-infringement. There was no error of principle in the Judge's exercise of discretion.

An interim injunction was also granted in a pharmaceutical case against a generic company in *Wyeth v Alpharma*. Wyeth sought to obtain an interim injunction preventing Alpharma from selling a generic version of its modified release tetracycline antibiotic. It submitted that there was an arguable case of patent infringement and passing-off and that the balance of convenience fell in its favour. The Defendant sought to persuade the Judge that the patent was clearly invalid and not infringed.

Notwithstanding his judgment in *Series 5 Software*, and without retracting any comments made in that judgment, Laddie J refused to be drawn on the merits of the claim - "most patent actions are too complicated to allow a Court to reach a reliable view as to the merits at an interlocutory stage, and certainly not without engaging in a hard-fought mini-trial". As long as the claims and defences are triable, the Court should move on to determining the balance of convenience. In weighing up the balance of convenience in the case, Laddie J considered the least unjust course to be to preserve the status quo since both parties agreed that the

case could be ready for trial in about four months and the Defendant had already delayed launch of the product by three and half months. Accordingly, he granted the Claimant the interim relief sought.

Orders for stays of proceedings may be reversed if there is a significant material change in circumstances

There were two applications for orders for stays of proceedings in the case of *General Electric v Enercon*, one by either party and both with different decisions reached. General Electric brought patent infringement proceedings against Enercon in respect of its patent for variable speed wind generators. The patent was subject to an opposition procedure at the European Patent Office (EPO) and to avoid unnecessary costs of litigation, the Defendant applied for a stay of proceedings pending the outcome of the opposition procedure. Laddie J refused to grant a stay since, although there were substantial arguments on either side and he did not find it an easy decision to arrive at, a stay would seriously undermine the value of the Claimant's rights if, at the end of the day, the patent was held to be valid. This was by virtue of the likely significant delay in obtaining a final determination from the European Patent Office Technical Board of Appeals.

During the course of the year, the EPO held the patent to be



Most patent actions are too complicated to allow a Court to reach a reliable view as to the merits at an interlocutory stage, and certainly not without engaging in a hard-fought mini-trial.

Laddie J, Wyeth v Alpharma



invalid and subsequently the Claimant sought a stay of proceedings pending the outcome of its appeal at the EPO. Importantly, pending the stay it offered undertakings to the Defendant for the period of the stay not to seek damages or injunctive relief or delivery up of infringing goods and not to seek interest in respect of past infringements and interim injunctive relief if it was successful in its appeal at the EPO.

Laddie J considered that an order for a stay of an action, or a refusal of an application to stay, can always be reversed if there is a significant material change in circumstances. The decision in the EPO was not a sufficient change in circumstances since the possibility of a successful opposition had been considered on the earlier application. The Claimant's offer, however, did amount to a significant change in circumstances since it was so extensive and offered so much protection to the Defendant, in effect cutting out the Claimant's monopoly for a period of two to three years.

Issues-based approach on costs often appropriate

An issues-based approach to cost was applied by Laddie J in the case of *Stena Rederi v Irish Ferries*. Although the Defendant successfully defended the claim for infringement by virtue of section 60(5)(d) of the Patents Act 1977 (see above), since validity of the patent was upheld, at a costs hearing the Judge ordered that the Claimant pay 20% of the Defendant's costs and that the Defendant pay 80% of the Claimant's cost. The Defendant appealed submitting

that an issues-based approach was inappropriate and that the bulk of costs should have been awarded in its favour since it had successfully rebutted the claim. The Court of Appeal dismissed this appeal endorsing the issues-based approach adopted by the Judge. Although determinative of the infringement action, the section 60(5)(d) point was decided relatively cheaply and quickly, whereas the rest of the issues involved a patent action with the need for detailed evidence and argument. This case can be contrasted with the decision in *McGhan v Nagor*, reported in our UK Patents Review 2002.

Grounds of Appeal will in future need to contain a succinct statement of the principle that the Judge is said to have infringed and authority for that principle

In a supporting judgment in the case of *Instituto Gentili & Merck v Teva* (see above) Buxton LJ commented upon appeal procedure in this jurisdiction.

Following the guidance given by the Court of Appeal in *Instance v Denny* and the House of Lords in *Designers Guild v Russell Williams*, a Court should only interfere with the views of the trial judge if it can be shown that he has erred "in principle". Buxton LJ stated that this phrase "has never been defined, and probably cannot be and does not need to be. At the least,

however, it can be said that an error of principle can only arise if the Judge has departed from a rule or practice that applies also outside the boundaries of the facts of the instant case; that rule or practice can be coherently encapsulated in verbal form; and can be demonstrated to be binding on the Judge".

Buxton LJ noted that in appeals frequently parties will assert that the Judge erred "in principle", but not identify the relevant principle often since on any view no such errors had occurred. In other cases where there might have been a matter of principle involved, it is difficult to extract what the principle is. Further, sometimes although principles are stated, they are not acted on.

In light of this experience, Buxton LJ suggested that in future, when a trial Judge's conclusions on anticipation or obviousness are challenged, the Grounds of Appeal should, in respect of each complaint, contain a succinct statement of the principle that the Judge is said to have infringed and, unless self-evident, what the authority is for that principle. Buxton LJ suggested that trial Judges keep this approach in mind when considering whether to grant permission to appeal. The Vice Chancellor, endorsing this practice suggested that there be an amendment to CPR Rule 52 or its Practice Direction.



An error of principle can only arise if the Judge has departed from a rule or practice that applies also outside the boundaries of the facts of the instant case.

Buxton LJ, Instituto Gentili & Merck v Teva



Reported case analysis

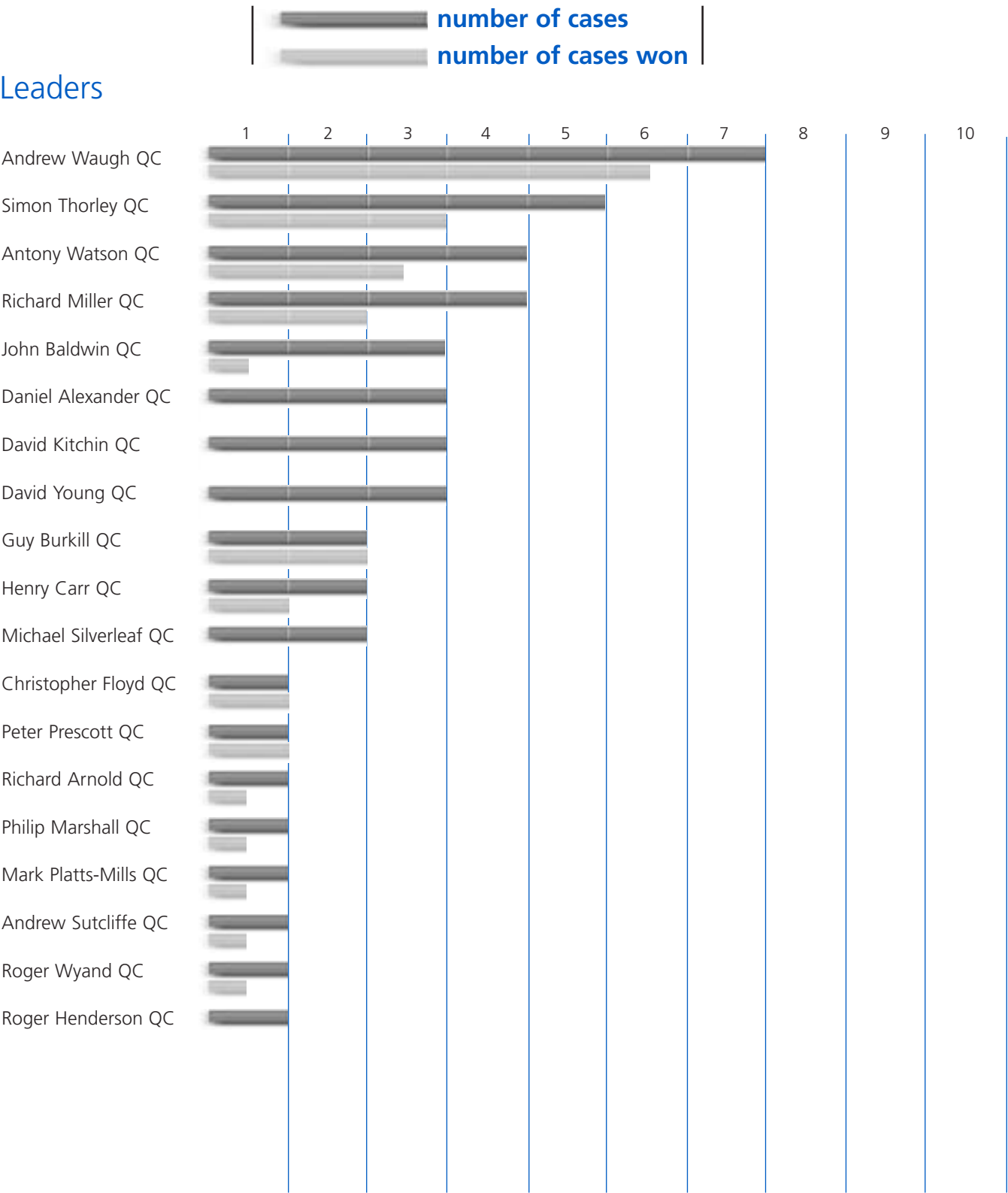
This is an analysis of reported cases, which can be found on the following websites: www.courtservice.gov.uk and [www.newLawonline.co.uk](http://www.newlawonline.co.uk)
The following analysis of how Counsel and Judges compared is based only on these reported cases. Other cases may have been reported elsewhere.
The successful party is indicated in bold.

No.	Case name	Judge(s)	Date	Product	Infringement
1	Teva Pharmaceutical Industries Ltd v Instituto Gentili Spa & anr	Jacob J	21.1.03	Pharmaceuticals	
2	Stena Rederi Aktiebolag & anr v Irish Ferries Ltd	Aldous LJ Chadwick LJ Munby J	6.2.03	Ships	✓
3	Synthon BV v SmithKline Beecham Plc	Jacob J	14.2.03	Pharmaceuticals	
4	SmithKline Beecham Plc & anr v Apotex Europe Ltd & ors	Aldous LJ Carnwath LJ Sir Christopher Staughton	14.2.03	Pharmaceuticals	✓
5	General Electric Co v Enercon GmbH & ors	Laddie J	17.2.03	Wind generators	
6	Mandy Haberman v Comptroller General of the Patent Office (1) Playtex Products Inc (2)	Peter Prescott QC	5.3.03	Baby cups	
7	Coflexip SA & anr v Stolt Offshore Ltd & ors	Aldous LJ Kay LJ Jonathan Parker LJ	13.3.03	Laying flexible pipes	
8	Takeda Chemical Industries v The Comptroller General of the Patent Office	Jacob J	2.4.03	Pharmaceuticals	
9	Rockwater Ltd v Coflexip SA & anr	Laddie J	15.4.03	Laying flexible pipes	✓
10	Daesang Corporation & anr v Ajinomoto Co Inc	Laddie J	7.5.03	Sweeteners	
11	Synthon BV v SmithKline Beecham Plc	Aldous LJ Sedley LJ Rix LJ	25.6.03	Pharmaceuticals	
12	BASF AG v SmithKline Beecham Plc	Aldous LJ Sedley LJ Lindsey LJ	25.6.03	Pharmaceuticals	
13	SEB SA v De'Longhi SpA	Peter Gibson LJ Scott Baker LJ Sir Martin Nourse	4.7.03	Deep fat fryers	✓
14	Koninklijke Philips Electronics NV v Princo Digital Disc GmbH & ors	Pumfrey J	7.7.03	Compact discs	
15	Celltech Chiroscience Ltd v Medimmune Inc	Arden LJ Longmore LJ Sir Andrew Morritt V-C	17.7.03	Pharmaceuticals	
16	SmithKline Beecham Plc v Generics (UK) Ltd and BASF AG v SmithKline Beecham Plc	Aldous LJ Chadwick LJ Latham LJ	25.7.03	Pharmaceuticals	
17	Vericore Ltd v Vetrepharm Ltd & anr	Laddie J	29.7.03	Pesticides	
18	Storage Computer Corp & anr v Hitachi Data Systems Ltd	Aldous LJ Mance LJ Jacob J	30.7.03	Digital storage system	
19	Xtralite (Rooflights) Ltd v Hartington Conway Ltd	Pumfrey J	31.7.03	Roof lights	
20	Coflexip SA (1) Technip Offshore UK Ltd (2) v Stolt Offshore MS Ltd & ors	Jacob J	31.7.03	Laying flexible pipes	
21	Fraser & ors v Oystertec Plc & ors	Peter Prescott QC	8.9.03	Radiators	
22	Koninklijke Philips Electronics NV v Princo Digital Disc GmbH & anr Sir Andrew Morritt V-C	Pumfrey J	9.9.03	Compact discs	
23	Instituto Gentili SpA & anr v Teva Pharmaceutical Industries Ltd & ors	Buxton LJ Laws LJ Sir Andrew Morritt V-C	6.11.03	Pharmaceuticals	
24	Merck & Co Inc v Generics (UK) Ltd	Laddie J	27.11.03	Pharmaceuticals	✓
25	Apotex Europe Ltd & ors v SmithKline Beecham Plc	Pumfrey J	5.12.03	Pharmaceuticals	✓
26	General Electric Co v Enercon GmbH & ors	Laddie J	12.12.03	Wind generators	
27	Wyeth Holdings Corporation & ors v Alpharma Ltd	Laddie J	13.12.03	Pharmaceuticals	✓
28	R v HM Comptroller of Patents Trademarks & Designs	Laddie J	22.12.03	not available	

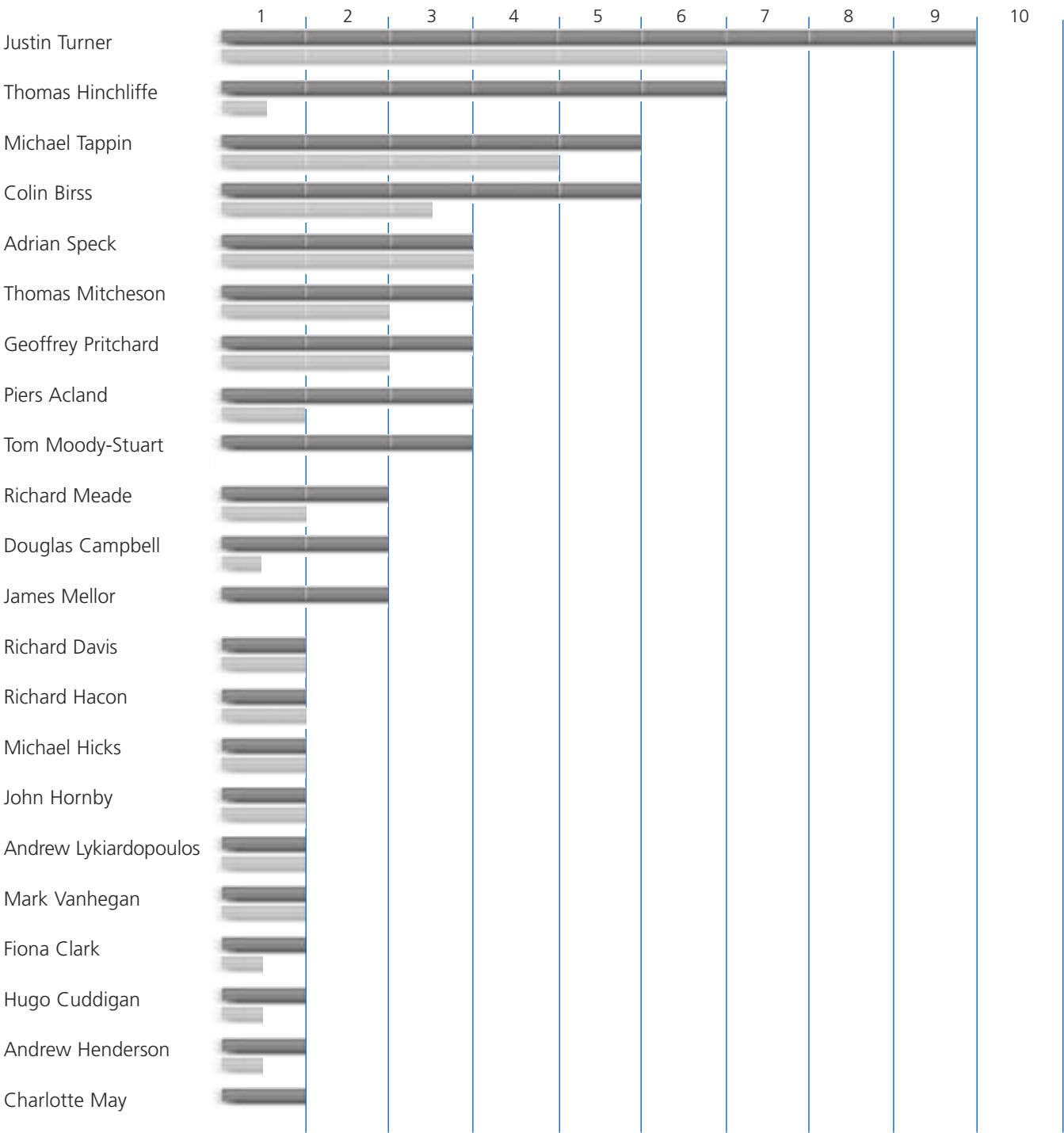
Novelty	Obviousness	Added matter	Insufficiency	Threats	Amendment	Procedure	SPC
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	✓						
					✓		
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How Counsel compared

(Based on reported case analysis on page 18)

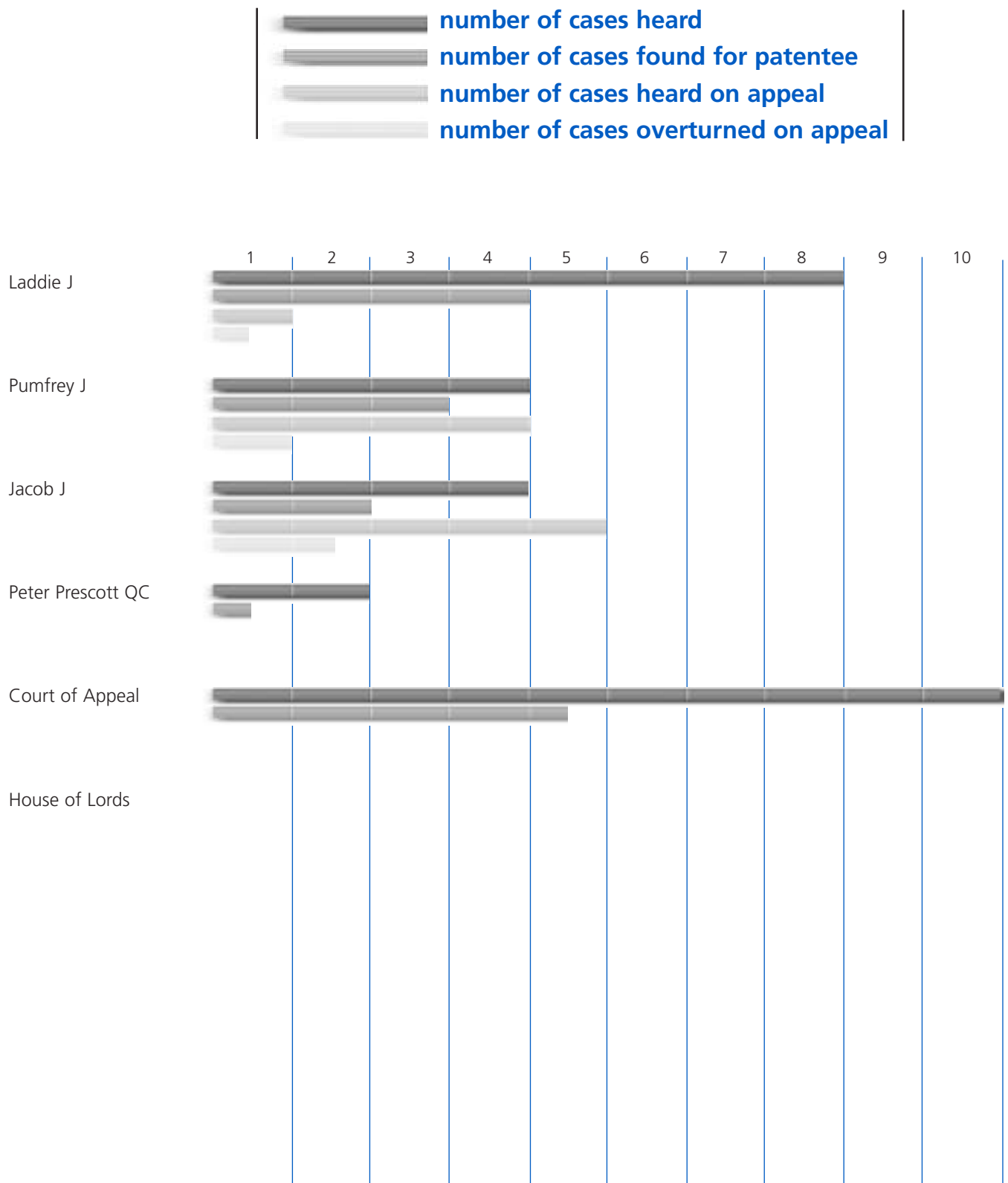


Juniors



How Judges compared

(Based on reported case analysis on page 18)



Time to trial or appeal

This analysis is based on the cases listed on page 18 that have proceeded to a full trial or appeal. The issue dates have been obtained from the Chancery Registry of the High Court.

Trials

Cases Heard	Time from Issue of Claim Form to Judgment at First Instance (months)
Teva Pharmaceutical Industries Ltd & anr v Instituto Gentili SpA & anr*	14
Rockwater Ltd v Coflexip SA & anr	14
Daesang Corporation & anr v Ajinomoto Co Inc	20
Koninklijke Philips Electronics NV v Princo Digital Disc GmbH & ors*	21
Merck & Co Inc v Generics (UK) Ltd (speedy trial ordered)	5
Apotex Europe Ltd & ors v SmithKline Beecham Plc*	14
Average 14.7	

* Consolidated actions - time calculated from the date of issue of the earliest claim form.

Appeals

Cases Heard	Time from Judgment at First Instance to Judgment on Appeal (months)
Stena Rederi Aktiebolag & anr v Irish Ferries Ltd	10
SmithKline Beecham Plc & anr v Apotex Europe Ltd & ors (appeal on interim injunction)	3
Coflexip SA & anr v Stolt Offshore Ltd & ors (Submission for damages)	8
Synthon BV v SmithKline Beecham Plc	12
BASF AG v SmithKline Beecham Plc	11
SEB SA v De'Longhi SpA	12
Celltech Chiroscience Ltd v Medimmune Inc	9
SmithKline Beecham Plc v Generics (UK) Ltd and BASF AG v SmithKline Beecham Plc	12
Storage Computer Corp & anr v Hitachi Data Systems Ltd	11
Instituto Gentili SpA & anr v Teva Pharmaceutical Industries Ltd & ors	10
Average 9.8	



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