McDermott Will&Emery

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PATENTS

Court of Appeal of England and Wales Allows Damages Under a Cross-Undertaking in Respect of an Interim Injunction

In *Les Laboratories Servier and another v Apotex Inc. and others [2012] EWCA Civ 593*, the Court of Appeal of England and Wales has allowed an appeal against a High Court decision that an importer of pharmaceutical products made in Canada could not recover damages under a cross-undertaking in respect of an interim injunction after the UK patent was invalidated, because the Canadian patent had been held valid and infringed.

BACKGROUND

Les Laboratories Servier (Servier) had patent protection for Perindopril. The original patents expired by 2006, but Servier had obtained a European patent covering a new form of Perindopril (the *947* patent). This was opposed, but the opposition was dismissed on 27 July 2006. Apotex is a generic drugs manufacturer that decided to manufacture Perindopril in Canada and sell it in Europe, having been advised that the *947* patent was invalid. It obtained marketing authorisation and began selling Perindopril on 24 July 2006. Servier commenced proceedings on 1 August 2006, and later applied for an interim injunction. This was granted with the usual cross-undertaking as to damages.

On appeal, it was held that the *947* patent was in fact invalid and the injunction was discharged. The case returned to the High Court for determination of the damages due to Apotex. The High Court held, however, that an importer of pharmaceutical products made in Canada (*i.e.,* Apotex) was not entitled to recover damages under a cross-undertaking in respect of an interim injunction after the UK patent was invalidated, owing to the fact that the patent in Canada had been valid and infringed by these products. The Court of Appeal, however, held that this refusal was incorrect and allowed Apotex's appeal.

DECISION

It was common ground that the illegality principle was capable of applying to a claim under a cross-undertaking as to damages.

It is not correct however, that, where the illegality was the infringement of a patent, the illegality defence could never apply unless the claimant was aware of the patent, knew it was valid and intended to infringe it. The Court of Appeal accepted that infringement of a patent was a tort of strict liability, but there was an obvious difference between committing an offence without knowledge of the relevant facts and of the law, and this situation, in which Apotex committed an offence with full knowledge of the Canadian patent but was willing to take a conscious commercial risk on it being invalid.

However, there were factors that pointed clearly in favour of allowing Apotex's appeal, despite the fact that infringement of a Canadian patent constitutes a statutory wrong under Canadian law, irrespective of the state of mind of the infringer. A competitor taking a commercial risk in marketing a product in breach of a patent, with reasonable belief and in good faith that the patent was invalid, is low on the scale of culpability in terms of the illegality defence. Apotex was also willing to make a concession that guaranteed that Servier was compensated for the Canadian infringements. Based on this and certain other factors, the Court of Appeal allowed Apotex's appeal.

COMMENT

The case serves as a good example of the difficulties that arise when a patent is found to be invalid in one country, but the equivalent patent is upheld in another. The major factor as to why the Court of Appeal reached a decision different to the High Court on applying the illegality rule here was the acknowledgment made by Apotex in the appeal proceedings, which guaranteed that Servier was compensated for the Canadian infringements and that Apotex was in the same position as if no interim injunction had been granted. It appears that the Court of Appeal is capable of showing sympathy to a competitor using a patent it had good reason to believe was invalid.

PATENTS

Advocate General Recommends Dismissal of AstraZeneca Appeal

On 15 May 2012, Advocate General (AG) Mazak gave an opinion on the appeal by AstraZeneca against a judgment by the General Court that upheld the European Commission's decision to fine AstraZeneca for abusive patent misuse.

BACKGROUND

In 2005, the EU Commission fined AstraZeneca €60 million for having abused its dominant position under Article 102 of the Treaty on the Functioning of the European Union (TFEU). The Commission found two separate abuses, which it viewed as part of AstraZeneca's strategy to exclude generic competitors from its ulcer drug and to restrict parallel imports of the drug.

AstraZeneca appealed the Commission's decision to the General Court, seeking annulment of that decision, but the General Court upheld the majority of the findings of the Commission. AstraZeneca subsequently appealed the ruling of the General Court to the Court of Justice of the European Union (CJEU). Its argument is that the General Court made a number of errors of law in its assessment of the two abuses. AstraZeneca has also challenged the level of fine.

OPINION

With respect to the first finding of abuse (providing misleading information to national patent offices, which caused uncertainty, delay and disruption to generic firms' preparations for market entry for generic products), the AG concluded that the General Court had made detailed and clear findings of fact about AstraZeneca's actions and had found objectively that its representations to the patent offices were lacking in transparency and highly misleading. The AG took the position that the General Court did not have to examine AstraZeneca's subjective beliefs on the interpretation of law; it only had to assess its actual conduct.

With respect to the second finding of abuse (selective deregistration of marketing authorisations specifically in countries where generic companies had applied for marketing authorisations covering generic versions of the drug, which prevented the generic companies from using a simplified and faster procedure to obtain their authorisation), the AG upheld the finding of abuse and found that the main feature of the abuse was AstraZeneca's selective deregistration in Denmark, Norway and Sweden. What constituted the abuse was the *context* in which deregistration took place and not the mere fact of deregistration.

The AG also dismissed AstraZeneca's claim that the fine imposed on it was excessive and should have been reduced owing to the novelty of the infringements and their minimal effects on competition. The AG reiterated that the General Court concluded that the actual substance of the abuses was not novel and clearly were highly anti-competitive and capable of having a significant effect on competition.

The judgment of the CJEU is expected by the end of this year and although the opinion of the AG is not binding on the CJEU, in the majority of cases the judgment does follow the opinion.

COMMENT

The AstraZeneca case is the first in which abuse of regulatory process has been held to be an abuse of a dominant position under EU competition law. In the event that this approach is adopted by the CJEU, then it can be expected that more cases of this nature will be brought and not necessarily just against the pharmaceutical sector. If the CJEU's final judgment follows the recommendations of the AG, this will confirm that an abuse of regulatory procedures can constitute an abuse of a dominant position under EU competition law.

PATENTS

Advocate General Opinion on The Interpretation of "First Marketing Authorisation" for Supplementary Protection Certificates

Advocate General Trstenjak (the AG) has rendered an opinion in a preliminary reference relating to *Neurim Pharmaceuticals Ltd* [1991] C-130/11 that it should be possible to grant a Supplementary Protection Certificate (SPC) for a second medicinal product that comprises the same active ingredient as a medicinal product covered by a prior marketing authorisation (MA), if the scope of the basic patent protecting the second medicinal product does not extend to the earlier medicinal product.

BACKGROUND

Neurim discovered that certain formulations of melatonin could be used as a medicine for insomnia. It applied for, and was granted, a patent for these formulations, but it took over 15 years from filing the patent to being granted a MA. Neurim accordingly applied for a SPC, basing its application on the June 2007 MA.

The UK Intellectual Property Office (UKIPO) refused to grant the SPC on the basis that the June 2007 MA was not the first MA. The IPO identified an earlier MA for the product melatonin: sold under the trade mark REGULIN, it was used in sheep to regulate

seasonal breeding activity. REGULIN was the subject of a patent different to Neurim's insomnia treatment patent.

Neurim referred the matter to the English courts, but Arnold J upheld the decision of the UKIPO to refuse the SPC. Neurim then appealed to the Court of Appeal, which decided to make a reference to the Court of Justice of the European Union (CJEU) to determine whether SPC Regulation 1768/92/EC, now 469/2009/EC, precluded the granting of an SPC based on a second authorisation to place a product on the market, even where the second medicinal product, which comprised the same active ingredient as the medicinal product covered by the first MA, was protected by a basic patent for the common active ingredient, the protective scope of which did not extend to the earlier medicinal product.

OPINION

The AG gave consideration to both literal and teleological interpretations of the SPC Regulation. In this case, following a purely literal interpretation would mean that no SPC could be granted to Neurim as, strictly speaking, the first MA to place the active ingredient, melatonin, on the market was the MA for REGULIN.

However, the AG regarded the aim of the SPC Regulation, which is to achieve a balance between companies that pursue expensive research in the pharmaceutical sector and patients that benefit from new medicines on the one hand, and the producers of generic medicines and patients that benefit from the lower prices of generic medicines on the other, to be of paramount importance. The AG referred to Article 54(5) of the European Patent Convention, which recognises expressly the ability to patent inventions resulting from research into known active ingredients (second and further use patents). As such, it followed that a SPC may also be granted on the basis of a second or further MA. At the same time, the AG noted that this interpretation must not over-reach the aim of the SPC Regulation. The AG determined that this balance of interests could be achieved if the interpretation of the MA was made with reference to the relevant basic patent.

Taking this into account, the AG advised that an SPC for a product that is protected by a basic patent in force may be granted only on the basis of the first authorisation, which permits that product to be placed on the market as a medicinal product, that is within the scope of protection conferred by the basic patent in the EU Member State for which the application is made.

COMMERCIAL

Court of Justice of the European Union Considers Whether Unfair Terms and Practices Invalidate Agreements

In *Jana Perenicova and another v SOS financ spol. s.r.o.* (CJEU) (C-453/10), the Court of Justice of the European Union has considered whether a contract is invalidated if it contains unfair terms or was obtained by unfair commercial practices.

BACKGROUND

A lender—SOS financ spol. s.r.o—provided a loan to a Slovak consumer by way of a standard loan agreement. The agreement at issue contained an erroneous annual percentage rate (APR) and other contract terms that the consumer claimed were unfair. As a result, the consumer asked the national court to declare the entire agreement invalid. The court stayed the national proceedings and asked the CJEU to provide guidance in respect of whether i) an agreement should be invalidated if it contains unfair terms and invalidating it would benefit the consumer; and ii) an agreement should be invalidated if an unfair commercial practice is found.

DECISION

The CJEU held that national courts must first, use national law principles to assess whether there are unfair contract terms in a consumer contract and second, assess objectively whether a contract can continue without its unfair terms, rather than simply declaring the whole contract invalid, as that would result in a more advantageous position for the consumer.

However, a finding of an unfair commercial practice does not necessarily justify a finding of unfair contract terms, therefore also has no effect on the validity of the contract.

The CJEU also held that EU Member States are permitted to pass national legislation providing a higher level of consumer protection than that provided by the Unfair Terms Directive (1993/13/EC). This could include legislation invalidating entire consumer contracts that contain unfair terms.

COMMENT

This CJEU decision clarifies that a finding of unfair commercial practices does not mean automatically that the relevant contract contains unfair contract terms, and that a finding of unfair terms does not necessarily invalidate the entire contract. It has now also been expressly confirmed by the CJEU that it is up to national legislators to set higher standards of consumer protection, if considered necessary.

DATA PROTECTION

90,000 Reasons To Consider Ongoing Data Protection Training as Critical

The United Kingdom Information Commissioner's Office (ICO) has issued a £90,000 penalty notice to Central London Community Healthcare NHS Trust for sending faxes containing patient information to an unauthorised fax number. The ICO found the Trust's lack of ongoing data protection constituted a failure to take appropriate organisational and technical measures to prevent unauthorised processing of personal data.

BACKGROUND

The ICO issued the penalty notice to the Trust on 27 April as a result of a breach of section 4(4) and a failure to comply with the Seventh Data Protection Principle which obligates a data controller to take "appropriate technical and organisational measures…against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data."

The Trust and a hospice had a fax protocol in place, under which the details of in-patients, such as medical diagnoses, information about domestic arrangements and resuscitation instructions were sent by the Trust to the hospice. Following each fax, a follow-up call was made between the parties to acknowledge receipt. In late March 2011, a request was made to add an additional number to the fax list. This was agreed to by an administrator, who changed the fax cover sheets to include the new number but did not change the fax protocol or seek management approval.

Approximately, 45 faxes were sent from late March to early June 2011 to both fax numbers. During the follow-up calls, the hospice only confirmed receipt of faxes to the original fax number. On 6 June 2011, a member of the public contacted the Trust stating that it had been receiving the faxes sent to the second number and had been shredding them.

SECURITY BREACH

It was clear that a serious security breach had occurred and that sensitive personal data was disclosed to a third party who had no reason to see it and the disclosure had the potential to cause substantial distress and harm to the individuals concerned. The ICO found that the Trust should have been aware of this risk and should have provided adequate training on an ongoing basis to reduce the possibility of such breaches occurring.

It appears that the Trust did not have appropriate technical standards in place, as it had not given any consideration to a possible alternative to the use of fax transmission, such as secure email. Neither did it have in place sufficient organisational standards as, at the time of adding the new number to the fax cover sheets, the administrator had not been trained specifically on obtaining management approval or the process required to ensure the second number was added to the fax protocol.

It is notable that, in issuing the penalty, the ICO took into account the Trust's previously good record in this area, the substantial remedial action taken by the Trust and the voluntary reporting and ongoing co-operation of the Trust with the ICO in this matter.

COMMENT

Human error is a common theme in security breaches. Although often seen as expensive and disruptive, ongoing training of staff to ensure that processes, and the rationale behind them, are communicated and understood is critical in any data protection compliance programme. At best, failure to keep on top of training may be negligent, at worst it could lead to an expensive penalty and the related negative publicity.

The £90,000 penalty issued in this case is a clear indication that the ICO is focusing on promoting compliance with the Data Protection Act. Any party that is processing personal data must be aware that compliance is an ongoing obligation. This case highlights the need for periodic review of both technical and organisational measures that are in place, to ensure that data is processed in line with current standards.

COPYRIGHT

Protection of Computer Programs Revisited by the Court of Justice of the European Union

The Court of Justice of the European Union has again examined the question of which elements of a computer program are protectable by copyright. In line with its previous decisions, it has confirmed that the functionality, language and data format of a program are not protectable as they are part of the ideas or principles underlying the program.

BACKGROUND

The reference for a preliminary ruling in the present case was made from the High Court of England and Wales. It sought interpretation of a number of provisions of European law concerning the legal protection of computer programs by way of copyright.

The questions arose from a dispute between SAS Institute Inc. (SAS) and World Programming Ltd (WPL). SAS is a developer of analytical software, written in a proprietary language. WPL, on realising there was a market for software

capable of emulating the components of the SAS product, developed a program with the same functionality as that of the SAS program. WPL did not have access to the source code of the SAS product.

DECISION

Rather than answer the detailed questions posed by the High Court, the CJEU grouped the questions into three general considerations of the applicable law.

The first was whether Article 1(2) of Directive 91/250, which excludes ideas and principles underlying a computer program from protection, should be interpreted as allowing for the protection of the functionality, programming language and data format of a computer program. The response of the CJEU was negative, subject to the *caveat* that if the source code of the original program had been used in the creation of the new program, then this would constitute at least partial reproduction of the source code and consequently infringement of the copyright in the source code.

The second question answered by the CJEU concerned Article 5(3) of Directive 91/250, which grants a person with a right to use a program the further right without authorisation to observe, study or test the functioning of the program during its use. As WPL had purchased copies of the SAS program under a licence that restricted the use of the program to non-production purposes, the CJEU was effectively asked to consider whether the right in Article 5(3) extends to circumstances where the person carries out acts with a purpose that goes beyond the framework established by the licence, as in the present case.

The CJEU considered that it was not possible to restrict the right in Article 5(3) through the terms of the licence. However, for this to apply, the user—as in the present case—must not have had access to the source code. The CJEU noted that interpretation is in line with Article 6(2)(c) of Directive 91/250, which states that information obtained through the decompilation of a programme cannot be used to develop a new one.

The final issue addressed by the CJEU was whether the reproduction in a computer program, or the user manual for that program, of certain elements described in the user manual for another program infringes the copyright in this manual. Following a previous ruling of the CJEU, the deciding factor in these circumstances will be whether the element reproduced constitutes the expression of the intellectual creation of the author of the user manual. This, predictably, is a question for the national court to decide.

COMMENT

The approach of the CJEU should come as no surprise, following as it does its previous line on the subject of the protection of computer programs. Underpinning each is the fundamental proposition that the ideas and principles underlying the program cannot be protected by copyright. This includes the programming language, the format of data files and the functionality of a program. In rejecting protection for these features, the CJEU agreed with the opinion of the Advocate General that allowing for such protection would amount to a monopoly on the ideas underlying the software, which would be to the detriment of technological progress.

This decision clearly favours developers of new software, rather than the owners of existing computer programs that the developers seek to emulate. That said, these developers should take note of how rapidly their protection fades away if it can be proved that the source code of the original program was accessed.

GENERAL INTELLECTUAL PROPERTY

OHIM Tasked with IP Infringement Monitoring Role

By way of a Regulation 386/2012, which was published on 16 May 2012, the Office for Harmonization in the Internal Market (OHIM) has been entrusted with certain tasks relating to tackling the infringement of intellectual property rights.

BACKGROUND

In 2008, the European Commission established the European Observatory on Counterfeiting and Privacy. The Observatory consisted of a network of experts tasked by the Commission with enhancing the enforcement of IP rights in the European Union. It was to serve as a central resource for gathering, monitoring and reporting information related to the infringement of IP rights, and was to be used as a platform by national authorities to discuss best practices.

As part of its review of the European Trade Mark system, the European Council called on the Commission to involve OHIM in the enforcement of IP rights. The rationale was, as OHIM already acts as a Europe-wide registrar of rights, and in doing so cooperates extensively with national authorities, it has the experience and expertise to provide the infrastructure for the Observatory. Accordingly, under Regulation 386/2012, the Observatory has been brought within OHIM's remit. It has also been re-titled the "European Observatory on Infringement of Intellectual Property Rights". The Observatory will monitor the

rights set out in the Enforcement Directive (2004/48/EC), which includes copyright, trade marks, design rights and patents.

EUROPEAN OBSERVATORY ON INFRINGEMENT OF IP RIGHTS

The tasks of the Observatory are broad, but it is important to note that the Observatory—and therefore OHIM—is not granted an enforcement role *per se*. As its title suggests, the role of the Observatory is observe and assess the state of IP infringement in the European Union; the Regulation excludes explicitly the involvement of the Observatory in individual investigations. Instead, the aims of the Observatory are to raise awareness and understanding of IP infringement, the technical tools available to prevent and tackle infringement, and to foster international cooperation to build strategies to enforce IP rights.

As part of its organisation of the Observatory, OHIM is required to provide regular assessments and reports by economic sector, geographical area and the type of rights infringed. National authorities are obliged, on request (or at their own initiative), to supply OHIM with information regarding infringement and their policies. OHIM is also tasked with drawing up publications to raise awareness amongst citizens of the impact of IP infringements. OHIM is required to organise meetings of the Observatory at least once per year and fund the activities of the Observatory from its own budget.

COMMENT

Although commentators have questioned the benefits of a body tasked merely to observe infringements rather than act on them, OHIM is well placed to collate such information and push for the adoption of best practice. Infringement remains a question for national courts, but the position of OHIM on enforcement policies is likely to be persuasive when national authorities are asked to provide their views as national approaches are reviewed.

A uniform approach to infringement across the European Union would naturally benefit right holders, but this appears to be a long way from fruition. Given the limitations on the competence of the Commission to grant enforcement powers to OHIM, and OHIM's well-documented budget surplus, placing the Observatory in the hands of OHIM should be seen as a tentative step in the right direction.

TRADE MARKS

Counterclaims for The Invalidity of a Community Trade Mark Are a Shield, Not a Sword

The High Court of England and Wales has confirmed that counterclaims for the invalidity of a Community trade mark can only be brought by a defendant where the counterclaim would result in a defence to the claimant's claim for infringement. Counterclaims that would not impact the main claim should be struck out.

BACKGROUND

The judgment concerned an application made during the course of a wider dispute between Adobe Systems Inc., and Netcom Distributors and others. Adobe alleged that Netcom had infringed Adobe's UK trade marks and CTMs by way of parallel imports. Netcom's defence to these allegations was to argue that Adobe was abusing a dominant position and other related competition law points. Netcom also counterclaimed for revocation of a number of Adobe's trade marks on the basis of non-use. However, the classes for which non-use was alleged did not include the classes for which infringement was claimed. In essence, the counterclaim would not enable Netcom to defend the infringement claims.

On this basis, Adobe questioned whether the court had jurisdiction to hear a counterclaim in respect of the CTMs where the counterclaim would not provide a defence to the infringement claim. This was the question put before Mr Justice Mann.

DECISION

The focus for both parties and the judge was the correct interpretation of Article 96 of the Community Trade Mark Regulation (CTMR). Article 96 of the CTMR sets out the jurisdiction of CTM courts, in particular Article 96(4) provides CTM courts with the jurisdiction to hear counterclaims for revocation or a declaration of invalidity pursuant to Article 100 of the CTMR. Both articles are silent on whether the counterclaim has to be in defence of the initial claim.

Adobe submitted that these provisions should be read purposively, denying the court jurisdiction, whilst Netcom argued for a literal interpretation that would not prevent the court hearing the counterclaim in the present case. Both cited various authorities for these propositions, but the judge pointed out that none had any direct bearing on the problem at hand. With no direct authority on the point, the judge was left with trying to ascertain what the European Council meant by its choice of wording in the specific context.

The judge was persuaded by the reasoning that the purposive approach to Article 96 was effectively an "absurdity argument". It would be strange for a national court to acquire a jurisdiction it would not otherwise have just because the claim took the form of a counterclaim. The purpose of Article 96(4) was to allow the relevant CTM court to dispose of the totality of a dispute without having to refer the case to the Office of Harmonization for the Internal Market (OHIM) for a ruling on the validity of the marks in suit. Accordingly, the counterclaim must be linked to the defence of the main claim; in the judge's words, this would be a "sensible encroachment on the regime which would otherwise leave validity matters to OHIM".

On the contrary, the judge could find no justification for Article 96 granting a CTM court a jurisdiction wider than was necessary to allow a dispute to be dealt with in one forum. The judge was satisfied that this conclusion could be reached without a reference to the Court of Justice of the European Union.

COMMENT

Counterclaims for revocation of a mark are a powerful strategic weapon in the armoury of a defendant in infringement proceedings, as naturally they raise the stakes for claimants. This decision suggests in respect of CTMs that such attacks should be limited to the classes of the marks on which the infringement claims are based. From the perspective of the claimant, when drafting a claim for infringement, caution should be exercised to avoid exposing the mark to counterclaims for revocation unnecessarily.

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