MAUCHER JENKINS

Patent *issues*

Spring 2018

UK Ratifies the UPC Agreement

- Hugh Dunlop

The UK has ratified the Unified Patent Court Agreement to pave the way for the new Unitary Patent and the new court. This is a major step forward for the system, which was first agreed in February 2013 but was put in doubt following the Brexit referendum of June 2016. In our Autumn 2016 edition of **ipNews** we explained that there need not necessarily be any exit from the UPC upon Britain's exit from the EU. With the UK leaving the EU on 29 March 2019, ratification now gives the UK the opportunity to get the system started and negotiate continued participation later.

See page 2 for full story

Dosage regimes come under close scrutiny in the UK courts

- Reuben Jacob and Dr Janet Strath

We bring to readers' attention two cases where dosage regimes were found obvious to try.

See pages 4-11 for full story

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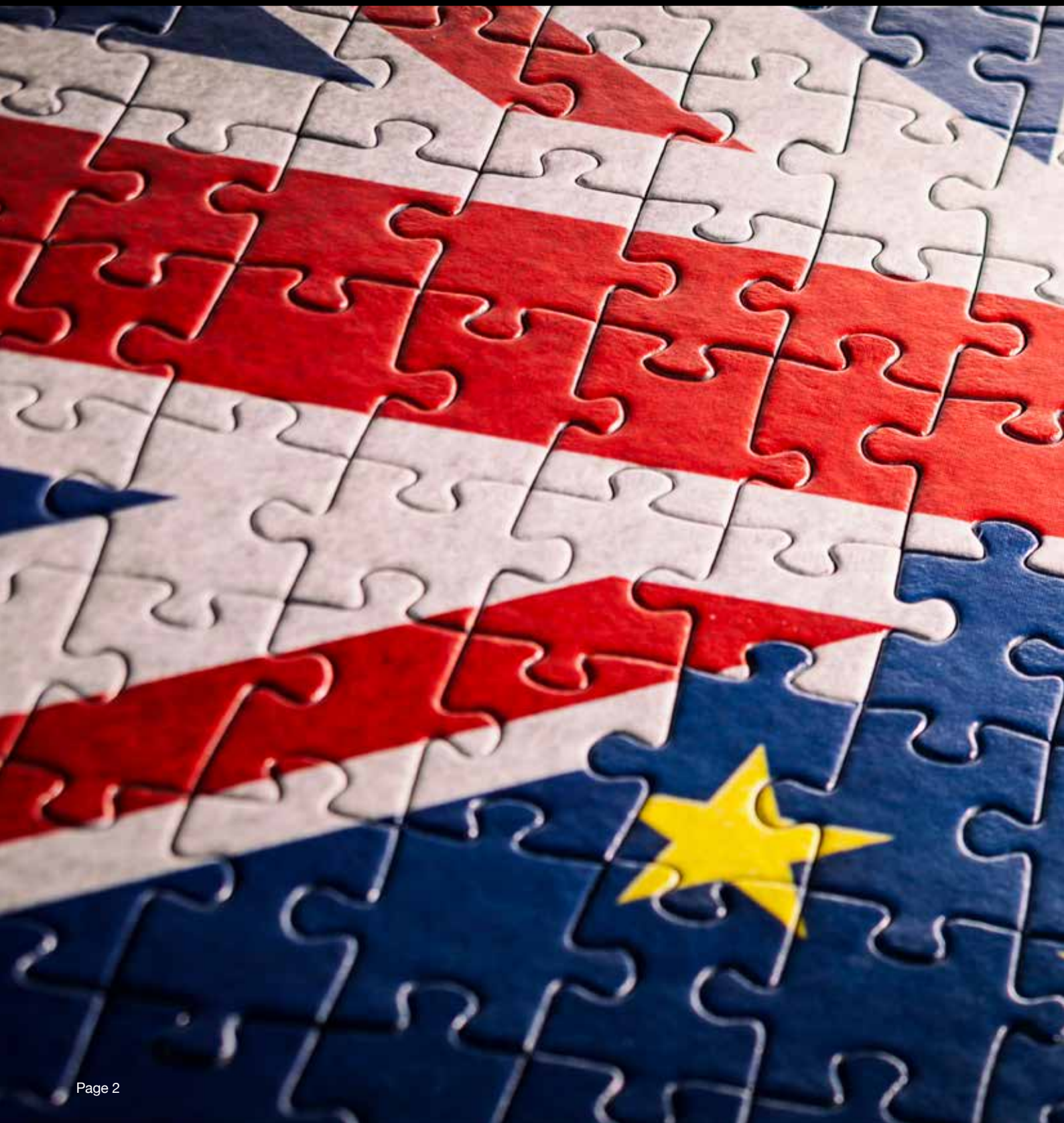
UK RATIFIES THE UPC AGREEMENT

BY HUGH DUNLOP



Continued from page 1

On 26 April the UK Minister for IP, Sam Gyimah MP, announced that the UK government has ratified the Unified Patent Court Agreement. The instrument of ratification was signed by Foreign Secretary, Boris Johnson, and deposited with the General Secretariat of the EU Council.

Ratification by the UK is not the last hurdle for the UPC and the Unitary Patent system. Ratification by Germany is required, which is on hold pending resolution of a complaint before the German Federal Constitutional Court, scheduled on the Court's diary to be heard at some indeterminate time in 2018. (It is one of 36 cases scheduled this year before the Court's Second Senate.)

The system begins on the first day of the fourth month following ratification by Germany (and the provisional application phase begins earlier). All eyes are now on the timing and outcome of the hearing by the German Federal Constitutional Court and on the transitional Brexit deal for whether the system can get started in its present form.

TRYING TIMES FOR PATENT OWNERS IN THE COURT OF APPEAL: *ACTAVIS v ICOS*

BY REUBEN JACOB

Reuben Jacob

This decision was a reversal of a decision of Mr Justice Birss that the patent concerning tadalifil was valid and infringed.

In the course of reaching its decision, the Court of Appeal considered the question of what made an invention "obvious to try", and found nothing made the claimed dosage regimen of tadalafil inventive, in the light of the prior art.

The question of whether a routine pre-clinical and clinical trial programme had a fair prospect of success was dismissed, as the claimed dosage regime simply equated to the dose at the lower limit of a therapeutic plateau and, therefore, was something that would have been investigated as a matter of routine in Phase IIb dose ranging studies during a clinical trial programme.

Here we consider the Court of Appeal's reasoning and also report on Eli Lilly's subsequent failed application for an interim injunction pending further appeal.

Tadalafil is an inhibitor of the PDE5 enzyme and is sold by Eli Lilly (licensed from ICOS) under the brand name **CIALIS** to treat male erectile dysfunction and **ADCIRCA** to treat pulmonary arterial hypertension.

The patent, EP(GB)1173181, covered the dosage regimen for tadalafil.

The case is particularly interesting because of the guidance it provides on the role of the "obvious to try" test, dispelling the notion that an expectation of success is an essential element of an obvious to try case.

Background

The defendants were ICOS Corporation (the registered owner of the patent) and Eli Lilly & Company, the exclusive licensee. We will collectively refer to them as "Lilly".

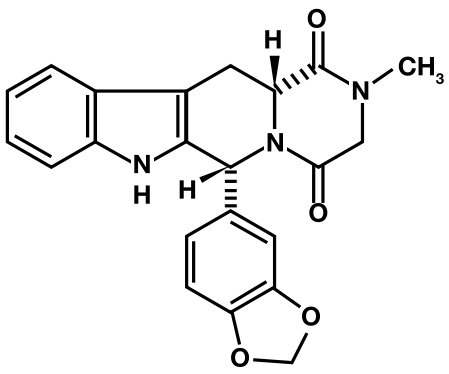
The claimants (Acatvis, Teva and Mylan) were seeking to "clear the way" by revoking the patent in order to launch generic tadalafil products. They alleged that the relevant claims of the patent were invalid for lack of novelty over WO 00/53148 *(Stoner)*, which was an international patent application filed by a third party (Merck) and a co-pending patent application. The claimants also argued that all of the relevant claims were obvious in the light of WO 97/03675 *(Daugan)*.

At first instance, Birss J found that claims 2 and 12 lacked novelty in the light of Stoner but that at least claim 7 was valid and would be infringed by the claimants if they were to launch their intended products.

The claimants appealed on a number of grounds; as discussed below, the one that succeeded was that the judge had erred in his assessment of obviousness and should have found nothing inventive in any of the claims, in the light of *Daugan.*

In issue were Claims 1, 7 and 10 of EP(GB)1173181 which, together with the claims on which they depended, read as follows:

1. A pharmaceutical unit dosage composition comprising 1 to 5mg of a compound having the structural formula:



2. The dosage form of claim 1 comprising 2.5mg of the compound in unit dosage form.
3. The dosage form of claim 1 comprising 5mg of the compound in unit dosage form.
4. The dosage form of any one of claims 1 through 3 wherein the unit dose is in a form selected from a liquid, a tablet, a capsule, or a gelcap.
5. The dosage form of any one of claims 1 through 3 wherein the unit dose is in the form of a tablet.
6. The dosage form of any of claims 1 through 3 for use in treating a condition where inhibition of PDE5 is desirable.
7. The dosage form of claim 6 wherein the condition is a sexual dysfunction.
10. Use of a unit dose containing 1 to 5mg of a compound having the structure [of tadalafil] for the manufacture of a medicament for administration up to a maximum total dose of 5mg of said compound per day in a method of treating sexual dysfunction in a patient in need thereof.

Court of Appeal's decision

Lord Justice Kitchin described the submission that the claimed invention was obvious as being, *"in the circumstance of this case, a powerful one"*. The prior art for the purposes of obviousness was *Daugan*, an application which had been published before the earliest possible priority date patent.

Daugan taught the use of PDE5 inhibitors for the treatment of ED, specifically disclosed tadalafil and its potency of inhibition (IC50) of PDE5 and described examples of a tablet containing a 50mg dose. It explained that doses of tadalafil would generally be in the range of from 0.5 to 800mg daily for the average adult patient. The disclosure of *Daugan* and claim 1 of the patent differed in that Daugan did not specifically disclose a tablet containing 5mg of tadalafil, and *Daugan* differed from Claims 7 and 10 in that it did not disclose that such a dose was an effective treatment for sexual dysfunction.

The claimants argued that it would have been perfectly obvious at the priority date for the skilled team, given *Daugan*, to take tadalafil forward into a routine pre-clinical and clinical trial programme to assess its use as an oral treatment for sexual dysfunction. In the course of that programme, a 5mg per day dose of tadalafil would be used in patients and would reveal the invention (i.e. that it was safe, tolerable and effective).

Lilly argued that the claimants' case was really one of "obvious to try" and could only lead to a finding of invalidity if the skilled team would consider that the programme had a fair prospect of success, which was not the case because, at the start of the programme and given *Daugan*, the skilled team would have had no idea that a 5mg per day dose of tadalafil would be safe, tolerable or efficacious with minimal PDE5 related side effects when used for ED treatment.

At first instance, Birss J accepted that it would have been entirely routine for a skilled team after reading *Daugan* to start a pre-clinical and clinical trial programme to find out more about the properties of tadalafil not mentioned in *Daugan*, such as bioavailability and tissue compartmentalisation. The fact that the skilled team would not be able to accurately predict the outcomes in advance, and might come across unexpected results, would not make the claims inventive.

In reality, after *Daugan* was published, Lilly did embark on two Phase IIb studies: LVBG, which found that tadalafil administered daily in the dose range of 10-100mg was safe, generally well-tolerated and improved patient's erectile function and sexual satisfaction; and a subsequent LVBF study, which found that on-demand tadalafil in the dose range of 2-25mg was safe, well-tolerated and improved erectile function. However, on the evidence, Birss J found that it would not have been routine to conduct a dose ranging study which included a 5mg/day dose and, although on the balance of probabilities it was "obvious to try" such a study, there was no reasonable expectation of success. Accordingly, he held that a 5mg daily dose of tadalfil as a treatment for ED was not obvious over *Daugan*; in particular, claim 7 of the '181 patent involved an inventive step.

The claimants submitted it was striking that, despite finding that taking tadalafil forward into a clinical testing programme was "very obvious", and despite finding that the skilled team would test a dose of 5mg of tadalafil and find it safe and efficacious for the treatment of ED, the judge held that the claimed dosing regimen amounted to an invention. Such a decision, according to the claimants, was "irrational and wrong".

Kitchin LJ found that

the judge had lost sight of the fact that, on his own findings, the claimed invention lies at the end of the familiar path through the routine pre-clinical and clinical trials' process.

He explained that the skilled but non-inventive team would have embarked on that journey with a reasonable expectation of success and, along the everyday pathway of research and clinical trials, dose-ranging studies would be performed with the aim of finding out, among other things, the dose response relationship. It was very likely that the skilled but not inventive team would have tested a dose of 5mg tadalafil per day, found that it was safe and efficacious and, at that point of the journey, they would have arrived at the claimed invention. It was irrelevant that such a low dose was surprisingly effective because the result

would be arrived at by the standard, routine enquiries into dose response which are required by Phase IIb clinical trials. The surprising result, once uncovered, does not make these routine enquiries inventive.

Accordingly, the claimants' appeal was allowed. The court found claims 1, 7 and 10 of the patent were invalid for lack of inventive step and that the judge ought so to have held.

The interim injunction application

Following the court's decision that the judge had erred in finding that the claimed dosage regimen was inventive, Lilly nevertheless made an application for an interim injunction to restrain the launch of generic tadalafil by Acatvis, Teva and Mylan. As the relevant SPC for tadalafil was due to expire at midnight on Monday 13 November 2017, the application was heard urgently on Friday 10 November 2017.

To succeed in an interim injunction, Lilly would have had to establish that they had a realistic prospect of success on appeal to the Supreme Court. This was a long shot given that Lilly had not even been granted permission to appeal. Lilly attempted to argue that the Court of Appeal had fallen into error on an important point of law (see our discussion below), but in Carr J's judgment, the Court of Appeal had ruled on the facts as found by the judge applying existing and settled principles of law. Accordingly, he refused to grant the injunction.

Comment

The crux of the Court of Appeal's judgment is routine Phase IIb dose ranging studies. If there is some evidence of efficacy and the patent is a dosing patent, then it would be routine for the skilled team to embark upon a pre-clinical and clinical trial programme, including routine Phase IIb dose ranging studies in larger groups of patients.

Although on the balance of probabilities it was obvious to try a dose ranging study, Birss J had found that there was no reasonable expectation of success, as the skilled team would have to make value judgments along the research pathway.

The judge had allowed himself to become side-tracked at first instance in drawing a distinction between:

1. routine studies that involved stepwise tests performed only for the purpose of obtaining necessary results without any expectation of success and which did not require any "value judgments" to be made along the way; and
2. other stepwise inventions which required the skilled team to make "value judgements" regarding whether or not to carry out particular testing.

In contrast, Kitchin LJ found that this was not a case in which the skilled team would be faced with a series of parallel avenues of study, with no expectation that any one of those avenues would be fruitful or more likely to be fruitful than any other. Instead, it was a case involving two avenues – on demand and daily dosing – and both would reveal tadalafil's half-life, and each would be very likely to lead the skilled team to the invention.

Lord Justice Floyd, agreeing with Kitchin LJ, said:

"The whole purpose of embarking on the routine Phase IIb dose ranging study was to identify a dose response. The discovery of a plateau indicated that the routine study would have to be repeated at a lower dose, because it was not complete. Completion of the study would inevitably lead the skilled team to test 5 mg/day, whether that dose was still on the plateau, or in a region of the curve where a dose effect is observed. Which it is does not matter, because the result is that the skilled person would at this stage have arrived at a dosing regimen within the claim".

Not an extension of the "Obvious-to-try" doctrine

Lord Justices Floyd and Lewison warned of the danger in extending the "obvious line of enquiry" principle too far:

> *"It is important not to let this approach to obviousness extend beyond its proper bounds. There will hardly ever be an invention for which it is not possible to 'show how it might be arrived at by starting from something known, and taking a series of apparently easy steps'[1]. Nearly 100 years later, Moulton LJ's view that this approach was 'not countenanced by English law' was said by Jacob LJ[2] to be 'as true today as when it was first said'."*

Lord Justice Lewison agreed, and added a few words of his own concerning Lilly's main argument that an expectation of success was an integral component of an "obvious to try" case: "In my judgment that is not the law - some experiments undertaken without a particular expectation as to the result are obvious".[3]

In this particular case, the claimed dosage regime was simply the dose at the lower limit of the therapeutic plateau, which is something that would be investigated as a matter of routine. A patent should not be awarded to the first party that performs an obvious piece of research. The process of research is often quite obvious and produces obvious results, which are quite rightly not patentable. It should not be a goal in life science patent litigation to make the skilled person so witless that they cannot even perform basic research studies and come to a logical conclusion.

Two questions recur in the "obvious to try" case law: Was the invention obvious to try? If so, was it also obvious to succeed?

Phrased in such a fashion, it seems like an invention is not obvious to succeed if success cannot be predicted in advance, no matter how obvious to try and how easy the success. However, if we instead consider whether there has been an inventive step, rather than whether the invention would obviously succeed, then success does not have to be predicted in advance, provided that the trial itself did not require any ingenuity or experimentation that would deserve a patent reward.

This means, as Kitchin LJ noted in the present case, that in an "obvious to try" scenario which involves routine research methods that do not deserve a patent reward, we may ask the single and relatively simple question: was it obvious to the skilled but unimaginative addressee in light of the prior art and the common general knowledge to make a product or carry out a process falling within the claim? Unfortunately for the defendants, the answer was yes.

1. per Moulton LJ in *British Westinghouse v Braulik* (1910) 27 RPC 209 at [230]
2. *Technip France SA's Patent* [2004] RPC 46 at [112]
3. Quoting *Gedeon Richter v Bayer Schering* [2011] EWHC 583 (Pat), [114]

GENERICS (t/a MYLAN) v YEDA RESEARCH

DOCTRINE OF EQUIVALENTS DOES NOT [YET] APPLY WHEN ASSESSING NOVELTY

ACTAVIS v LILLY; THE MADNESS BEGINS

In Autumn 2017 ***Patent issues*** we reported the introduction, in the UK, of a doctrine of equivalents by the Supreme Court in *Actavis v Eli Lilly*.

One of the questions opened by such a doctrine is how far to open up the claims to equivalents when the boot is on the other foot and one is considering validity of a patent.

This question has been considered in ***Generics (t/a Mylan) v Yeda*** Research, in which the Patents Court held that the doctrine of equivalents does not apply when assessing novelty.

This represents a significant change from the previous position in English patent law, namely that claims must be construed the same way for purposes of assessing patent validity and patent infringement.

The patent at issue covered a dosage regimen for the administration of glatiramer acetate (GA) for the treatment of relapsing forms of multiple sclerosis (MS).

- The dosage regimen consisted of three subcutaneous injections of 40 mg GA every seven days with at least one day between each injection ("40 mg TIW").
- Previously, GA was approved for administration in a regimen consisting of a daily subcutaneous injection of 20 mg ("20mg QD").
- There was also a prior art patent reference (referred to as ***"Pinchasi"***), that taught administration of 40 mg GA via subcutaneous injection every other day ("QOD").

The claimants, Mylan and Synthon, contended that the patent was invalid on the grounds of lack of novelty, lack of inventive step and insufficiency. The claimants had previously introduced a 20 mg GA generic product, and wanted to clear the way for the launch of a 40 mg GA generic product for which they had obtained a marketing authorisation.

There was no dispute that the claimants' intended acts in relation to the claimants' product infringed the patent if validity was upheld.

Mr Justice Arnold found the patent was novel but invalid for obviousness, as the dosage regimen was nothing more than a small and simple variation on the teaching of a prior art patent.

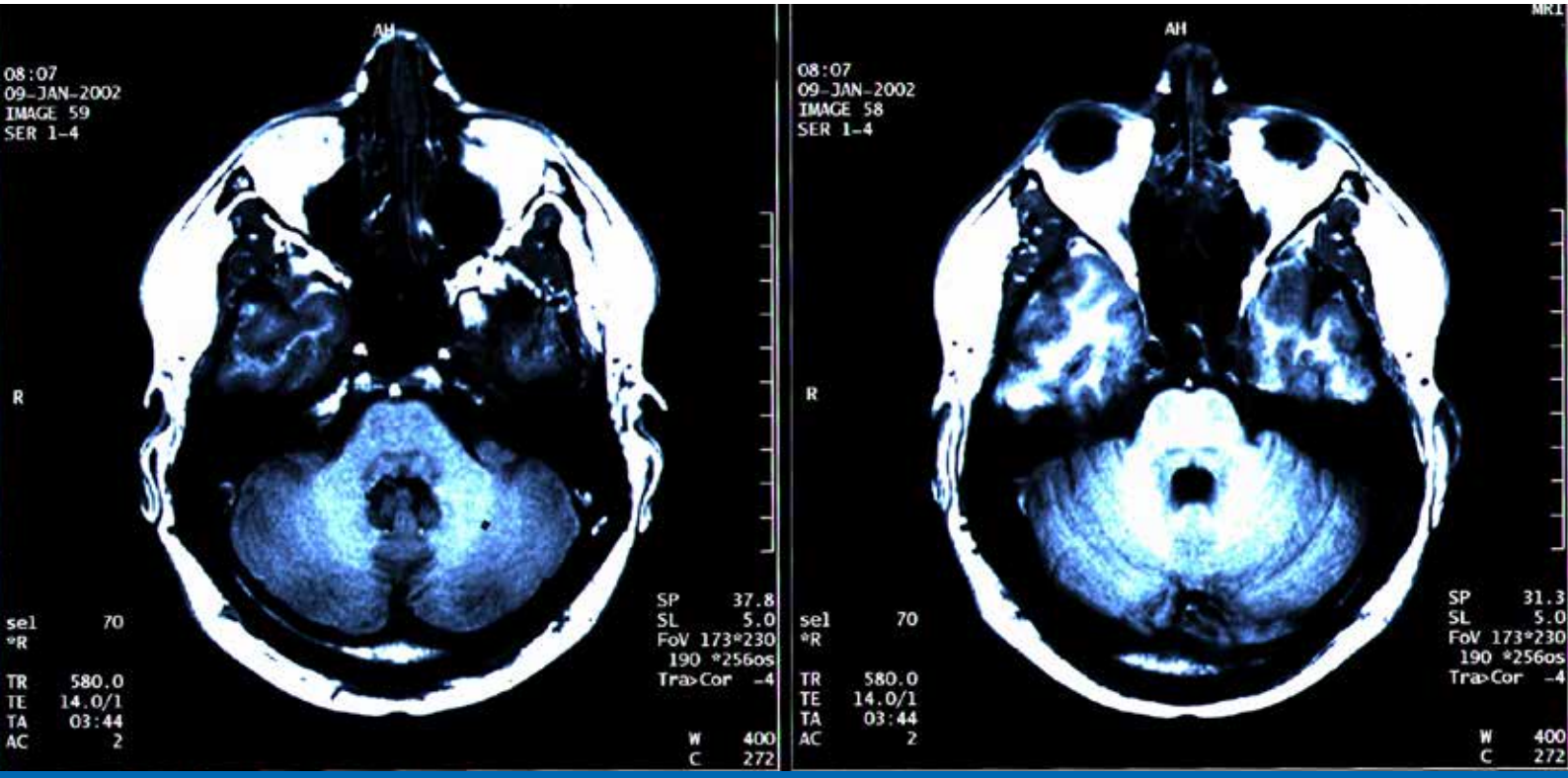
BY DR JANET STRATH

The patent of Yeda Research was exclusively licensed to Teva Pharmaceutical Industries Ltd. Teva markets GA for the treatment of MS under the trade mark Copaxone.

Worldwide sales of Copaxone in the year ending 31 December 2016 were about $4.2 billion, representing nearly a fifth of Teva's worldwide sales and a significantly higher percentage of its profits.

A large proportion of prescriptions of GA were written for the 40 mg TIW regimen following the authorisation of administration of GA in accordance with the 40 mg TIW regimen.

GENERICS (t/a MYLAN) v YEDA RESEARCH (continued)

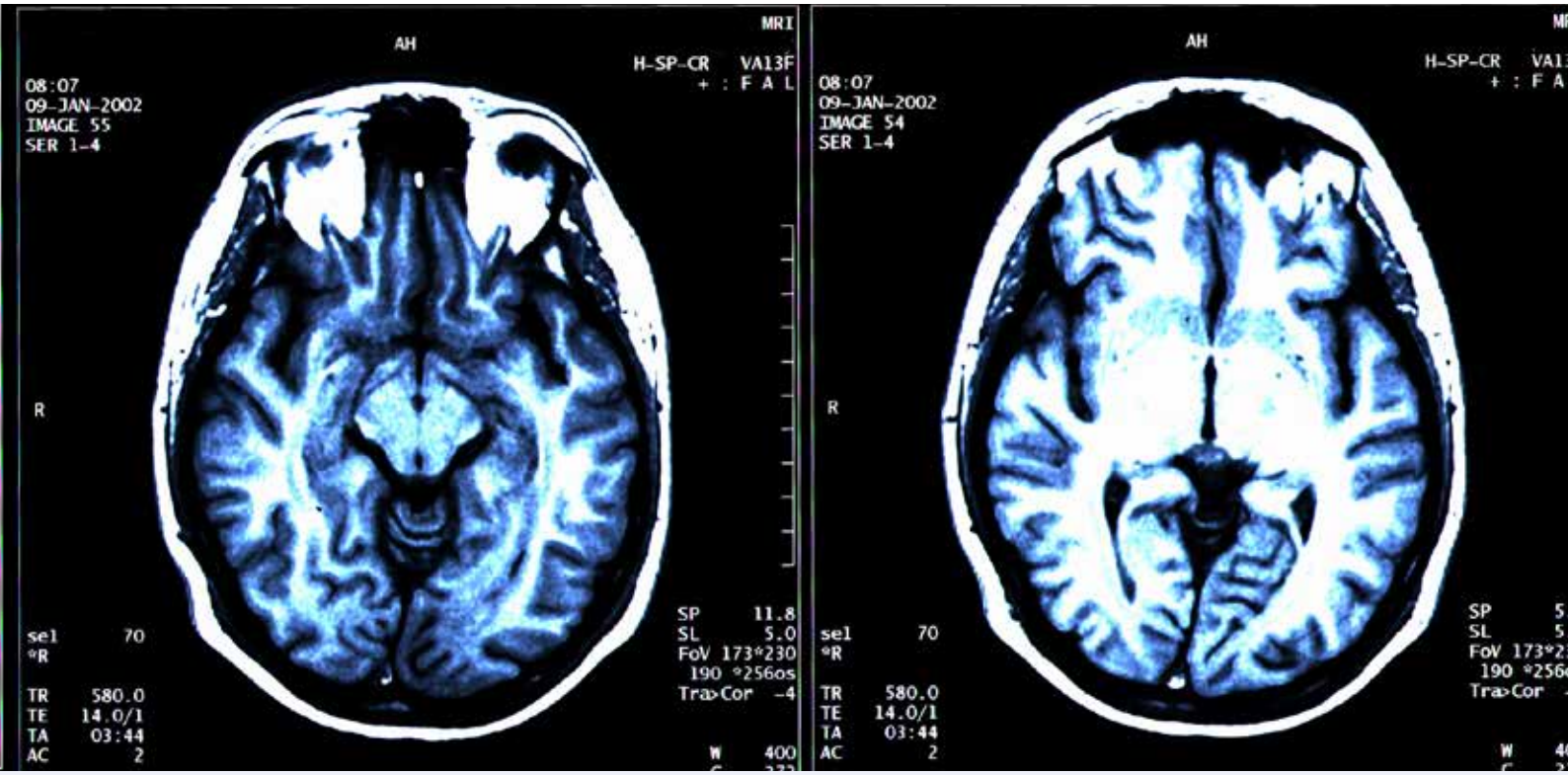


Interpretation

For 35 years, the principles of "purposive construction" has been applied to patent claims and, since 2004, the ultimate question has been what the person skilled in the art would have understood the patentee to have used the language of the claim to mean, which involved interpreting the claim having regard to the fact that the patentee's purpose was to describe and claim an invention.

The defendants (patentees) argued that, in light of *Actavis v Lilly*, these decades of law should be set aside and a patent claim should be interpreted literally – in the same manner as a clause in a commercial contract – and without regard to the patentee's purpose. Arnold J disagreed.

> Patents differ from commercial contracts in two key ways.
>
> First, a contract is (at least in principle) a bilateral statement agreed between the contracting parties, whereas a patent is a unilateral statement made by the patentee and addressed to the class of persons represented by the person skilled in the art.
>
> Secondly, whereas a contract is a document containing promises by the contracting parties to each other (in some cases for the benefit also of third parties), a patent is a document which describes and claims an invention for the purposes of establishing a legal monopoly with regard to that invention.
>
> A patent [is] to be interpreted through the eyes of the person skilled in the art and [the exercise involves] interpreting the words of the claim in context. The context must include the very purpose for which the document exists, namely to describe and claim an invention.



Novelty

Mylan and Synthon argued that it remained the law that a claim lacked novelty if the prior publication disclosed subject-matter which, if performed, would infringe the claim, and that, applying *Actavis v Lilly*, it was sufficient that the subject-matter would infringe the claim applying the doctrine of equivalents.

The defendants submitted that the claim would only lack novelty if the prior publication disclosed subject-matter which fell within the claim on its proper interpretation, i.e. it was not sufficient that the subject-matter would infringe the claim applying the doctrine of equivalents.

Arnold J concluded that the defendants were correct. The Supreme Court had been concerned with infringement and not with validity. ***It would require another decision of the Supreme Court*** to supply a definitive answer to the question of ***whether the law of novelty had changed***.

On the basis of normal construction, Arnold J held that a skilled person would regard the administration of 40 mg GA via subcutaneous injection every other day ("QOD"), as taught by *Pinchasi,* to be distinct from the 40 mg TIW regimen claimed in the patent. Accordingly, the patent was novel.

(In case the case should go further, he considered what the position would be if it was legally possible for a claim to be deprived of novelty by virtue of the doctrine of equivalents. In such circumstances, and assuming that the skilled person would consider it plausible that 40 mg TIW was efficacious as claimed by the '335 patent, he held that the claims would lack novelty over *Pinchasi*.)

Inventive step

The difference between the administration of 40 mg GA QOD as taught in the prior art patent and the 40 mg TIW regimen claimed amounted to ***just one dose every fortnight***.

Overall, Arnold J found that this was obvious to try and that the skilled person would have had a fair expectation of success.

No need for an *Arrow* declaration

Teva's patent in suit was a divisional of another patent, and there were two pending divisional applications which covered the 40 mg TIW regimen for administration of GA. Mylan and Synthon sought an *"Arrow"* declaration "to clear the way", but when asked why an *Arrow* declaration should have any greater persuasive value than a reasoned judgment on the validity of the patent in suit, they had no real answer. Arnold J declined to grant such a declaration, finding that the defendants had not improperly sought to shield the subject-matter of the patent from scrutiny by the courts (to the contrary, they had vigorously defended the validity of the patent at issue), and an *Arrow* declaration would not have any greater persuasive value than his reasoned judgment on invalidity.

Comment

As the judge noted, this decision could represent a radical departure from English patent law which had dictated, prior to 12 July 2017, that a claim should be interpreted in the same manner, and had the same scope, for the purposes of considering both novelty and infringement, thereby ensuring that the patentee could not maintain a broad scope of claim for the purposes of infringement, but a narrow one for the purposes of validity.

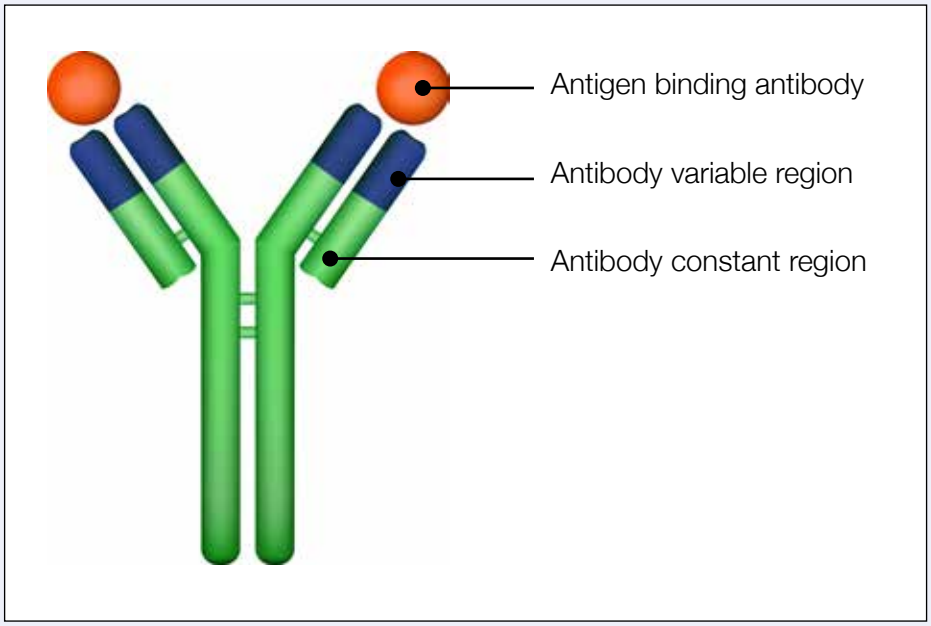
UK COURT OF APPEAL PROVIDES WELCOME GUIDANCE ON WHAT CONSTITUTES A SUFFICIENT DISCLOSURE

BY DR. EDWARD RAINSFORD

Dr. Edward Rainsford

In the Decision of *Regeneron v Kymab & Novo Nordisk*, the Court of Appeal has clarified what is considered sufficient disclosure of a claim to a generalised concept even if certain specific parts of the scope of the claim cannot actually be put into practice at a patents filing date.

The patents in question (European Patent (UK) No 1360287 and its divisional European Patent (UK) No 2264163) claim a new way of producing human antibodies using transgenic mice as well as the transgenic mice themselves.



Antibodies comprise variable regions, which can be tailored to specific targets, and constant regions, which form the remainder of the antibodies structure.

Previously, transgenic mice were used to produce fully human antibodies with both human variable regions and constant regions. The endogenous mouse genes were "knocked out" of the mice and the genes replaced with the corresponding human counterparts. However, it was found that mice producing fully human antibodies have a reduced immune response. In order to overcome this problem, the patents described *in situ* replacement of mouse variable region gene segments with human variable region gene segments, while maintaining the mouse constant regions. This creates a "reverse chimeric locus".

Kymab argued that the patents lacked sufficiency of disclosure because the claims covered an embodiment of the invention, set out in Example 3 of the specification, which could not be carried out at the priority date. Example 3 described the deletion and replacement of a large segment of DNA and it was ***generally agreed that the skilled person at the priority date would not have been able to carry out the invention exactly as contemplated in the example.*** Regeneron, on the other hand, argued that the skilled person would be able to use his or her common general knowledge to adapt the technique to supplement the teaching of the patent and arrive at the invention, e.g. through creating a "minigene" and inserting this rather than the entire gene.

The Court of Appeal sided with Regeneron and was of the opinion that the skilled team, equipped with the common general knowledge, ***could have produced without undue effort*** a transgenic mouse falling within the scope of the claim.

It is well-established that the skilled person is ***not bound to carry out the invention precisely as described*** *and can use the common general knowledge to perform the invention and make any obvious changes that may be necessary, provided of course that any work involved is not undue.*

The skilled person would have regarded the implementation of Example 3 as ***extremely challenging*** and in these circumstances the obvious thing to have done would have been to shorten the inserts. The team would also have understood that there was no need to carry out deletions in the same step as insertions, and that any necessary deletions could be effected without undue difficulty in a later and separate step.

The law does not require a patentee to enable each and every embodiment *of a claimed invention . . . were protection to be limited to only those embodiments which could have been made at the priority date without undue effort, the protection provided by the patent would have rapidly become ineffectual.*

Comment

In practical terms, there has been no change in the law regarding sufficiency of disclosure. There has however been a welcome clarification that the patentee can rightfully expect to be safe-guarded against unfair limitations on the scope of an invention where it applies to a general principle which could be adapted in the future in ways not possible at the priority date of a patent.

SPOT OF BOTHER – NO SHORTCUT TO PROPER CLAIM ANALYSIS

BY HUGH DUNLOP

It is unusual these days for claims of patent and design infringement to be enforced in one court action, but this was the case when RN Ventures brought out its Magnitone™ product in competition with L'Oréal's Clarisonic™ range of skin cleansing brush products. L'Oréal sued for patent infringement and registered community design infringement and won on both counts.

The case for design infringement is an excellent case study in how the UK Patents Court assesses the scope of protection of a registered design, and we discuss that aspect of the case in our sister newsletter **Design *features***. Meanwhile, here in **Patent *issues***, we select this case for review because it has several takeaway points for patent owners and practitioners.

HUGH DUNLOP

L'Oréal's skin cleansing brush patent described how acne can arise when bacteria multiply within a blocked skin pore, leading to rupture of the follicular wall and an inflammatory response. It said that acne could be prevented by opening the skin's pores and loosening the sebaceous plugs that block the pores. Application of differential motion locally to the pore opening would open a blocked pore. The skin area is deformed slightly and then released to a relaxed position and then deformed slightly in the opposite direction and then again released to a relaxed position, at a specified frequency. This was said to result in the plugs being loosened from their position in the skin pores. The loosened plugs could then be removed by wiping or washing, permitting normal skin secretion of lipids, and avoiding more fully developed acne.

The claims called for a device that ***reciprocally moves at least one moving contacting element*** (i.e. a brush bristle or tuft of bristles) ***bi-directionally through a neutral position relative to at least one adjacent contacting element (bristle or tuft) to produce alternating tension and compression of the skin.*** Thus ***"when positioned so that the end faces of the contacting element contact the skin, an action on the skin … is produced to remove sebum plugs from skin pores."***

The figures (right) showed alternating shear movement of skin around a blocked pore.

RN Ventures had a device that did not drive bristles relative to other adjacent bristles. Their device was, they believed, more akin to prior art devices that reciprocally drove all bristles together.

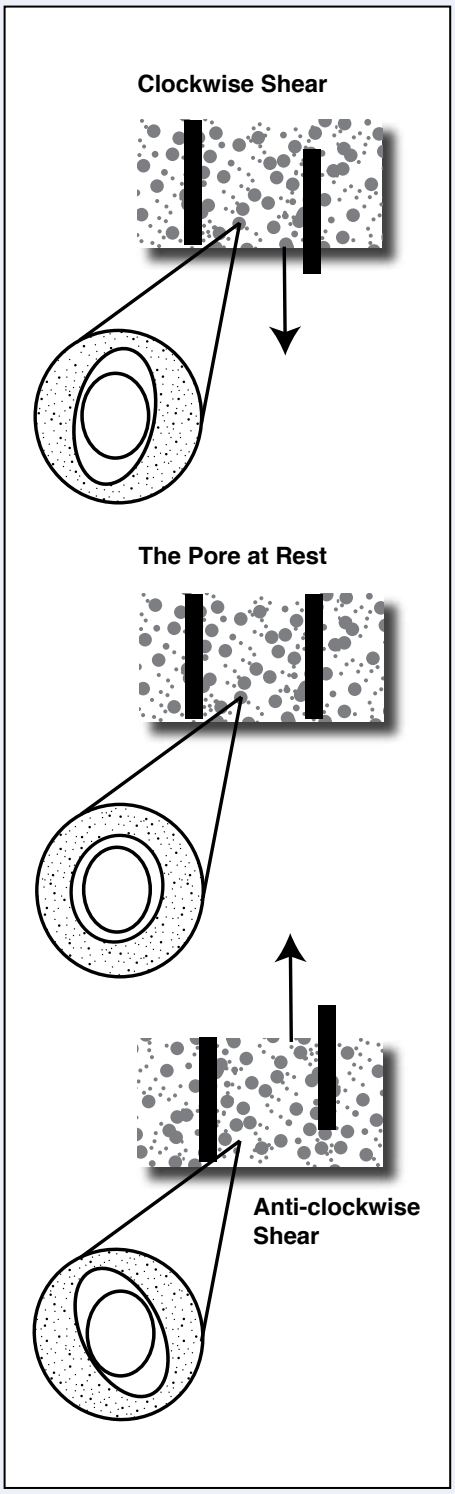
They presented a ***Gillette*** defence – i.e. a squeeze argument to the effect that it did not matter whether the claims were to be interpreted broadly or narrowly, because if broad, they could not be valid and if narrow, they could not be infringed.

RV Ventures were very confident in their ***Gillette*** defence. The prior art had bristles that were all driven through "use of a single set of elements" and the Court held that such an arrangement fell outside the claim.

They were so confident that when the patent was held to be valid and infringed they asked the judge (Mr Justice Henry Carr) to review his decision as it appeared internally inconsistent. "Not so" said he. The claim refers to the ***effect on the skin*** (the bristle tips) and ***not the way the bristles are driven*** (at their roots). The same effect can be achieved using bristles of differing flexibility, and the evidence indicated that at least one of the defendant's products used bristles of differing flexibility and therefore fell within the scope of the claim on a classic interpretation (without having to invoke a doctrine of equivalents).

L'Oréal's witness admitted that bristles of uniform length and thickness achieve the same result, but there was no evidence before the court that the prior art bristles were non-uniform. Furthermore, the embodiment described in the patent that was held to fall outside the claim was not specific on this point, so RN Ventures could not rely on that.

Frustratingly for the defendants, the line between the claim and the prior art was fuzzy and they neither clarified the line based on the operation of the prior art nor that their product lay on the safe side of the line.



Register your license if you want to recover costs

As a general rule, in the UK, the loser has to pay the winner's legal costs. Having won the infringement action, a further hearing was necessary to adjudicate on the level of costs L'Oréal should be awarded, because one of the claimants (L'Oréal (UK) Ltd.) was an exclusive licensee under the patent and there had been delay in registering the licence on the Register of UK Patents.

It was proper for the exclusive licensee to be a named claimant, because that party is the one that suffers damage in the UK. But the UK Patents Act has a provision that penalises a licensee that does not register is licence.

Section 68 of the Patents Act 1977 prevents the recovery of patent infringement costs by the holder of the exclusive licence and as a matter of discretion, Carr J. decided to reduce the overall amount recoverable by the claimants in order to reflect the purpose of s 68, namely to ensure the accuracy and completeness of the register by providing a costs sanction for failure to register an exclusive licence within six months of the parties entering into such a transaction.

People need to know who is on the register. This section is aimed at making the people who own the monopolies get on the register. [1]

Costs Decision

70% of the infringement took place before the exclusive licence between L'Oréal SA and L'Oréal UK was registered on the patent's register and approximately 30% had occurred post-registration.

Half of the legal costs were attributable to the patent infringement proceedings (and the rest to the design infringement action and the patent revocation action).

Carr J ruled that the costs should be allocated fifty-fifty to the two claimants.

So the appropriate deduction from the award of costs (the "windfall" to the defendant for the failure on the part of the licensee to register the licence) was 70% x 0.5 x 0.5 = 17.5%.

Section 68 of the UK Patents Act 1977:

Where a person becomes the proprietor or an exclusive licensee of a patent and the patent is subsequently infringed before the licence is registered, the court shall ***not award costs or expenses*** unless it was registered ***within 6 months*** of its date or as soon as practicable thereafter.

Comment

This decision presents a salutary tale for anyone seeking to rely on a *Gillette* defence. There is no substitute for, nor shortcut to, proper claim analysis. Unfortunately, however, post *Actavis*, claim analysis is doubly complicated by the need to consider the doctrine of equivalents.

In *L'Oreal v RN Ventures*, the Court had to consider whether the arrangement that was described (albeit incompletely) and that fell outside the claim meant that there was a "deliberate selection" from among the possible equivalents. "Deliberate selection" is a doctrine that has grown in German patent law to curb some of the excesses of the doctrine of equivalents. Carr J. declined to apply this principle, because he was able to find infringement on a more traditional interpretation (i.e. without resorting to a doctrine of equivalents).

For the present at least, it seems that the UK Patents Court would prefer to reach a finding of infringement on more settled law if at all possible.

1. *Schütz v Werit* [2013] RPC 16 para. [85], approving *LG Electronics v NCR Financial Solutions Group Ltd* [2003] FSR para. [24]

EPO REAFFIRMS ITS POSITION ON THE ALLOWABILITY OF UNDISCLOSED DISCLAIMERS

BY DR. EDWARD RAINSFORD

Dr. Edward Rainsford

The Enlarged Board of Appeal in its Decision of G1/16 has clarified the requirements for the use of undisclosed disclaimers.

There are a limited set of circumstances in which undisclosed disclaimers can be used and these were set out in the Enlarged Board of Appeal Decision G1/03. In essence, undisclosed disclaimers can only be used to restore novelty over certain types of prior art documents and to remove subject-matter excluded from patentability.

"Gold Standard"

The issue of disclaimers was also addressed in the Decision of the Enlarged Board of Appeal of G2/10 and in this Decision it was suggested that the "gold standard" disclosure test had to be applied in the assessment of any amendment, including undisclosed disclaimers, for compliance with the added matter requirements of the European Patent Convention. The gold standard requires that the subject matter of an amendment must ***be directly and unambiguously derivable*** from the application as filed.

In light of G2/10 and the requirements of the gold standard, conflicting approaches were taken on the application of undisclosed disclaimers. As pointed out by the Board of Appeal referring the case to the Enlarged Board of Appeal, if the gold standard is applicable, then in most cases an undisclosed disclaimer would not be allowable, i.e. how can the subject matter of an undisclosed disclaimer be at the same time not described in the application and also directly and unambiguously derivable from the application as filed.

Exceptions for undislosed disclaimers

The Enlarged Board of Appeal stated conclusively that the "gold standard" does not apply to amendments introducing an undisclosed disclaimer. This is good news for applicants as it provides greater opportunities for removing subject matter that may otherwise prevent grant of a patent application.

A **disclaimer** is a limitation in a claim that excludes certain subject matter from its scope of protection, for example a claim may recite "a plastic, excluding polyethylene".

A so-called ***"undisclosed disclaimer"*** is a disclaimer in which neither the disclaimer nor the subject-matter excluded from the scope of the claims is disclosed in the application as filed.

PROPOSED OPTION TO DEFER EXAMINATION AT THE EPO

BY HUGH DUNLOP

Hugh Dunlop

The European Patent Office has proposed an option to defer examination for 3 years. The scheme is referred to as "User Driven Early Certainty" and is explained in memo CA/PL 4/18 of 25 January 2018 from the President to the Committee for Patent Law.

It was presented as ready for publication with a start date of 1 July 2018 but various user groups have expressed reservations and outgoing President Batistelli told the eip Council at its 40th anniversary meeting on 20 April 2018 that he is passing this particular baton to his successor, António Campinos and it is up to the new president whether to take it forward. The proposed launch date is postponed and a revised paper is expected later this year.

Summary of the proposed scheme

- There is to be no fee for deferral
- The option to defer comes after the obligation to reply to the Search Report (or to confirm the desire to proceed with examination as the case may be)

  - Accordingly, there need be no change to the Rules
- The applicant can lift the deferral and resume examination at any time within the 3 years
- Third parties can lift the deferral but only by filing substantiated non-anonymized observations.

Other IP5 offices already permit applicants to influence start of examination

- At the JPO, examination may be requested within 3 years from filing the application.
- At the KIPO a request for examination may be filed within 3 years from the filing date of the application.
- At the SIPO examination may be requested within three years from filing the application.
- At the USPTO applicants may request a deferral of examination for a period of up to three years from the earliest filing date.

Reasons given for the new scheme ("user feedback")

- Applicants may have an interest in postponing the prosecution of their application to align with external factors:
  - filing of an application at a very early stage in the product development cycle;
  - need to align with regulatory approval requirements;
  - need to align with funding or licencing activities.
- Increase prosecution efficiency for both applicants and the EPO

CHANGES TO THE EPO GUIDELINES – SUMMONS AS A FIRST ACTION IN EXAMINATION

BY DR. SILKE PETZOLD

Revised Guidelines for Examination of the EPO are in force since November 2017.

The most important change for applicants is the possibility that the first action in examination can now be a summons for oral proceedings instead of a mandatory examination report (Chapter C-III. 5).

This measure has been introduced to increase efficiency of the examination procedure. According to the EPO, a Summons as a first action in examination may be issued when, despite the applicant's reply to the search opinion, the Examining Division believes that there is no realistic possibility that the application will be granted.

It appears that an invitation to oral proceedings is only issued instead of a first examination report if:

i) the content of the ***claims is not substantially different*** than that of the claims which served as a basis for the search; and

ii) one or more of the ***objections raised in the search opinion***, which are ***crucial*** to the outcome of the procedure, ***still apply*** at this point of the examination procedure.

Accordingly, the Summons may not include any new objections or cite new documents which have not been included during the search stage, and the Annex to the Summons must justify why Summons are issued as a first action. Also, the invitations to oral proceedings are issued with at least 6 months notice.

We believe that this change of procedure may violate Article 94(3) EPC, which specifies that the Examining Division shall invite the applicant as often as necessary to file observations and amendments if the examination reveals that the application or the invention to which it relates does not meet the requirements of the EPC.

Thus, it seems to us that the Examining Division must send at least one examination report to comply with the requirement of Article 94(3) EPC.

Discussions are ongoing behind the scenes, and further amendments which may further limit the use of the Summons as a first action and thus bring the Guidelines again closer to the provisions of the EPC might be forthcoming.

However, currently the amended Guidelines allow invitations to oral proceedings to be issued as the first action during examination.

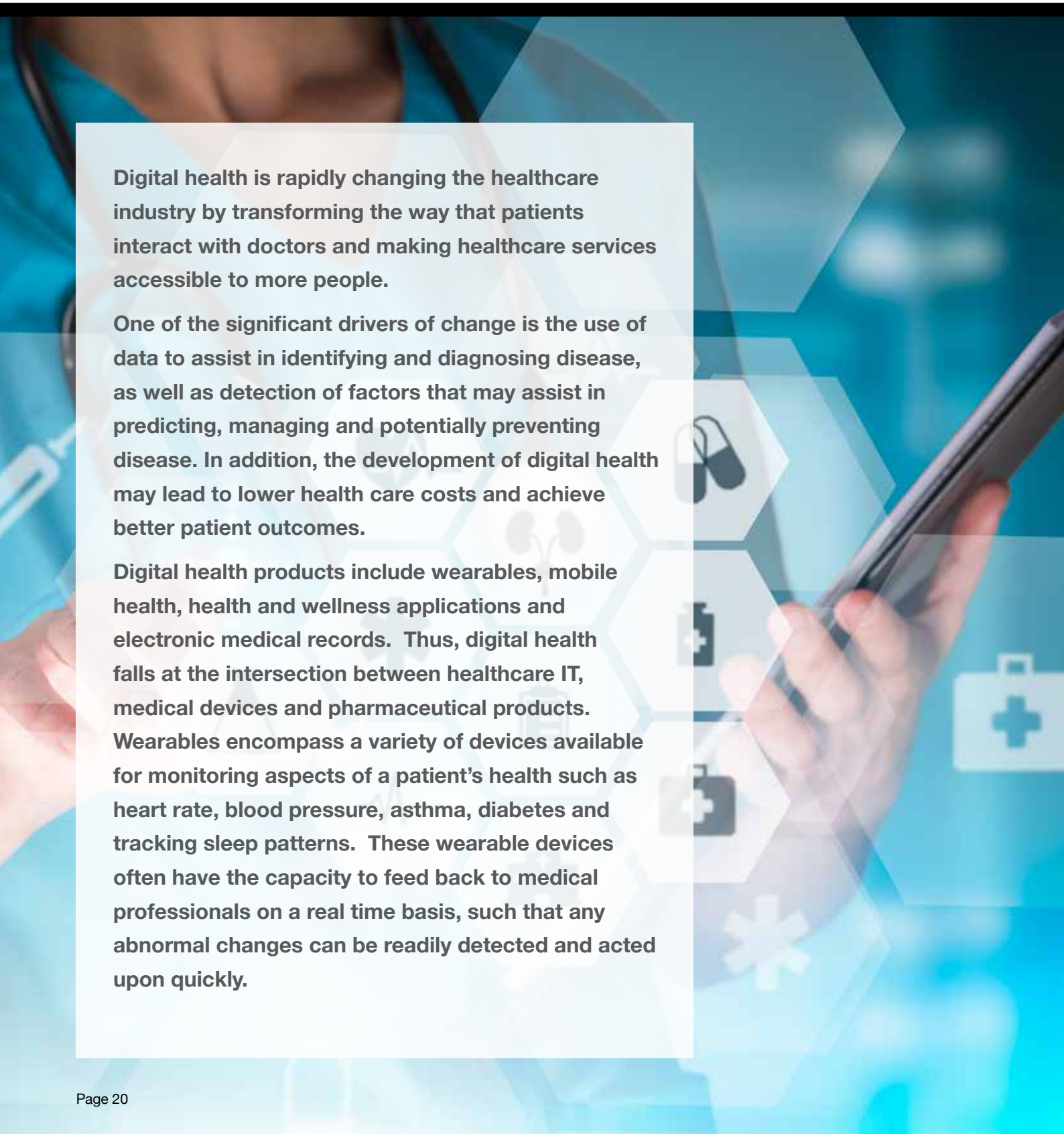
For the applicant it is thus important to identify and address all critical issues raised during the search stage in order to avoid a Summons being issued early. It might be advantageous in some cases to consider filing of auxiliary requests even as early as the search stage, to manoeuvre amendments before examination begins.

Another possibility which may help in avoiding to receive a Summons as a first action is to file a Demand during the International phase, in order to advance examination at an early stage.

However, it remains to be seen how much use the EPO will make of the possibility to issue a Summons as a first action during the examination procedure.

IP CONSIDERATIONS IN DIGITAL HEALTH

BY DR FIONA KELLAS



Digital health is rapidly changing the healthcare industry by transforming the way that patients interact with doctors and making healthcare services accessible to more people.

One of the significant drivers of change is the use of data to assist in identifying and diagnosing disease, as well as detection of factors that may assist in predicting, managing and potentially preventing disease. In addition, the development of digital health may lead to lower health care costs and achieve better patient outcomes.

Digital health products include wearables, mobile health, health and wellness applications and electronic medical records. Thus, digital health falls at the intersection between healthcare IT, medical devices and pharmaceutical products. Wearables encompass a variety of devices available for monitoring aspects of a patient's health such as heart rate, blood pressure, asthma, diabetes and tracking sleep patterns. These wearable devices often have the capacity to feed back to medical professionals on a real time basis, such that any abnormal changes can be readily detected and acted upon quickly.

DR FIONA KELLAS

In contrast to some other healthcare industries (e.g. pharmaceuticals) which are typically developed over a slower period of time, in the digital health industry product life cycles are typically much shorter. Thus, digital health businesses need to develop and regularly revise their IP strategy. In addition, businesses should ensure that procedures and contracts are put in place when working with any third parties, to establish ownership of any IP that may arise during development of the digital health product.

Various aspects of the digital health product may be protected using IP, such as the hardware, the software and any data analytics that may be involved. An example of a digital health product that is typical of those being developed in this area is as follows:

A research team in a medtech company have developed a non-invasive wearable sensor that can measure blood glucose levels over programmed time intervals. The sensor will transmit high or low blood glucose alerts to the sensor wearer or to an individual identified by the wearer. The sensor also stores the collected data in a database that is accessible by the sensor wearer and medical professionals via a web based application on either a mobile device or a computer. Additional data such as prescription medication, weight, daily exercise and diet can be added and stored in the database.

In the above example, the areas of IP that may be used to provide protection are patents (for example, to protect the mechanical aspects of the device), designs (to protect the appearance of the device), copyright (for example, to protect the programs and algorithms that are used by the device), database right (to protect the data stored in the database). These forms of protection are discussed in greater details below:

1. Patents

Digital health products often comprise mechanical, chemical and/or electrical components which may be patentable if they are novel and inventive.
In addition, further aspects of the device, methods and protocols associated with using the device may be patentable. However, digital health products often comprise a software and/or a computer-based element which may be difficult to protect using patents. Therefore, developing a meaningful patent portfolio around these innovations can be challenging.

In Europe, in order for a patent to be granted for a computer implemented invention, a technical problem needs to be solved in a new and inventive manner. Thus, when considering patent protection in Europe, it is necessary to demonstrate that the software component of the digital health product has a technical effect.

In the US, developments over recent years have increased the difficulty associated with protecting innovations where the underlying software or technology is built on abstract ideas or laws of nature. This is due to the finding of the US Supreme Court case *Alice v CLS Bank International 134 S. Ct. 2347 (2014)* which found that a patent is invalid if the claims relate to an abstract idea, since such abstract ideas are excluded from patentability. Following Alice, it is important for digital health companies to think more strategically about how to acquire patent protection.

Although there may be challenges associated with protection IP within this area, many successful digital health companies have been able to secure patent protection for their inventions and in some cases are pursuing enforcement of these patents.

2. Registered and Unregistered Design Protection

Due to the competitive nature of the digital health industry, it may be important to protect aspects of the appearance of the digital health device. For example, it is possible that the customer may be drawn to the product due to its size, colour, or a feature of the design of the user interface of the device. If there are aspects of the appearance of the digital health device that may be important in driving sales of the device, design protection should be considered.

3. Trademarks

The use of trademarks may be important in protecting the brand of the product, for example, where the user associates the product with its name. This can be seen with brands such as Fitbit ® where the product is associated with the name of the device.

4. Copyright and Database Right

Digital health devices often collect and store data which may be transmitted to a healthcare professional or a hospital. Data is one of the grey areas of IP and establishing the ownership of the data may be complex. Patients often own their own data and medical records. However, consolidated and anonymised data often belongs to the NHS. In addition, data sets that are licensed from third parties will be subject to the terms of those licenses and the restrictions of any copyright that may apply.

Digital health devices may be linked to a database in which the data is collected and stored. Database Rights are defined in Directive 96/9/EC. A database is defined as ***"a collection of independent works, data or other materials which are arranged in a systematic or methodical way and are individually accessible by electronic or other means".***

The data stored in a database may be protected: (1) under the law of copyright and the rules that apply in relation to databases; and (2) under the UK Copyright and Rights in Databases Regulations 1997.

Databases are treated as a class of literary works and may have copyright protection for the selection and/or arrangement of the contents provided that they were recorded in a medium and that they were the author's own intellectual creation. Since the copyright owner is the creator of the database, digital health companies need to be careful when using a contractor to create a database. This is because the contractor is likely to be the owner of the copyright in the database. Therefore, if a company wants to own the copyright, it must enter into an agreement with the contractor which contains an assignment of the copyright.

If a set of data comes within the definition of a database and there has been a "substantial investment" in obtaining, verifying or presenting the contents of the database, it will qualify for protection under the Database Regulations. In contrast to copyright, the maker of the database is the first owner. Database right lasts for 15 years from the end of the calendar year in which the production of the database was completed. However, updating the database may extend this term.

Copyright may also exist in the programs and algorithms used by the digital health device.

5. Contracts and Licensing

As in other sectors, the development of digital health products and services may involve a number of parties. It is therefore important to assess any contracts and licences that may apply and to be clear about the ownership of any IP that may arise.

Conclusion

The digital health sector is rapidly growing and many medtech companies are moving into this area. Thus, the use of IP to protect innovations in this sector is increasingly important. Whilst there may be challenges associated with IP protection of digital health innovation, many companies are successfully navigating these challenges.

Team news

Welcome to:

Oksana Thomas joined our London office in January as a Technical Assistant in our patents group. She has a degree in Astrophysics and an MSc Management of Intellectual Property and Post-Graduate Certificate in IP from Queen Mary University of London.

Sharon Kirby joined the firm in March as a Senior Associate based in the trade marks team in London. Sharon is a qualified UK and EU Trade Mark Attorney, Higher Courts Litigator and an Irish Trade Mark Agent. Sharon has experience of managing trade mark portfolios for a range of clients from start-ups, to long-established businesses with registrations in more than 60 countries.

Pramod Patel joined the London office as a Paralegal in the trade marks team. Pramod has previously worked within intellectual property, particularly in the field of trade marks gained from working within international law firms.

Stephanie Foy joined as an Associate Solicitor in our London office trade marks group. Stephanie has specialised in general commercial and intellectual property litigation and is experienced in dealing with intellectual property disputes and has extensive experience of handling contractual disputes, in particular the construction of vague clauses.

Maucher Jenkins is delighted to announce that technical assistant May Xu gave birth to baby Chase, a brother to Jacquelin. Mother and baby are well.

Out and about - external event attendance

Who	Details	When
Katie Cameron, Tim Pendered, Felix Rummler, Kana Enomoto, Handong Ran, Dr. Kei Enomoto, Nicole Ockl, Tim Young	INTA, Seattle, Washington	19 – 23 May
Dr. Fiona Kellas	BIODundee International Conference, Dundee, Scotland	22 – 23 May
Reuben Jacob, Dr. Fiona Kellas, Dr. Edward Rainsford	BIO International Convention 2018, Boston, USA	4 – 7 June
Trade Mark Team	ECTA 37th Annual Conference, Athens, Greece	13 – 16 June
Handong Ran, Alec Clelland, Dr. Edward Rainsford	China Patent Annual Conference (CPAC), Beijing	30 – 31 August
Joanne Ling	MARQUES 32nd Annual Conference, Paris	18 – 21 September
Reuben Jacob, Phil Treeby	AIPPI World Congress, Cancun, Mexico	23 – 26 September
Katie Cameron, Kana Enomoto	PTMG Autumn Conference, Dubrovnik, Croatia	3 – 6 October
Nicole Ockl	ECTA 76th Autumn Council and Committee Meetings, Geneva, Switzerland	18 – 20 October
Maucher Jenkins Team	AIPLA Annual Meeting, Washington, USA	25 – 27 October
Reuben Jacob, Dr. Fiona Kellas, Dr. Edward Rainsford	MEDICA Düsseldorf, Germany	12 – 15 November
Phil Treeby, Dr. Kei Enomoto	APAA, New Delhi, India	17 – 21 November

Maucher Jenkins hosted events

Dr. Cornelius, Mertzlufft-Paufler, Johannes Lange	Free consultation for inventors, IHK Südlicher Oberrhein in Lahr, Germany	17 May 19 July
Dr. Cornelius, Mertzlufft-Paufler	IP Showcase, Basel, Switzerland	4 June
Dr. Cornelius, Mertzlufft-Paufler, Dr. Manuel Kunst, Henrich Börjes-Pestalozza,	Free consultation for inventors, IHK Südlicher Oberrhein in Freiburg	2 August 6 September 4 October
Felix Rummler, Kana Enomoto, Sascha Zieglmeier, Nicole Ockl, Georg Messerle	IP Day, Munich, Germany	October (TBC)

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