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Patents: jurisdiction and declaratory relief

Summary

The High Court has refused to strike out a claim for a declaration that a generic manufacturer would have a Gillette defence to a claim for infringement of a divisional patent application once granted.

Background

The High Court has held that it had discretionary power to grant a declaration that a generic pharmaceutical was obvious at the priority date of divisional patent applications (an Arrow declaration) (*Arrow Generics Ltd v Merck & Co Inc* [2007]).

Where an alleged infringement differs in only a non-novel or non-obvious way from the prior art at the priority date of the patent, the defendant has a good defence to infringement (Gillette defence) and it is not necessary also to challenge the validity of the patent (*Gillette Safety Razor Co v Anglo-American Trading Co Ltd* [1913]).

Facts

AB and AU (together, A) owned patents protecting a drug used to treat inflammatory diseases, and a related supplementary protection certificate (SPC), which were due to expire. A filed numerous applications for secondary patents protecting dosing regimes, formulations and uses of the drug (the secondary applications).

F intended to launch a **generic equivalent** in the UK when the SPC expired, so wanted to clear the way of any patents granted on A's secondary applications. F brought an action against AB seeking revocation of two European patents and an Arrow declaration (the first action). F's application to strike out the claim for an Arrow declaration was dismissed. F's appeal against this decision is pending.

F brought an action against A (the second action) seeking:

- An Arrow declaration to provide F with protection against subsequent claims for infringement of any patents within a family of the secondary applications.
- An injunction to restrain A from threatening or commencing proceedings for patent infringement in respect of acts covered by the declaration.

In the second action, F was granted permission to serve on AB outside the jurisdiction.

A applied to set aside the order in respect of AB, and to strike out, alternatively for summary judgment dismissing, the claim against AU.

Decision

The court dismissed A's applications. The court had power to grant an Arrow declaration, including a negative declaration. An Arrow declaration served a useful purpose because it was in effect a declaration that F would have a Gillette defence to a subsequent claim for patent infringement in relation to its product. Arrow declarations do not involve the validity of a patent being put in issue. Rather, they enable the court to pre-emptively determine a patent infringement case before the patent has even been granted without having to decide whether the patent would be invalid, or not infringed, when granted.

F sought an injunction restraining A from threatening or bringing patent infringement proceedings. The court had power to grant a domestic anti-suit injunction against A on the ground that the proceedings which A threatened to bring were vexatious or oppressive or an abuse of process. However, this power had to be exercised with caution and any injunction was likely to be qualified so as to permit A to commence proceedings with the permission of the court. The scope of the injunction would have to be carefully considered at trial. F had a real prospect of obtaining an injunction, but not independent of the Arrow declaration.

F's claim for an Arrow declaration was concerned with the validity of prospective European patents because it would require the court to determine the single question of whether F had infringed a valid claim of those patents. The fact that it would enable the court to do so pre-emptively before the patents had been granted was irrelevant. It did not matter that the court would not have to decide whether the patents would be invalid, or whether F's product would not infringe any of the patents because it would fall outside the claims. If the Arrow declaration was granted, it would mean that the claims would either be invalid or not infringed, and it did not matter which.

F had a good arguable case that the court had jurisdiction over its claim for an Arrow declaration against AB on the basis of a tort claim where jurisdiction is conferred on the courts for the place where the harmful event occurred or may occur, which may be either the place where the damage occurred or the place where the event giving rise to the damage occurred. This also applied to claims for negative declarations. Alternatively, jurisdiction could be on the basis that A was a necessary or proper party, or on the basis of an injunction to do or refrain from doing acts in the jurisdiction.

There was no alternative forum. England was the appropriate forum for F's claims because they were concerned to establish F's freedom to market its product in the UK under UK patent law. The strength or weakness of F's claim for an injunction was irrelevant to the exercise of the discretion to give permission to serve out of the jurisdiction, given that England was clearly the appropriate forum and more than one of the jurisdictional gateways had been established.

Comment

The combination of the Gillette defence and the power to grant Arrow declarations makes the UK a favourable jurisdiction for generic pharmaceutical manufacturers faced with a patent owner attempting to extend its monopoly over a very profitable drug by extensive filings of secondary formulation, dosage and use patents. As a result of this decision, steps taken during the prosecution of these patents which appear to have no good reason apart from continuation of uncertainty as to the scope and validity of those patents will make it easier for a generic company to get an Arrow declaration. However, A's appeal challenging the correctness of the Arrow decision in the first action has yet to be heard.

Case: Fujifilm Kyowa Kirin Biologics Company Ltd v Abbvie Biotechnology Ltd and AbbVie Ltd [2016] EWHC 2204 (Pat).

Patents: obviousness and common general knowledge

Summary

The High Court has held that a patent for smart utility meters was obvious, and proposed amendments would not be allowed as they added matter, but if the patent had been valid, it would have been infringed.

Background

A patent is invalid for lack of inventive step if the invention claimed was obvious to a person skilled in the art having regard to the state of the art at the priority date (*section 3, Patents Act 1977*). The Court of Appeal set out a structured approach to the assessment of obviousness in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* ([1985] RPC 59).

Facts

M was the exclusive licensee of a patent for smart utility meters.

B commenced proceedings in the Intellectual Property Enterprise Court for revocation of the patent for invalidity.

M issued a claim for infringement in the High Court against B, together with an application to transfer B's invalidity proceedings to the High Court. B's invalidity proceedings were transferred to the High Court and both proceedings were consolidated. B and M were ordered to produce amended statements of case, to include a statement of case as to the essentiality of the patent, setting out its alleged relevance to the UK Department of Energy's Smart Metering Implementation Programme. Essentiality and any other relief would be determined at a separate hearing.

Decision

The court held that the patent was invalid as being obvious over the prior art and that the requested amendment was not allowable. It also held that if the patent had been valid, B would have infringed it.

The court rejected M's argument that B should be limited to the validity case pleaded in its statement of case. The case had to be determined by reference to the evidence given at the trial. Statements of case were to assist the parties in the preparation of their cases, but they could not be used to preclude the court from deciding the case on the evidence actually given.

However, greater caution was required if the case advanced of alleged obviousness over common general knowledge alone had not been pleaded in the statement of case. Arguments based on common general knowledge alone were more susceptible to hindsight by ignoring inconvenient features of actual prior art references and needed to be treated with care. Where a party was relying on obviousness over common general knowledge alone, it should set out in its statement of case not only what the common general knowledge was alleged to be, but also how that differed from the invention of the patent and why this rendered the claim obvious. That required a pleading not of just the starting point, but of the allegedly obvious route to the claimed invention so that the notional thinking of the skilled person could be seen and evaluated.

Usually, a case of obviousness over common general knowledge would be set out in a statement of case before expert reports and the case might reasonably develop from them on the evidence. Inconsistency during a case of the argument as to why a patent was obvious over common general knowledge might sometimes shed light on whether the argument was sound and whether it was really obvious, but the mere fact that this argument had developed in the light of the way that the patentee developed its case, as here, gave this inconsistency limited weight.

The court rejected M's argument that the invention was the idea of using a neutral identifier for the purpose of opening up a pre-payment meter to wireless access unconstrained by suppliers. This was not justified by

the specification or the claims of the patent. It seemed to be a reconstruction, using hindsight, of an allegedly more specific inventive concept that was not contained in the patent itself.

In determining whether an alleged invention would have been obvious, the court had to assume that the skilled person had common sense. This approach ensured that patents were not granted for the application of common sense to technical problems, even though the prior art did not specifically say that a particular technique ought to be used and it was not possible to point to specific direction to do so from the common general knowledge.

The court rejected B's defence of experimental use. While trials for mixed commercial and research purposes may still be experimental, here the purpose of the trials was not directly related to the patent's claimed subject matter.

Comment

This decision is a warning to patentees that, just as those attacking their patent cannot use hindsight, they are not permitted to use hindsight to construct a defence of their patent from a general statement in the description that was not claimed nor clearly described in the specification.

The decision also highlights the difficulties of preparing a statement of case at a relatively early stage of revocation proceedings. Careful consideration should be given as to whether it is possible to base an obviousness case on common general knowledge alone, given the requirement that the statement of case should, in addition to specifying the common general knowledge relied on, show the route by which the invention could be reached from this information by the skilled person.

Interestingly, a meter which could nowadays be operated as a pre-payment meter by installing software, rather than one hard-programmed to act as such, could still infringe the patent, even if that facility was not activated. However, the court noted damages or injunctive relief might not be available where meters were installed with that capability but the facility was not activated. *Case: Meter-Tech LLC & Another v British Gas Trading Ltd [2016] EWHC 2278 (Pat)*.

Data protection: disclosure of third party data in subject access request

Summary

The High Court ruled that the General Medical Council (GMC) should not disclose a GP's fitness to practise report to a former patient in response to a data subject access request (SAR).

Background

Individuals have a right of access to their personal data, exercisable by making a data SAR (*section 7, Data Protection Act 1998*) (DPA) (*section 7*).

Where a data controller cannot comply with a request without disclosing information relating to another identifiable individual, it need not comply with the request unless that individual has consented to disclosure, or if it is reasonable in all the circumstances to comply with the request without this consent (*sections 7(4) and 7(5), DPA*).

There is a presumption that the individual's consent should be obtained before disclosure, but this may be rebutted if it is reasonable in all the circumstances to comply with the request without obtaining consent (*Durant v Financial Services Authority, www.practicallaw.com/9-102-6113*).

Section 7(6) of the DPA identifies four non-exhaustive factors in the balancing exercise, which include any duty of confidentiality owed to the other individual and any express refusal of consent by the other individual.

The court may make an order for disclosure of documents before civil proceedings have started in certain circumstances (*Civil Procedure Rule (CPR) 31.16*). Generally, a document that is disclosed under CPR 31 may only be used for the purpose of the proceedings in which it is disclosed (*CPR 31.22*).

Article 8 of the European Convention on Human Rights (Article 8) provides that everyone has the right to respect for their private and family life, their home and their correspondence.

Facts

P complained to the GMC, arguing that the incompetence of his GP, D, had resulted in a one-year delay in P's diagnosis of bladder cancer.

While investigating P's complaint, the GMC obtained an independent expert's report concerning D's professional competence. The report criticised the care that D had provided, concluding that it fell slightly below the expected standard. The GMC closed the complaint and provided a one-page summary of the report to D and P.

P submitted an SAR to the GMC for a full copy of the report. D refused to consent to disclosure of the report to P on the basis that it was D's personal data and the purpose of the request was litigation. However, the GMC decided that it was entitled to disclose the report to P without D's consent on the basis that this was consistent with its legitimate interests in the transparency of its decision-making process.

D issued proceedings against the GMC to prevent it from disclosing the report.

Decision

The High Court held that the medical report should not be disclosed to P.

The competing privacy rights of P and D in the personal data in the report had to be balanced. The GMC had given undue weight to less relevant factors such as the transparency of its proceedings. However, four factors pointed to refusal of the disclosure request:

- Following *Durant*, the GMC should have started with the rebuttable presumption against disclosure in the absence of D's consent.
- The focus of the report was on D's professional competence and the GMC had not given adequate weight either to D's status as a data subject or his privacy right in the report. D's privacy rights under Article 8 included the protection of his professional reputation. D had a reasonable expectation of privacy in the report, which was supported by the GMC's policy of disclosing a one-page summary to complainants in the event of a decision to take no further action. Interference with privacy rights had to be proportionate to the achievement of a legitimate aim.
- D had explicitly refused to consent to disclosure and the GMC had not given that fact sufficient weight.
- The GMC's decision did not take adequate account of the purpose of the request, which was intended litigation against D. P was not seeking the information to ensure the accuracy of personal data as contemplated by the DPA. If the report were to be disclosed under the DPA, D would be deprived of the protection provided by CPR 31 and in particular the CPR 31.22 restrictions on subsequent use of the document. CPR 31 was the appropriate procedure, given P's real interest in obtaining the report and the reduced interference with D's privacy rights.

The court set out three steps to guide data controllers in future balancing exercises:

- The exercise involves a balance between the respective privacy rights of data subjects.

- In the absence of consent, the starting point is against disclosure. Express refusal of consent is an additional specific factor to take into account.
- If the sole or dominant purpose is to obtain a document for litigation purposes, then that is a weighty factor in favour of refusal on the basis that CPR 31 is the appropriate procedure.

Comment

This decision demonstrates the difficulty of conducting the balancing exercise to protect the rights and interests of both parties in mixed data cases. Although each case must be decided on its own merits, the judgment sets out three-step guidance for data controllers on conducting balancing exercises in cases of this type. As consent is a key factor, data controllers should consider contacting any third-party data subject identified soon after receiving an SAR to ask if they consent to disclosure.

If the sole or dominant purpose of the SAR is litigation, that is a weighty factor in favour of refusing the request. CPR 31 provides a more appropriate procedure, with protection against subsequent use of the disclosed document. Potential requesters should bear this in mind when considering the procedure to obtain the information, and when framing their request.

Case: Dr DB v General Medical Council [2016] EWHC 2331 (QB).



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