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The skilled person: an evolving concept

Liz Cohen* & Claire Davies

The skilled person is a concept central to patent law, underpinning the analysis of obviousness, sufficiency, claim construction, novelty, added matter and priority. Identifying such a person correctly, particularly the level of skill and the common general knowledge that they should possess, is critical to determining whether a patent is valid and/or infringed and has significant implications for the pharmaceutical industry. However, the concept can be difficult to define. Once referred to as 'The man on the Clapham omnibus' of patent law, the skilled person is a technician who is skilled in the art yet wholly devoid of imagination. Nevertheless, his attributes and knowledge, which are context-dependent and vary from art to art, are continually evolving. This article will look at the evolution of the skilled person, focusing on the implications for the future of pharmaceutical patents and patent litigation.

An introduction to the skilled person

Also referred to as the 'person skilled in the art', the 'person having ordinary skills in the art', and the 'skilled addressee', the skilled person is a legal fiction, the precise attributes of which are notoriously hard to identify. Described as a skilled technician who is well acquainted with workshop technique and who has carefully read the relevant literature, with an unlimited capacity to assimilate the content of scores of specifications but who is "incapable of a scintilla of invention" [1], the skilled person provides a perspective through which issues relating to validity and infringement must be considered. For this reason, the skilled person may be seen as 'The man on the Clapham omnibus' of patent law*, and the knowledge attributed to them in a given context will often determine whether a patent is upheld or revoked.

The level of skill and knowledge ascribed to the skilled person has crucial implications for the pharmaceutical industry. Patents are relied upon to make products profitable to develop and manufacture and to secure investment for future research, while a key issue for generic companies in particular is evaluating whether or not a patent is valid, or may be revoked to enable it to enter the market at the earliest opportunity. The importance of determining who the skilled person is and what they should be deemed to know has therefore been highlighted in several key pharmaceutical cases, including *Kirin Anzen vs Hoechst Marion Roussel Ltd* [2], *Conor Medsystems, Inc. vs Angiotech Pharmaceuticals, Inc.* [3] and, more recently, *Intercept UK Ltd vs Merial* [4].

However, as will be discussed below, the attributes of the skilled person have developed over time. Recent case law has established that such a person might be a notional team of people with different skills and has also considered whether the person skilled in the art must have the same attributes for all aspects of patent law [5]. In highly technical areas such as pharmaceuticals, the level of knowledge ascribed to the skilled addressee will also increase as advances are made and become widely applied.
known within the relevant field. The skilled person may therefore be more accurately characterized as a set of legal fictions, which are continually evolving. This article will consider how the skilled person is evolving, the factors driving this evolution, the consequences for the pharmaceutical industry, and the practical implications for running patent litigation and selecting expert witnesses, substantially as seen with the eyes of an English practitioner.

The skilled person in patent law
The concept of the skilled person plays an integral role in almost all aspects of patent law, providing a basis for the analysis of obviousness, sufficiency, claim construction, novelty, added matter and priority. These issues, upon which arguments for the validity and infringement of patents rest, are of great importance to the pharmaceutical industry, where R&D costs are high and products require lengthy clinical trials and approval procedures with no guarantee of a successful outcome. In such an environment, patent protection is essential in order to achieve an adequate return on any investment made: 'no patent equals no product' [6]. However, the involvement and contribution of the skilled addressee varies in relation to each aspect of patent law as considered below.

- **Inventive step**
  In the context of determining a patent’s validity, the patentee must demonstrate to the relevant court or patent office that there has been an inventive step. Therefore, there must first be the determination of the invention, or the problem to which the invention is directed, followed by an assessment of the prior art. Once the prior art has been identified, the court can ascertain whether a person of ordinary skill in the art, having knowledge of the prior art and the common general knowledge, which such a skilled person would possess, would consider the invention as nonobvious, or involving an inventive step.

The importance of the skilled person to the assessment of obviousness was underlined in *Sandoz GmbH vs Roche Diagnostics* [7]. The court held that in order for something to be obvious to try, the skilled addressee must have tested it as something that held out a prospect of producing valuable results: because of their innate lack of inventiveness, such a person would not carry out their trials for the sake of doing so, but would restrict their tests to what they believe might assist them in solving their problem. Furthermore, in *Omnipharm Limited vs Merial* [8], the court concluded that a spot-on formulation was not obvious over a spray-on formulation, asking whether the skilled person would consider (with a fair expectation of success) that a spot-on formulation would distribute over the surface of the skin. Given that there was no basis in the prior art for the skilled person to predict that the result could be achieved, the patent was held to have an inventive step.

- **Sufficiency**
  A pharmaceutical patent, like any other patent, must disclose any feature essential for carrying out the invention in sufficient detail to render it apparent to the skilled person how to put the invention into practice [9]. The skilled person’s role in assessing sufficiency was recently discussed in *Eli Lilly & Co vs Janssen Alzheimer Immunotherapy* [10]. Here, the patent in question disclosed and claimed pharmaceutical compositions comprising an antibody to amyloid-beta peptide (Aβ), thought to be a causative element in Alzheimer’s disease. The court considered issues such as whether the specification enabled the skilled team to make suitable antibodies to Aβ without undue burden and whether the production of an appropriate antibody to Aβ would be routine work for the skilled immunologist, ultimately concluding that the patent was invalid for insufficiency.

- **Claim construction**
  Establishing the identity of the skilled person and the knowledge, and the assumptions that should be attributed to that person is also vital when construing a patent. This determination is of critical importance: if a patent is interpreted too broadly, it will unfairly benefit the patentee and could prevent others from patenting inventions in a similar area, while if it is interpreted too narrowly, the patentee will not benefit sufficiently from the invention.

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'The expression possibly derives from a phrase coined by 19th Century journalist Walter Bagehot to describe the ordinary man of London, and the concept has been used in tort law to refer to a hypothetical reasonable person who provides a standard against which the parties' conduct may be measured.'
Although the skilled person is not expressly referred to by the UK 1977 Act or by the European Patent Convention (EPC) in relation to construction, the concept is mentioned in the Protocol on the Interpretation of Article 69 of the EPC, which also applies to the UK 1977 Act. Within the EU, it is settled both in the EPO and at a national level that the correct, purposive approach to the construction of patent claims requires the court to give the language of the claim the meaning that would have been understood by the skilled addressee. In *Kirin Amgen vs Hoechst Marion Roussel Ltd*, a case relating to methods for the production of erythropoietin, the court reiterated that in construing the claims, it must consider what the skilled person would have understood the patentee to be using the language of the claim to mean. Courts will therefore determine how the skilled person understands the respective elements of the patent claim in their overall technical context, using the description and the drawings to interpret this context.

### Enablement

One of the most important aspects of the above test for novelty is that a prior disclosure must 'enable' the invention in order to anticipate it, and the skilled person's level of skill and knowledge plays an important role in determining whether this is the case. According to the Guidelines for Examination in the EPO 2012 edition (the EPO Guidelines), subject-matter described in a document can only be regarded as having been made available to the public if the information given to the skilled person is sufficient to enable him, at the relevant date of the document to practice the technical teaching, taking into account also the general knowledge at the time in the field to be expected of him.

The same test has been adopted by national courts within the EU and has been used in several cases involving pharmaceutical patents. In *Synthon vs Smithkline Beecham*, involving a patent for paroxetine methanesulfonate in crystalline form, the House of Lords upheld the judge's conclusion that although a previous patent application had disclosed the use of a solvent that proved unsuitable for crystallisation, the skilled person would have tried some other solvent mentioned in the application or forming part of their common general knowledge. Such a person would therefore have been able to make paroxetine methanesulfonate crystals within a reasonable time, meaning that the patent was invalid by reason of this enabling disclosure.

### Priority

In the pharmaceutical industry, where the body of knowledge common to practitioners is constantly growing as advances are made, the issue of priority is of great significance. It means that information contained in the first patent filing will not form part of the prior art when novelty and inventive step are considered of a later application, providing that later application is filed within the appropriate grace period and is in relation to the same invention.

Article 87 EPC, which deals with priority, does not explicitly refer to the skilled person. Nevertheless,
established jurisprudence, both in the EPO and at a national level, makes it clear that in assessing priority, the skilled person plays a key role. For instance, the subject matter of the claim in the European patent (or patent application) must be derivable “directly and unambiguously, using common general knowledge, from the previous application as a whole”, taking into account the common general knowledge of a person skilled in the art [19]. This principle is also set out in the EPO Guidelines [20].

A similar approach towards cases where a challenge to entitlement to priority is made has been adopted by the English courts: the skilled person, equipped with common general knowledge, must generally be able to derive essentially the same information as forms the subject matter of the granted claim from the previous application as a whole, such that he is then able to work the invention in accordance with that claim [4].

In Intervet vs Merial [4], which involved a patent for a method for the in vitro diagnosis of type II porcine circovirus infection and diagnostic reagents, the judge considered how the patent would have been read by the skilled person and, on this basis, concluded that the priority document did not therefore disclose the same invention as the patent.

Attributes of the skilled person

- Hypothetical construct of patent law

As stated above, the skilled person is a hypothetical construct of patent law: real individuals with all the necessary characteristics rarely, if ever, exist [25]. The skilled person is typically characterized as an ordinary worker of average skill in the relevant art, who has an exhaustive familiarity with all the common general knowledge in that field and accepts all the conventional prejudices associated with it. He must also have a scrupulous and diligent capacity for understanding and applying any piece of prior art that may be relevant. Importantly, he is not possessed of any inventive capacity [25]. Discussions of the skilled person by the UK courts have produced a very similar list of attributes [26]. When assessing obviousness, the skilled person may make a ‘mosaic’ out of the relevant documents so long as it is a mosaic, which can be put together by an unimaginative man with no inventive capacity, but where this is not possible, they should be seen as forgetful when reading a piece of prior art, understanding and digesting it before putting it completely out of their mind before moving on [27]. In light of these discussions, Jacob LJ considered it settled that this man, if real, would be very boring — a nerd [28].

- Level of skill & common general knowledge

The level of skill and common general knowledge possessed by the skilled person is crucial to disputes over validity and infringement: if the level is set too low, nothing may be obvious but the patent may appear insufficient, but if the level of skill is set too high, everything will appear obvious. Determining how skilled a notional skilled person should be and what they should know in a particular context often makes the difference between a patent being upheld or revoked in litigation: in Mayne Pharma Ltd vs Debiopharm SA (Validity of Patents) [29], the judge’s conclusion that the common general knowledge at the priority date of the application would include a “proper understanding of the chemistry of platinum-based compounds was sufficient to render the relevant patent invalid.

The average level of skill expected of the skilled person varies from art to art but in areas such as pharmaceuticals, where postdoctoral researchers are routinely
employed, the person skilled in the art has a corresponding level of skill and experience. Nonetheless, the skilled person must be neither over- nor under-qualified: courts endeavour to identify the ordinary, average level of skill possessed by someone working in the relevant field at the priority date. The EPO stated that a person skilled in the art is an expert in the relevant field who is possessed of average knowledge and ability but is not an exceptional, outstanding or brilliant expert, even if a number of scientists working in the field at the time were actually awarded the Nobel Prize [30].

Conor vs Angiotech, a case involving a patent for the use of a stent coated with polymer, loaded with the drug taxol, also emphasized the need to try to reflect, to the extent that the evidence permits, the actual ordinary skills of the real-life contemporaries of the skilled man at the priority date [3].

**The skilled team**

The courts have recognized that the hypothetical skilled person may require knowledge and experience from more than one area of expertise, meaning that the skilled addressee should be viewed as a team of individuals. The EPO Board of Appeal has stated that in appropriate circumstances, the knowledge of a team of people with different expertise can be taken into account when assessing inventive steps [31]. This may be appropriate when the alleged invention is directed to technical skills in more than one field, meaning that for the solution of a part of the problem an expert is appropriate, while for another part of the problem one would need to look into another expert in a different technical field [32]. The EPO test in creating a skilled team is whether, in context, one member of the team would routinely be expected to consult another. For example, it may be necessary and typical for a person skilled in electronics to consult a computer programmer if a relevant document in the prior art contains sufficient indication that further details of the facts described in it are to be found in a program listing attached as an annex [33].

The concept of the skilled team has played a crucial role in several pharmaceutical cases. For instance, in Teva UK Ltd vs AstraZeneca AB [34], which involved a European patent for a sustained release formulation of the antipsychotic drug quetiapine, the Court of Appeal upheld the trial judge’s conclusion that the skilled person to whom the patent was addressed was a team of people, comprising a clinician, a pharmacologist, a formulation scientist and a pharmacokineticist. Furthermore, in Glenmark Generics (Europe) Ltd vs Welcome Foundation Ltd [35], the court upheld the revocation of a patent relating to an antimalarial pharmaceutical composition comprising a combination of two drugs on the grounds of obviousness on the basis that previous trials using a combination of the same drugs yielded promising results, which would inevitably have led a skilled team to further research the prospects of treating malaria using the relevant composition.

Nevertheless, the fact that the skilled person may be a team of individuals introduces potential complications, including the issue of hindsight. The knowledge of the skilled person does not extend far beyond his own field and care must be taken not to assemble a hypothetical skilled team from disparate fields of technology, using hindsight provided by the alleged invention, thereby creating a skilled team that is likely to find the alleged invention obvious. In addition, disputes may arise over the relative contributions of members of the hypothetical team [36], bringing an additional level of complexity into the characterization of the skilled person.

It is clear from the above that the characteristics of the skilled person will vary between technical fields and that a skilled team may be a more helpful concept to use in appropriate circumstances. However, this does not necessarily make the correct identification of the skilled person any more straightforward. Recent cases have established that the role and attributes of the skilled person may differ in the context of various aspects of patent law, particularly in relation to the assessment of novelty, obviousness and sufficiency.

**Novelty & sufficiency**

The role of the person skilled in the art, when considering a piece of prior art, is different in relation to disclosure and enablement [36]. In the case of disclosure, when the matter relied upon as prior art consists of a written description, the skilled person is taken to be trying to understand what the author of that description meant, using his common general knowledge. However, once the meanings of the prior disclosure and the patent have been determined in this way, the disclosure is either of an invention that, if performed, would infringe the patent, or it is not and the person skilled in the art then has no further part to play. In relation to enablement, on the other hand, the question is no longer what the skilled person would think the disclosure meant but whether he would be able to work the invention, which the court has held it to disclose [36].

**Obviousness & sufficiency**

The courts have also recognized that the relevant technical field, and accordingly the attributes of the person
skilled in the art, may differ when considering obviousness and sufficiency. The correct identification of the skilled person, and the common general knowledge that such a person should be taken to possess, is particularly important where a 'squeeze' arises between sufficiency and obviousness. The squeeze arises because the addressee of the patent must have sufficient skill and knowledge to put the invention into effect, or the patent will be insufficient. However, the higher the level of skill and knowledge of those in the art, the greater the risk that the invention may be considered to be obvious.

The EPO has held that the level of skill of the skilled person is the same for the purposes of both assessing inventive step and sufficiency, although for sufficiency the skilled person will additionally be aware of the invention [37]. However, the Board of Appeal has also indicated that for the purposes of inventive step, the skilled person comes from the technical field of the closest prior art [38]: if the skilled person were drawn from the technical field of the solution, which was different, there would have been an unacceptable tendency for him to find the solution obvious, starting from the closest prior art. This should be compared with the identity of the skilled person for the purposes of assessing whether an invention is sufficiently disclosed under Article 83 EPC who is necessarily drawn from the technical field of the invention. These cases imply that the two skilled persons could be different.

This appears consistent with the UK court's decision in Schlumberger vs Electromagnetic Geoservices [5], in which the identity of the members of the skilled team was a pivotal issue. In this case, the patentee had suggested that there could be different skilled addressees for the purposes of obviousness and sufficiency in an effort to avoid a squeeze argument between the two. The Court of Appeal confirmed that the person skilled in the art for obviousness is not necessarily the same person skilled in the art for performing the invention once it is made, stating that that the notional team for considering obviousness might have wider skills than the team required for sufficiency. It also held that the skilled teams used in these fields may differ where the invention itself was art-changing by putting together two disparate arts: the skilled team used for the purpose of assessing the question of obviousness in the pre-invention period need not include workers from both arts where the invention itself is art-changing, in contrast with the skilled team in the postinvention period (for the assessment of claim construction and sufficiency). The characteristics of the skilled person may therefore differ according to the aspect of patent law in which they are being invoked.

The skilled person as an evolving concept
The characteristics of the skilled yet unimaginative technician will vary from art to art and according to the circumstances, such a person may be an individual or a team. They may also have a split personality, having different attributes according to the aspect of patent law, which they are considering. Furthermore, the concept itself is continually evolving, in line with rapid developments in technology and the law. The skilled addressee has traditionally been presumed to be skilled, within a given field, at repetitive processes that produce expected results [39]. However, the average level of skill and common general knowledge of such a person is increasing as developments occur in fields such as pharmaceuticals, causing practitioners to increase the scope of their common general knowledge.

This knowledge attributed to the skilled addressee has also expanded to incorporate principles of patent law, and the courts have taken into account the circumstances in which researchers and academics may operate when describing the skilled person's attributes. This evolution and the consequent changes in the role played by the skilled addressee have significant implications for the way in which the concept can be used by the courts.

Development of the average level of skill & common general knowledge
As advances are made in technical fields such as pharmaceuticals, the scope of the common general knowledge attributed to the skilled person in those fields has also expanded. Thus, although criteria such as inventive step and novelty will consistently be judged from the perspective of the skilled person, a standard that does not differ from one field of technology to another, the common general knowledge of the skilled person incorporating developments in the relevant literature and prior art will clearly change, influencing what is deemed to be obvious. This issue is of particular relevance in fast-moving areas such as pharmaceuticals and biotechnology, where "a method that was cutting-edge technology yesterday may be an industry standard today" [40].

Increasing knowledge of patent law

- Basic principles of patentability
Although the skilled person's technical skills will vary according to the technical field in question, the English courts have recently attributed an increasingly complete understanding of patent law to those working in areas such as the pharmaceutical industry. The basic principles of patentability are now therefore part of the common general knowledge in this field: in Kirin Amgen vs Hoechst Marion Roussel Ltd, a case where the
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The basis of the invention was the discovery and sequencing of the erythropoietin gene. Lord Hoffmann observed that "the person skilled in the art (who must, in my opinion, be assumed to know the basic principles of patentability) might well have thought that the claims were restricted to existing technology because of doubts about sufficiency rather than lack of foresight about possible developments" [2]. The skilled person's increasing knowledge of the principles governing patentability therefore has significant implications for claim construction.

- Awareness of drafting conventions, divisional patents & claim sets

The skilled person's knowledge of patent law has also recently been expanded beyond the basic principles of patentability to cover the drafting conventions relating to patents and their claims. In Virgin Atlantic Airways Ltd v Premium Aircraft Interiors Group Ltd [41], the Court of Appeal made it clear that the skilled reader, who would have in mind the explicit drafting conventions by which a patent and its claims are framed, would be aware of the fact that reference numerals are not to be used to limit a claim and would also know regarding the nature of the two-part claim structure, in which features found in the prior art are incorporated into the precharacterising portion. Furthermore, the skilled addressee is now also deemed to possess an awareness of divisional patents and an understanding of claim sets, including Swiss-type claims [42]. According to the court in Virgin, a real skilled man reading a patent that was referred to 'the parent application' would surely have asked what a 'parent application' was, and he would have gone on to ask a man who knew, probably a patent agent.

This evolution in the skilled person's knowledge has had significant implications for claim construction. In Virgin, it was emphasised that the skilled person would "strongly incline to the view that what was contained in the precharacterising portion of the claim was old, knowing that the patentee was trying to claim something which he, the patentee, considered to be new" [41]. Furthermore, if the patentee not only acknowledged that a particular piece of prior art was old but then had a precharacterising clause, which was fairly obviously based on it, the skilled reader would be even more strongly inclined to read that clause as intended to describe that old art. The patentee would not therefore be expected to have used language that covered what he had expressly acknowledged was old. The court also pointed out that the skilled man would have been influenced by the fact that the claim was drafted in accordance with the EPC drafting convention, reinforcing the expectation that the pre-characterising portion was about something the patentee considered old. The legal knowledge attributed to the skilled person is therefore expanding, along with his understanding of developments in his own technical field.

- Recognition of the circumstances in which the skilled person may carry out research

In technical fields such as pharmaceuticals, where the skilled person is likely to be involved in research, the characteristics of the skilled addressee have been further developed by the courts to take into account the circumstances in which such a person may work. For instance, it has been made clear that the skilled addressee (or their team) should have the best equipment available to them and are not constrained by either the amount of time they can address to a particular problem or how they obtain their funding [43]. They may also have specialist facilities available to them. Furthermore, if evidence shows that a team of skilled addressees at a certain date would have sub-contracted certain tasks to outside workers, this may be built into the 'skilled addressee' concept in a particular case [44]. The skilled addressee may also attend and deliver papers at conferences (either domestically or internationally) [45]. It is therefore clear that the courts have developed the concept of the skilled person to take into account the particular context in which researchers and academics operate.

Knowledge of the context in which inventions are developed & used

In addition to technical and legal knowledge, the skilled person also has a broader awareness of the context in which inventions are developed and used, a development that is closely connected to the purposive approach to claim construction. This approach is an important part of European law, a point highlighted by the Protocol on the Interpretation of Article 69 of the EPC. It may not therefore now be beyond the realms of possibility that the skilled person considers why a patentee may have chosen to patent what he did (e.g., one enantiomer over another).

Furthermore, the courts have recognized that commercial considerations may play a role in determining what the skilled person would view as obvious. In Uiox Pharmaceuticals UK Ltd v Akeza Nobel BV [46], the Court recognised that commercial reasons, including the desire to emulate a successful product without infringing a patent if the means of doing so were technically obvious, might be sufficient reasons to take a person skilled in the art down a particular path.
Impact of the above on the role played by expert witnesses in patent litigation

The choice of expert witness is of particular importance in patent litigation in the English Courts, where experts can be cross-examined, and is of crucial importance to debates over the characterisation of the skilled person. This is because the Court will rely heavily on expert evidence in order to determine whether a particular fact was within the common general knowledge of the skilled addressee at the relevant date [47]. Regeneron Pharmaceuticals Inc vs Genentech Inc. [48], Floyd J cited expert evidence when identifying the skilled team when acknowledging that "vascular and molecular biologists worked closely with clinicians and therefore had a good knowledge of how blood vessels operate in a range of disease states characterized by excessive angiogenesis." Nonetheless, he expressed certain 'reservations' regarding the evidence of one of the expert witnesses and highlighted areas where he felt that the expert in question had "exaggerated the position", including the role played by VEGF in angiogenesis.

The evolution of the skilled person's knowledge therefore has clear implications for the knowledge that an expert witness will be required to possess, indicating that they too may need to understand the intricacies of patent law and drafting conventions. These are areas from which patent practitioners have typically tried to shield their experts. Developments of this kind may result in the selection of experts who can both testify well in court and also have skills as patent practitioners.

This development is complicated by the fact that experts must maintain an impartial perspective on the patent(s) in suit and they have no place at all on the issue of construction. In Medimmune vs Novartis [49], Justice Arnold acknowledged that while close cooperation between lawyers and experts is necessary in patent actions, such that it is usually the lawyers that draft the reports, he explained how to avoid two common pitfalls in presenting the written evidence that could lead to the appearance of a partisan opinion. First, he highlighted the importance of dealing with (and not merely maintaining silence in respect of) ambiguities or even counterpoints in the prior art and, second, the importance of pointing out an expert's own work in the field where that is close to the invention at issue. The judge also reiterated that the correct approach to instruct an expert is to ask him or her to consider the prior art and other relevant documents (such as priority documents) first and only then to provide the expert with the patent, so that the expert can formulate an opinion on the prior art without knowledge of the invention. The written evidence should be drafted in a manner that reflects this.

Must an expert witness embody the skilled person?

Parties in the process of selecting such a witness have queried whether they should choose an outstanding academic or someone who is closer to the ordinary skilled worker. Clarification as to the correct approach to take was given by the Court of Appeal in Technip SA's Patent (2004) RPC 46 [28]. Here, Lord Justice Jacob stated that "the attempt to approximate the real people to the notional [skilled person] is not helpful" as the primary function of expert witnesses in patent actions is to educate the court in the relevant technology. He went on to say that "For that purpose it does not matter whether they do or do not approximate to the skilled person. What matters is how good they are at explaining things." The idea that a distinction should be made between an expert witness, who is at the top of their profession and the skilled addressee, who was not, was reinforced in Laboratorios Almirall vs Boehringer Ingelheim [50].

Nevertheless, some comparisons between the skilled person and the expert witness in question may be drawn, with implications for the parties' choice of experts in the course of litigation. The observations made in Technip's Patent were considered and explained by Arnold J in Datacard vs Eagle Technologies [51]. He held that "Given that what matters are the experts' reasons (for their opinions) and whether they would be perceived by the skilled person, it is relevant to consider to what extent the expert's qualifications (as opposed to their degree of inventiveness) approximate to those of the skilled person. If one expert was in the field at the relevant time, and particularly if he considered the problem to which the patent is addressed at that time, then his evidence is likely to carry more weight than that of another expert who was not in the field at the relevant time." In Eli Lilly & Co vs Janssen Alzheimer Immunotherapy, the judge specifically noted that the patent was addressed to a skilled team consisting of a neuroscientist, an immunologist and a clinician with a research interest in the prevention and treatment of amyloidosis, particularly AD and that one expert witness combined most of the necessary expertise whereas two other witnesses had no clinical expertise [52]. It is therefore clear that although the expert, who will give evidence as to what the skilled person would have known at the priority date, should...
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Future perspective
In *Kirin-Amgen vs Hoechst Marion Roussel Ltd* [2], Lord Hoffmann stated that underlying the purposive

not embody the skilled person, this evidence will be given more weight by the court if their qualifications approximate to those of the skilled person.

Executive summary

An introduction to the skilled person
- The skilled person is a legal fiction, a technician who is skilled in the art yet wholly devoid of imagination. However, the attributes of the skilled person vary from art to art and have not remained static over time. Such a person may be more accurately characterized as a set of legal fictions, which are continually evolving.

The skilled person in patent law
- The skilled person is a concept central to almost all aspects of patent law and courts will consider obviousness, sufficiency, claim construction, novelty, added matter and priority from the perspective of the skilled addressee.

Attributes of the skilled person: hypothetical construct of patent law
- The skilled person has traditionally been seen as an ordinary worker of average skill in the relevant art, who has an exhaustive familiarity with all the common general knowledge in that field and accepts all the conventional prejudices associated with it.

Attributes of the skilled person: level of skill and common general knowledge
- The average level of skill expected of the skilled person varies from art to art. In areas such as pharmaceuticals, where postdoctoral researchers are routinely employed, the person skilled in the art will be similarly qualified, with a corresponding level of skill and experience.

Attributes of the skilled person: the skilled team
- The courts have recognized that the hypothetical skilled person may also require knowledge and experience from more than one area of expertise, meaning that the skilled addressee should instead be viewed as a team of individuals.
- Recent cases have established that the role and attributes of the skilled person may differ in the context of various aspects of patent law, particularly in relation to the assessment of novelty, obviousness and sufficiency.

The skilled person as an evolving concept
- The concept of the skilled person is continually evolving, in line with rapid developments in technology and the law. The average level of skill and common general knowledge increases as advances are made in fields such as pharmaceuticals, also expanding to incorporate principles of patent law, and the courts have also taken into account the circumstances in which researchers and academics may operate when describing the skilled person's attributes.

Development of the average level of skill & common general knowledge
- Although criteria such as inventive step and novelty will consistently be judged from the perspective of the skilled person, a standard that does not differ from one field of technology to another, the common general knowledge of the skilled person, incorporating developments in the relevant literature and prior art, will clearly change, influencing what is deemed to be obvious.

Increasing knowledge of patent law: basic principles of patentability
- The basic principles of patentability are now part of common general knowledge in the pharmaceutical industry.

Increasing knowledge of patent law: awareness of drafting conventions, divisional patents & claim sets
- The skilled person's knowledge of patent law now also covers the drafting conventions relating to patents and their claims.

Increasing knowledge of patent law: recognition of the circumstances in which the skilled person may carry out research
- The skilled addressee (or their team) should have the best equipment available to them and should not be constrained by either the amount of time they can address to a particular problem or how they obtain their funding. They may also have specialist facilities available to them. Furthermore, if evidence shows that a team of skilled addressees at a certain date would have subcontracted certain tasks to outside workers, this may be built into the 'skilled addressee' concept in a particular case.

Knowledge of the context in which inventions are developed and used
- The skilled person also now has a broader awareness of the context in which inventions are developed and used.

Implications of the above developments for the role played by the skilled person in patent litigation
- Claim construction and the involvement of the skilled person in this exercise may have public policy implications, with ramifications for the pharmaceutical industry.

Impact of the above on the role played by expert witnesses in patent litigation
- The evolution of the skilled person's knowledge indicates that experts may need to understand the intricacies of patent law and drafting conventions, while maintaining an impartial perspective on the patent(s) in suit.

Must an expert witness embody the skilled person?
- The primary function of expert witnesses in patent actions is 'to educate the court' in both the relevant technology and the attributes and common general knowledge of the skilled person. A distinction should therefore be made between an expert witness, who is 'at the top of their profession' and the skilled addressee, who is not.
construction of claims was the need to set clear limits upon the monopoly so that third parties have a clear idea of what would constitute infringement and patentees are able to draft claims without fear of constructions, which will include prior art. If the claims are interpreted too broadly, this could discourage competition, while too little protection gives inventors and patentees little incentive to innovate and disclose their work to the public. It has therefore been argued that the skilled reader, who has knowledge of the context in which inventions are made and used, is a tool wielded by the courts to better achieve a balance between the interests of patentees, technology users and society.

The skilled person can therefore no longer simply be considered as a nerd, an ordinary worker with no imagination and an unlimited capacity to assimilate information that he forgets immediately. Instead, he has evolved to become a technically able, sophisticated addressee (who may in fact be a team) with knowledge of patent law and patent drafting conventions. In light of the role played by the skilled person in almost every aspect of patent law, this evolution has affected the way in which the skilled addressee may be used by the courts, particularly when striking a balance between patentees and society as a whole. This evolution has also affected the selection and the role of expert witnesses in patent litigation, influencing a trend towards experts who have an increasingly broad knowledge of patent law themselves. It is clear that this is a concept that is set to continue to evolve.

The question is how skilled can the skilled man be to remain a useful reference point by which the patents are judged.

Financial & competing interests disclosure
The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

References
Papers of special note have been highlighted as:

- of interest
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1 Technograph v. Mills & Rockley, FSR 188 (1971).
2 Kirin Amgen vs Hoechst Marion Roussel Ltd, UKHL 46 (2004).
3 The UK confirmed that a purposive approach to construction should be adopted in accordance with Article 69 EPC and its Protocol (see discussion on Article 69 EPC above).
5 The House of Lords made it clear that obviousness was to be determined by reference to the claim; for example, whether it would be obvious, from the perspective of the skilled person, to use a taxol-coated stent to treat or prevent restenosis.
6 Internet UK Limited vs Merial, EWHC 294 (Pat) (2010).
7 Schlumberger Holdings Ltd vs. Electromagnetic Generators AS, EWCA Civ 819 (2010).
8 The UK court held that the identity of the person skilled in the art could differ according to whether the issue of obviousness or sufficiency were being considered, and that the skilled teams used in these fields may differ where the invention itself was art-changing by putting together two disparate arts (see discussion below).

12 Patents Act 1977, Section 125(3).
14 T190/99 Woven Slide Fastener Stinger.
15 G1/92 Availability to the public of OJ EPO, 1993, 277.
17 The House of Lords considered the scope of the patent covering citalopram, clarifying the law on insufficiency.
19 Lord Hoffman made a clear distinction between disclosure and enablement, stating that the matter relied upon as prior art must disclose subject matter, which if performed, would necessarily result in an infringement of the patent and defining enablement as meaning that the ordinary skilled person would have been able to perform the invention that satisfies the requirement of disclosure.
20 EPO Guidelines (C-I-V, 94).
The court discussed the identity of the skilled person in some detail and considered issues such as sufficiency, obviousness and novelty from the skilled person’s perspective.

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