BIRD & BIRD

Life Sciences Update

May 2008

A periodical update on legal and regulatory developments in the life sciences sector

In this edition, we have reported on a range of recent developments in the life sciences sector both at EU and national level.
From an EU perspective, we report on, amongst other topics, the Commission's consultation to combat counterfeit medicines and the Advocate General's opinion in GSK's dispute with Greek exporter wholesalers. At national level, we report on the English Court of Appeal's decision in *H. Lundbeck A/S v Generics (UK) Limited*, the Dutch Patent and Research & Development Box and the Swedish Governmental Report on patent protection for biotechnological inventions, amongst other topics.

We hope you enjoy reading this update and are happy to address any comments or questions you may have, either through your usual contact or through any of the contacts on the back page of this update.

International Life Sciences Group

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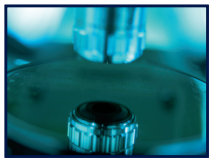
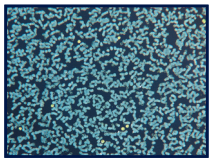
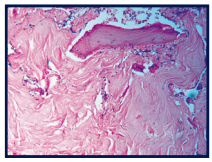
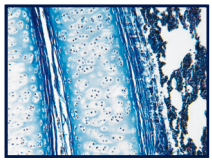
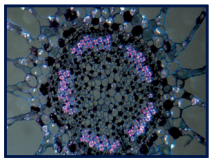
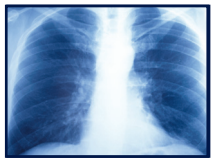
On 12 May 2008, we will be holding a seminar on Spanish Public Procurement Law at Hotel AC Palacio del Retiro, Alfonso XII n° 14 in Madrid.

On 1 May 2008, a new Public Procurement Law came into force in Spain implementing Directive 2004/18/EC on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts. This new legislation introduces major changes in the procurement of a large number of entities in the public sector and is particularly relevant to the health sector as the public sector is responsible for acquiring the majority of the medicinal products in Spain. The seminar will be presented in Spanish and is free of charge. It is primarily aimed at those working within the Life Sciences sector who wish to familiarise themselves with public procurement issues.

Should you wish to attend, please contact Olga Dones on:

Tel: +34 91 790 60 00 / 06
Fax: +34 91 790 60 11
E-mail: olga.dones@twobirds.com

EU: Counterfeit medicines: consultation of European Commission

Counterfeit medicines have become an increasing threat to public health over the past few years. Not only has the quantity of counterfeit medicines on the market increased, in particular through the classical supply chain and the internet, but there has also been a rise in instances of defective manufacture and impurities in active substances by the counterfeiters themselves. There has also been a shift in the focus of counterfeiters away from just 'lifestyle' medicines such as erectile dysfunction and weight loss medicines and now towards life-saving drugs as well.

On 11 March 2008, the Directorate-General Enterprise and Industry of the European Commission launched a public consultation in preparation for a legal proposal to combat counterfeit medicines for human use. The aim of this public consultation is to amend current European pharmaceutical legislation.

Three areas have been identified where the regulatory framework for medicines should be improved. These relate to:

- medicinal products placed on the market: issues of traceability, product integrity and distribution chains;
- medicinal products that are imported, exported and in transit (transhipment);
- manufacture and the placing active ingredients on the market: issues of regulation of active substances.

Key proposals may include:

- Subjecting all parties in the distribution chain of medicinal products to pharmaceutical legislation, i.e. the obligations for wholesalers will apply to other parties such as brokers, agents and retailers as well;
- Tightening the rules on inspection and supervision, in particular regarding inspections in third countries;
- Improving product integrity through an obligatory sealing of the outer packaging, which would reveal any subsequent opening or tampering. The right to open the unique seal should be restricted to the marketing authorisation holder and the end user;
- Introducing a central and efficient traceability system for medicinal products such that there is a unique and centrally accessible record of all past ownership and dealings with a medicinal product (the so-called pedigree). This pedigree would include transactions between the manufacturer, the wholesaler(s) and the supplied retailer/ pharmacist. Further, traceability should not be limited to batches but additionally to specific packages which should also be traceable by coding (mass serialisation);
- Tightening requirements for the import/export/transit of medicinal products. Ensuring that imported medicines intended for export (not necessarily subject to

marketing authorisation) are subject to the rules for imports into the EU.

- Submitting the manufacture and import of active ingredients to a mandatory notification procedure for manufacturers/importers of active substances and improve audit and enforceability of GMP and inspections.

Stakeholders and other interested parties, such as industry and healthcare professionals, are invited to submit their comments to the European Commission by 9 May 2008 at the email address: **entr-pharmaceuticals-counterfeit@ec.europa.eu**

Armand Killan &
Manon Rieger-Jansen, The Hague

EU: Advocate General's opinion supporting parallel trade in Greek case against GSK

The long running saga of disputes between Greek exporter wholesalers and GSK following GSK's refusal of supplies for export purposes has taken a new turn. In the European Court of Justice (ECJ) proceedings referred from the Greek court, *Efetio Athinon*, the Advocate General issued his opinion on 1 April 2008 which favours a conclusion that GSK was abusing a dominant position in refusing supplies to the exporter wholesalers (Joined Cases C-468/06 - 478/06). This opinion goes against the trend of recent European Court and national court judgments, and also the previous opinion in the *Syfait* case given by Aggregate General Francis Jacobs, and therefore comes as a surprise. However, the ECJ is not bound to follow the opinion of the Advocate General when it adopts its full judgment in a few months' time.

In the *Syfait* case, following a complaint by various Greek wholesalers, the Hellenic Competition Commission referred questions to the ECJ for a ruling under EC law on whether GSK was abusing a dominant position by failing to meet in full all the orders that the wholesalers had placed for export purposes. The ECJ declined to give judgment on jurisdictional grounds, because it concluded that the Hellenic Competition Commission was not a court or tribunal authorised to make a reference within the meaning of Article 234 EC. Meanwhile, Advocate General Jacobs had issued his opinion (in October 2004) to the effect that it was not abusive in the circumstances of the case for GSK to refuse to supply the wholesalers in full, in order to prevent parallel trade, taking into account the specific characteristics of the pharmaceutical sector, including the pervasive regulation of price and distribution in the Member States, which were imposed on the pharmaceutical companies.

In the similar issues now raised in the proceedings referred to the ECJ by the *Efetio Athinon* (Joined Cases C-468/06 - 478/06), the ECJ was asked to rule on:

- Whether the refusal by a dominant undertaking to meet pharmaceutical wholesalers' orders in full, as a means of limiting parallel trade, constitutes *per se* an abuse of dominance, taking into account the profitability of parallel trade for wholesalers because of the price differentials resulting from state intervention; and
- Insofar as such conduct is not an abuse of dominance in every case, which factors are relevant in assessing the possible abuse?

Advocate General Ruiz-Jarabo proposes that the ECJ should rule that a dominant undertaking which refuses to meet in full the wholesalers' orders of pharmaceutical products, in order to protect itself against the effects of parallel trade, commits an abuse of that dominant position. The Advocate General denied that GSK had put forward sufficient evidence to demonstrate economic efficiencies to justify its refusal in this particular case, but he took the view that it is possible that an undertaking could provide objective justification for such conduct by showing that the regulation of the pharmaceuticals market compels it to take such action to protect its legitimate business interests. However, the Advocate General also stated that it is not possible to rely for such purposes on the pricing system for medicinal products (because the system allows for an element of negotiation by pharmaceutical companies with national price control authorities) nor on the impact of parallel trade on incentives to innovate. On the last point, the Advocate General rejected the idea of a causal link between the loss of income because of parallel trading and the producer's reduction of investment in research and development.

The opinion of the Advocate General takes the opposite position to the rulings of national courts in France and Spain, and also the ruling of the Hellenic Competition Commission in the *Syfait* case (in September 2006), all of which have supported the conclusion that a refusal by a dominant pharmaceutical company to supply exporter wholesalers was normally unlikely to be abusive in the economic and regulatory context of the industry. The Advocate General's present opinion is also inconsistent with the judgment of the European Court of First Instance (ECFI) also in September 2006 in *GSK v Commission* in which the ECFI quashed a decision of the European Commission to refuse exemption under Article 81(3) EC to GSK's agreement involving a dual pricing regime in Spain whereby wholesalers were charged the national regulated price for sales for domestic consumption and a higher price on supplies for exports. In that case, the ECFI ruled that the European Commission needed to carry out a full balancing exercise under Article 81(3), inter alia comparing the advantages of intra-brand competition through parallel exports with the advantages of inter-brand competition at

innovation level as between pharmaceuticals producers who for this purpose had an interest in protecting their revenue by limiting parallel imports. This case is also under appeal to the full ECJ.

The issues surrounding the Advocate General's present opinion are therefore very contentious. There is a rich background of economic and legal issues for the ECJ to consider, in deciding whether or not to follow the Advocate General's opinion.

Richard Eccles, London

EU: European Commission launches pharmaceutical investigation

The European Commission has, using its investigatory powers under Article 17 of Regulation 1/2003, launched an inquiry into competition in the pharmaceuticals sector. The inquiry has not been launched in response to any indication of specific transgressions but will examine the reasons why fewer new pharmaceuticals are being brought to the market and the apparent delay to the entry of generic pharmaceuticals.

In particular, the inquiry will look at whether pharmaceutical companies are infringing the EC Treaty's prohibition on restrictive practices (Article 81) with agreements such as patent dispute settlements. It will also examine whether the EC Treaty's ban on the abuse of a dominant market position (Article 82) has been contravened by the creation of artificial barriers to entry of the market by, for example, misuse of patent rights or vexatious litigation.

Innovation in the pharmaceutical sector is assisted by patents and other intellectual property rights. However, active competition in the sector is important to the public to ensure value for money on health spending. The Commission has stated that its action will complement, rather than challenge, intellectual property laws.

The Commission can use a wide range of investigative measures to gather information, including requests for information. Companies are likely to view the information sought, such as the use of intellectual property rights and litigation, as highly confidential.

The inquiry is limited to medicines for human consumption; it will take into account differing regulatory frameworks but will not question the various health schemes of the Member States. Its findings will allow any future action to be taken on the most serious competition concerns. An interim report is expected in Autumn 2008 with the final results of the inquiry planned for Spring 2009.

Tim Harris, London

UK: Court of Appeal explains the limited application of the Biogen principle to product claims and upholds broad product claim protection for a novel enantiomer

In a judgment given on 10 April 2008 in *H. Lundbeck A/S v Generics (UK) Limited & Ors*, the English Court of Appeal reversed in part the decision of the Patents Court and in so doing upheld broad product claim protection for escitalopram, the (+) enantiomer of the racemate citalopram, and that is responsible for the SSRI activity of citalopram.

The judgment is of especial significance because the Court of Appeal analysed the extent to which an attack of insufficiency, along the lines that had succeeded some ten years previously in the House of Lords in *Biogen v Medeva*, and that had succeeded at first instance in the Patents Court in this present case, had application to a product claim where only two synthetic routes to manufacture a product had been disclosed but the desirability of making such product was obvious. This analysis has particular authority as the leading judgment was delivered by Lord Hoffmann, who normally sits in the House of Lords, and who, when so sitting, had given the lead judgment in *Biogen*, but as to which he here concluded:

> "40. *Biogen* should therefore not be read as casting any doubt upon the proposition that an inventor who finds a way to make a new product is entitled to make a product claim, even if its properties could have been fully specified in advance and the desirability of making it was obvious."

There were three grounds of attack on the validity of the three claims of the escitalopram patent in issue:

(a) Product claims 1 and 3 lack novelty by reason of the disclosure of the racemate in the earlier published patent for citalopram;

(b) Product claims 1 and 3 and process claim 6 are invalid for obviousness;

(c) Product claims 1 and 3 are invalid for insufficiency because they claim the enantiomer made by any method, but the specification discloses only two ways of making it.

As to novelty, it was common ground, consistent with EPO and English case law (in contrast for example to that in Germany as to this issue), that the prior disclosure of a racemate did not in itself amount to a disclosure of each of its enantiomers. However it was argued that claim 1, to the enantiomer, was not only for the pure enantiomer but was also for the enantiomer as an unresolved (ie unseparated) moiety of the racemate. The Court of Appeal rejected this argument and agreed with the first instance judge, in holding that a claim to the enantiomer should be construed as not covering an unresolved part of the racemate.

As to obviousness, it was argued that the claim 6 process, one of the two claimed processes for producing the enantiomer, was obvious, along with another process

that had not been disclosed or claimed. The evidence at trial had established the difficulty at the priority date of resolving citalopram (it had taken the patentees seven years to succeed in so doing), and the unpredictability of success of the 13 different approaches that might have been considered to resolve citalopram. However it was argued that claimed process had been "obvious to try". The Court of Appeal accepted that the trial judge had correctly stated the principle to be applied as:

> "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."

The Court of Appeal then accepted that the trial judge had correctly applied this principle to the facts of the case, having first noted that there were "a number of avenues of research" open to the skilled man seeking a solution to the problem and that therefore the skilled man would not have taken the claimed route unless satisfied that there was a "real prospect" that it would work, which on the evidence the trial judge found not to be established. Accordingly the Court of Appeal upheld the Patents Court judgment that neither the claimed process in issue, nor the product claims, was obvious.

As to insufficiency, the trial judge had found the escitalopram product claims to be insufficient because these were to one enantiomer of citalopram however made, when all that the patentees had discovered was one way of making that enantiomer, it being already known at the priority date that such enantiomer must exist and that either it or the other enantiomer or both must have a medicinal effect. The Court of Appeal reversed this finding. Lord Hoffmann confirmed that a product claim would usually be enabled if the specification and the common general knowledge enabled the skilled man to make it, and that for this purpose one synthetic method was enough. He explained that the *Biogen* case on which the trial judge had based his finding concerned not a claim as here simply to a novel product but to a type of "product by process" claim to "a molecule identified partly by the way it has been made ... and partly by what it does..." Such claim was to a class of products which satisfied the relevant conditions, one of which was that the molecule had been produced by recombinant DNA technology. Lord Hoffmann went on to observe:

> "34. ... But the specification in *Biogen* described only one method of making the molecule by recombinant technology and disclosed no general principle. It was easy to contemplate other methods about which the specification said nothing and which would owe nothing to the matter disclosed.

"35. In my opinion, therefore, the decision in *Biogen* is limited to the form of claim which the House of Lords was there considering and cannot be extended to an ordinary product claim in which the product is not defined by a class of processes of manufacture. It is true that the House in *Biogen* indorsed the general principle stated by the Board of Appeal in T409/91 *Fuel Oils/EXXON* [1994] OJ EPO, that—

"the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported or justified."

"36. The judge said that in holding claim 1 insufficient, he was applying this principle. But then he treated the relevant "technical contribution to the art" as being the inventive step, namely a way of making the enantiomer. That, I respectfully consider, was a mistake. When a product claim satisfies the requirements of section 1 of the 1977 Act, the technical contribution to the art is the *product* and not the process by which it was made, even if that process was the only inventive step."

Lord Hoffmann then went on to explain how this approach was consistent with EPO case law, and also with the public policy justification for product claims as demonstrated by the approach to these throughout history by the courts and the legislature.

Lord Justice Jacob agreed with Lord Hoffmann's conclusions but added several valuable observations of his own. In particular he pointed out that careful thinking was called for in considering claims to desirable ends, giving the following example of one type of product claim that could still be attacked as being insufficient:

"61. So, for example, if a man finds a particular way of making a new substance which is 10 times harder than diamond, he cannot just claim "a substance which is 10 times harder than diamond." He can claim his particular method and he can claim the actual new substance produced by his method, either by specifying its composition and structure or, if that cannot be done, by reference to the method ... but no more. The reason he cannot claim more is that he has not enabled more – he has claimed the entire class of products which have the known desirable properties yet he has only enabled one member of that class. Such a case is to be contrasted with the present where the desirable end is indeed fully enabled – that which makes it desirable forms no part of the claim limitation."

Thus the *Biogen* principle still has application to product claims in certain circumstances, but not, it would seem, to product claims drawn in terms of conventionally chemical terminology, such as that in issue in the present case.

Trevor Cook, London

Italy: New rules on direct supply to the public and wholesale distribution of medicinal products for human use under the Italian Medicines Code (Legislative Decree No 219/2006) as recently amended by decree no. 274/2007 (the "Decree")

The Decree introduces, *inter alia*, new rules on dispensing medicinal products under prescription, the possibility of new forms of dispensation of OTC products (e.g. via automatic distributor machines remotely connected to a pharmacist - so called "*Pharmaclick*") and *ad hoc* requirements as to medical information activities addressed to healthcare professionals operating in non-public structures (e.g. in case of gadgets to be freely distributed). It also introduces new provisions on the direct supply to the public and wholesale distribution of medicinal products for human use.

Article 16 of the Decree, amending Article 100 of the Italian Medicines Code, expressly introduces the possibility for pharmacists, undertakings operating pharmacies and undertakings running estate pharmacy to wholesale distributing medicinal products for human use.

These amendments are intended to:

(i) align existing practice with recent developments/innovations introduced by Decree No 223 of 4 July 2006 transposed into Law No. 248 of 4 August 2006 (the so-called *"Bersani Decree on privatisations"*, as a result of which the sale/direct supply of all medicinal products, except prescription medicines is now generally permitted in Italy provided that at least one qualified pharmacist constantly supervises the sale/supply of the products); and

(ii) implement the Communication of the Italian Antitrust Authority ("AGCM") on the *"incompatibility between wholesale distribution and direct supply to the public of medicinal products"*, while respecting the fundamental principle of protection of public health (e.g. by imposing that all pharmacies have a manager who is a qualified pharmacist).

The intention of the legislator is to foster competition in this field for the benefit of consumers and patients, for example via the price reduction of medicinal products.

In particular, according to the AGCM Communication, the Italian Medicines Code should be further revised to consider:

(a) the incompatibility between wholesale distribution and direct supply to the public of medicinal products. The AGCM does not believe there is a real risk of a conflict of interest due to both the provisions already in place relating to the wholesale distribution of medicinal

products (i.e. Legislative Decree 30 December 1992 No. 538 implementing Directive 92/25/CE) and the ethical rules applicable in this situation.

(b) the ban preventing non-pharmacists running pharmacy activities. The AGCM believes that this limitation of a commercial activity may be justified in principle only in cases where it is necessary to ensure that the individuals formally running such activities have the required specific expertise but not in cases where the same result can be otherwise achieved by for example simply employing an individual with the required expertise to supervise the sale.

Mauro Turrini, Rome

Sweden: The Government Official Report on Patent Protection for Biotechnological Inventions

The Directive on the legal protection of biotechnological inventions (98/44/EC) was implemented in Swedish law in 2004. The legislative amendments resulting from the implementation did not entail any extension of patent protection for biotechnological inventions but rather constituted a clarification of the practice already applied. When the Directive was implemented, the Government noted that there was broad consensus that the availability of effective patent protection in the biotechnology area constituted an important incentive, for example for developing new and improved medicines. At the same time the Government noted that there were fears that patent protection, if it became too extensive and strong, would risk counteracting its purpose. In the light of this, the Government stated that there was a need to follow the case law developments as regards the application of both the fundamental patentability conditions and the limitations of the extent of protection. The Government also stated that special measures for coordinating and facilitating licence agreements should be considered in order to encourage access to diagnostic tests on reasonable terms. Moreover, the Government stated that the effects of the development of the patent system for research should be followed closely. For this reason, in 2005 the Government decided to set up a committee, the report of which has now been published (SOU 2008:20).

Fundamental patentability conditions: The committee has found that the EPO case law in the biotechnology area in recent years has taken a restrictive course as regards the application of the patentability requirements of

inventive step and industrial applicability. On several occasions the EPO has stated that vague indications of possible medical use for a chemical substance did not meet the industrial applicability requirement. In the opinion of the Committee, the application of the fundamental patentability requirements in both the EPO and the Swedish Patent and Registration Office (PRV) is appropriate. Accordingly, no changes to the Swedish Patent Act were proposed.

Extent of protection: Absolute product protection implies that all use of a chemical substance falls within the patent's scope of protection. Absolute product protection constitutes a central issue with regard to the scope of patent protection for gene sequences and the fear that protection in this area may be too wide and strong. Sweden applies absolute product protection for gene sequences and micro-organisms (unlike e.g. France and Germany). The Committee has concluded that Sweden should not aim for a transition to use-bound product protection for patents on gene sequences.

Access to diagnostic tests: The Committee found that on the whole, access to patented genetic and diagnostic tests in the health and medical care sector can be regarded as satisfactory. If issues were to arise, the Committee deemed that such situations can be dealt with firstly by competition law measures and possibly by means of the compulsory licencing regime.

Research: With regard to the experimental use exemption, the Committee found that the present Swedish regulation is satisfactory. The right to make experiments on but not with a patented invention is an appropriate allocation of rights that allows for continued research on the patented product while protecting the justifiable interests of those who develop new and improved research tools. At a more general level, the Committee noted that the access to patented biotechnological inventions for research purposes seems to be satisfied by way of licensing. The Committee gave credit to the 2006 OECD Guidelines for the Licensing of Genetic Inventions and recommended that at a European level, efforts should be made to create a standard agreement for biological material transfers.

Ethical issues: The Committee noted that as a result of the implementation of the Biotech Directive, the limitations and borders circumventing patents on inventions involving human biological material have been made clearer. Although The Committee found that such patents are still an ethically sensitive issue for many people, in light of the restrictive practice of EPO, there is no need for additional changes to the Patent Act. The Government however is recommended to monitor the outcome of an embryonic stem cell technology patent case pending before the EPO Enlarged Board of Appeal (G 2/06).

In summary, the Committee has made no proposals for introducing changes to the Swedish Patent Act in relation to biotechnological inventions. Although slightly outside the scope of its remit, the

Committee has proposed that the Government should amend the Patent Act to make it clearer that the first, second and following medical indications are patentable in accordance with Article 54.4 and 54.5 of the EPC 2000. Such amendment, if eventually proposed by the Government, would only be a matter of clarification and not a change of law.

Richard Lewinson, Stockholm

The Netherlands: Dutch Patent and Research & Development Box

Introduction

The Dutch government stimulates innovation and R&D activities through corporate income tax incentives in the Dutch Patent and Research & Development Box (the "Patent Box"). In the Patent Box, all profits allocable to self-developed intangible assets that are patented or qualifying research & development activities are subject to a special tax regime at a rate of 10%. The profits covered include royalty income and capital gains upon the (partial) disposal of the assets less their depreciation costs. Trade marks and similar assets do not fall within the scope of this special tax regime.

Patent Box -conditions

The Patent Box applies provided certain conditions are satisfied:

- The company (taxpayer) applies the Dutch Patent Box regime to its patented intangible asset or intangible assets that results from certain research & development projects (see below).
- The Patent Box regime must be elected in the corporate income tax return.
- The patent must be self-developed and not acquired from third parties on the market (but acquired intangible assets that are embedded in the ultimate patent are not excluded).
- The patent or research & development project contributes to at least 30% of the total profits realised from the intangible asset.
- Under the Patent Box, the costs of producing the intangible assets are deductible in the year covered. Conversely, the income realised with the intangible assets is taxed in the Patent Box at the reduced rate of 10% to the extent the income exceeds (threshold) the total amount of production costs of all elected Patent Box intangible assets (on an ongoing basis). In addition, the maximum amount of income from the intangible assets taxed at the reduced rate of 10% is capped at four times the total amount of the production costs of the elected Patent Box intangible assets (on an ongoing basis).
- Income not exceeding the threshold and income exceeding this capped amount will be taxed at the statutory rate of 25.5%.
- Intangible assets patented prior to 1 January 2007 do not qualify for the Dutch Patent Box;

Research & Development - conditions

Intangible assets that are not patented are also available for the Patent Box provided the intangible assets are the result of certain qualifying research & development projects. The threshold is set at €100,000 and the cap at €400,000. This expansion of the Patent Box tax rate applies from 1 January 2008 and promotes smaller research & development projects and activities.

Dutch double taxation treaties

If the Dutch owner of the intangible assets begins to license its intellectual property, it will generally generate royalty income under the license agreements from the licensee. Apart from EU Member States, most countries levy royalty withholding tax on payments of the royalties to a foreign licensor at rates of up to 30%. The Netherlands has a wide tax treaty network that provides for reduced royalty withholding tax rates reducing the tax leakage on royalty income to just 0%-15% withholding tax on royalties paid to licensors that are tax resident in The Netherlands. This makes The Netherlands an attractive jurisdiction to own intangible assets (intellectual property rights) and operate (license) the intangible assets out of The Netherlands at the same time.

Conclusion

The combination between this low tax regime in the Dutch Patent Box and the reduced withholding tax rates for royalties under the widespread Dutch double taxation treaties makes The Netherlands an attractive option for establishing R&D centres.

Ernst Barten, The Hague

The Netherlands: Recent patent decisions

In April 2008, two patent decisions were handed down by The Hague court:

Threat of infringement; sunset clause and out of court warnings

On 7 April 2008, The Hague preliminary relief judge handed down judgment in a patent infringement suit between Eli Lilly and Ratiopharm. Eli Lilly had argued that Ratiopharm threatened to infringe its European patent (and SPC) for olanzapine, the active ingredient of its blockbuster drug Zyprexa. The preliminary relief judge, however, concluded that no such threat had been made and therefore refused to grant a preliminary injunction.

At the time of the action, Ratiopharm had an application pending for a marketing authorisation (MA) for generic olanzapine via the decentralised procedure. In The Netherlands, it is standing case law that the mere holding of (or applying for) an MA does not constitute a threat of infringement. A patentee will have to demonstrate additional, specific circumstances that would make it plausible that the defendant is planning to introduce a competing drug during the term of the patent (or SPC). Such additional, specific circumstances were not demonstrated by Eli Lilly.

Amongst other things, the preliminary relief judge held that the so-called 'sunset clause' does

not constitute such an additional, specific circumstances. According to this clause (Article 47(4) of the Dutch Medicines Act, which is the Dutch implementation of Article 24(4-6) of EU Directive 2001/83; and for centralised MAs Article 14(4-6) of EU Regulation 726/2004) an MA shall cease to be valid if a product under the MA has not actually been placed on the market or been on the market for a period of three consecutive years. Eli Lilly had argued that the three year term starts at the date of grant, and indicated that Ratiopharm will therefore launch the product before expiry of its exclusive rights (11 September 2011). The preliminary relief judge, however, held that *"the obligation to enter the market with a product* [..] *only starts when the product can actually be brought onto the market, taking into account the various protection rules, that is to say after expiration of* (*extended*) *patent protection."*

Furthermore, Ratiopharm's pre-trial refusal to provide an undertaking of non-infringement did not constitute such additional, specific circumstance either. The preliminary relief judge held that *"under the circumstances of this case – where account must be taken of the fact that there was no prior actual infringement – the latter is not something to which Lilly is entitled. There is no general obligation under law to any written confirmation by third parties* (*or competitors*) *of anyone's absolute rights* [..]. *A refusal to provide such therefore does not constitute an* (*urgent*) *interest to obtain such in preliminary injunction proceedings, at least not without additional circumstances* [..]."

First ex parte provisional patent infringement injunction

On 1 May 2007, the Dutch rules implementing Directive 2004/48/EC (the so-called IP Enforcement Directive (IPED)) entered into force. As of that date, IP owners with an urgent interest can request the Dutch court to hand down preliminary injunctions without hearing the defendant to prevent a threatened infringement. 'Urgent interest' is particularly assumed if delay would cause irreparable harm to the IP owner.

On 1 April 2008, in *Meijn Food Processing Technology vs. Tieleman Food Equipment et al.*, the Hague court for the first time granted such an ex parte preliminary injunction in a patent infringement case.

Until now, patentees have adopted a rather reticent attitude towards the application of this enforcement tool. Amongst other reasons, it was not clear how the Dutch courts would deal with the criteria of urgent interest/irreparable harm in patent cases, especially considering that Dutch procedural law also provides for swift inter partes preliminary relief proceedings.

In its decision of 1 April, The Hague court did not set a very high threshold for urgent interest/irreparable harm. Ten years ago Meijn had warned one of the (group related) defendants. In its application for ex parte relief anno 2008, Meijn asserted that it had recently discovered that the defendants were infringing or threatening to infringe the patent.

Further, it asserted that due to the infringements that had occurred and due to the ongoing infringements that threatened to occur, it suffered irreparable harm. According to Meijn, the deterioration of its patent based exclusive position cannot (easily) be remedied by a financial compensation, taking into account the of price reduction effect caused by third party trade in the patented products. This was considered sufficient by the court.

Now that the first *ex parte* preliminary injunction has been handed down in a patent infringement action, it is likely that more will follow. In trade mark matters, *ex parte* preliminary injunctions are already relatively common. Given the reasoning of urgent interest/irreparable harm in Meijn's successful application, innovative drug companies may also want to test this enforcement tool for use in anticipated first generic entry.

Parties fearing that they may become the target of *ex parte* preliminary injunctions (or other *ex parte* measures under the implemented IPED rules) can file a so-called 'protective letter' with the courts. In such a protective letter - similar to the German 'Schutzschrift' - the potential defendant can request the court to refuse the preliminary measures that a third party may institute, or in any case not to render a decision without an *inter partes* hearing of the matter at hand. It should be noted that not all relevant courts in The Netherlands accept protective letter filing and therefore careful planning is advised.

Marc van Wijngaarden, The Hague

Contacts

Paul Hermant (Belgium) - paul.hermant@twobirds.com

Matthew Laight (China and Hong Kong) - matthew.laight@twobirds.com

Yves Bizollon (France) - yves.bizollon@twobirds.com

Wolfgang von Meibom and Ulrich Goebel (Germany) - wolfgang.von.meibom@twobirds.com / ulrich.goebel@twobirds.com

Massimiliano Mostardini (Italy) - massimiliano.mostardini@twobirds.com

Erik Limpens and Armand Killan (The Netherlands) - erik.limpens@twobirds.com / armand.killan@twobirds.com

Raquel Ballesteros (Spain) - raquel.ballesteros@twobirds.com

Richard Lewinson (Sweden) - richard.lewinson@twobirds.com

Gerry Kamstra (UK) - gerry.kamstra@twobirds.com

BIRD & BIRD

www.twobirds.com

Beijing

3614 China World Trade Centre,
Tower 1
1 Jianguomenwai Dajie
Chaoyang District
Beijing 100004, PRC
Tel: +86 10 6505 6667
Fax: +86 10 6505 9469

Brussels

Avenue d'Auderghem 22-28 bte 9
1040 Brussels
Belgium
Tel: +32 (0)2 282 6000
Fax: +32 (0)2 282 6011

Düsseldorf

Carl-Theodor-Straße 6
40213 Düsseldorf
Germany
Tel: +49 (0)211 2005 6000
Fax: +49 (0)211 2005 6011

Frankfurt

Taunusanlage 1
60329 Frankfurt am Main
Germany
Tel: +49 (0)69 74222 6000
Fax: +49 (0)69 74222 6011

The Hague

Van Alkemadelaan 700
2597 AW The Hague
P.O. Box 30311
2500 GH The Hague
The Netherlands
Tel: +31 (0)70 353 8800
Fax: +31 (0)70 353 8811

Helsinki

Mannerheimintie 8
00100 Helsinki
Finland
Tel: +358 (09) 622 6670
Fax: +358 (09) 622 6677

Hong Kong

33/F, Three Pacific Place
1 Queens Road East
Hong Kong
Tel: +852 2248 6000
Fax: +852 2248 6011

London

15 Fetter Lane
London
EC4A 1JP
UK
Tel: +44 (0)20 7415 6000
Fax: +44 (0)20 7415 6111

Lyon

23 boulevard Jules Favre
Lyon
69006
France
Tel : + 33 (0) 4 78 65 6000
Fax: + 33 (0) 4 78 65 6011

Madrid

Jorge Juan, 8, 1°
28001 Madrid
Spain
Tel: + 34 91 790 6000
Fax: + 34 91 790 6011

Milan

Via Montenapoleone, 10
20121 Milan
Italy
Tel: +39 02 30 35 6000
Fax: +39 02 30 35 6011

Munich

Pacellistrasse 14
80333 Munich
Germany
Tel: +49 (0)89 3581 6000
Fax: +49 (0)89 3581 6011

Paris

Centre d'Affaires Edouard VII
3 square Edouard VII
75009 Paris
France
Tel: +33 (0)1 42 68 6000
Fax: +33 (0)1 42 68 6011

Rome

Via di San Sebastianello, 9
00187 Rome
Italy
Tel: +39 06 69 66 7000
Fax: +39 06 69 66 7011

Stockholm

Norrlandsgatan 15
Box 7714
SE-103 95 Stockholm
Sweden
Tel: +46 (0)8 506 320 00
Fax: +46 (0)8 506 320 90