

INTELLECTUAL PROPERTY & TECHNOLOGY UPDATE

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European Patent Strategy: A Helpful Framework



Two Patent Systems

Two systems exist by which a patent can be granted in European states.

The first is via a national filing in each country so that, for example, one applies to the UK Intellectual Property Office for a UK patent. The second mechanism is through the operation of the European Patent Convention (EPC) and the European Patent Office (EPO) located in Munich, Germany. This system is designed to minimize the amount of bureaucracy necessary to achieve patents in the states that have signed up to the EPC. Essentially, a single application is made that designates those nation states where the applicant wishes to have protection.

The application is examined centrally and, if no fundamental objections are found, it is published. Thereafter it is subject to an opposition period during which third parties can seek to persuade the EPO that the patent should not be granted. If the application survives the opposition period intact, it will be granted. Separate applications then arise in each national patent system designated by the applicant. In recent years a number of additional formalities (e.g., the payment of fees or filing of translations of the patent into local languages) required by certain states before the granting of a patent have been significantly reduced.

The important point is that Europe has not created a "European Community Patent" in the way that it has achieved a Community trade mark system. All patents remain national in their geographic scope. Thus, a European patent designating the UK (often referred to by the shorthand "EP (UK)") is precisely the same in terms of its scope of protection as a patent granted following a single national filing at the UK Intellectual Property Office. Some potential subtleties about the tests to be applied (Patents Act or Protocol under the EPC when determining

validity and infringement) are too delicate to fall into consideration in a note of this scope.

Can One Choose Among the Available Courts?

European countries have, for a number of years, sought to regulate the potential conflict of different jurisdictions that might exist between states and to create a series of rules about where actions can and should be brought. This is an important part of any European policy designed to create harmonization between states over matters such as trade. The rules were founded in the Brussels and Lugano Conventions and, more recently, are set out in the Brussels Regulation. What follows is something of a gross oversimplification of the rules, but nonetheless hopefully a handy guide.

The general principle is that in civil cases one should sue a defendant in the territory in which that defendant is domiciled. That basic principle, however, (which is essentially "defendant friendly") is subject to a number of important exceptions:

- First, in relation to torts (patent infringement being a statutory tort), one is entitled to bring proceedings where the harmful activity occurred.
- Second, in relation to emergency protective measures (such as interim injunctions) one is also entitled to seek remedies in the court for the jurisdiction in which the harm arose.
- Third, disputes concerning the registration or validity of a patent should be determined in the jurisdiction where the patent is registered or where the patent application has been filed.

These exceptions are clearly very important in intellectual property cases and normally mean that the overall effect of the rules on where one can sue is claimant friendly. Essentially, the claimant has the ability to choose the forum in which it wishes the dispute to be heard.

The position is, in fact, slightly more subtle than described above. As noted, one can issue proceedings for patent infringement in either of those jurisdictions in which (i) the

harmful event took place or (ii) the cause of the tortious activity was located. This might seem to be a fine distinction, but it can have an impact in relation to damages.

There is no possibility of a “pan-European injunction.”

For example, imagine a claimant owning one European patent that designates France, Germany and the UK as the three territories in which it provides protection. The defendant has one factory in the UK and then makes sales of the product in France, Germany and Spain. No action could be brought in relation to sales in Spain because the claimant has no patent protection there. In relation to France and Germany, a patent action could be brought in the local courts but damages could only be recovered in relation to those infringing acts taking place in each of those jurisdictions. By contrast, an action brought in the UK courts would cover all of the damage suffered. So there may be some benefit in examining where the financial impact of the infringement has its root.

Remedies Available From Each of the Courts

Taking the examples of France, Germany and the UK, the remedies available for patent infringement are all essentially the same: each court is able to grant financial compensation for the damage caused by the infringement (or the wrongful profit made by the defendant) and, more importantly, each court can grant an injunction preventing further infringement and other remedies such as delivery up of the infringing product or destruction under oath. Ultimately, some courts (although, notably, not the German courts) will have the power to invoke criminal law against those who ignore a validly served injunction.

There is no possibility of a “pan-European injunction.” The decision of a UK court that a patent has been infringed may have a striking commercial effect in bringing the defendant to the negotiating table to seek a license or stop its activity on a pan-European basis, but the English court will not be able to grant an injunction that will be effective in Germany. That position is the same for each of the courts being considered in the above example. In other

words, invalidating the patent in Germany will not have the effect of invalidation in the UK or France – although in practice it may make those patents of little economic or commercial value following an adverse finding in Germany.

The only substantially different “remedy” between French, German and UK courts is the treatment of costs. That issue is dealt with separately below.

Comparison of the Different Systems

So far, we have dealt with what one might (mixing IP vocabulary) call “absolute grounds” for making a decision to pursue an action in one court or another – i.e., grounds that either entirely permit or entirely prohibit an action from being commenced. The various factors that go into assessing the merits of pursuing an action as well as the merits of acting in a particular jurisdiction are summarized below.

(1) Legal system

The courts in England, Wales and Scotland operate on a common law system. By comparison, both France and Germany operate a codified civil law system in which case law has a lesser role to play. It is difficult to say how this factor plays out in a particular case except that some claimants (for example, a claimant based in the US) may find a common law system instinctively easier to understand.

(2) Language

Although many French and German lawyers have excellent linguistic skills, there is a measure of extra complexity in the process of obtaining and receiving instructions and giving tactical advice where the language of the proceedings will not be English. Conversely, of course, a German patentee might feel more at home with proceedings in the German courts.

(3) Philosophy

Perhaps the most nebulous of the differences between the Continental courts and the UK courts is that the UK courts operate an adversarial system whilst the European courts tend to operate upon “inquisitorial” lines. It is difficult to

give concrete examples of exactly how these tendencies express themselves. An example might be the philosophy of the Continental courts that the *court* will collect and assess the evidence with a view to identifying the truth. In an adversarial system, the obligation (or right) to collect and analyze the evidence is placed much more firmly in the hands of the parties and the court seeks to determine which of the parties has put forward the best (most probably correct) case rather than to conduct its own investigation of the evidence.

In Germany a number of courts have gained a reputation as specializing in patent proceedings, even though judges in those courts do not necessarily have technical backgrounds. In the UK all of the judges in the Patents Court and the Patents County Court are former barristers with technical specialism.

(4) Quality of the judicial consideration

Approximately 90 percent of all patent actions in Europe are held either in the courts of Germany or in the UK. Between those two jurisdictions, Germany has by far the majority, in terms of absolute number of cases. The “market” for patent law in France is considerably smaller, which means that the available pool of skilled practitioners (and indeed the available pool of skilled judges) is smaller.

In Germany a number of courts (particularly the *Landgerichte* (district courts) of Düsseldorf and Mannheim) have gained a reputation as specializing in patent proceedings, even though judges in those courts do not necessarily have technical backgrounds. In the UK all of the judges in the Patents Court and the Patents County Court (PCC) are former barristers with technical specialism (usually at least a degree in a science subject and sometimes a previous career in science). Because they hear only intellectual property cases, these judges are generally much more familiar with the kind of arguments that are deployed. Again, it is difficult to know whether this is an advantage or disadvantage.

For a marginal case, putting the matter before a non-specialist judge may give the claimant an advantage, but there are also issues as to whether any resulting judgment is given as much credence in other courts. In any event, the technical ability of the judges is only one of the overall factors in assessing the quality of justice delivered.

A point of relevance to those with US experience: none of the systems under consideration use juries.

(5) Ability of a single court to deal with the proceedings

In the UK patent cases are either dealt with in the Patents Court (part of the High Court) or the PCC, a lower court designed to provide a swifter and simpler form of justice. Both deal with issues of infringement and any counterclaim of invalidity. By contrast, in Germany the *Landgericht* (which deals with issues of infringement) does not have the power to deal with questions of validity. Validity issues are dealt with by the Federal Patent Court in Munich. In cases where infringement is alleged and invalidity is counterclaimed, the infringement proceedings are subject to an application for a stay. In the stay application, the *Landgericht* judge makes an initial finding as to whether or not the validity claims are *prima facie* strong, thus giving an initial (albeit imperfect) view on validity. If the case on validity appears more than merely shadowy, the infringement proceedings will be stayed and the issue of validity dealt with in the federal court. Once a validity decision has been reached, the matter is returned to the *Landgericht* for consideration on the infringement issue.

The French system involves a case being brought before the *Tribunal de Grande Instance* (effectively a regional High Court).

(6) Appeals

The German system allows appeals on questions of infringement to the *Oberlandesgericht* (higher regional court) and then to the Federal Supreme Court, which is the final court. Invalidity issues are appealed directly from the Federal Patent Court to the Federal Supreme Court. Liability and damages are normally decided at separate hearings.

French proceedings normally start in the *Tribunale de Grande Instance* or the Trade Court, with appeals to the *Cour d'Appel* and the *Cour de Cassation*. Liability and damages are heard together. The UK system starts in the Patent Court (with appeal to the Court of Appeal and Supreme Court) or in the PCC (for simpler and lower value matters), with appeal to the Court of Appeal and the Supreme Court.

Appeals in Germany to the higher regional court are effectively re-hearings, whilst those to the Federal Supreme Court are essentially restricted to matters of law. In France the ability to introduce new evidence on appeal often makes the appeal process similar to a re-hearing. In UK courts appeals at all stages are limited to errors in the treatment of the evidence or errors of law.

There are almost no obligations of disclosure in either French or German patent proceedings.

(7) Procedural differences

The most significant procedural differences between French, German and UK courts in patent actions relate to witnesses and disclosure. The UK has a sophisticated and wide ranging series of disclosure obligations and allows the production of expert reports, the operating of experiments and the cross-examination of both experts and witnesses of fact. The average trial length of a patent case brought in the High Court in the UK is seven to 10 days.

In stark contrast, there are almost no obligations of disclosure in either French or German patent proceedings. The arguments, both legal and factual, are put before the court in a trial that normally does not extend beyond one day and where the calling and cross-examination of witnesses is rare.

Again, this is a double-edged sword. Generally, however, patentees who feel that they have a strong case (or wish the issues to be explored to their fullest extent) prefer UK proceedings over those in France or Germany.

(8) Costs

The disadvantage of thoroughness (or the advantage of limited disclosure and examination of the evidence) is that the cost of proceeding in UK courts is significantly greater than in Continental courts. One would normally expect a patent action on infringement issues alone to cost approximately €20,000 to €40,000 (US\$28,000 to US\$56,000) in the German courts. Even assuming an attack on validity and the potential for an appeal, litigation would probably cost less than €75,000 (US\$105,000). Because trials are shorter and the issues more heavily prescribed, decisions are often reached within nine to 12 months.

By contrast, a significant patent action in the High Court in England with all of the costs of disclosure, experts, barristers and so on, will cost perhaps 10 times as much as a European equivalent. Cases in the High Court will probably take 12 to 14 months to come to trial.

There are, however, a number of other important factors to consider on the issue of costs when comparing the two jurisdictions:

First, a successful litigant in the English courts will be able to recover from his opponent approximately three quarters of the costs of the action. So a losing party in a major patent action may be confronted not only with a bill for more than €750,000 (US\$1,053,000) from his own lawyers but also something similar for his opponent's costs.

There are a number of ways the courts have sought to deal with issues of costs and limit the ability of parties to use costs as a "weapon" in litigation, but it must be said that there is still some truth in the comment of one judge: "English justice is open to everybody, just like the Ritz hotel." Inevitably, however, the pressure created by the burden of costs and the casino-like effect of "winner takes all" means that large and sophisticated organizations sometimes choose the UK courts to put economic pressure on defendants.

By contrast, recoverability of costs in French and German courts is much more restricted by reference to particular

scales of recoverable costs based on the value of the action. In practice, therefore, a party may only have a cost exposure of €40,000 to €75,000 (US\$56,000 to \$105,000) in a German court, but they will, even if victorious, only be able to recover a small fraction of that amount.

The relatively inexpensive nature of German proceedings is one reason German courts have become generally regarded as “jurisdiction of choice” for patent litigants in Europe. In recent years, however, the UK government introduced the PCC as a deliberate attempt to provide a forum for more efficient and speedy resolution of matters. Very recently additional regulations in relation to the PCC have created a system not dissimilar to that operating in Germany with very restricted disclosure, the potential to restrict expert and witness evidence or exclude it altogether and a total cap on recoverable costs of £50,000 (US\$77,000). It will be interesting to see if these measures provoke an increase in the number of cases brought before the UK courts, but at least now there is some form of equivalence between the UK and German systems if this forum is used.

(9) Construction of claims for or against patentees

Finally, it is worth mentioning that there is some support for the notion that German courts are broadly more favorable to patentees than UK courts. This arises because German courts have traditionally taken a more liberal approach to the construction of claims than UK courts (and also perhaps because disclosure obligations and the chance to cross-examine witnesses give judges more time to develop criticisms of the patentee’s case). One should not, however, overemphasize this tendency, which is very much a question of impression and is not based on, for example, the application of substantially different legal tests.

Conclusion

In addition to the issues that arise in forum selection in patent actions across Europe, further layers of complexity are imposed by the specific filing requirements of every country. Also, it is important to keep in mind the commercial considerations of the client, including the state

of opposition proceedings and other issues in relation to the wider patent portfolio of the patentee and the practical use of the patent.

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The Use of Cookies in the European Union



An EU law that recently came into force requires a user's informed consent before a cookie (or similar information) can be placed onto their device. Cookies are small text files saved onto a device allowing that user to be

recognized on subsequent visits. This allows webpages to display custom features and preferences that often enhance user experience.

Cookies also allow Internet companies to compile information about their users (such as their interests and hobbies) for purposes such as targeted behavioral advertising. In order to further protect users from perceived data protection and privacy implications that can result from the use of cookies, the European Commission has amended the E-Privacy Directive (09/136/EC). This was required to be transposed into European Member States national law by 26 May 2011.

The previous, less rigorous, regime required that Internet users be given the right to opt out of saving cookies, meaning that the default position resulted in cookies being saved. Under the new regime, the only exceptions from the requirement to obtain informed consent are when the cookie is used solely for technical transmission purposes or is strictly necessary for the functioning of a service (e.g., a function of the website) that has been specifically requested by the user. A good example of strictly necessary cookies are those used by online stores that allow the website to "remember" items in users' shopping baskets. This exception is limited to cookies that are "strictly necessary" and does not apply to those that merely make it more convenient for the user or the website operator.

The Law

At the time of writing only the UK, Denmark, Estonia, Finland and Sweden had introduced measures to

implement the Directive with the majority of Member States still kicking their heels over its interpretation. The controversy surrounds certain somewhat ambiguous provisions. For example, the main provision requires that users give their "informed consent" to the storage of cookies on their device, yet Recital 66 of the Directive suggests that consent can be given by browser settings (i.e., the user sets the browser to automatically accept or deny cookies).

The use of browser settings as a viable solution is not currently endorsed by the European Commission, an opinion shared by the Article 29 Working Party (Art 29 WP), the EU data protection stakeholder group. This opinion is based on three factors: (i) as they currently operate, browser settings are not sophisticated enough to obtain informed consent (ii) certain cookies can be respawned on a device after being deleted; and (iii) bulk consent, such as is produced with most of the popular browsers currently on the market, without knowledge of the purpose of any future cookies cannot be deemed informed.

Not surprisingly, this uncertainty means different Member States have unique approaches, making it more difficult for Internet companies to comply across the EU as a whole. In addition, a number of Member States have official and unofficial positions that seemingly contradict one another, e.g., national law stating a provision that, in practice, will be enforced in a specific way. In an attempt to demonstrate this, the UK regime, which has a peculiar dichotomy, is outlined below.

The UK Approach

The UK is one of the few Member States to enact national law that gives effect to its EU counterpart, so in a strict sense UK companies must comply with the implemented requirements of the Directive as from 26 May 2011. However, the Information Commissioner's Office (ICO), an independent authority that upholds data protection principles in the UK, has stated that UK businesses will have 12 months to "get their house in order." During this period, companies will be given the opportunity to take steps to comply, as part of their conformity plans, without

significant fear of enforcement action. If companies are not seen to be doing this, they could face a warning that, if not remedied, may be taken into account after May 2012.

The UK government has stated that it agrees with the Art 29 WP that browser settings are not currently sufficient to obtain user consent and has announced that it is working with Google, Microsoft, Mozilla and others to develop a technical solution to this problem.

Types of Cookies

- *Behavioral advertising* may record searches, pages and ads viewed to allow targeted marketing.
- *Third party* are placed on a website by a third party (e.g., an adserver).
- *Analytical* record the popularity of certain features (e.g., how often users visit) and are usually purely for the website operator's benefit.
- *Cookies that save preferences* allow users to tailor a webpage (e.g., Google homepage).
- *Shopping baskets* remember users' items allowing purchase at a later time.

Practical Options for Internet Stakeholders

It is highly recommended that companies carry out a "cookie audit" and use the opportunity to remove old cookies that are now obsolete. Companies are also advised to perform a risk assessment of the cookies used on their website. For example, if the cookies merely make user experience easier by remembering saved preferences, then breaching the law by not obtaining informed consent from the user is less likely to impact users in a negative way. In contrast, if a website uses cookies for more "privacy intrusive" purposes and a breach occurs, the impact upon the user could be much greater, especially if their personal data has been collected and used for commercial purposes without their consent. Thus, the more intrusive the cookie, the more likely the ICO will be to take enforcement action for a breach of the new law.

Companies could also follow the approach of the ICO's own website by using a header that pops up on a first visit that requests consent to the use of cookies. To ensure informed consent, a link should accompany such requests

giving additional information. In particular, this additional information should include the different types of cookies used, the purpose of these cookies, how long they will be saved on a device and how they can be disabled.

Sanctions

The ICO now has the power to impose civil monetary penalties of up to £500,000 (US\$800,000). This power will be used only if a serious breach of the law causes or is likely to cause substantial damage or distress and the contravention is deliberate or the company knew or should have known a contravention would occur and failed to take reasonable steps to prevent it. For example, if a company knew an individual had not consented to cookies or did not take steps to check whether consent had been obtained and still collected and used sensitive information on an individual in a way that caused the user substantial damage or distress, then a serious breach may have occurred and the ICO could impose a financial penalty.

European Commission

Similar to the UK, the European Commission has suggested that companies implement protective measures and develop a legal standard for gaining consent by June 2012. Recently, Neelie Kroes, the Digital Agenda Commissioner, stated that the European Commission would take action to protect users if businesses do not comply.

Other Member States

France has, by contrast, taken an approach that favors Internet companies. A draft Bill, which was in its first reading in Parliament at the time of writing, states that browser settings are sufficient to count as valid consent under the Directive. Germany, on the other hand, has not yet interpreted the Directive, choosing to wait for industry-wide discussion on the issue. The Netherlands goes further than the Directive requires with an extremely restrictive interpretation. A late amendment of their draft Bill requires companies to prove that users have consented to the use of their data.

Conclusion

As a result of this uncertainty, companies should be wary about how to approach the issue of cookies. It is currently difficult for companies to be certain that their cookie use complies with the law in each of the different jurisdictions in the EU. A cautious approach would be for companies to implement changes now to prevent breaches of the Directive.

However, whilst taking the recommended steps to examine cookie use and consider internal strategy on compliance, some businesses will prefer to wait until the regulatory landscape becomes clearer. In the UK, for example, those using potentially more privacy intrusive cookies, such as behavioral advertising, should make every effort to demonstrate a move towards compliance by becoming involved in industry-wide discussions on a viable solution (e.g., the Interactive Advertising Bureau is leading discussions in relation to online behavioral advertising with its new self-regulatory framework and “privacy icon”).

Companies can, therefore, show their dedication in making steps towards developing a feasible solution that will protect users’ interests without unduly restricting the online industry in the EU.

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Territorial Scope of the Rulings of the Community Trade Mark Courts of EU Member States



On April 12, 2011 the Court of Justice of the European Union rendered its decision in Case C-235/09 regarding a preliminary ruling on the interpretation of Article 98(1) of Council Regulation (EC) No. 40/94,

which defines the territorial scope of the rulings from Community trade mark courts of the Member States.

Chronopost SA owned French and Community trade marks for "WEBSHIPPING" in Classes 35, 38, 39 and 42 relating, in particular, to services for the collection and delivery of mail. Chronopost filed suit against DHL Express (France), which had used the signs "WEB SHIPPING," "Web Shipping" and "Webshipping" to designate an express mail management service accessible via the Internet. Chronopost alleged infringement of the Community trade mark WEBSHIPPING.

Acting as a second-instance Community trade mark court on the appeal, the *Cour d'Appel de Paris* deemed the use by DHL of the signs Webshipping and WEB SHIPPING as an infringement of Chronopost's French and Community trade marks. Subject to a periodic penalty payment in the event of infringement of the prohibition, the court prohibited DHL from continuing to use these signs. DHL appealed this decision to the *Cour de cassation*¹, and Chronopost brought a counter-appeal, submitting that the ruling infringed Articles 1 and 98 of Regulation No. 40/94 insofar as the prohibition against further infringement of the Community trade mark WEBSHIPPING, subject to restraining fine in the event of persistence of said infringement, did not extend to the entirety of the European Union.

In that context, the *Cour de cassation* stayed proceedings and referred the following questions to the Court of Justice² for a preliminary ruling:

1. Must Article 98 of Regulation [No. 40/94] be interpreted as meaning that the prohibition issued by a Community trade mark court has effect as a matter of law throughout the entire area of the European Union?
2. If not, is that court entitled to apply specifically that prohibition to the territories of other Member States in which the acts of infringement are committed or threatened?
3. In either case, are the coercive measures that the court, by application of its national law, has attached to the prohibition issued by it applicable within the territories of the Member States in which that prohibition would have effect?
4. In the contrary case, may that court order such a coercive measure, similar to or different from that which it adopts pursuant to its national law, by application of the national laws of the Member States in which that prohibition would have effect?

With reference to the first question, the Court of Justice took into account (i) that a Community trade mark court holds the power to act on infringements committed within the territory of any of the Member States; (ii) that a Community trade mark court likewise has jurisdiction in respect of acts of infringement committed within the territory of one or more Member States, or even all the Member States, thus, its jurisdiction may extend to the entire European Union; and (iii) the exclusive right of a Community trade mark owner extends to the entirety of the European Union, throughout which Community trade marks enjoy uniform protection and have effect.

Based on such considerations, the Court of Justice ruled that the scope of the prohibition against further infringement of a Community trade mark issued by a Community trade mark court extends to the entire area of the European Union.

With reference to the second, third and fourth questions, the Court of Justice considered that a coercive measure, such as a periodic penalty payment, ordered by a

Community trade mark court by application of its national law, in order to ensure compliance with a prohibition against further infringement, had effect in Member States (other than the Member State of that court) to which the territorial scope of such a prohibition extended, under the conditions laid down in Council Regulation (EC) No. 44/2001. Where the national law of one of those other Member States does not contain a coercive measure similar to that ordered by the Community trade mark court, the objective pursued by that measure must be attained by the competent court of that other Member State by having recourse to the relevant provisions of its national law to ensure that the prohibition is complied with in an equivalent manner.

Comment

This is an interesting development for EU law and will perhaps become a powerful tool in enforcing a brand's unitary monopoly rights throughout the whole Union. In time, however, the decision will also highlight the lack of harmonization in the intellectual property rights enforcement regime throughout the EU. France has a relatively brand protective history, other jurisdictions less so.

Jesús Carrasco, partner, Madrid

1. The *Cour de cassation* is France's Supreme Court having jurisdiction over all matters tryable in the judicial stream, but only scope of review to determine a miscarriage of justice or certify a question of law based solely on issues of law.
2. The Court of Justice of the European Union is the highest court in the European Union in matters of EU law. The Court of Justice is tasked with interpreting EU law and ensuring its equal application across all EU member states.

Drug Patents in the EU: Up to 15 Years and Six Months' Protection from Marketing Authorization



The German Federal Patent Court requested that the Court of Justice of the European Union (the Court) provide a ruling as to whether a Supplementary Protection Certificate (SPC) may be

granted if it would not result in a "positive" term, because marketing authorization (APM) for a drug had been obtained within five years of the filing of the corresponding patent application. The question was referred in the context of the availability of a six-month extension to an SPC under Article 36 of European Council Regulation 1901/2006 (the Paediatric Regulation). The Court's Advocate General concluded¹ that the six-month exclusivity extension conferred by the Paediatric Regulation was not predicated on the APM being obtained at least five years after the filing of the patent application covering the drug. The Advocate General also concluded that an SPC could indeed have a "negative" period from which the starting date of the extension would be determined.

Background

In Europe the SPC regime is intended to encourage innovation in the pharmaceutical industry. It can often take many years for a new drug to obtain APM, thereby shortening the period of exclusivity provided by a patent and potentially discouraging companies from continuing to invest in research and development. Therefore, implementation in the early 1990s of European Council Regulation 1768/92 (SPC Regulation) meant that businesses were able to apply for an SPC to extend the period of protection for a patented medicinal product to compensate for delays in commercializing the product arising from the need to obtain APM. An SPC is a national right and separate applications must be made in each European territory.

In most countries, the term of a patent is generally 20 years from the date on which the application for the patent is filed. The SPC has a duration equal to the period between:

- a) the date of filing of the application for the patent upon which the SPC is based; and
- b) the date of the first authorization to place the product on the market in the Community, minus 5 years. SPCs take effect at the end of the term of the patent and have a maximum duration of 5 years.

The total combined period of market exclusivity provided by the basic patent and the SPC cannot normally exceed 15 years. To further encourage investment in drugs of benefit to the paediatric population, which can take even longer to come to market with their APM, the EU enacted the Paediatric Regulation, which enables companies to obtain an additional six months of protection with the SPC. The maximum combined protection would therefore be 15.5 years.

If, however, a patent was applied for on 1 January 2000, for example, and APM was granted on 1 September 2004, the SPC would effectively have a term of minus four months. Prior to the Paediatric Regulation, there was no point in applying for an SPC with a negative term; as that Regulation affords an additional six months of SPC duration, however, pharmaceutical companies have been keen to exploit the extra protection it provides – in the above case, two months of unfettered supply to customers. Given that the market for a particular drug can be worth hundreds of millions of Euros annually, this apparently short period is nevertheless significant.

In the case prompting the referral to the Court, Merck Sharp & Dohme Corp., formerly known as Merck & Co., filed a patent application for a drug in July 2002. It obtained the APM in March 2007 and applied for an SPC in September 2007, but this was rejected by the German Patent and Trade Mark Office (DPMA) in July 2008 as such an SPC – which would have a negative term – could not be granted.

Merck appealed the decision to the German Federal Patent Court on the basis that it was implementing a paediatric investigation for the drug and should, accordingly, benefit from the six-month extension to its exclusivity period under the Paediatric Regulation. As this would be an extension to the duration of the SPC, Merck argued that it should be granted an SPC even if it were for a zero or negative period. Merck further argued that the six-month extension should run from either March or July 2022; that is, either 15 years from the date on which APM was obtained for the drug or from the date on which the patent would expire, respectively.

The German Federal Patent Court requested a ruling from the Court as to whether, following the adoption of the Paediatric Regulation, it could issue an SPC of either zero or negative duration. It noted that the applicable Regulations did not explicitly provide for such an SPC and that Merck had, nonetheless, obtained one in several other EU Member States (including the UK and the Netherlands).

The Advocate General considered whether the grant of an SPC of positive duration was a prerequisite to the additional six-month exclusivity extension under the Paediatric Regulation.

Advocate General's Opinion

It is in this context that the Advocate General, an advisor to the Court, considered whether the grant of an SPC of positive duration was a prerequisite to the additional six-month exclusivity extension under the Paediatric Regulation.

In his Opinion, the Advocate General explained that the German Federal Patent Court had referred to Regulation 469/2009, which entered into force later than July 2008 (i.e., after the date of the decision subject to the appeal). Accordingly, the relevant text was that of the SPC Regulation. The Advocate General noted that several EU Member States and the EU Commission had submitted comments to the Court which were opposed to the grant of

a negative or zero duration SPC, arguing, among other things, that an SPC had to have a positive duration.

The Advocate General rejected the arguments, reasoning that:

- a) Under the system arising from the SPC Regulation and the Paediatric Regulation, an SPC could be granted even if less than five years had elapsed between the patent application and the APM as:
 - i. The issue of whether an SPC of a positive duration was a prerequisite to obtain the six-month extension period was not clearly dealt with by the SPC Regulation or the Paediatric Regulation. As a result, the answer must be found by analyzing the system and the objectives of the two Regulations;
 - ii. The duration of the SPC was not one of the conditions for the six-month extension under Articles 7 and 8 of the Paediatric Regulation;
 - iii. The duration of the SPC was mentioned in Article 13 of the SPC Regulation, i.e., after Article 10, which describes how an SPC is granted or an application rejected. It was, therefore, not a condition for obtaining an SPC;
 - iv. Article 36 of the Paediatric Regulation simply describes how the SPC and the six-month extension work together when both are granted; and
 - v. An SPC with a negative duration was not originally envisaged, as the aim of the SPC was solely the extension of a patent's exclusivity period. With the Paediatric Regulation, the use of the SPC expanded.

- b) The objectives of the SPC Regulation and the Paediatric Regulation clearly justify the granting of a SPC even if less than five years have elapsed between the patent application and the APM as:
- i. The SPC Regulation is intended to provide a monopoly of up to 15 years to the holder of a drug patent starting from the drug's APM;
 - ii. The Paediatric Regulation compensated – with a six-month extension of the monopoly – for the extra costs and constraints borne by the holder of a drug patent in implementing a paediatric investigation plan for the drug; and
 - iii. The combined objectives of the regulations were to offer a maximum protection of 15 years and six months to the holder of a drug patent when the drug's APM had been granted more than five years after the application for the patent.
- c) The arguments of the opposing parties were contrary to the objectives of the two Regulations as:
- i. It would have been disproportionate either to grant or not to grant the six-month extension on the basis that it took approximately five years to obtain the APM; and
 - ii. The financial impact of obtaining the APM less than five years after the patent application could lead patent owners to delay the date at which they obtained their APM, contrary to the principle of public health protection, which requires a drug to be made available to patients as early as possible.

Although the referring German tribunal did not ask the Court to rule on it, the Advocate General gave his view as to the date on which the six-month “paediatric extension” to the SPC under the Paediatric Regulation should start. He

stated that the maximum period of marketing exclusivity offered by the two Regulations should be 15 years and six months. On this basis, the extra six months is to be added to the negative term SPC (i.e., the commencement date of the extension is calculated by deducting from the expiry date of the patent the SPC term). In the Merck case, the SPC term was determined to be minus three months, 14 days, so that the addition of the paediatric extension would provide a protection period of two months and 16 days beyond the expiry date of the patent.

Comment

The Advocate General followed a purposive approach in his interpretation of how the Paediatric Regulation fits into the existing system of the SPC Regulation for both the availability of the extension and its starting date. He appears to have taken account of the importance of patent protection to the pharmaceutical industry and the need to encourage more investment in paediatric drugs, which were the original objectives of the Regulations. Of course, the suppliers of competing generic drugs will take a different view, as every extra day that they are restricted from entering the market is of detriment to their business. The beneficial effect of the Advocate General's interpretation applies to all cases where the APM is obtained between four years and six months and five years after the filing of the corresponding patent application. It will be interesting to see whether the Court follows the Advocate General's Opinion – it does so more often than not. It has been speculated that the Court will go further and decide that the six-month SPC extension is to run from expiry of the patent. In any event, that the Court will, for the first time, have the opportunity to address the mismatched approach currently taken throughout the EU to additional protection under the Paediatric Regulation is to be welcomed.

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1. *Merck Sharp & Dohme Corp., formerly known as Merck & Co. v. Deutsches Patent-und Markenamt* (Case C-125/10) – Opinion of Advocate General, 9 June 2011.

License Agreements Under the Japan Antimonopoly Act



In 2010 the Japan Fair Trade Commission (JFTC), which oversees enforcement of the Japan Antimonopoly Act, set a record high for total fines imposed – in excess of US\$875 million – more than double the total fines imposed in 2009, and nearly triple the fines imposed in 2008.

Although the most significant violations involved public works bid-rigging and price-fixing cartels, JFTC's increased enforcement activities are expected to continue their upward trend, and license agreements (which are one of the most common forms of agreements in cross-border transactions¹) can expect to come under heightened scrutiny in the coming years.²

The JFTC's Guidelines for the Use of Intellectual Property under the Antimonopoly Act (IP Guidelines) provide a comprehensive overview of the types of arrangements or agreements involving IP rights that are permissible or impermissible under the Antimonopoly Act. The Guidelines describe varying degrees of restrictions based on, for example, their impact or effect on competition within the market, and theoretically can be divided into three categories³: (1) Level 3 Restrictions which have a major impact on competition, or have a high likelihood of being deemed anticompetitive and would very likely to trigger JFTC scrutiny; (2) Level 2 Restrictions which may or may not be deemed anticompetitive depending on the facts and circumstances of each case; and (3) Level 1 Restrictions which are the least problematic types of restrictions. Common examples within these categories are set forth below.⁴

Level 3 Restrictions:

- Restrictions on a licensee's sale, resale, or export price of products incorporating licensed technology;
- Restrictions on a licensee's R&D activities;
- Restrictions on a licensee's adoption and use of alternative forms of technologies; and
- Licensee's compulsory assignment or grant of an exclusive license to licensor for any improvements to licensed technology.

Level 2 Restrictions:

- No-challenge or non-assertion clauses that prohibit a licensee from challenging the validity of licensed technology or asserting IP rights against the licensor;
- Cross licenses or patent pool arrangements whereby the contracting parties agree to restrict licenses to certain third parties, or otherwise agree to limit the price or quantity of products incorporating licensed technology, or the scope of licensable technology;
- Horizontal or vertical arrangements that prohibit sales to certain customers, limit sources for raw materials or restrict exportation;
- License fees that are not related to the utilization of the licensed technology; and
- Requirements for payment of license fees even after bases for the licensed technology (e.g., patent rights) are extinguished.

Level 1 Restrictions:

- Restrictions on the scope of use of licensed technology;
- Geographical or territorial restrictions;
- Restrictions on the license period;
- Restrictions on sublicenses;

- Minimum quantity requirements for products that use, incorporate or are sold applying licensed technology; and
- Requirements that licensees grant licensors a non-exclusive license to any improvement in the licensed technology.

Of the three types of restrictions, the Level 2 Restrictions pose the thorniest problems, including whether such restrictions will be deemed anticompetitive or, worse, come under JFTC scrutiny. Recently, the most notable prosecution of a non-Japanese company by the JFTC involved a Level 2 Restriction – a non-assertion clause found in Microsoft’s standard software license agreements. In that case, the JFTC found that Microsoft’s large market share and superior bargaining position effectively “forced” licensees to accept a standard license agreement, which included a non-assertion clause, and that this non-assertion clause materially disincentivized licensees from pursuing R&D activities in the PC audio-visual technology field, which in turn adversely affected competition in that market.⁵ JFTC’s findings were highly fact specific, and its 143-page ruling was issued following an investigation spanning over four years. More recently, another US-based licensor’s (Qualcomm) non-assertion clause (in its license agreements with Japanese licensees) has come under JFTC review, resulting in a cease and desist order for rescission of all such provisions in the applicable license agreements, among other things. The matter, however, is still pending final decision before the JFTC.

Conclusion

The restrictions discussed above are relevant even if none of the contracting parties is a Japanese company. So long as an agreement or arrangement pertains to IP rights and has a material effect on the Japanese market,⁶ the Antimonopoly Act and IP Guidelines apply, and the JFTC’s increased enforcement is likely to result in additional scrutiny of not only licensing activities, but also other activities relating to IP rights in or affecting the Japanese market.

Kate E. Kim, associate, Tokyo
Kohei Murakawa, associate, Tokyo

1. In his annual message, the chairman of the JFTC expressed a commitment to oversight of international transactions that have “increasingly powerful influences” on the Japanese market in light of the “globalization of corporate activities in recent years.”
2. The JFTC’s annual budget (approximately US\$114 million) is comparable to that of the US Department of Justice’s Antitrust Division.
3. From 1999 through 2007, the Guidelines specifically described three categories of restrictions. In 2007, however, the JFTC revised the Guidelines and moved away from the specific categorization model to a more general description of the various types of restrictions based on their overall effect. Many practitioners and experts, however, still use the three categories of restrictions (sometimes also called “black,” “grey” and “white” restrictions) for purposes of framing the relevant issues under the Antimonopoly Act.
4. Some of these restrictions are subject to certain market share threshold requirements that are outside the scope of this article. The general rule of thumb, however, is that in the technology market, parties with less than or equal to 20 percent market share have a “minor effect” in reducing competition by their restrictions.
5. Additionally, the JFTC found that, to the extent a licensor’s technologies relate to certain “essential” or core technology, the IP Guidelines could render a licensor’s activities to be anticompetitive, if, for instance, it would be unreasonably burdensome for the licensee to use or incorporate another type of technology, or the use of a licensor’s technology is so widespread as to make it effectively impossible for potential licensees to use an alternative technology. Ultimately, the JFTC found that the anticompetitive effect of the non-assertion clause in the license agreements outweighed any purported commercial benefit or rationale proffered by Microsoft.
6. After the US, Japan has the second highest number of Patent Cooperation Treaty applications in the world.

Contributor Profiles

Editor



Alicia M. Choi focuses her practice on the area of patent law. Her experience includes preparing and prosecuting utility patent applications in the areas of electrical and computer engineering including information technology, software systems, wireless communication, medical diagnostic devices, semiconductors, analog and digital circuitry, and consumer electronics such as optical storage media and audio devices for US and international clients. Her experience also includes conducting novelty, patentability, invalidity and infringement analyses for various electrical devices and systems. In addition Alicia has been involved in reissue and reexamination proceedings and provided litigation support in patent infringement claims.

Editorial Review



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Jerry Dodson is one of the most highly regarded patent trial lawyers in the United States. With his engineering degree, he is able to direct both the litigation and technical aspects of cases. Jerry has represented businesses in a wide range of industries including biotechnology, medical devices, optical, and electronic hardware and software. Before entering private

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Kate E. Kim focuses her practice on corporate matters, particularly mergers and acquisitions. She represents buyers and sellers with stock and asset acquisitions and divestitures, mergers, joint ventures, strategic alliances and similar transactions. Kate has worked with clients in medical diagnostics, pharmaceuticals, electronic components manufacturing, and other industries including real estate, and information and communications technology. She also advises clients on US litigation and international arbitration matters. Kate has represented clients in general commercial, securities, intellectual property, insurance and complex construction litigation cases.

Julie-Anne Lucchetti joined Squire Sanders in August 2009 as a trainee solicitor. She focuses her practice on general legal matters and regularly publishes case reports for *WTR Daily* and the *ITMA Review*. Her former experience includes working in international law firms in France and Slovakia.



Chris McLeod is the director of trade marks based in our London office. He has more than 20 years' experience in the field and his particular expertise covers advice in relation to all aspects of trade marks from pre-filing searches and clearance, through filing and prosecution, to post-registration matters and third-party conflicts. He also advises in relation to registered and unregistered designs and copyright. He is a director and officer of ITMA, the UK Institute of Trade Mark Attorneys, a committee member of INTA, the International Trademark Association and an active member of PTMG, the Pharmaceutical Trade Marks Group.



Kohei Murakawa focuses his practice on bankruptcy and restructuring, intellectual property and antitrust law; Japan-based litigation; mergers and acquisitions; and general corporate matters. Kohei has represented clients in the manufacturing, electronics and trade firm industries. His experience includes submitting a leniency application to the Japan Fair Trade Commission for an international cartel case; arbitrating before the Japan Intellectual Property Arbitration Center concerning JP domain names; advising on reorganization matters; and resolving a cross-border dispute between a Japan-based and a US-based company.



Julian Reynolds focuses his practice on intellectual property, in particular patent filing and prosecution. His particular expertise covers advising on patentability of inventions and patent filing strategies, patent procurement, and patent infringement and validity opinions. Julian specialises in inventions and patents in electronics and computing, as well as handling telecommunications, mechanical, physics and optical technologies. He has experience of a wide range of patent and other IP matters, gained both in industry and private practice.



Carl Rohsler leads the Intellectual Property and Technology Practice Group in Europe. His practice covers the full range of intellectual work including patents, trademarks and designs, copyright and confidential information. Although working on both contentious and noncontentious matters, Carl is best known for his work as a trial lawyer, having been involved in a number of leading cases in this field since 1995. He is a solicitor advocate (High Court: Civil 2001). Carl is also known as one of the UK's leading experts on gambling law, acting for a number of the leading online and bricks and mortar gambling operations in the UK and across the world. In addition to his expertise in intellectual property and gambling regulation, he has considerable experience in advertising and marketing regulation, data protection, e-commerce and labeling and packaging law.

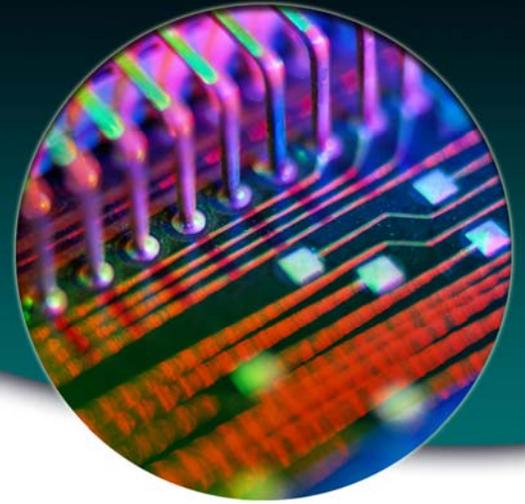
Tim Taylor advises on commercial contracts, intellectual property and data protection, with particular expertise in the media, advertising, technology and sports industry sectors. He recently spent time on secondment with the media-buying division of the world's largest marketing group, building up detailed industry knowledge and expertise in negotiating and advising on media planning and buying agreements. Tim's practice also covers data protection and privacy issues, particularly in the context of e-commerce (including the use of cookies) and marketing. He has particular expertise in social media, online behavioral advertising and market research.

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