

UK Patents Review 2001

Revival of the
Patents County
Court?

Laddie J brought
into line

New problems
for patentees in
pharma and biotech
industries

Swiss type claims
upheld

No more implied
licence to repair?

Case analysis

How counsel
compared?

How the judges
compared?

Patents



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2001



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Amendment

CPR limit the obligations of disclosure on unopposed amendments - no requirement to waive privilege

In our UK Patents Review 2000, we reported the Court of Appeal decision in *Kimberley-Clark v Procter & Gamble*. The case clarified that the Court still has discretion to refuse amendments under Section 75 of the Patents Act, contrary to a number of first instance decisions in 1999. The Court's view was that what is needed is not a curtailment of the discretion given by Section 75, but rather active case management so as to

the practice almost invariably followed in amendment applications of disclosing privileged matter. He commented that it is unlikely that an adverse inference will be drawn in amendment proceedings from a failure to disclose such privileged material.

This issue has now been considered at length in the case of *Oxford Gene Technology v Affymetrix (2)*. Although Judgment at first instance was given in private, the Court of Appeal considered the issues raised to be of such importance to practitioners for the Judgment to be delivered in open Court. OGT was the proprietor of a European patent for a

inspected the documents, solicitors for Affymetrix sought permission to disclose such documents to their client and US attorneys. On an application before Pumfrey J it was held that privilege had been waived by disclosure of such documents to the UK solicitors, although the Judge exercised his discretion to limit use of the documents to the purpose for which they were disclosed, namely for the purpose of the amendment proceedings. Both parties appealed.

The Court of Appeal in its judgment sought to correct some mis-perceptions by practitioners. Although an applicant to amend is under an obligation to put relevant facts before the Court to enable it to exercise its discretion, there is no obligation upon a patentee to trawl through his documents to see whether they are relevant to the exercise of the discretion. Indeed there is no obligation to disclose documents at all, the obligation merely being to disclose material facts. There is "no warrant for a patentee throwing all his documents at the Court as a policy of caution". Importantly, there is no obligation upon a patentee in amendment proceedings to waive privilege in respect of any document. Although a patentee's case may be best advanced by waiver of privilege, the decision on whether to waive privilege is one for him and not for the Court. There is an obligation to disclose all relevant non-privileged matters.

The Court of Appeal's guidance will be welcomed by patentees and is fully in line with the underlying principles of the Civil Procedure Rules. It demonstrates the Court's pro-active use of its case management powers in eliminating oppressive requests for disclosure that disfigured the conduct of much civil litigation in the past.

"I can see no warrant for a patentee throwing all his documents at the Court as a policy of caution."
(*Pumfrey, J – Oxford Gene Technology v Affymetrix (2)*)

require proper particularisation of allegations, and the elimination of fishing and abusive requests for disclosure. In *Swintex v Melba* the Patents Court has now provided such active case management in the case of an unopposed amendment. The Court indicated that case management under the Civil Procedure Rules requires a different approach to be taken to applications to amend. In the case of an unopposed amendment, the Judge, Pumfrey J, could see no reason for requiring the patentee to make disclosure of all relevant matters as if it were an ex parte (or without notice) application. If there were any legal objections to the amendment, then such objections could form the basis of an allegation of invalidity by an alleged infringer who was sued at a later date. Pumfrey J also indicated that he did not necessarily endorse

method and apparatus for analysing polynucleotide sequences and brought proceedings against Affymetrix for infringement. The patent was also under opposition in the EPO and there were patent proceedings in the US in respect of the corresponding US patent. OGT gave notice of intention to seek amendment of the patent. On an application by Affymetrix, Laddie J ordered disclosure by list of all documents relevant to the Court's discretion to permit or refuse amendments in accordance with OGT's obligation of utmost good faith. OGT served a list of documents and both in correspondence and in the list made it clear that such documents were the subject of legal professional privilege and were disclosed to Affymetrix's solicitors and UK Counsel only. Having

“Two bites at the cherry is wastful of resources.”
(Chadwick, LJ - Coflexip v Stolt)

On the facts of the case, the Court of Appeal found that privilege had not been waived by OGT as a result of its disclosure of documents to Affymetrix’s UK solicitors. The disclosure was to be construed in the context of the clear correspondence between solicitors to the effect that such disclosure was to be confidential to the solicitors. The Court held that it was better to view this as an “attempted disclosure” and an exploratory step towards an agreement that had failed rather than a waiver of privilege. Further, whilst it was not necessary to decide on the issue, the Court did indicate that it disagreed with the first instance decision as to restrictions to be placed on disclosure. Where it was right for disclosure of facts to be made by one party to his opponent’s advisors before trial, the opponent itself was entitled to know the facts so disclosed to understand the case it had to meet. An exception to this general rule was where there was a risk of trade secrets leaking out. This was not such a case. Further restricting use of documents to the amendment proceedings, although perhaps desirable, was unworkable.

Patent Agents only required to consider novelty not obviousness

The Court’s discretion on amendment was also considered by Pumfrey J at trial in *Kimberley Clark v Proctor & Gamble*. The objection raised was one of covetousness on the basis that the Defendant alleged that the patentee was aware at the time of application that an essential feature of the invention was missing, such feature subsequently being sought as an amendment. Pumfrey J held that a claim for covetousness could not begin

to be made out unless it was established that the draftsman of the specification had sought to obtain a claim of a breadth which was unjustified on the material available to him. Discretion would not be exercised in the absence of conduct which could be described as “blameworthy”.

The Defendant also alleged that the patentee had failed to make full and frank disclosure to the Court on seeking amendment, in particular failing to produce evidence from either the inventors or from the patent attorney primarily responsible for prosecution. Such criticism was not acceptable to the Court. Before a patentee is required to undertake a wide ranging exercise in disclosure there have to be adequate grounds for them to suppose that discretionary grounds for refusing the amendment truly exist.

Finally, the Defendant attempted to persuade the Court to exercise its discretion to refuse amendment on the ground that the patentee’s patent attorney had only considered the issue of novelty in drafting the specification and not inventiveness. This, however, is the function of the patent agent and the Court held that it is not a matter of criticism that the broadest claim formulated has novelty, but may lack inventive step, if the patent agent considered that it could successfully be prosecuted through the Patent Office.

Amendments before EPO have direct effect in United Kingdom

In *Boston Scientific v Palmaz*, Palmaz sought to amend its patent in suit, both before the EPO and at first instance in the Patents Court on Boston Scientific’s revocation

action and request for a declaration of non-infringement. The Court of Appeal held that the Judge at first instance, having refused the amendments, was right to try the case on the unamended claims, since at that time the amendment had not taken effect. The EPO had, however, subsequent to the case at first instance in the Patents Court and prior to the case before the Court of Appeal, allowed the amendments. These amendments had direct effect and, accordingly, the Court of Appeal was required to consider the claims as amended. Since the full amended specification had not been considered at first instance, the appeal was to be by way of re-hearing.

Amendment of pleadings – two bites at the cherry by amendment on appeal wastful of resources

In *Coflexip v Stolt*, the Defendant on appeal sought to amend its Particulars of Objection to rely on new prior art. The Claimant resisted such amendments and the Court exercised its discretion to refuse such amendments as not in accordance with the overriding objective of the Civil Procedure Rules. To allow two bites at the cherry was wastful of resources. The fact that the Claimant would not be prejudiced if there were to be a re-trial ignored the interests of other Court users which was of particular concern in patent cases with a limited number of nominated patent judges and the heavy demands on the Patents Court. A defendant in a patent action must thus decide the extent of any search he wishes to make and, except in very unusual circumstances, will be held by the Court to the decision he takes.



Infringement

Reference to the specification and definitions in published material can cause difficulties in construction

It is inherent in the forensic process conducted in construing a patent that every aspect of the specification of the patent in suit which appears to cast favourable light on a party's contention will be put forward by its representatives as a factor to be taken into account when determining the meaning of a claim in that patent.

Neuberger J in *Rohm & Haas v Collag*, however, stated that this process can be

detail in limiting the wording of the claim. The Judge also warned against the dangers of using definitions or uses of a particular word in text books and other publications in different context to that used in the patent in suit. Greater assistance would come from publications intended to be practical documents than from textbooks. Neuberger J commented that "a definition of a word in a textbook may be too wide for the purpose of defining how the word is used in another, more specialised, context, such as a patent".

On the issue of construction, the Judge commented that if a Defendant can show that a narrower construction of a patent involves claiming a process which is exclusively novel whereas a wider construction would extend it to processes which are not novel, then this is a powerful argument in favour of the narrower construction. See in contrast, however, the Court of Appeal's decision in *Coflexip v Stolt* (reported below) that construction of a patent cannot depend on whether a claim would otherwise be obvious.

Derivatives of pharmaceutical products must be claimed specifically

In *American Home Products v Novartis* the Court of Appeal allowed Novartis' appeal of Laddie J's finding that AHP's patent was sufficient and infringed. The patent related to the chemical product, Rapamycin. This was previously known to have anti-fungal and anti-tumour properties. Subsequently it was found also to have immunosuppressant qualities and to be useful to suppress transplant rejection. The patent was thus claimed in the Swiss type form for a second

"A definition of a word in a textbook may be too wide for the purpose of defining how the word is used in another, more specialised, context, such as a patent." (Neuberger J, *Rohm & Haas v Collag*)

dangerous, not so much for the advocates, but for the tribunal deciding the case since it inevitably involves careful consideration of every part of the patent in suit, including the specification, and therefore encourages the Court to adopt a "detailed semantic analysis" of the specification as warned against by Lord Diplock in *Catnic*. (See also *Cadcam v Proel* below). The Judge warned that the Court must avoid the trap of being too easily persuaded to invoke words in the specification to cut down the natural and wide meaning of the words of the claim, being the trap into which the Judge himself had fallen earlier in *Cartonneries de Thulin v CTP White Knight*. The Judge proceeded to construe the terms of the specification in

medical use. Novartis produced an immunosuppressant (SDZ RAD) which was a derivative of Rapamycin. On appeal, Novartis argued that the claims of the patent did not cover such a derivative, and that if they did the patent was invalid for insufficiency since it did not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art. Whilst the specification of the patent referred, in general terms, to derivatives of Rapamycin, no specific derivatives were mentioned and the claims solely referred to use of Rapamycin. Adopting “the Protocol questions” (as referred to in *Wheatley v Drillsafe*), Aldous LJ found that although the specific derivative, SDZ RAD, appeared not to materially affect the way the invention worked, this would not have been obvious to a skilled person at the priority date. Although, as the Judge at first instance had held, there was a strong probability that other derivatives would work, it was impossible to predict with certainty whether any particular one would and lengthy tests would be required to determine which ones worked. The Court of Appeal rejected AHP’s Counsel’s argument that a lower test should be incorporated into the second Protocol Question such that an affirmative answer be given if the skilled person would have “expected” that the variant would not produce a material effect (even if this would not have been “obvious”). This was inconsistent with settled law. Although the third Protocol Question did not need to be considered, with the second question having been answered in the negative, the Court found that the skilled person would have understood the language of the claim as

denoting the molecule Rapamycin and not its derivatives. Accordingly the patent was found to be not infringed. On the basis of this construction, the patent was also found to be sufficient. On AHP’s asserted construction, however, the patent would have been found to be insufficient.

Of further interest were Aldous LJ’s comments concerning the value of patents in the pharmaceutical field and his disagreement with Laddie J who, at first instance, had commented that the restriction of a monopoly to the second use of a single chemical (and not to any of its derivatives) would render the patent virtually valueless. Aldous LJ “did not agree that a patent limited to the second use of Rapamycin is virtually valueless”. Aldous LJ did not believe that the patent system should be used to enable a person to monopolise more than that which he had described in sufficient detail. If it was, it might stifle research such as, in this case, to find a derivative of Rapamycin that was a substantially better immunosuppressant than Rapamycin itself.

“A device for” means “a device suitable for” - but must be capable of being an effective use

In *Coflexip v Stolt*, the Court of Appeal gave consideration to the meaning of the words “a device for operating” as claimed in the patent. At first instance, the Judge had accepted the Defendant’s arguments that the words should be construed as meaning “when used for” since the construction suggested by the Claimant would render the claim invalid for obviousness. The Court of Appeal disagreed with this construction considering that the meaning of the claim

“For my part, I do not agree that a patent limited to the second use of Rapamycin is virtually valueless”.

(Aldous LJ, – American Home Products v Novartis)

could not depend on whether a certain construction would mean that the claim was obvious.

Although the principal invention of the patent was the process, it was clear that the patentee was also claiming a device suitable for operating such process and the construction suggested by the Defendant would mean that there was no device claim. This was a wrong construction. The Court of Appeal considered that the normal and natural meaning should be given to the words "a device for operating", namely that the device is "suitable for operating" the process but need not necessarily be used for such process.

On the other hand, a claim to an apparatus that is "suitable for" a purpose, must be capable of being effective for that purpose. In *Lilly v Pfizer*, Laddie J gave consideration to the construction of the claim "the use of...for the curative or prophylactic...treatment of...". Pfizer, opposing Lilly's application to invalidate and revoke its patent covering, amongst other things, the anti-impotence drug Viagra, successfully argued for a narrow construction of such claim - the words were only fulfilled by use of a compound which was both for the purpose of trying to treat the target illness and which also was suitable for treating that illness, that is to say that, in relation to at least some individuals, the treatment worked. Support for this view can also be found in the Court of Appeal decision of *Bristol Myers Squibb v Baker Norton* (see below). The success of the treatment did not, however, need to be attributable to the use of the identified compound alone - where two or more agents were used together to treat a disease, then each was "used...for the...treatment of" the disease. In light of this construction, Lilly's claim that the patent lacked novelty failed, since the particular piece of prior art relied upon failed to demonstrate efficacy. The patent was, however, held to be obvious over three cited prior publications.

Catnic applied....

The principles of construction set out in *Catnic* and *Improver* have again been applied in a number of cases in 2000, including the following:

Dyson v Hoover - the term "frustro-conical", like the term "vertical" in *Catnic*, was construed purposively to mean "sufficiently frustro-conical to do its job". Similarly, the terms "sequentially" and "within" were construed purposively - the former not necessarily requiring a direct connection in the context of the patent in suit and the latter meaning "partly within" and not necessarily "wholly within".

Stoves v Baumatic - the perforations admitting air to the oven door were held to be variants which would be clear to a skilled man to have no effect upon the object of the invention and were not otherwise meant to be excluded by the patentee.

Minnesota Mining v ATI Atlas - the phrase "bacteria impermeable", whilst superficially absolute in its meaning, was construed as meaning sufficiently obstructive to the ingress of bacteria to prevent there having any effect upon the sterility test of the patent in suit.

Rocky Mountain Traders v Hewlett Packard - the term "unitary" in the context of the patent required the CD labelling device to be in one piece.

T H Goldschmidt AG v EOC Belgium NV - the claim to a pH in the range 5-8 was to be interpreted as being to one decimal point (eg. 4.95 is rounded to 5.0 and pH values of 4.6 – 4.9 are included within such range).

....and reconsidered

The *Catnic* principles have, however, been reconsidered in the case of *Monsanto v Merck*. Monsanto was the proprietor of a patent claiming a class of organic compounds possessing anti-inflammatory and/or analgesic activity with "gastric sparing" qualities. Claim 1 of the patent expressly covered various 2-hydroxyfuran derivatives. Merck's anti-inflammatory product was the keto-tautomer of such a derivative. It was common ground that it was not, however,

expressly listed in Claim 1. Monsanto claimed that the keto-form of tautomer was, on a true construction, within the scope of Claim 1, since in aqueous solution the keto-form of tautomer would inevitably be present. The Court, however, rejected Monsanto's arguments, considering the meaning of the claim to be clear and unambiguous and therefore not to admit of variants. Although the keto-form of tautomer would inevitably be present in aqueous solution, the fact that it had not been mentioned suggested deliberate exclusion. It was not for the skilled man to speculate why this should be so. The case is particularly interesting for its comments on the principles, set out in, *Catnic* and *Improver*. The Court considered that these principles did not provide it with a licence to employ a "Humpty Dumpty" construction, in which words mean what the Court wanted them to mean. In *Monsanto v Merck*, the claims were clear. The Court further noted that there were problems with the universal application of the principles of *Catnic* and *Improver*, both of which were mechanical cases and where the terms in issue were descriptive in *Catnic* ("vertically") and narrow in *Improver* ("helical spring"). In particular, such principles were not applicable to a claim where every term was unambiguous and devoid of any question of degree. Furthermore, the third Protocol Question presented difficulties in respect of class claims. The very nature of class claims was that not every member of the class would be exemplified and described. It was therefore difficult to decide whether the patentee had intended to exclude a particular member of the class by the fact that it had not been mentioned. On the facts, since the presence of a tautomer was a matter of common general knowledge, the fact that there was no reference suggested a deliberate exclusion. The decision is being appealed.

Joint Tortfeasorship

The Patents Court needs to be satisfied that there are proper grounds and a good arguable case before it will allow foreign parties to be

exposed to the expense and inconvenience of joinder to proceedings in this country. In order to show infringement by common design, the Court in *Allergan v Saufron* held that it was necessary for the Claimant to show some act in furtherance of the common design and not merely an agreement.

Implied licence to repair is the incorrect test

In *United Wire v Screen Repair* the House of Lords upheld the Court of Appeal's decision that the concept of an implied licence to repair has no place in relation to infringement proceedings dealing with the manufacture of patented products.

The patent covered screens for sifting drilling mud. They consisted of a mesh screen supported by a frame. The defendants removed the worn mesh screen, reconditioned the frames and fixed new screens and then sold the complete screen assembly. They claimed this was repair.

The judge at first instance had held that this was repair. As reported in our UK Patents Review 2000 this decision was overturned by the Court of Appeal.

The House of Lords has now, in the only patent case to come before it in 2000, agreed with the Court of Appeal holding that the defendant had, in effect, made a patented product and the concepts of implied licence to repair and exhaustion of rights had no part to play in cases involving the manufacture of a product. In such cases it was inappropriate to consider whether the Defendant had "repaired" the Product. The issue to be decided was rather whether the Defendant could be said to have infringed the patent. On the facts, the defendant had "made" the patented article and so infringed.

"The passages in Improver and Catnic... do not provide me with a licence to employ a Humpty Dumpty construction in which words mean what I want them to mean"
(*Pumfrey J, Monsanto v Merck*)



Validity

Subsidiary invention of priority document becoming principal invention of patent in suit still entitled to claimed priority date

In *Stoves v Baumatic*, consideration was given to whether the invention was supported by matter disclosed in the priority document and thus entitled to its claimed priority date. The priority document was primarily concerned with an invention whose principal object was to cool an oven control panel, the cooling of the oven door being a subsidiary invention separately claimed. On prosecution of the patent in suit, the subsidiary invention (the cooling of the oven door) had become the principal invention of the patent in suit. It was held that the disclo-

tion indicators, the subject of the litigation, were generally microbiologists. The inventive step lay in the discovery of use of enzymes in such process which involved matters that the Defendants alleged would be obvious to any enzymologist. As a matter of principle, the Court commented that invention cannot lie in bringing into a notional team working on a particular problem a new notional member with different skills from those of the existing notional team. It was held, in any event, that the notional team consisted of both a microbiologist and an enzymologist.

A useful commentary and review of the criteria by which the skilled addressee is viewed appears in the case of *Lilly v Pfizer*. Of particular interest were Laddie J's comments that if the art specifically flagged a technology in which the skilled addressee would regard themselves as inadequately skilled, then they would consider getting help from someone else. A skilled addressee may thus be an expert in all fields of technology raised by the patent in suit.

The level of common general knowledge will differ in different fields. In the field of development of anti-inflammatory drugs considered in *Monsanto v Merck* (see above), the level was very high and changing rapidly. Where a particular level of common general knowledge was asserted in a patent, the Defendant had a choice between accepting such assumption of skill and claiming the patent to be invalid for obviousness, or else challenging such assumption of skill and asserting the patent to be insufficient.

"As a matter of principle, invention cannot lie in bringing into a notional team working on a particular problem a new notional member with different skills from those of the existing notional team."

(Pumfrey J, Minnesota Mining v ATI Atlas)

sure of the priority document provided more than adequate support for the claims of the patent in suit which accordingly was entitled to its claimed priority date.

Skilled addressee and common general knowledge

In the case of *Minnesota Mining v ATI Atlas*, the Court considered the difficult question of the addressee of the specification. Prior to the date of the patent in suit, persons principally concerned with sterilisa-

“The fact that any particular worker in the art had fewer attainments, more limited funds or was more stupid than the notional skilled man cannot turn something that is obvious to the latter into an invention”
(*Pumfrey J, Minnesota Mining v ATI Atlas*)

Obviousness - ex post facto analysis and hindsight reasoning acceptable where no technical need or advantage

In addition to the common warnings against hindsight reasoning and ex post facto analysis referred to, for instance, in *Technograph and Beloit v Valmet*, and reiterated in 2000 in *City Technologies v Alphasense* and *Coflexip v Stolt*, Pumfrey J added a further note of caution in the case of *Minnesota Mining v ATI Atlas* in respect of allegations of obviousness in the light of common general knowledge alone. These, he considered to be particularly prone to be tainted by hindsight. Pumfrey J stated that the fact that others in the art had followed a different course from that pursued by the inventor was only indicative of non-obviousness, and not determinative. “The fact that any particular worker in the art had fewer attainments, more limited funds or was more stupid than the notional skilled man cannot turn something that is obvious to the latter into an invention”. Accordingly, in such cases the time and money spent investigating what particular groups were doing at a particular time may be disproportionate to the usefulness of the evidence obtained. The same remarks could be made in respect of cases of obviousness in the light of particular publications or prior uses, but in such cases the history of those actually skilled in the art at the material time is generally of less interest, unless it can be shown that those skilled in the art had, in fact, been aware of the relevant information. On the facts, the invention was found to be obvious over specified items of prior art, but not common general knowledge alone.

Applying the standard *Windsurfing* approach to obviousness, the Patents Court in *Stoves v Baumatic* held that there was no scope for invention in blowing air between the walls of an oven door rather than sucking it. There was no evidence of any unforeseeable technical advantage in doing so, it was just an alternative. There was no reason to doubt ex post facto reasoning when there had been no evidence either of a technical need or long-felt want nor of technical advantage or commercial success from which it was possible to draw an inference of non-obviousness. Where there was no particular advantage, there was no point in asking why the particular invention had not been made before.

No conflict in raising allegations of both obviousness and insufficiency

In *Kimberley Clark Inc. v Proctor & Gamble*, in addition to an allegation of insufficiency, the Defendants alleged that the patent in suit involved no inventive step. Pumfrey J commented that, notwithstanding that it is often said that a specification cannot be both obvious and insufficient, this was not necessarily the case. In the present case, in addition to a finding of an insufficiency, Pumfrey J also held the overall inventive concept to be obvious over two prior publications. Pumfrey J held that, although the teaching of the patent in suit was twofold, describing both a surge management means and a test to decide whether particular fabrics would be suitable to be used as such surge management means, the test was irrelevant to the inventive concept of the patent in suit and all other aspects of the claims were obvious. Further, the test was an arbitrary one and no

guidance could be obtained from the purpose of the test, nor could parallels be obtained in the common general knowledge or through other sources. This ambiguity in the description of the crucial test, which would not be able to be resolved by the skilled reader, led also to a finding of insufficiency.

Obviousness - commercial success must be pleaded

In *Dyson v Hoover*, whilst commercial success was not pleaded, Dyson did attempt to rely on what it called “technical acclaim” for its product. The Court rejected Dyson’s argument considering it to be “back door” commercial success. In modern practice, the rules regarding reliance on commercial success in patent infringement actions are subject to specific procedural requirements set out in para 9.3 of Part 49 of the CPR.

Added matter - implicit disclosure; Insufficiency - difficulties in claiming a number of nucleotide sequences; Obvious to try - all research is a gamble

In *Novo Nordisk v DSM*, the Court rejected Novo’s assertion that the patent was invalid for added matter. It was an oversimplification to say that because a claim in a patent was added or amended after the application was filed, that there was added matter merely because the addition or amendment relied on technical matter which was not claimed or otherwise referred to in the patent. Whilst such proposition might be a good general basis from which to start, it was not always the right conclusion. Each case must be looked at on its own facts. The concept of implicit disclosure by an applica-

tion has previously been recognised by the Court of Appeal in *AC Edwards v ACME Signs & Displays*.

On the facts, “degeneracy” in the context of the DNA code was something which needed to be explained as little as the meaning of pH. The patent was, however, as reported below, revoked on the grounds of insufficiency and obviousness.

As concerns sufficiency, the particular claim of the patent claiming DNA sequences hybridising at low stringency conditions if taken literally was extraordinarily broad in its effect and unworkable. Modification of the stringency conditions would affect the scope of the patent, but the patent provided no teaching as to what stringency conditions were appropriate and interpretation of the patent depended upon the stringency conditions selected by the person carrying out the work. Accordingly, the patentee found itself in a “squeeze” from which it could not escape. In finding the patent insufficient, Neuberger J did not overlook the point that it is unrealistic to confine a patentee to specific amino acid and nucleotide sequences, since to do so would give a patent no practical or commercial effect, since proteins of a similar nature can vary subtly from each other. The draftsman of a patent thus faced a difficult task. Whilst having to ensure that he did not formulate his claim as broadly as that of the patent in suit, as he would thereby fall foul of insufficiency, it was also pointless to formulate the claims narrowly to specific amino acid and nucleotide sequences. A suggested way around this problem may be to consider incorporation of a clear and sufficient “relationship” between the particular sequences. No doubt this is an issue that will be considered further in future cases.

The patent in suit also failed for obviousness over common general knowledge and the cited prior publication. Although the method disclosed for cloning, sequencing and the recombinant expression of the gene for fungal phytase may not have been the first method of choice, it was a known method and would have been an obvious technique to try. Of interest was the Court’s rejection of Simon Thorley QC’s argument

that a researcher in the field would not be a “gambler”. Neuberger J commented that “in a sense, any research is a gamble, because it involves embarking on a voyage which either is one of uncertainty, in the sense that the researcher has no notion of what he will find, or is one which has a certain destination, but the researcher is nonetheless seeking an end which, almost by definition, no one has so far achieved”. In either case, there must be a degree of uncertainty as to whether there would be a result which could be characterised as successful. To that extent, any research was a gamble. The Court thus held that the skilled addressee would not have been diverted from experimenting with the cited prior art, notwithstanding certain problems it raised. The Court did, however, reject Novo’s argument that the patent was a “discovery” rather than an invention. Subject to the Court’s findings on obviousness and insufficiency, the invention was something that could properly be claimed, particularly in light of the reasoning of the Court of Appeal in *Genentech’s Patent* and the House of Lords’ reasoning in *Biogen v Medeva*.

Appellate court will not overturn findings of fact unless an error of principle

The Court of Appeal in *Boston Scientific v Palmaz* has once again reiterated the principles of *Biogen v Medeva* that the Court should not interfere with a finding of fact by the trial judge, who had the benefit of hearing the evidence, unless there was insufficient evidence for the judge to form the view that he did. (See also *Cartoneries de Thulin v CTP White Knight*). Whilst previously such principles have applied to questions of obviousness, in *Boston Scientific* these principles were applied to the question of novelty.

Obvious to try - eventually or not at all

In defending the patent in suit in *Instance v Denny Brothers* from an attack on obviousness, Christopher Floyd QC in skilful cross-examination, asserted that potential difficulties with the cited prior art would mean that it was not “obvious to try” using it.

“...in a sense, any research is a gamble, because it involves embarking on a voyage which either is one of uncertainty, in the sense that the researcher has no notion of what he will find, or is one which has a certain destination, but the researcher is nonetheless seeking an end which, almost by definition, no one has so far achieved”
(*Neuberger J, Novo Nordisk v DSM*)

Laddie J, however, did not accept such argument since it carried with it two, inconsistent, suggestions. On the one hand, it was suggesting that of the things that would be tried, adaptation of this piece of prior art would not be the first, and secondly it suggested that adaptations of this piece of prior art would not be tried at all. On the evidence, the Judge found that the adaptation would eventually be tried and the claims thus failed for obviousness.

Insufficiency - difficulties in claiming a class of compounds

If a patent claims a wide class of compounds and provides the teaching to identify which compounds work for the particular use in question and which are most preferred for such purpose, is such a patent insufficient? This was the question considered by the Patents Court in *Monsanto v Merck*. The essential underlying concept is that of the enabling disclosure. The patentee is not entitled to protection wider than the contribution which he has made to the art. Following the analysis of Lord Hoffman in *Biogen v Medeva*, if an invention discloses a principle capable of general application, then the claims may be in correspondingly general terms. If, however, the claims are specific to a number of discrete methods or products, then the patentee must enable the invention to be performed in respect of each of them. Thus, if a class of compounds is claimed to have a particular beneficial effect, then all members of such class (save possibly for a few exceptional cases) must demonstrate such beneficial features. The invention is to enable the skilled reader to predict without conducting empirical research each time. The Court needed to consider, however, what the position was if the unifying characteristics were not possessed by all members of the class. In such situation there were two possibilities. Either, the claim would be read as covering only those members of the class possessing the desired characteristic. This, however, would only tell the skilled reader that some of the family of compounds may or may not possess some desirable characteristic.

Alternatively, there was the approach taken by the Court in *Biogen v Medeva*. The Court considered this latter approach to be the correct one. If compounds having the features of the claim may or may not possess the qualities which the patent says unify the class, it cannot be said that the claim reflects a true class at all. It is rather just a generalised description of a large number of chemical compounds. On the facts, the claims of the patent were found to be insufficient, since the experimental evidence adduced demonstrated that the class identified merely provided the skilled man with a class of compounds which may or may not show the claimed features - the benefits of the class were thus unpredictable. For similar reasoning, the patent was not entitled to its earlier priority date.

The plaintiffs (appellant's) Counsel argued that the claim had two novel features over and above what had been disclosed in the lecture, namely that taxol was suitable for treating cancer when infused over 3 hours; and the reduction in neutropenia. The Court of Appeal held that the tenor of the lecture made it clear that taxol was suitable for treating cancer using a 3 hour treatment.

The Court also held that carrying out a 3 hour treatment would inevitably result in less neutropenia. When a patient was being treated the physician would inevitably monitor the patient's blood. The monitoring would inevitably reveal the reduced neutropenia.

The claimed invention was disclosed by the lecture and the patent was invalid. (Claim 1 was also held to be obvious).

The Court of Appeal also considered

"There are therefore strong reasons for maintaining the view expressed by the patent judges in the John Wyeth case" (that Swiss-type claims be accepted)
(*Aldous LJ, Bristol-Myers Squibb v Baker Norton*)

Swiss-type claims continue to be allowed

In *Bristol-Myers Squibb v Baker Norton* the Court of Appeal upheld the first instance decision of the Patents Court referred to in our UK Patents Review 1999. In this case BMS held a patent for the manufacture of taxol, a compound known to have anti-tumour activity, for treating cancer. The claim was a second medical use, Swiss-type claim: "use of taxol...for manufacturing a medicament for...administration of [taxol] over a period of 3 hours or less as a means for treating cancer and simultaneously reducing neutropenia".

The inventor had disclosed the use of taxol in short doses, 3 hours as against 24 hours, in a public lecture. 24 hours doses had been given to reduce risk of anaphylactic shock.

The Court of Appeal held that the Judge was right to conclude that this was not a claim for second therapeutic use. Taxol was known for treating cancer.

whether the claim was to a method of treatment and so unpatentable under section 4 of the Patents Act (not industrial application). While the Patents Court had held that the claim was not one to a method of treatment, the Court of Appeal took the view that this was a method of treatment, which the patentee had attempted to disguise by drafting it in Swiss form, and was accordingly unpatentable.

The Court of Appeal did, however, feel that there were strong reasons for upholding the EPO's decision in *Eisai* and continuing to allow second medical use claims in general, and refused to contemplate reviewing either the *Eisai* or *Mobil* decisions.



Evidence

Expert's duty is to the Court

Cadcam v Proel, one of the few Patents County Court decisions of the year, provides a timely reminder of the need for expert witnesses to remember their duty lies to the Court. In the case, all witnesses for the Claimant failed to provide fair and impartial evidence. One witness being impressive from only one point of view, in that he had the interests of his company very much at heart, and was also noted to be argumentative, not impartial and inclined to prevaricate.

The Claimant attempted to argue that the skilled reader would have interpreted

Playing the system not an abuse of process

In *Rohm & Haas v Collag*, the Patents Court considered, amongst other things, upon whom the burden of proof rested in connection with the preliminary issue before it. The Claimant's patent concerned a process for manufacturing water-dispersible granules containing propanil, a herbicide used in agriculture. In its original pleading the Claimant merely alleged that the Defendant's product infringed the patent in suit. It subsequently came to light that the Defendant employed two different processes for manufacturing its product. In the course of correspondence the Claimant made clear that it was only in respect of one such process ("Process A") that infringement was claimed. The Claimant refused, however, to acknowledge that the second process ("Process B") did not infringe. Accordingly, the Defendant, in addition to denying infringement and counterclaiming for the revocation of the patent in suit, also sought a declaration that Process B did not infringe the patent. A determination of this preliminary point was ordered. In determining upon whom the burden of proof lay, the Claimant argued that, since the preliminary issue solely arose out of the Defendant's counterclaim, and since it was the Defendant who was seeking the relief, the burden of proof lay with the Defendant. In the absence of special circumstances, this position was accepted by the Defendant. The Defendant, however, argued that there were such special circumstances in this case, in that the declaration of non-infringement was only sought as a result of the Claimant's failure to provide the requested acknowledgement in correspondence. The Court accepted the Claimant's

"Mr Bell was impressive from one point of view, in that he had the interests of his company very much at heart."

(Mr P Prescott QC, Cadcam v Proel)

the claim in a narrow way since it would have been apparent to him that not to do so would have a materially adverse effect on the way the invention worked. The Claimant thus attempted to use the *Catnic/Improver* tests as a means of restricting the claim to counter an allegation of obviousness (rather than, in the usual manner, to widen a claim in the context of infringement issues). On the facts, such arguments were not accepted by the Court. We await to see whether the decision is subsequently appealed in line with so many previous Patents County Court decisions.

arguments that in normal circumstances the burden of proof in such a case would rest on the Defendant. The Court did not consider that special circumstances existed in this case since although the Claimant's attitude to Process B in these proceedings could be thought of, according to taste, as "unattractive, tactical, canny or commercial" it was certainly not an abuse of the process of the Court. The worst that could be said about the Claimant was that it was "playing the system". This was not a valid reason for changing the burden of proof.

Get real with experiments

In both *Dyson v Hoover* and *Novo Nordisk v DSM*, the Court has given guidance on the need for caution in the conduct of experiments in patent actions. In *Dyson*, the Court commented that in repeating any prior art proposal by experiment, in that case with a view to proving lack of novelty, the party seeking to do so must adhere faithfully to the teaching of the source document. Moreover, interpretation of the cited document for the purpose of such experiment was deemed to be assessed as at the date of its publication. Hoover in that case failed to carry out its experiment in accordance with such requirements, the scale of their model not at all reflecting what the prior art had taught ("they saw an elephant and drew a mouse"). Similarly, in *Novo Nordisk*, Neuberger J commented that the Court should always approach any experiment designed to show that a patent is insufficient (or, indeed, one designed to show that it is sufficient) with care. This is since it is almost inevitable that however much expert witnesses are enjoined to adopt a neutral stance, the experiments

they design (and, even more, the experiments which the parties themselves design or commission) will have a degree of "spin". It was not, however, enough for the other party to invite the Court to disregard an experiment on this ground. On the facts *Novo's* experiment had been validly carried out.

Collection of evidence – professionals entitled to delegate tasks

The Court of Appeal has upheld the Patents Court decision in *Arbiter Group v Gill Jennings and Every*, finding that the English patent agents were entitled to rely upon information provided to them by a US firm of patent searchers instructed by them, without obtaining written confirmation or corroboration of such information. The US firm of patent searchers incorrectly informed GJE that the specified US patent was still in force. This information was passed on by GJE to its client who claimed against GJE in negligence for its lost opportunity of exploiting the US market. The Court of Appeal held that a professional in appropriate circumstances is entitled to delegate tasks provided he does so to a suitably qualified and experienced person. There will always be inherent in delegation a risk that a mistake may be made, but having entrusted a task to respective experts in the field, a person was entitled to rely on them and not carry out further enquiries themselves.

"They saw an elephant and drew a mouse"
(*Mr R Fysh QC, Dyson v Hoover*)



Remedies

Normal form on injunction continues to apply

Laddie, J's decision at first instance in *Coflexip v Stolt* was understandably a cause for concern for patentees. Notwithstanding the agreement of the parties that the usual form of injunction was the appropriate order, the Judge concluded that the injunction should not be in the usual form, but should be of more limited scope relating to the particular acts of infringement pleaded rather than an injunction prohibiting infringement of the patent generally. The Court of Appeal has thankfully overturned the Judgment of Laddie, J and restored the

been validly granted and infringed, it was the infringer who should seek guidance from the Court if it wished to "sail close to the wind". This decision should go some way to alleviating patentees' concerns to the scope of injunctive relief.

"Set-off" of costs appropriate with infringement of partially valid patents

In *Nutrinova v Scanchem*, the Patents Court, having found the patent in suit to be partially valid and such claims as were valid to have been infringed, directed the Claimant to apply to amend the patent by deletion of the invalid claims and considered various issues concerning the relief available to the Claimant in such circumstances. The Court firstly considered the issue of costs. Rather than have two assessments in such a situation, Pumfrey J stated that it would normally be more convenient to make a percentage deduction from the costs which would otherwise be paid to the Claimant. In response to the Defendant's allegations, the Court commented that where appropriate the Court would look with great care at disproportionate employment of resources by a successful party. At the same time, however, a substantial expenditure could not be regarded per se as disproportionate. The Court held that the Claimant's expenditure, of approximately £1.1 million, was not so great as to be disproportionate such that a special order was required over and above the normal scrutiny of a costs judge. The Court also considered the Claimant's application for an interim payment of costs. The Court's discretion to award interim costs was a wide one and would be dependent upon a number of factors, including the parties' financial positions and

"It is the infringer who should seek guidance from the Court if it wishes to "sail close to the wind".
(*Aldous LJ, Coflexip v Stolt*)

usual form of injunction. The Court found that the form of injunction proposed by Laddie, J suffered from some basic deficiencies - it was not linked to the term during which the patent existed and, without modification, would continue even when the patent expired; it exceeded the statutory right given by Section 60(1) and (2) of the Patents Act in failing to exclude acts which would otherwise be exempted from infringement; it also raised considerable difficulties on construction incorporating the Defendant's product and process description which contained a considerable amount of detail that was irrelevant to infringement. On such issues of construction, the Court considered that, the statutory right having been held to have

“In heavy pharmaceutical actions of this kind the fact that two large drug companies are facing a common enemy does not ... “make them friends”.
(*Holman J, Bristol Myers Squibb v Baker Norton*)

prospects of appeal. The Court further noted that the Defendant was “far from rich” and held that any advance on costs was to be made in instalments - the best guide to which was to consider payments previously made by the Defendant to its lawyers in connection with the litigation.

The Court also considered the Claimant's application for disclosure of the names of the purchasers of infringing material from the Defendant. It is settled law that the Court has jurisdiction to make such an order and that in exercising its discretion, the interests of the parties need to be balanced. In a case where the Defendant's good faith was not in issue, however, the Court held that there would need to be strong circumstances to justify such an order where there was a bona fide appeal. Such disclosure was refused in this case.

Costs of both co-defendants recoverable

In *Bristol Myers Squibb v Baker Norton* the Defendants had each been represented by their own solicitors and junior counsel and had both instructed Simon Thorley QC as leader. The Patents Court had awarded only one set of costs.

The Court of Appeal held that it was not inevitable that two successful Defendants who instruct different legal teams should be deprived of their costs, even if they adopted a common approach. The Claimant had sued two Defendants. It was not unreasonable for each Defendant to recover its own costs from the Claimant - “In heavy pharmaceutical actions of this kind the fact that two large drug companies are facing a common enemy does not ... “make them friends”.

Threats - “All for one and one for all”; without prejudice threats - “to be or not to be”.

In *T H Goldschmidt AG v EOC Belgium NV*, the Patents Court held that the Claimant's threats of proceedings were justified, notwithstanding that the Claimant succeeded in demonstrating the validity of only one of the three patents in suit and despite the fact that threats had been made to a number of customers who were not subject to the proceedings. The finding of infringement and validity of one of the patents justified the threats in respect of all three patents.

In *Kooltrade v XTS*, XTS attempted to prevent Kooltrade from importing competing children's buggies in two without prejudice letters sent by its solicitors to Kooltrade and its principal customer, Tesco. The first letter referred mainly to purported infringement of XTS' exclusive distribution rights; the second letter, however, in addition referred to purported patent infringement. It was held that XTS had no relevant intellectual property rights in relation to the buggies in the United Kingdom and that the second letter constituted an unjustified threat of patent infringement. In contrast to the case of *Unilever v Proctor and Gamble* (reported in our UK Patents Review 2000), the claim in this case was not so grave and unambiguous an impropriety as would justify invasion of the without prejudice privilege if otherwise the privilege were available. On the facts, however, Pumfrey, J found that at no material time were any relevant negotiations entered into and accordingly the without prejudice rule did not apply. “Without prejudice” was not a label which could be used indiscriminately

so as to immunise an act from its normal legal consequences where there was no genuine dispute or negotiation.

The case is also interesting for Pumfrey J's demonstration of active case management in accordance with the overriding objective of the Civil Procedure Rules. At an initial hearing he gave directions for a trial on witness statements only, without cross-examination, on two specific issues. He further indicated to the parties that the matter was one which he considered to be suitable for mediation. The parties did not, however, accede to his latter suggestion.



Reported case analysis

The cases

Case name	Judges names	Date	Industry sector
TH Goldschmidt AG & anr v EOC Belgium NV & ors	(D Young QC)	25.01.00	Pharmaceuticals
Allergan Inc & anr v Sauflon Pharmaceuticals Ltd	(Pumfrey J)	02.02.00	Contact Lenses
Monsanto Co & ors v Merck & Co Inc	(Pumfrey J)	04.02.00	Pharmaceuticals
Boston Scientific Ltd & anr v Palmaz & anr	(Henry LJ, Aldous LJ)	20.03.00	Medical Devices
Oxford Gene Technology Ltd v Affymetrix Ltd & ors	(Jacob J) (Aldous LJ, Brooke LJ, Sedley LJ) (Aldous LJ, Brooke LJ, Sedley LJ)	07.04.00 02.11.00 23.11.00	Biotech
David J Instance Ltd v Denny Bros Printing Ltd	(Laddie J)	14.04.00	CD Labels
Swintex Ltd v Melba Products Ltd	(Pumfrey J)	10.05.00	Clothing
Nutrino Nutrition Specialties & Food Ingredients GmbH & anr v Scanchem UK Ltd	(Pumfrey J)	8.05.00	Pharmaceuticals
Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc & anr	(Aldous LJ, Buxton LJ, Holman LJ)	23.05.00	Pharmaceuticals
Cartonneries de Thulin SA v CTP White Knight Ltd	(Gibson LJ, Brooke LJ, Walker LJ)	25.05.00	CD Packaging
Arbiter Group plc v Gill Jennings and Every (a firm) & anr	(Swinton Thomas LJ, Waller LJ, Arden LJ)	26.05.00	Professional Liability
Wheatley & anr v Drillsafe Ltd & ors	(Aldous LJ, Sedley LJ, Mance LJ)	05.07.00	Oil Drilling
Kooltrade v XTS Ltd	(Pumfrey J)	11.07.00	Babies' Buggies
United Wire Ltd v Screen Repair Services (Scotland) Ltd & anr	(House of Lords)	20.07.00	Oil Drilling
Kimberly-Clark Worldwide Inc v Procter & Gamble Ltd & anr	(Pumfrey J)	21.07.00	Nappies
American Home Products Corp & anr v Novartis Pharmaceuticals (UK) Ltd & anr	(Simon Brown LJ, Aldous LJ, Sedley LJ)	27.07.00	Pharmaceuticals
Rohm & Haas Co v Collag Ltd	(Neuberger J)	28.07.00	Agrochemicals
Stoves Ltd v Baumatic Ltd	(Pumfrey J)	28.07.00	Cooling Systems
Jon Sapey v Trianco Red Fyre Ltd	(Pumfrey J)	31.07.00	Boilers
Coflexip SA & anr v Stolt Comex Seaway MS Ltd & ors	(Aldous LJ, Chadwick LJ, Buxton LJ)	31.07.00	Pipe Laying
Dyson Appliances Ltd v Hoover Ltd	(R Fysh QC)	03.10.00	Vacuum Cleaners
City Technology Ltd v Alphasense Ltd	(D Young QC)	26.10.00	Electrochemical Gas Sensors
Amersham v Amicon & ors	(Laddie J)	26.10.00	Chemicals
Minnesota Mining and Manufacturing Co v ATI Atlas Ltd & Anr	(Pumfrey J)	31.10.00	Biotech
Lilly Icos LLC v Pfizer Ltd	(Laddie J)	08.11.00	Pharmaceuticals
Cadcam Technology Ltd v Proel SRL & anr	(P Prescott QC)	29.11.00	Textiles
Asahi Medical Co Ltd v Macopharma (UK) Ltd	(Laddie J)	05.12.00	Medical Devices
Rocky Mountain Traders Ltd v Hewlett Packard GmbH & ors	(Aldous LJ, May LJ, Sir Christopher Slade)	20.12.00	CD Labelling
Novo Nordisk A/S v DSM NV	(Neuberger J)	21.12.00	Biotech

Useful links

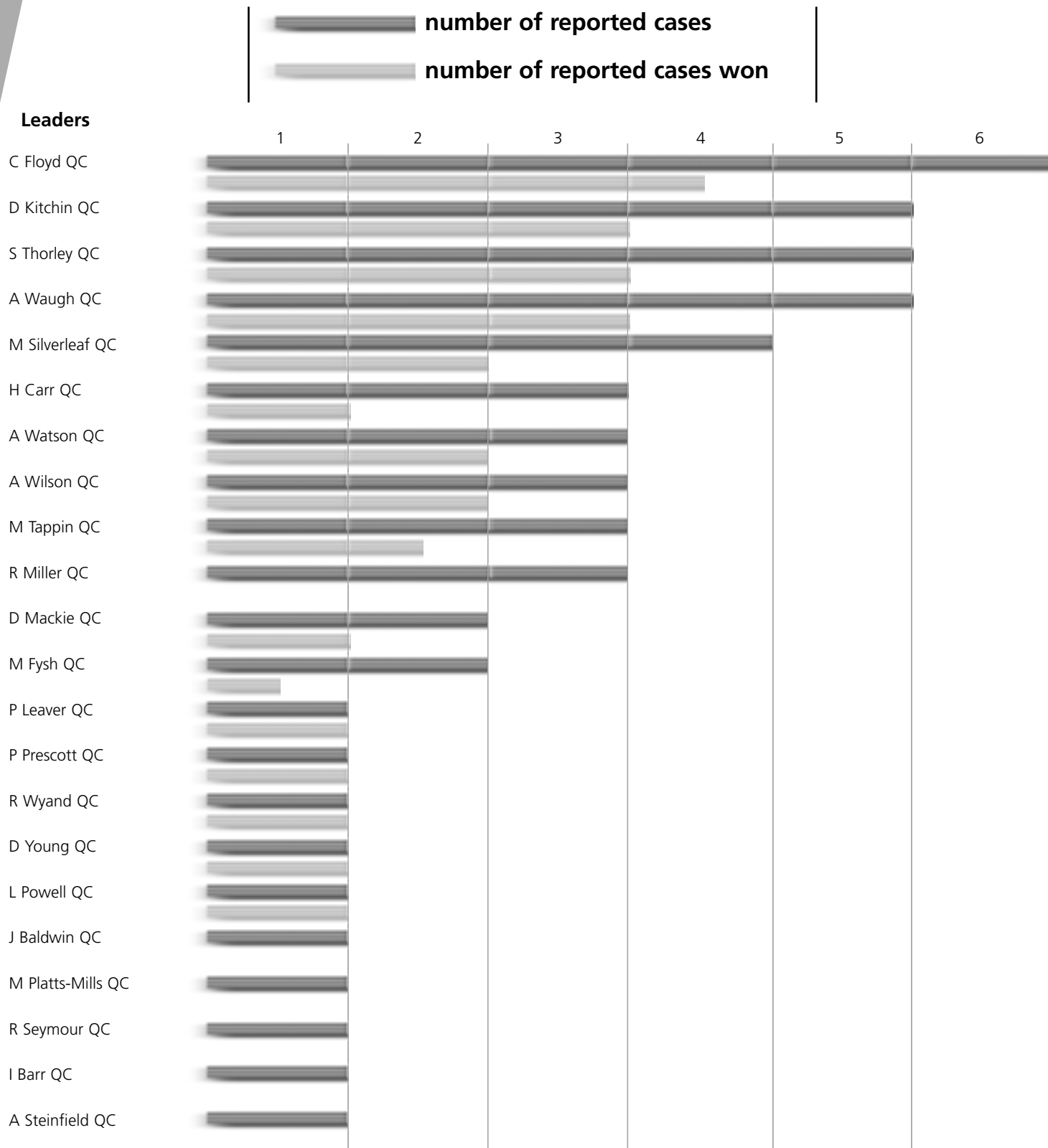
This is an analysis of reported cases, which can be found on the following websites - www.courtservice.gov.uk [www.newLawonline.co.uk](http://www.newlawonline.co.uk). Other cases may have been reported elsewhere. The following analysis of how counsel and judges compared is based only on these reported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

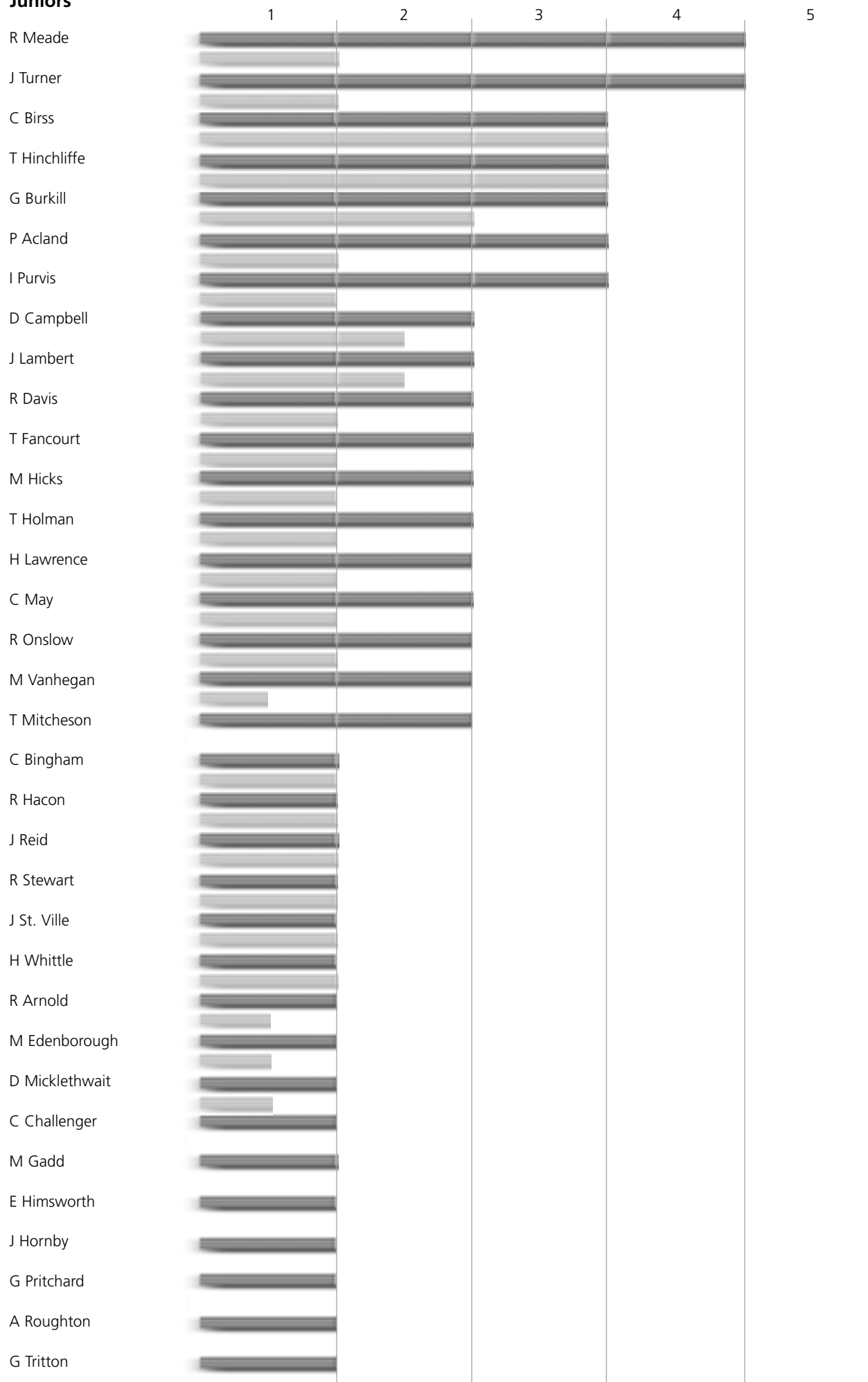
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✓	✓	✓	✓	✓	X	
✓	X	X	X	X	X	✓
✓	X	✓	X	X	X	X
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X	X	✓	✓	✓	X	X



How Counsel compared

(based on reported case analysis on page 18)



Juniors

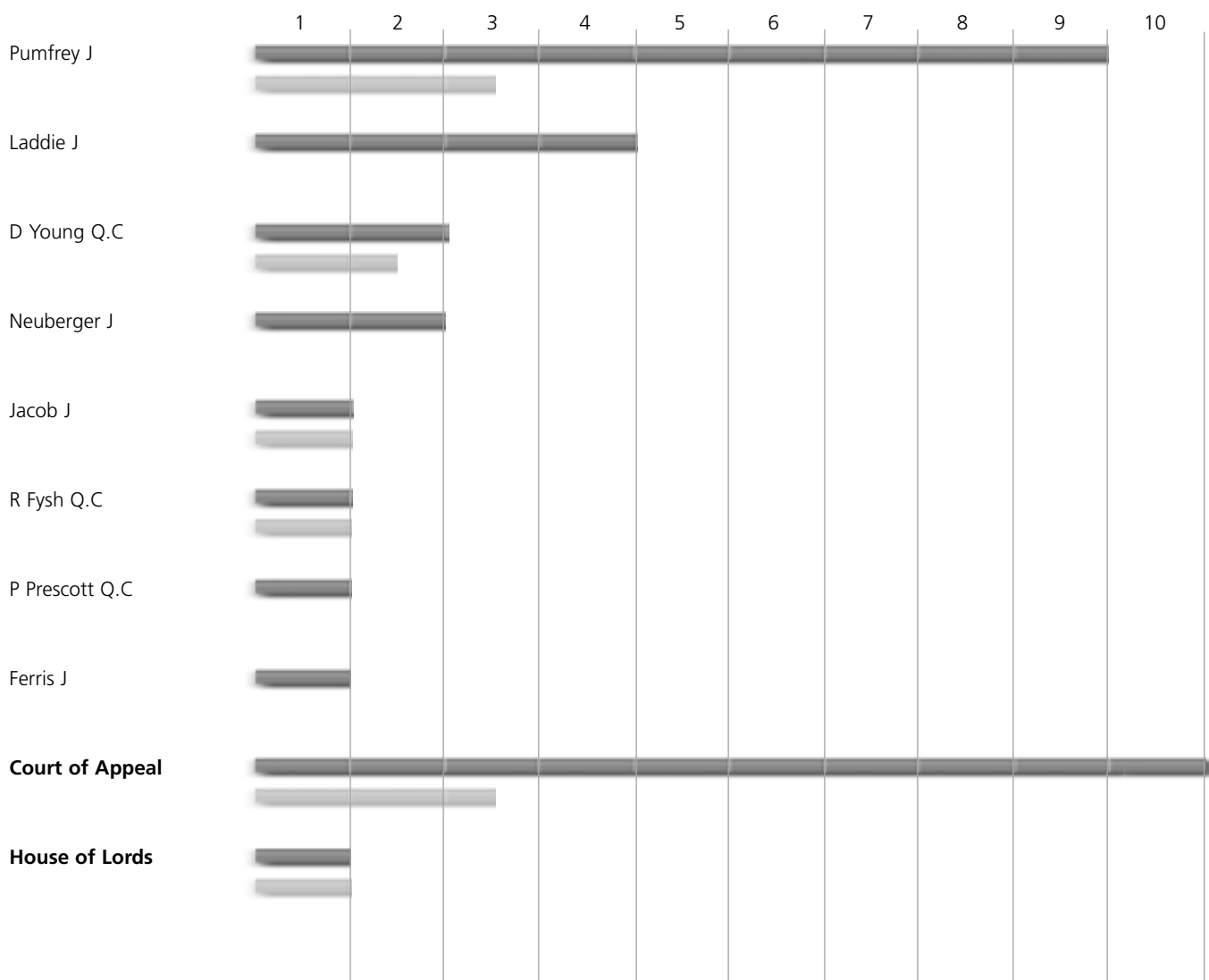


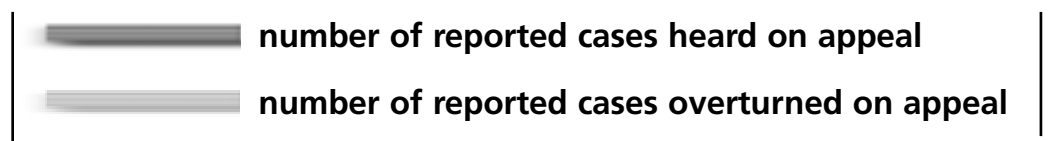
How the Judges compared

(based on reported case analysis on page 18)

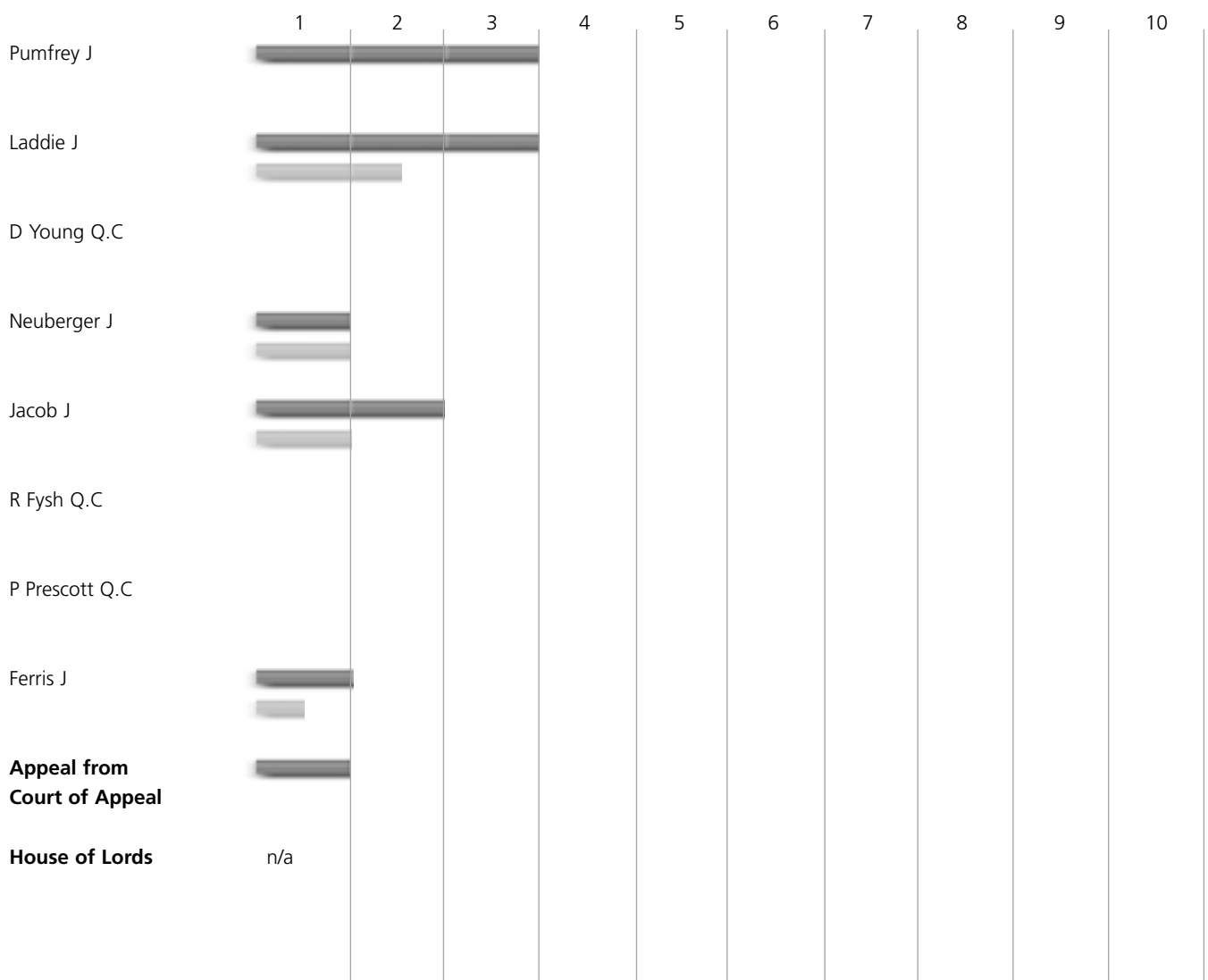


Patents Court/Patents County Court





Appeal from Patents Court/Patents County Court



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