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Editorial

In this edition we explore a number of pharmaceutical and computing hot topics. Notably patenting blockchain technology is gaining increasing interest across a range of applications. The EPO issued new Guidelines for Examination in November last year which include extensively re-drafted sections on computer implemented inventions, AI and machine learning. We have substantial experience in computing and software technologies and will be pleased to offer advice on how the new guidelines can influence drafting for European patents, including blockchain technologies. We hope you find this issue both interesting and relevant to your work.

Editor:
Anthony Albutt

Events

03-06 June 2019
BIO Convention, Philadelphia USA
Simon O'Brien and Zöe Clyde-Watson will be attending the BIO International Convention.

24-26 September 2019
IPO Annual Meeting, Washington DC, USA
Garreth Duncan (contributor to the IPO Pharmaceutical & Biotechnology Issues standing committee) and Nicholas Malden (contributor to the Software Related Inventions standing committee) will be attending this meeting.

24-26 October 2019
AIPLA Annual Meeting, Washington DC, USA
Antony Craggs and Uli Foerstl will be attending the AIPLA annual meeting in October.

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Patenting blockchain related technologies EPO guidance for distributed computing environments

Blockchain seems to have become a new buzzword in the tech industry. We are told it has the power to transform everything from finance to supply chains, to decentralise the control of data and even to revolutionise intellectual property itself.

According to the European Patent Office there were over 2,000 blockchain patent families published in 2018 compared to zero in 2008. The territories with the largest number of filings during this time were the US and China (by far) followed by the EPO and South Korea.

The top worldwide applicants include IBM, Mastercard and Visa. The top EPO applicants include Visa, Mastercard, Nokia and Sony.

What exactly is blockchain? What type of blockchain inventions might be patentable?

To demonstrate the principles of blockchain, let's look an example in which a blockchain is used to store a digital ledger. A ledger is a set of ordered transactions between a plurality of parties. Our example shared ledger (figure 1) involves four participants, Alice (A), Bob (B), Charlie (C) and Dave (D).

Figure 1 (digital ledger):

(1) A sends B £50
(2) B sends C £120
(3) B sends D £20
(4) C sends A £40

We will assume that each of our participants A, B, C and D start with £100.

After transaction (1), A has £50 and B has £150.
After transaction (2), B has £30 and C has £220.
After transaction (3), B has £10 and D has £120.
After transaction (4), C has £180 and A has £90.

The ledger can thus be used for financial transactions between A, B, C and D in place of physical money.

Each transaction must adhere to certain rules in order for it to be accepted and added to the ledger.

- Rule 1 is that no party should be able to send more money than they have available. So, if A were to try to send more than £100 as transaction (1), this should be rejected. Similarly, if B were to try to send more than £30 as transaction (3), this should be rejected.
- Rule 2 is that it should only be possible to send money from one party to another with the permission of the sending party. So, transaction (1) can only occur with the permission of A, transaction (2) can only occur with the permission of B, etc.

Rule 1 can be enforced by the initial amounts of each party being included as initial lines on the ledger (in the form "A has £100", "B has £100", etc.), for example. The amount of money each party has available to "spend" at any given time is then given by the running total of credits to and debits from that party (e.g. transaction (1) is a debit from A and a credit to B, transaction (2) is a debit from B and a credit to C, etc.).

Rule 2 can be enforced by requiring that each transaction contains some unique information and is digitally signed by the sender (e.g. transaction (1) contains the unique number "1" and is digitally signed by A, transaction (2) contains the unique number "2" and is digitally signed by B, etc.).

The transaction is only added to the ledger if the digital signature can be verified. The digital signature can only be verified if it has genuinely been created by the sender and the transaction has not been altered in any way.

Who stores the digital ledger?

Conventionally, the ledger is stored centrally by a single, trusted party X. Each of A, B, C and D must trust that X will, for example, check that each transaction it receives satisfies rules 1

and 2 and add all such transactions and nothing but those transactions to the ledger. X may be a bank, for example.

An alternative to a central ledger is that each party A, B, C and D stores their own copy of the ledger. When one of the parties wishes to add a transaction to the ledger, they broadcast that transaction to each of the other parties. So, A broadcasts transaction (1) to each of B, C and D. B broadcasts transactions (2) and (3) to each of A, C and D. C broadcasts transaction (4) to each of A, B and D. Each party then adds that transaction to their copy of the ledger. Each party thus, in principle, has their own copy of the ledger and each copy of the ledger is the same (this is referred to as a shared or distributed ledger). There is therefore no need for X and the central ledger.

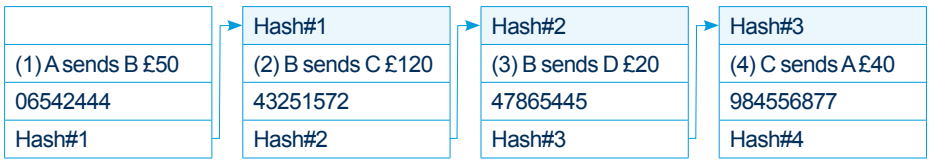
There remains a problem, however. The distributed ledger relies on the parties A, B, C and D all trusting each other in a similar way that X was trusted as holder of the central ledger.

For example, when B receives transaction (1) ("A sends B £50") from A and records transaction (1) on its ledger, B must trust that A has also sent transaction (1) to C and D to allow C and D to record transaction (1) on their ledgers. If A has not done this (either by mistake or to deliberately defraud B), then neither C nor D will accept transaction (2) ("B sends £120 to C") when they receive it from B because they will think that B only has £100 (not £150 due to transaction (1)). The copy of the ledger held by B (with transaction (1)) is thus different to the copies of the ledger held by C and D (without transaction (1)) and the £50 received by B from A in transaction (1) is no good to B if they wish to transfer money to C or D. This is a big problem with distributed ledgers.

Blockchain solves this problem by making it virtually impossible for a single party to add a transaction to the shared ledger without broadcasting that transaction to each of the other parties.

Figure 2 shows the same ledger as shown in figure 1 stored as a blockchain. The

Figure 2 (blockchain):



blockchain comprises multiple blocks (blocks 1, 2, 3 and 4). In this example, each block contains a respective one of the transactions (1) to (4) (including, though not shown, the digital signature of that transaction). In reality, each block may contain multiple transactions (each including its respective digital signature).

Hash of previous block
Transaction
Proof of work
Hash

Cryptographic hash

Each block also contains a cryptographic hash of the block, the cryptographic hash of the previous block (the first block does not have this because it has no previous block) and a "proof of work" (explained below). Each party A, B, C and D stores their own copy of the blockchain.

The cryptographic hash of each block is generated by applying a cryptographic hash algorithm to certain information held in the block (this information is an input to the cryptographic hash algorithm). For example, Hash#1 of block 1 is generated using the combination of the transaction information "(1) A sends B £50" and the proof of work information "06542444" as input information. Hash#2 of block 2 is generated using the combination of the transaction information "(2) B sends A £120", the proof of work information "43251572" and Hash#1 as input information. Hash#3 of block 3 is generated using the combination of the transaction information "(3) B sends D £20", the proof of work information "47865445" and Hash#2 as input information, and so on. Including the hash of the previous block when generating the hash of the current block "chains" the blocks together (hence the term "blockchain").

Cryptographic hashes have the special property that it is very difficult to predict in advance the input information which generates a particular cryptographic hash. Furthermore, even a small change in the input information will completely change the cryptographic hash in an unpredictable way. Thus, for example, if transaction (1) in block 1 were changed to "(1) A sends B £60", the resulting Hash#1 would be completely different to the Hash#1 generated when transaction (1) is "(1) A sends B £50". Furthermore, since the hash of each block (other than the first block) has the hash of the previous block as one of its inputs, changing any information in any one of the blocks requires the hash of that block and all subsequent blocks in the chain to be recalculated in order to maintain the chain. For example, if Hash#1 is different (due to changing transaction (1)), then Hash#2 (whose input includes Hash#1) will be different. If Hash#2 is different, then Hash#3 (whose input includes Hash #2) will be different, and so on.

Proof of work

The "proof of work" in this example is a number (06542444 for block 1, 43251572 for block 2, etc.) which is included in each block to give the hash of that block a particular characteristic. For example, if each hash takes the form of a 256 bit number (e.g. when the SHA256 cryptographic hash algorithm is used), the particular characteristic may be that the hash of each block begins with a certain number of consecutive zeros (e.g. 8 zeros, so that each hash begins with 00000000…).

Because a cryptographic hash is unpredictable, the only way to determine the proof of work number is to try adding different

Continued overleaf (page 04)...

candidate proof of work numbers to the block (e.g. using a random number generator) and calculating the hash until the "right" proof of work number is found and the generated hash therefore has the desired characteristic.

This is a very computationally expensive process. Once the proof of work is known, however, it is very easy for any party to verify it simply by entering it as part of the input to the cryptographic hash algorithm used and ensuring that the generated hash has the desired characteristic.

Generating the blockchain of figure 2 thus includes the following steps:

1. A sends a digitally signed message containing transaction (1) to parties B, C and D. Each of B, C and D verify the digital signature of the message.

2. A, B, C and D each try to find the proof of work which gives Hash#1 of block 1 the desired characteristic (e.g. so it starts with 8 consecutive zeros). The proof of work is 06542444 in this case, but none of A, B, C or D know this until it is found by one of them as they all try as many different numbers as necessary. Finding the proof of work is known as "mining". In some blockchains (e.g. Bitcoin), parties are incentivised to mine by awarding a financial prize to the first party which finds the proof of work of a given block.

3. Whoever finds the desired proof of work announces it to everyone else. Each party individually verifies that the announced proof of work gives Hash#1 of block 1 the desired characteristic (e.g. so it starts with 8 consecutive zeros). Each party then adds block 1 (with the verified proof of work number) to their individual copy of the blockchain.

4. Repeat for each subsequent transaction. The number of blocks in the blockchain thus gradually increases (i.e. the blockchain grows in length) as transactions are added to the blockchain.

Because it is very computationally expensive to calculate the proof of work of each new block, it becomes virtually impossible for a single party to add transactions to the blockchain without telling the other parties and to make that blockchain longer than the "legitimate" blockchain made up of transactions announced to all parties. For example, for a fraudulent party A to convince party B that transaction (1) has been added to the "legitimate" blockchain without party A informing all the other parties of transaction (1), party A would have to generate a blockchain longer than that generated by all of the other parties working together.

Assuming that legitimate transactions are continuously being announced to all parties and that all parties are working on adding blocks to the block chain (and announcing when each new block, with its verifiable proof of work, is generated), as time goes by, it becomes virtually impossible for the blockchain generated by party A to be the longest blockchain. It is therefore safe to trust the longest blockchain as the legitimate blockchain.

The elegance of blockchain is therefore that each party can trust the distributed ledger represented by the longest blockchain even though there is no trusted central entity controlling the blockchain and there is no trust between individual parties. All that is required is to find the longest blockchain and verify it by verifying the digital signature of each transaction and verifying that the hash of each block is what it is supposed to be.

Digital signature and hash verification are computationally simple and can be done by any party with a copy of the blockchain. In particular, hash verification is easy once the proof of work has already been found. You simply put the relevant input information of the block concerned (including the transaction(s), proof of work and, for all blocks other than the first block, the hash of the previous block) into the cryptographic hash algorithm and check that (i) the hash which comes out is the same as the hash included in the block and (ii) the hash has the desired "proof of work" characteristic (e.g. starts with 8 consecutive zeros).

Application of the blockchain

Using blockchain to represent a distributed financial ledger is just one of many envisaged blockchain applications. A common theme amongst these potential applications is the tracking of commodities with unique identifying characteristics (e.g. original artwork, precious stones, delivery packages with a unique barcode or intellectual property rights) as they change ownership (e.g. during transactions or as they are passed through a global supply chain).

There is also scope for improvements to the core implementation of blockchain technology itself. For example, one problem is the huge amounts of electricity used by the computers doing the proof of work calculations in popular blockchains. Is there a robust alternative which uses less power?

> It seems that both the applications and implementation of blockchain technology are likely to involve significant inventive activity in the coming years. But, will these inventions be patentable?

EPO Guidelines for Examination - computer implemented inventions

In November 2018, the European Patent Office re-wrote the Guidelines for Examination on how it handles Computer Implemented Inventions (CII). In this update to the guidelines, there were two important clarifications in respect of blockchain.

- Firstly, the EPO acknowledged that a distributed computing environment, such as that used in blockchain, is a CII. Given this, and the comments made at its "Patenting Blockchain" conference in December 2018, it is clear that the EPO treats a blockchain related invention as a CII. This is similar to the practice at other patent offices, most notably at CNIPA (formally SIPO). We shall look at how the EPO handles CII later.

Each party can trust the distributed ledger represented by the longest blockchain

- Secondly, a new allowable claim category directed towards a distributed computing environment, such as those using blockchain to maintain a distributed ledger, was introduced. On the face of it, this seems like a very positive change by indicating that the EPO is more willing to adapt its allowable claim types in view of current technology. However, whilst welcome, it is unlikely that this new type of claim will be particularly powerful.

The guidelines note that, in order to avoid a clarity objection, it may be necessary to refer to specific features of the different entities and to define how those features interact with one another. This means that in the likely event that the distributed computer network spans several jurisdictions, and involves several parties each being involved in carrying out different features of the distributed computer network, bringing an infringement action will be complicated.

Therefore, if possible, the claims should be drafted to ensure that only the operation of one of the entities is covered in a single claim. The claim to the distributed network should be included, but this, ideally, should not be the sole claim type in the application.

Computer implemented inventions

The examination of CII at the EPO has been consistent for many years. The challenge faced by many CII is that inventions must be concerned with, and solve, a technical problem.

In the context of blockchain related inventions, this can sometimes be difficult to show. For example, if the invention relates solely to the use of blockchain to track the movement of commodities (instead of a database) using a known characteristic of the commodity, this would be unlikely to be patentable at the EPO. This is because the difference between the invention and the prior art is solely the use of the blockchain (the technical features of which are already known) instead of a database.

However, if, for example, the invention relates to a previously unknown technical mechanism for generating a unique characteristic of the commodity and placing that characteristic on the blockchain, then that would likely be patentable. This is because the invention lies in the previously unknown technical mechanism for generating the unique characteristic. Similarly, if the invention relates to a more processor-efficient mechanism for generating a known unique characteristic of the commodity and placing that characteristic on the blockchain, then that too would likely be patentable. This is because the invention lies in the technical feature of the more processor-efficient mechanism for generating the known characteristic.

Blockchain and fintech innovation

One very active area of development for blockchain is in the financial sector. The use of blockchain in this area presents very specific problems for patenting these inventions. This is because methods of doing business, as such, are not seen as having technical character at the EPO. Changes to an underlying business or administrative method using blockchain are therefore likely to be seen as non-technical by the EPO (e.g. because they merely circumvent a particular technical problem rather than solving it) and will therefore be ignored when assessing inventive step. It is thus important when drafting applications in this area to concentrate on how the invention solves a technical problem, rather than describing and claiming changes to the underlying business or administrative method.

For example, if the invention relates to reducing the power consumption in the proof of work calculation by simply not performing certain steps of the calculation and accepting that the resultant proof of work is not as robust, then this would likely be seen as a change in the administrative process and would not contribute to inventive step. However, if the invention relates to reducing the power consumption in the proof of work calculation by using a new algorithm that provides an equally robust or better proof of work, then this would likely be seen as contributing to inventive step.

Conclusion

Blockchain has the potential to be a hugely disruptive technology. Where there is such disruption, it is common for patent offices to be slow to react to these changes. However, the EPO has been very proactive in giving guidance on the examination of applications in this area. If you have any questions about patenting blockchain inventions, please contact your usual D Young & Co adviser.

Authors:
Jonathan Jackson & Arun Roy

CJEU comes down against SPC applicants

No grant of SPCs for new formulations of previously marketed active ingredients

Supplementary Protection Certificates (SPCs) are available in EU member states for medicinal or plant protection products where (among others) the product is protected by a basic patent and where a valid marketing authorisation (MA) has been granted for the product in an EU or EEA member state. An additional requirement for the grant of an SPC is that the MA must be the **first** authorisation to place the product on the market in the EU or EEA (Article 3(d) of the SPC Regulation).

The case at issue here was concerned with the question of whether a marketing authorisation for a new formulation of a previously known and previously marketed active ingredient could constitute the "first authorisation" within the scope of Article 3(d).

Background

C-443/17 is based on a referral from the High Court in England & Wales, to which Abraxis had appealed a decision from the UKIPO to refuse their application for an SPC for their product: Abraxane® (see our review in our December 2016 newsletter: https://dycip.com/abraxis-nab-paclitaxel).

Abraxane® contains a combination of nanoparticles of paclitaxel coated with albumin (nab-paclitaxel). It was claimed by Abraxis that nab-paclitaxel demonstrated greater efficacy than earlier formulations of paclitaxel for the treatment of certain cancerous tumours. An MA was granted for nab-paclitaxel in 2008. However, it was not disputed that paclitaxel had been marketed in another form by other companies under previous MAs prior to the date on which the MA for nab-paclitaxel was granted to Abraxis.

On the basis that the MA granted for nab-paclitaxel in 2008 was not the "first authorisation" to place the product on the market, the Comptroller refused the application for an SPC. In particular, it held that, although Article 3(d) permits the grant of an SPC for a new and inventive therapeutic **use** of an old active ingredient, its scope does not extend to a new and inventive **formulation** of an old active ingredient.

High Court of England & Wales refers question to the CJEU regarding "first authorisation"

Question referred to CJEU

Abraxis appealed this decision on the basis that an MA for a new and inventive formulation did meet the requirements of Article 3(d) based on the solution in C-130/11, Neurim Pharmaceuticals (reviewed in our July 2012 newsletter: https://dycip.com/neurim).

The High Court took the view that the scope of the judgment in Neurim was not clear, and thus referred the following question to the CJEU :

"Is Article 3(d) of [the SPC Regulation] to be interpreted as permitting the grant of an SPC where the [marketing authorisation] referred to in Article 3(b) [of that regulation] is the first [marketing authorisation] within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?"

The CJEU noted that, in order to answer this question, the court in fact needed to answer two questions as set out below.

1. Is a new formulation a new "product" within the meaning of the SPC Regulation?

The CJEU first considered the definition of the term "product" provided in Article 1(b) of the SPC Regulation, and whether a new formulation of an old active ingredient could be considered to fall within this definition.

In other words, the CJEU first considered whether the new formulation (nab-paclitaxel) consisting of a carrier linked together with an old active ingredient (paclitaxel) in nanoparticle form constituted a **different product** to the previous product that

Case details at a glance
Jurisdiction: European Union
Decision level: Court of Justice
Parties: Abraxis Bioscience LLC, Comptroller General of Patents
Citation: C-443/17
Date: 21 March 2019
Full decision: https://dycip.com/c-44317

consisted solely of the same active ingredient.

Article 1(b) of the SPC Regulation stipulates: "product" means the active ingredient or combination of active ingredients of a medicinal product.

Referring to established case law, the CJEU noted that an "active ingredient" does not include substances forming part of a medicinal product that do not have an effect of their own on the human or animal body. Established case law also provides that the term "product" is understood to mean an active ingredient in the strict sense, irrespective of pharmaceutical form.

The CJEU thus held that, since the albumin carrier in nab-paclitaxel does not have any therapeutic effect of its own, it cannot be regarded as being an active ingredient within the meaning of Article 1(b), **even if** its association with the active ingredient leads to an increased efficacy. It was further noted that the combination of albumin with paclitaxel could **not** be regarded as a combination of active ingredients within the meaning of Article 1(b).

> Therefore, it was held that a new formulation of an old active ingredient which consists of that active ingredient with a non-therapeutic carrier **cannot** be regarded as being a product that is distinct from the product consisting solely of that active ingredient.

In essence, the answer to question 1 was: no.

2. Is the MA for the new formulation the first authorisation to place the product on the market?

It follows from the answer to the first question, that the answer to the second question was also no since the product, nab-paclitaxel, was not considered to be a distinct product from the previous product, paclitaxel.

The CJEU noted, in particular that "a literal interpretation of Article 3(d) of [the SPC Regulation] presupposes that the first MA for the product as a medicinal product within the meaning of that provision means the first MA for a medicinal product incorporating the active ingredient or the combination of active ingredients at issue". Thus, only the MA in respect of the first medicinal product consisting of the product concerned may be regarded as the first MA within the meaning of Article 3(d).

The CJEU thus concluded that Article 3(d) in conjunction with Article 1(b) must be interpreted to mean that the MA relied on in support of an SPC application concerning a new formulation of an old active ingredient cannot be regarded as being the first MA for the product concerned, where that active ingredient has already been the subject of an MA.

Objectives of the SPC Regulation

In arriving at this conclusion, the CJEU pointed out that the entire purpose of the SPC Regulation is to encourage research into new medicinal products by compensating applicants for the time and money invested in drug development.

However, as set out in the Explanatory Memorandum of 11 April 1990 to the Proposal for a Regulation, the legislature is intended to protect not all pharmaceutical research giving rise to the grant of a patent, but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product.

The CJEU considered that such an objective would be contravened if one had to ignore a previous MA which had already been granted for an active ingredient when considering merely a new formulation of an old active ingredient.

With regard to Abraxis's arguments regarding Neurim, the CJEU did not consider that that case allowed for a broader interpretation of Article 3(d). Rather, Neurim merely allowed for the grant of an SPC for a new therapeutic application of an old product even if the same product had been the subject of an earlier MA but for a different therapeutic application, provided that the new application is within the limits of protection conferred by the basic patent. This was not the case for nab-paclitaxel, which was authorised for the same application as previous formulations.

> The take-home message must therefore be that an SPC **cannot** be granted for a new formulation of an active ingredient if that active ingredient has already been the subject of an earlier MA.

This is irrespective of the fact that the formulation itself may be the subject of a granted patent, and thus be considered to be new and inventive.

This decision therefore supports a narrow interpretation of Article 3(d) of the SPC Regulation, with the decision taken in Neurim to be seen perhaps as a narrow exception to the rule.

Author
Sophie Blake

Useful links

"SPCs: eligibility of a protein-bound drug", Laura Jennings, 16 December 2016:

https://dycip.com/abraxis-nab-paclitaxel

"CJEU decides on Neurim SPC application" Garreth Duncan, 24 July

2012: https://dycip.com/neurim

BDI v Argent
IPEC offers useful summary of patent entitlement law

In BDI v Argent, the Intellectual Property Enterprise Court (IPEC) of England & Wales has provided a useful summary of the law on entitlement. For those dealing with European patent entitlement issues, it is helpful reading and demonstrates why the IPEC is a useful forum in which to resolve these disputes.

Background

In 2004, Argent commissioned BDI to design and oversee the construction of a plant to make biodiesel from fats, oils and greases recovered from sewers and grease traps.

In 2014, Argent filed two European patent applications, published as EP 3 011 041A and EP 3 078 724A. Shortly before grant BDI filed a claim before the IPEC for a declaration that it was entitled to the patents. As a result, the European Patent Office (EPO) stayed the grant process pursuant to rule 14 of the European Patent Convention (EPC).

Proceedings were settled in relation to EP 3 078 724A, but progressed to trial in relation to EP 3 011 041A.

What is the applicable law?

The national court of the applicant has jurisdiction to determine the ownership of a European patent application pursuant to art. 2 of the EPC Protocol on Recognition and sections 12 and 82 of the Patents Act 1977 (the 1977 Act).

s. 7 of the 1977 Act states who may apply for a patent:

"7. ... (2) A patent for an invention may be granted— (a) primarily to the inventor or joint inventors; (b) in preference to the foregoing, to any person or persons who, by virtue of any enactment or rule of law, or any foreign law or treaty or international convention, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of the making of the invention entitled to the whole of the property in it (other than equitable interests) in the United Kingdom; ... (3) In this Act "inventor" in relation to an invention means the actual deviser of the invention and "joint inventor" shall be construed accordingly."

In Yeda v Rhone-Poulenc, Lord Hoffmann explained that ss. 7(2) and (3) are an exhaustive code for determining who is entitled to the grant of a patent:

"[19] In my opinion, therefore, the first step in any dispute over entitlement must be to decide who was the inventor or inventors of the claimed invention. Only when that question has been decided can one consider whether someone else may be entitled under paragraphs (b) or (c). In many cases, including the present, there will be no issue about paragraphs (b) or (c). …

[20] The inventor is defined in s.7(3) as 'the actual deviser of the invention'. The word 'actual' denotes a contrast with a deemed or pretended deviser of the invention; it means, as Laddie J. said in University of Southampton's Applications [2005] R.P.C. 11, [39], the natural person who 'came up with the inventive concept.' It is not enough that someone contributed to the claims, because they may include non-patentable integers derived from prior art: see Henry Brothers (Magherafelt) Ltd v Ministry of Defence [1997] R.P.C. 693, 706; [1999] R.P.C. 442. As Laddie J. said in the University of Southampton case, the 'contribution must be to the formulation of the inventive concept'. Deciding upon inventorship will therefore involve assessing the evidence adduced by the parties as to the nature of the inventive concept and who contributed to it. In some cases this may be quite complex because the inventive concept is a relationship of discontinuity between the claimed invention and the prior art. Inventors themselves will often not know exactly where it lies."

HHJ Hacon summarised this as follows:

> "At root, there are two questions to be answered in an entitlement dispute: (1) What is the inventive concept? (2) Who devised the inventive concept?"

He noted that it was common ground between the parties that the party seeking to be added as an inventor bears the burden of proving that he contributed to the inventive concept. Further, if he seeks to be substituted as the sole inventor, he bears the further burden of proving that the named inventor did not contribute to the inventive concept.

What is the inventive concept?

"Inventive concept", while a term little used in statute, is one which pervades the case law. So what does it mean?

In statute, the term is directed towards the unity of invention (see s.14(5) and (6), 17(6) and 26(b) of the 1977 Act and Art. 82 of the EPC). HHJ Hacon noted that, in addition to the question of entitlement, the courts had used the term in two other contexts. In Actavis v Lilly, in relation to the doctrine of equivalents, the Supreme Court had considered the term to be synonymous with "the inventive core" of the claim, to be ascertained by focussing on the problem underlying the invention. In Pozzoli v BDMO, in the context of the assessment of inventive step, the Court of Appeal characterised the inventive concept this way:

"[17] ... 'It is the inventive concept of the claim in question which must be considered, not some generalised concept to be derived from the specification as a whole. Different claims can, and generally will, have different inventive concepts ...

18. So what one is seeking to do is to strip out unnecessary verbiage, to do what Mummery L.J. described as make a précis."

Drawing these together, HHJ Hacon drew a distinction between the use of the term inventive concept in statute and in common law.

He explained that the former addresses an overarching relationship between two or more inventions in a single European patent application, involving one or more special technical features in common. By comparison, the inventive concept discussed in Yeda, Actavis and

Case details at a glance
Jurisdiction: England & Wales
Decision level: IPEC
Parties: BDI HOLDING GmbH (claimant) and (1) ARGENT ENERGY LIMITED and (2) ARGENT ENERGY (UK) LIMITED (defendants)
Citation: [2019] EWHC 765 (IPEC)
Date: 13-14 February 2019
Full decision: https://dycip.com/bdi-argent

Argent commissioned BDI to oversee the construction of a plant to make biodiesel from fats, oils and greases

Pozzoli is part of a single invention.

HHJ Hacon went on to cite some of the metaphors attributed to this latter inventive concept including the core, the essence and the heart of the invention and the new technical insight conveyed by the invention.

How do you identify the inventive concept?

Returning to Pozzoli, here the Court of Appeal said:

"17 ... The first stage of identification of the concept is likely to be a question of construction: what does the claim mean? It might be thought there is no second stage – the concept is what the claim covers and that is that. But that is too wooden ... It is too wooden because if one merely construes the claim one does not distinguish between portions which matter and portions which, although limitations on the ambit of the claim, do not. One is trying to identify the essence of the claim in this exercise."

In Markem v Zipher, Jacob LJ elaborated on this explaining that the inquiry is not limited to looking at the claims:

"[101] Accordingly, we think one is driven to the conclusion that [the equivalent section on entitlement of domestic patents] is referring essentially to information in the specification rather than the form of claims. It would be handy if one could go by the claims, but one cannot. [The equivalent section] calls for identification of information and the rights in it. Who contributed what and what rights if any they had in it lies at the heart of the inquiry, not what monopolies were actually claimed."

HHJ Hacon also considered whether he should consider validity when identifying the inventive concept. While he noted that there was no place for him to find whether the patent application was valid or not, there was significant discussion (albeit incomplete evidence) on whether the inventive concepts were obvious or not (the rationale being that something uninventive could not be the inventive concept of the patent).

This may pave the way for similar lines of argument in the future.

What did the court decide?

The court considered the two inventive concepts advanced by the parties, agreeing with Argent that the compositions in claims 1 to 7 of the application best represented the inventive concept.

As there was no dispute that an Argent employee had developed this invention, it followed that Argent (the original applicant) was entitled to the patent.

Author
Antony Craggs

Useful link

Antony Craggs is author of the "Litigation and eligibility: UK" chapter of "Patents in Europe - Helping Business Compete in the Global Economy 2019/2020" published by IAM Patent. The guide provides further information about the English Patents Court and IPEC.

Readers can access the guide online at:

https://dycip.com/uk-patent-litigation

Actavis v ICOS
UK Supreme Court holds dosage regime patent obvious

This appeal relates to the application of the obviousness test under Section 3 of the 1977 UK Patents Act to a dosage regime patent. The Supreme Court unanimously ruled that the ICOS patent for a tadalafil dosing regime was invalid on the basis that the skilled team would have inevitably arrived at the alleged invention during routine dose-response studies in clinical trials.

Background

The patent under challenge, EP 1 173 181 (the 181 patent), relates to a low dosage of tadalafil for use in the treatment of sexual dysfunction. It is owned by ICOS and exclusively licensed to Eli Lilly.

Tadalafil is sold under the brand name Cialis as a medication for erectile dysfunction (ED). It is a PDE5 inhibitor and works in a similar way to sildenafil (more commonly known as Viagra). Tadalafil was found to be advantageous over sildenafil due to its increased selectivity for PDE5 over other PDE families, which results in fewer side effects. The alleged essence of the 181 patent is the discovery that tadalafil is effective in treating ED at such a low dose and with minimal side effects that it can be taken daily for chronic use rather than on demand. The 181 patent claims doses of 1 – 5 mg up to a maximum dose of 5 mg/day.

However, the use of tadalafil in the treatment of ED has already been disclosed in an earlier patent (the Daugan patent), which was filed by GlaxoSmithKline and later transferred to ICOS. The Daugan patent discloses that doses of tadalafil will generally be in the range of 0.5 mg to 800 mg daily for the average adult patient. It gives examples of a tablet containing a 50 mg dose of the active ingredient. However, Daugan does not purport to set out an appropriate dosage regime as an oral treatment of ED.

In order to clear the way for their own tadalafil generic, Actavis brought revocation proceedings in respect of the 181 patent, which were later combined with related proceedings brought by Teva UK Limited,

Did patent EP 1 173 181 lack inventive step over the Daugan patent?

Teva Pharmaceutical Industries Limited and Generics (UK) Limited (trading as Mylan). Actavis and others argued *inter alia* that the 181 patent lacked inventive step over the Daugan patent.

Earlier decisions - High Court

At first instance, Actavis argued that it would be obvious for a skilled team given the Daugan patent to take tadalafil forward into a routine pre-clinical and clinical trial programme as an oral treatment for ED at the priority date. Actavis submitted that while costly and time consuming, the programme would involve nothing other than routine work and no inventive effort was required. Lilly responded that the discovery of the dosage regime was the result of expensive and unpredictable research which was entitled to patent protection. Lilly argued that at the start of the programme it was not obvious to try a low dose like 5 mg/day as there was no reason to think that it would be effective at that dosage.

Birss J accepted neither argument in its entirety. Birss J held that it would have been "entirely obvious" for a skilled team given Daugan to take tadalafil forward into a routine pre-clinical and clinical trial programme as an oral treatment of ED at the priority date. Birss J considered that the skilled team would carry out a first dose ranging study using 25, 50 and 100 mg of the drug as part of Phase IIb studies with the expectation of finding a dose response relationship. However, the results would unexpectedly show no difference in efficacy between the three doses, demonstrating an apparent therapeutic plateau.

The critical dispute at this stage was whether in light of those findings it was obvious for the skilled team to conduct a further dose ranging study to investigate lower doses and determine the minimum effective dose. Birss J considered that it was "very likely" that the skilled team would carry out such studies. However, Birss J held that if a 5 mg/day dose of tadalafil was tested, it would not be tested with a reasonable expectation of success. Birss J considered that the discovery that tadalafil at a 5 mg dose was efficacious and had reduced side effects would surprise the team.

Birss J then looked at the programme as a whole and assessed obviousness overall. He concluded that, given Daugan, a 25 mg/day dose of tadalafil was obvious as a treatment for ED but that a 5 mg/day dose was not. Thus, he found the 181 patent to be valid (and infringed).

Earlier decisions - Court of Appeal

The Court of Appeal reached a contrary conclusion and allowed the appeal on the grounds of obviousness.

Kitchin LJ pointed out that Birss J found

Case details at a glance
Jurisdiction: England & Wales
Decision level: Supreme Court
Parties: Actavis Group PTC EHF and others (respondents) v ICOS Corporation and another (appellants)
Citation: [2019] UKSC 15 on appeal from [2017] EWCA Civ 1671
Date: 27 March 2019
Full decision: https://dycip.com/tadalafil

that the skilled team would "very likely" investigate lower doses of tadalafil after the first or, in the case of on demand dosing, a possible second dose ranging study. Kitchin LJ held that the finding that the skilled team could not predict at the outset that a 5 mg dose would be safe and efficacious was of little weight because at least one purpose of the Phase IIb studies is to understand better the dose-response relationship of the drug and so identify the appropriate dose. Kitchin LJ also held that little weight could be attached to the fact that it was surprising (a) that there was a therapeutic plateau from 10 mg to 100 mg, and (b) that a 5 mg/day dose was efficacious and had reduced side effects as they were the results of a routine trial programme. He also held that the unexpected reduced side effects were a bonus effect which did not cause the 5 mg dose to cease being obvious.

Kitchin LJ concluded that the claimed invention lies at the end of the familiar path through a routine pre-clinical and clinical trial process. Kitchin LJ held that the skilled but non-inventive team would embark on that process with a reasonable expectation of success and in the course of it they would carry out Phase IIb dose ranging studies with the aim of finding out, among other things, the dose response relationship. It is very likely that in doing so they would test a dose of 5 mg/day tadalafil and, if they did so, they would find that it is safe and efficacious. At that point they would have arrived at the claimed invention. Thus, Kitchin LJ declared the 181 patent lacked inventive step and was invalid.

Supreme Court

ICOS and Lilly appealed the Court of Appeal decision to the Supreme Court. They argued that the Court of Appeal's approach to inventive step went beyond the requirements of Section 3 of the 1977 UK Patents Act. They argued that Section 3 required the court to ask whether the claimed invention was obvious to the notional skilled but uninventive team at the priority date having regard to the state of the art at that date. They argued that the potential outcome of clinical trials should not form part of the analysis.

Lord Hodge (giving the judgment of the Supreme Court) was not persuaded by Lilly's arguments. Lord Hodge stated that Lilly's approach would require the court to disregard the work which a skilled person would carry out after the priority date of Daugan. Lord Hodge held that while the skilled person has no inventive capacity, that does not mean he has no skill to take forward in an uninventive way the teaching of the prior art.

Lord Hodge emphasised that the question of obviousness must be considered on the facts of each case taking into account any particular factors that may be relevant to the circumstances of that case. Lord Hodge then went on to consider ten factors relevant to the case at issue:

1. whether at the priority date something was "obvious to try";
2. the routine nature of the research and any established practice of following such research through to a particular point;
3. the burden and cost of the research programme;
4. the necessity for and the nature of the value judgments which the skilled team would have;
5. the existence of alternative or multiple paths of research;
6. the motive of the skilled person;
7. whether the results of research are unexpected;
8. hindsight;
9. whether a feature of a claimed invention is an added benefit; and
10. the nature of the invention.

Lord Hodge stressed, however, that the relevance of each of these factors and its weight when balanced against other relevant considerations depend on the particular facts of each case.

In the instant case, Lord Hodge agreed with the Court of Appeal that the 181 patent was obvious in view of Daugan. Lord Hodge concluded that the task of the skilled team would be to implement Daugan and that this would involve determining the appropriate dose of tadalafil, which would usually be the lowest effective dose. Lord Hodge held that the pre-clinical and clinical tests involved familiar and routine procedures and normally progressed to the discovery of the dose-response relationship in Phase IIb. In this case, the skilled team would have found the therapeutic plateau and would be very likely to test lower doses and so come upon the dosage regime which is the subject of the patent. Thus, the appeal was dismissed.

Comments

This case highlights that the assessment of inventive step requires a multifactorial approach and depends upon the specific facts of the case. It will be interesting to see how the ten factors identified in this case are applied to future cases.

The court considered the commonly used tests for the assessment of inventive step in the judgement, namely the UK Windsurfing/ Pozzoli test and the EPO problem-and-solution approach. The court held that while both approaches focus on the inventive concept put forward in the claims, neither approach should be applied in a mechanistic way. The court stated that both are glosses on the statutory texts and neither requires a literalist approach to the wording of the claims in identifying the inventive concept.

Interestingly, the court held that there is no policy reason why a novel and inventive dosage regime should not be rewarded by a patent. In addition, it was concluded that efficacious drugs discovered by research involving standard pre-clinical and clinical tests should be rewarded with a patent if they meet the statutory tests. Thus, this decision does not close the door on dosage regime patents. However, it is difficult to see how a dosage regime arrived at through routine pre-clinical and clinical tests could be considered inventive in view of this decision.

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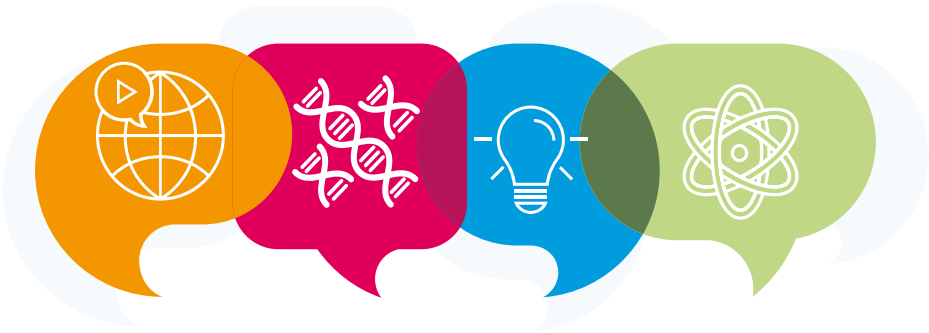
Michelle Montgomery

And finally...

Webinar catch up

European biotech patent case law
Webinar recordings now available!



Having recently broadcast our May European biotechnology patent case law webinar we are pleased to now be able to offer access to a recording of the webinar on demand.

The webinar provides a round up of this year's new and significant EPO decisions and is presented by European Patent Attorneys Simon O'Brien and Matthew Caines. The webinar will be of particular interest to in-house counsel and associates who are involved in or interested in European life sciences-related patent law.

The webinar agenda covered the following topics:

- New clinical situations
- T 433/14 - mechanism of action
- Regen Lab v Estar - equivalents
- Referrals to the EBoA: T 318/14 (double patenting) and G 2/19 (oral proceedings at Haar).

We would be delighted to share a recording of the webinar with readers on request. Please email us at registrations@dyoung.com and we will be in touch with a link to the webinar recording and slides.

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