



Patent law highlights on validity, 2023

Patent case law in 2023 generated many interesting issues on validity. The highlights of these are detailed below.

Priority and anticipation

The year began, in ***Nokia v OnePlus (16 January 2023)***¹, with a judgment looking at the interpretation of a novelty-only citation where only some of the matter contained in the prior art had the necessary priority. Oppo challenged the novelty of Nokia's patent on the basis of the prior art referred to as "Woo", relying on s.2(3) PA. Woo therefore could only be relied on in relation for the purposes of s.2(3) in respect of matter that it contained which had an earlier priority date than that of the patent (which was the patent's filing date). The Woo priority document asserted as relevant was 'PD8', an LGE US provisional application. Woo contained material that was *not* present in PD8. Patentee Nokia contended that such material informed the interpretation of the parts of Woo that Oppo *could* rely on (and in a way favourable to Nokia). Meade J agreed.

The first patent infringement/validity judgment of Charlotte May KC, sitting as a Deputy Judge of the High Court, was handed down mid-year in ***Ensygnia v Shell (26 June 2023)***². It concerned Ensygnia's patent to an information security method/system. Rejecting an anticipation challenge over prior art Schmidt, Charlotte May KC held that a disclosure that is capable of being carried out in a way which would infringe, but equally in a way that is not infringing, will not anticipate a claim.

Obviousness

As ever, in 2023 the bulk of the patent judgments addressed obviousness.

In ***InterDigital v Lenovo (19 January 2023)***³, the Court of Appeal confirmed His Honour Judge Hacon's conclusion that InterDigital's patent - a method implemented by a wireless transmit/receive unit comprising a number of steps - was valid (and essential and infringed). Lenovo's grounds of appeal were limited to obviousness. The Court of Appeal was presented with an opportunity to state some broad points of principle. In particular, the Court of Appeal reiterated that there is no general requirement that a patent needs to state what advantages an invention provides over the prior art. This is the practical consequence of the policy that a patent claim must satisfy the legal tests of novelty and inventive step over any prior art the party challenging validity cares to bring forward. However, there are some important exceptions to the general rule. One of these is 'prejudice' cases. These cases arise where the patentee's asserted invention is said to lie in finding out that something which the skilled person would have ordinarily thought should not be done, in fact is practical. In those cases, the patent

¹ *Nokia Technologies OY & Anr v OnePlus Limited Technology (Shenzhen) Co., Ltd & Ors* [2023] EWHC 23 (Pat) (16 January 2023) Meade J

² *Ensygnia IP Limited v Shell Oil Products Limited & Ors* [2023] EWHC 1495 (Pat) (26 June 2023) Charlotte May KC

³ *InterDigital Technology Corporation & Ors v Lenovo Group Ltd & Ors* [2023] EWCA Civ 34 (19 January 2023) Birss, Warby & Falk LLJ

document must explain why the proposal is in fact practical – why what was thought by the skilled person to be a "lion in the path" has turned out to be a "paper tiger".

In the meantime, technical trial C in the same case progressed towards judgment and in ***InterDigital v Lenovo (31 January 2023)***⁴ Mellor J concluded that InterDigital's patent was a rare example of one in which the invention lay in identifying the problem. Rejecting Lenovo's invalidity challenges, Mellor J considered post-priority date material in his obviousness analysis, both in the context of the secondary evidence and on the primary evidence (Lenovo's challenge raised the question of 'if it was obvious, why was it not done before'.

His Honour Judge Hacon's judgment in ***AutoStore v Ocado (30 March 2023)***⁵ addressed whether certain information had been made available to the public, and for this purpose which law governed whether that information was protected by an obligation of confidence on the part of the recipients. He explained the role of retained EU law Rome I (on the law applicable to contractual obligations) and Rome II (on the law applicable to non-contractual obligations). The upshot was that the applicable law was Russian law, Applying that law the disclosures of the relevant information had been without any obligation of confidence on either EVS or the Bank. In such circumstances AutoStore accepted that its patents lacked novelty/inventive step.

Before leaving obviousness, the Enlarged Board of Appeal's decision in ***G 2/21 Sumitomo (23 March 2023)***⁶ should be mentioned (noting it is further detailed by an article in this Review by Eden Winlow). The appeal was in the context of article 56 EPC (obviousness), in particular whether an exception should be made to the (civil law origin) 'principle of free evaluation of the evidence' such that evidence in support of technical effect that was not public before, and filed after, the filing date of the patent (post-published evidence) should be disregarded in the assessment of the article 56 challenge. Ultimately, the EBA left the question of whether to disregard the evidence to the Technical Board of Appeal (TBA), after making a number of points of principle – not all of which seem entirely reconcilable. It ruled that evidence submitted by a patentee to prove a purported technical effect relied upon for acknowledgement of inventive step may not be disregarded solely on the ground that such evidence had not been public before the filing date of the patent in suit. It also observed that the term 'plausibility' does not amount to a distinctive legal concept or a specific patent law requirement under the EPC, in particular under articles 56 and 83 (sufficiency) EPC. It rather describes a "generic catchword seized in the jurisprudence of the boards of appeal, by some national courts and by users of the European patent system".

Excessive claim breadth insufficiency / plausibility / promise of the patent

Two days prior to the EBA's judgment, Meade J's judgment in ***Gilead v NuCana (21 March 2023)***⁷ concluded that two NuCana patents were invalid inter alia for lack of **plausibility** (leading to insufficiency and lack of industrial application). Meade J said that a "low standard" is required for plausibility, which must be shown by reference to the specification of the patent in issue, along with the CGK. However, a technical contribution must be of some, even if low, real significance. *In vitro* data made it plausible that three exemplified compounds within the claims had some degree of cytotoxicity in some cell lines. But in view of the CGK that small changes to a nucleoside analogue could make a big difference to its activity, that isosterism was not regarded as predictive, and in view of the large number of compounds covered by the claims (which involved multiple changes being made that were known to be prone to removing activity), the person skilled in the art would not think it was plausible that meaningful cytotoxic activity would be preserved across the range of possibilities encompassed by the claims. Lack of plausibility was therefore established with the result that Gilead's insufficiency (lack of plausibility) challenge succeeded, as well as its lack of industrial application challenge. Nevertheless, with an eye on the pending judgment of the EBA in G 2/21, Meade J also addressed the 'ab initio

⁴ *InterDigital Technology Corporation & Ors v Lenovo Group Limited & Ors* [2023] EWHC 172 (Pat) (31 January 2023) Mellor J

⁵ *AutoStore Technology AS v Ocado Group plc & Ors* [2023] EWHC 716 (Pat) (30 March 2023) HHJ Hacon

⁶ *G 2/21 EPO EBA Sumitomo insecticide patent* (23 March 2023)

⁷ *Gilead Sciences Inc & Anr v NuCana Plc* [2023] EWHC 611 (Pat) (21 March 2023) Meade J

plausibility' and 'ab initio implausibility' lines of case law in the EPO and explained that the nuance made no difference to his decision in the present case.

Six weeks later, two weeks after the appeal was heard, in **Sandoz v BMS (4 May 2023)**⁸ the Court of Appeal unanimously dismissed BMS' appeal against Meade J's finding that its patent to apixaban was invalid for lack of plausibility (leading to lack of technical contribution obviousness and insufficiency). Declining to distinguish the UKSC's majority reasoning in *Warner-Lambert*, Arnold LJ held that when considering inventive step it is necessary to consider what technical problem the claimed invention solves. If it is not plausible that the invention solves any technical problem, then the patentee has made no technical contribution and the invention does not involve an inventive step. Equally, when considering (excessive claim breadth) insufficiency it is necessary to consider whether the specification sufficiently discloses the claimed invention. If it is not plausible that the invention solves any technical problem, then the patentee has made no technical contribution and the specification does not disclose any invention. The standard of plausibility to be applied was the standard adopted by the majority in *Warner-Lambert*. This corresponded to the *ab initio* plausibility test identified in *Sumitomo*. Accordingly, it was not sufficient for the application to encourage the person skilled in the art to carry out simple tests identified in the specification to confirm the efficacy of the claimed product, even if carrying out such tests would indeed show that the claimed product was likely to be efficacious. Subsequent data could not be a substitute for sufficient disclosure in the specification. In order for a claim to a single chemical compound to be patentable, the application must make it plausible, when read in the light of the skilled person's CGK, that the compound has the utility asserted for it. Arnold LJ explained that Lord Sumption's analysis was confirmed by the EBA's insistence in G 2/21 on focusing on the technical teaching of the specification read with the CGK.

Later in the year, in **Astellas v Teva (17 October 2023)**⁹, Mellor J drew upon the familiar authorities (*Regeneron v Genentech* [2013] EWCA Civ 93, *Warner-Lambert v Generics* [2018] UKSC 56, *FibroGen v Akebia* [2021] EWCA Civ 1279) in his assessment of Teva's excessive claim breadth insufficiency challenge. Astellas' patent was to a modified release formulation of mirabegron. A dispute about the construction of the claim language 'a pharmaceutical composition for modified release' had consequences for the outcome of the infringement and conventional obviousness issues. For the excessive claim breadth insufficiency issue, the construction point impacted how the three-step *FibroGen v Akebia* test applied, but not its outcome. In the three-step test, after identifying what falls within the scope of the claimed class, the second step is to determine what it means to say that the invention works. Working, in the case of Astellas' patent, meant the formulation reduced a food effect. This was the case whether the requirement was considered incorporated into the claim expressly (by the construction of the language) or understood as implied from the specification. On either basis, it was possible to make a reasonable prediction that compositions which satisfied the structural features of the claim and also satisfied the functional feature (the *in vitro* dissolution profile) would be capable of reducing the food effect that was seen in conventional tablets of mirabegron. Further, although there were no sharp boundaries between food effect and no food effect, the patentee had to place some boundary on the scope of the claim. From an insufficiency perspective there was nothing wrong with what appeared to be an arbitrary limit, provided the promise of the patent was delivered, in this case, between those limits.

Progressively, we see that the concept of plausibility is about the promise of the patent – is the promise reasonable across the scope of the claimed invention?

Gordon Harris, Ailsa Carter
1 November 2023

⁸ *Sandoz Limited v Bristol-Myers Squibb Holdings Ireland Unlimited Company* [2023] EWCA Civ 472 (4 May 2023) Arnold, Nugee & Warby LLJ

⁹ *Astellas Pharma Industries Limited v Teva Pharmaceutical Industries Limited & Ors* [2023] EWHC 2571 (Pat) (17 October 2023) Mellor J