

Life Sciences Newsletter

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Fasken Martineau DuMoulin LLP

Major legal and regulatory developments in the area of life sciences have taken place in North America and Europe. Fasken Martineau is proud to present an overview of the most important ones.

Some spread beyond the boundaries of their jurisdiction, as in the case of decisions in the United Kingdom and the United States respecting the validity of patents on DNA sequencing. There have also been a number of decisions in the United Kingdom and Canada on patent selection. Notably, the Supreme Court of Canada confirmed that selection patents are not necessarily invalid due to anticipation, obviousness or double patenting. In the United Kingdom, decisions have been handed down in which the courts have confirmed that patent applications can be filed for compounds previously disclosed in a general formula of a chemical class.

An interesting development has forged a connection between patent law and labour law in the United Kingdom, where a court has ordered payment of compensation to an inventor-employee following the commercial success of an invention. We will also be looking at outsourcing limits in the life sciences sector that flow from the TUPE regulation in the United Kingdom.

A few commercial aspects will also be broached. We will discuss defining the notion of competition with generic products in contracts and review the action that authorities have taken in respect of market place competition and financing problems in the biotechnology sector in these difficult economic times. This will be followed by an outline of the most important legislative and regulatory measures taken in the pharmaceutical industry.

If you are interested in any of the topics in this bulletin, please contact the partner with whom you usually do business or the resource person whose contact information appears at the end of this bulletin. Also, any comments or suggestions likely to improve our bulletins would be greatly appreciated.

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INTELLECTUAL PROPERTY

Industrial Application

By Tracy Ko

The English Patents Court case of *Eli Lilly & Co v Human Genome Sciences Inc* [2008] EWHC 1903 (Pat) gives guidance on the requirement that an invention must have industrial application in order to be patentable.

The case concerned a Human Genome Sciences Inc ("HGS") European patent for the nucleotide and amino acid sequence of Neutrokine-a (the "Patent"), which was a novel member of the Tumour Necrosis Factor cytokines ("TNF") superfamily (a grouping of proteins that act to cause inflammation in the human body).

The sequence was found through bioinformatics, whereby computers identify new DNA sequences for proteins by making comparisons to similar known sequences, rather than by traditional laboratory methods. HGS filed a patent application soon after the sequence was determined, without carrying out any further research to explore its function, activity or potential use.

Eli Lilly & Co ("Lilly") applied to revoke the patent. Lilly's arguments included that the Patent did not disclose an invention capable of industrial application and on the grounds of insufficiency.

The judge, Kitchin J, reviewed the limited amount of UK, EU and US law on industrial application and the European Directive on the legal protection of biotechnological inventions (Directive 98/44/EC). He set down the following principles:

- 'Industrial' must be construed broadly and does not need to be conducted for profit.
- The capability of industrial exploitation must be derivable by the skilled person reading the patent description with the benefit of common general knowledge.
- The description must disclose a practical way of exploiting the invention in at least one field of industrial activity or a sound and concrete basis

for recognising that the contribution could lead to a practical application in industry.

- The purpose of the invention and how it can be used to solve a certain technical problem must be disclosed in definite technical terms. If the purpose and use is not obvious from the nature of the invention or the background art, then there must be a real prospect of exploitation directly derivable from the specification.
- Industrial application will be shown by: (a) a description of a research result that might yield an unidentified industrial application; (b) a speculative indication of possible objectives that might or might not be achievable by carrying out research; or (c) a description that leaves it to the skilled person to find out how to exploit the invention.
- The purpose of granting a patent is not to allow the patentee to reserve an unexplored field of research or to give the patentee unjustified control over others investigating the same area.
- The industrial application requirement will be satisfied if it is a substance which has a function essential for human health and it is identified as having such a function. However simply identifying the substance, even where the disclosure is considered a scientific achievement of great merit, would not meet the requirement if its function is unknown or not fully understood, no disease has been identified to be linked to its excess or deficiency, or no other practical use is suggested for it.
- The mere use of the claimed invention to find out more about its activities does not of itself satisfy the requirement.
- Whilst it is relevant to how a skilled person would understand the disclosure, the fact that an invention has been found by homology studies using bioinformatics techniques does not prevent it from being capable of being patented.

Taking into account the above principles, Kitchin J concluded that HGS patent was invalid for lack of industrial application, based on the following findings:

- The only contribution made by HGS' patent was to identify Neutrokin-a, but its application was not obvious or identified.
- The patent specifications contained nothing more than mere speculation as to possible conditions, actions and broad categories of disease for which Neutrokin-a may be useful and general statements on its potential activity and expression but no evidence to substantiate those claims. In Kitchin J's view, a skilled person reading the patent would not have been able to derive any industrial application from the patent.
- Simply making Neutrokin-a available as research tool is not sufficient to establish that the patent had industrial application.

Kitchin J also agreed with Lilly that the patent specification was wholly insufficient to allow the invention to be performed by a skilled person, such that the patent was also invalid on the grounds of insufficiency, as the skilled person would be "faced with a substantial research programme with an uncertain outcome" before Neutrokin-a could be put to any therapeutic or diagnostic use.

Comment: In addition to giving guidance as to how the requirement of industrial application will be interpreted by the courts, the case illustrates the difficulties that companies face when attempting to balance the desirability of seeking early protection of the results of their research and the risk of having the patent being held invalid; or waiting until further research has been undertaken to ensure the validity of the patent, at the risk of being pre-empted by competitors.

Supplementary Protection Certificates

By Fran Boateng-Muhammad

The case of Daiichi Pharmaceuticals v Generics (UK) Limited looks at some of the issues that can arise in relation to supplementary protection certificates (SPCs), specifically the validity of the underlying patents and the appropriate commencement date for an SPC.

Daiichi owned European patent (UK) No. 0206283 for levofloxacin (an enantiomer of a racemic compound called ofloxacin which is a member of the quinolone class of anti-microbial agents. The (-) enantiomer of ofloxacin was called levofloxacin) and a process for its preparation (the "Patent"). Daiichi also held an SPC granted in July 1998 on the marketed product based on the Patent. The Patent expired on June 2006 but the SPC is not due to expire until June 2011.

Generics challenged the validity of the SPC under article 15 of Council Regulation (EEC) 1768/92 (on SPCs) because grounds existed which would have justified the revocation of the Patent, or its limitation to the extent that levofloxacin would no longer have been protected by the claims on the grounds, inter alia, of lack of novelty and obviousness. Generics also challenged the SPC on the basis that the SPC's term should be based upon earlier marketing authorisations for ofloxacin as the first marketing authorisation, rather than that of levofloxacin. Both challenges were dismissed by the court.

As to the validity of the Patent, on the evidence presented, none of the attacks were entitled to succeed and in those circumstances, the challenge to the SPC failed. Even though the skilled person would appreciate that ofloxacin was a racemate, and that one enantiomer might have better activity than the other or the racemate, the judge acknowledged the potential in relation to quinolones and that there was uncertainty as to whether the enantiomers of quinolones would produce a better compound than the racemate. The Court decided that the skilled person would consider it obvious to try to resolve ofloxacin into enantiomers only if it were relatively easy to do so. Generics' own evidence indicated the difficulties in resolving the ofloxacin into its enantiomers.

The Court also rejected the second challenge to the term of the SPC. The judge determined that ofloxacin and levofloxacin were different products commenting "that an authorisation to place ofloxacin on the market as a medicinal product cannot be considered an authorisation to place levofloxacin on the market as a medicinal product".

Comment: This case represented a rare victory for research-based companies as to the validity and term

of an SPC. The court appeared to be influenced by the greater expertise of Daiichi's experts in the field of quinolones and the claimant's failure to demonstrate that the resolution of ofloxacin was relatively easy...

Zyprexa Patents

By Tracy Ko

The October 2008 case in the Patents Court (Dr Reddy's Laboratories (UK) Limited v Eli Lilly and Company Limited [2008] EWHC 2345 (Pat)) raises two issues of interest - firstly whether an earlier patent claim for a wide class of compounds would destroy the novelty of a later claim for an individual compound in that class, and secondly, a discussion on selection patents.

Dr Reddy's Laboratories (Dr Reddy) applied for a revocation of Eli Lilly & Co's ("Lilly's") European patent for Zyprexa (olanzapine) for the treatment of schizophrenia (the "Patent"). Dr Reddy argued that the Patent was invalid as it lacked novelty and would be obvious to the skilled addressee based on the prior art of a prior provisional patent application filed by Lilly that claimed a "Markush" formula (a general chemical class formula wide enough to cover millions of compounds (including olanzapine, although it was not specifically mentioned in the provisional patent) and other published papers relating to compounds almost identical to olanzapine (but again olanzapine was not specifically named). Dr Reddy also argued that given the prior art, Lilly's patent could only be considered valid if it satisfied the requirements applicable to selection patents, which Dr Reddy argued was not the case and therefore the patent should be revoked on the grounds of insufficiency.

Dr Reddy's attack on the Patent ultimately failed as Floyd J held in favour of Lilly on each of the grounds raised by Dr Reddy.

In arriving at his decision, Floyd J undertook an analysis of the prior art and concluded that none of it was sufficient to deprive Lilly's patent of its novelty, holding that the disclosure of a general formula for a chemical class does not necessarily deprive a later patent application for a specific compound of that class of its novelty. Approving *Synthon's Patent* [2006] RPC 10, Floyd J stated that "there are two requirements for a

claim to be anticipated by a prior document: disclosure and enablement". In the case of the disclosure of a general formula, his view was that making such a disclosure was a powerful way of covering a large number of compounds, and therefore that the focus would be on compounds actually described in that disclosure in an "individualised form". Applying this to the prior art relied upon by Dr Reddy, Floyd J found that none of the prior art contained "a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent" and therefore was not a sufficient disclosure of olanzapine to take away the novelty of Lilly's patent. Further, whilst Floyd J acknowledged that in theory, Dr Reddy was correct when it argued that Lilly's prior provisional patent for the Markush claim allowed a skilled person to write down all possible permutations of the compounds in the class (which would therefore include olanzapine), he dismissed it as being "wholly artificial to supposed that anyone would."

Having found that none of the prior art deprived Lilly's patent of its novelty, Floyd J did not need to make a decision on the issue of whether Lilly's patent was a valid selection patent. However, Floyd J's judgment nonetheless contains a useful review of the case law concluding that: 1) a selection patent must be based on some substantial advantage to be secured by the use of selected members, 2) all of the selected members must possess that advantage, and 3) the selection must be in respect of a special character which can fairly be said to be peculiar to the selected group.

Comment: It remains to be seen whether the higher courts will agree with Floyd J's view on selection patents, but this decision may foreshadow a change in the way that patentees approach such patents in the future.

Sufficiency of Damages for a Wrongly Injuncted Generic

By Ralph Cox

The High Court suggested that purely compensatory damages may not always be sufficient compensation for the marketer of a wrongly injuncted generic. The judge considered

there may even be situations in which a generic pharmaceutical company held off the market by a wrongful injunction should receive an account of profits from the patent-asserting, innovative pharma company.

The action concerned perindopril, an ACE inhibitor used to treat hypertension, for which Les Laboratoires Servier ("Servier") held patent rights. Its first generation patent for the drug expired in 2006 but Servier had obtained a further, second generation patent that extended its monopoly rights beyond that date. Nonetheless, following expiry of the first patent, Apotex Incorporated and its associated companies ("Apotex") launched a generic version of perindopril. Servier sued for infringement of the second patent and, on 3 August 2006, obtained an injunction pending trial.

As is standard, to obtain the injunction Servier gave a cross-undertaking to compensate Apotex for any losses caused to it by the injunction if subsequently found to have been incorrectly granted. This is exactly what came to pass as in a judgment dated 6 July 2007 the High Court held the patent invalid. The injunction was discharged as the High Court refused to extend it pending Servier's appeal. In a very short judgment, the Court of Appeal agreed that the patent was invalid stating that it was "the sort of patent which can give the patent system a bad name" and that it was "the court's job to see that try-ons such as the present patent get nowhere".

As a result, Apotex's perindopril had been wrongly held off the market for 11 months and it was entitled to compensation under the cross-undertaking. The judgment deciding the amount of that compensation was handed down on 9 October 2008 and contains various points of general interest.

First, are the questions the judge raised as to the applicability and adequacy of standard, compensatory damages. As the award under a cross-undertaking is strictly equitable compensation and not damages, it is arguable that it ought not be fettered by rigid adherence to the common law rules. But, even if these rules are followed, there is scope for aggravated or exemplary damages for "a blatant or cynical interference with a defendant's right to enter a pharmaceutical market with a generic drug by means of a second generation patent

that is a "try on" Alternatively, "where a wrongful extension of patent protection results in a benefit to the patent holder which exceeds and outstrips the loss which is occasioned to the generic company... then... "restitutionary damages" might be called for". This would effectively mean the generic company getting an account of the pharma company's profits (in Servier's case £74 million).

The second interesting aspect is the judge's review of the market dynamics following entry of a generic drug and the strategies used by pharma companies to try to mitigate those effects. In Servier's case this included agreements with "authorised generics" and true generic companies, which included payments of approximately £10 million to several such companies to stay off the market.

Though fully aware of such conduct by Servier, and the Court of Appeal's views of the patent, the judge decided that this was not a case in which greater than compensatory damages were called for. He therefore assessed the profits that Apotex would have made over the 11 months reaching a figure of £17.5 million, which he compared against the payments made to the authorised generics and the profits made by Servier to check that this would not constitute over-compensation.

Finally, just before this damages judgment was handed down Servier made a late application to raise the issue that the Canadian court had just (on 2 July 2008) upheld the validity of a Canadian patent for perindopril (see below) for related report. This patent was not one of Servier's but they submitted that Apotex would have infringed this patent if they had been allowed on the market during the injunction period as Apotex manufactured their perindopril in Canada. Servier claimed that Apotex should not be awarded damages when they would have acted unlawfully in another jurisdiction. The judge held that this submission was raised too late but the point is interesting and may be one to consider in another case.

EMPLOYEE INVENTIONS

First Ever Court Award of Compensation to Employee Inventors (UK Patents Act 1977)

By Jeremy Morton

On 11th February 2009, Mr Justice Floyd in the English Patents Court gave the first ever court award of compensation to employee inventors under the UK Patents Act 1977. Moreover, the amounts awarded were substantial.

Drs Kelly and Chiu were part of a research team at Amersham International Plc (now GE Healthcare Limited) that first synthesised the compound that went on to form the basis of a highly successful, patented radioactive imaging agent, Myoview, launched in 1994. In part due to Myoview's success, Amersham entered into a joint venture with Sumitomo and acquired Nihon Medi + Physics ('NMP'), establishing it as a global player in the radiopharmaceuticals market. Three years later, Amersham acquired Nycomed on the basis of profit projections that relied on Myoview's success. Total sales for the product exceeded £1.3bn.

Dr Chiu earned between £12,000 and £15,000 per annum over the 2 years he spent with the company. Dr Kelly, during his career with Amersham/GE earned between £23,000 and £71,500 per annum.

For patents filed prior to 01 January 2005 a court may award an employee compensation to be paid by the employer where (in summary):

- the employee has made an invention belonging to the employer for which a patent has been granted anywhere in the world
- the patent is of outstanding benefit to the employer
- as a result it is just that the employee should be compensated.

Guidance is provided as what constitutes a fair share for the employee of the benefit derived.

The Court drew the following principles:

- Compensation is for inventors who contribute to the formulation of the inventive concept, rather than for those who merely contribute to the process.
- 'Outstanding' is not defined in the legislation but means 'something special' or 'out of the ordinary', more than one would normally expect from the employee's paid duties. The court must estimate the situation as if there had been no patent and make a comparison. The disparity in benefit between employer and employee should be 'extreme'.
- If the Court decides the patent was of some benefit, it must then consider whether that benefit is outstanding. Valuation of the benefit is done in the light of all the evidence as to what has been and may be achieved as a result of the patent (or invention).

The judge noted that here the benefits for Amersham of preventing generic competition went far beyond what could normally be expected from the employees' assigned work. He also took account of the significance of the patent in helping Amersham achieve the corporate mergers and acquisitions that were of enormous benefit to them.

Assuming sales of £1 billion, the Court concluded that revenues would have been reduced by generic competition by at least £50 million, in the absence of the patents. The Court decided that a 3% share of the employer's benefit was a just and fair award to the employees, and apportioned this 2% to Kelly (£1 million) and 1% to Chiu (£500,000).

Comment: Employers can expect potential claimants to be encouraged by this development, and should bear in mind that UK employees may be entitled to compensation in respect of patent rights worldwide under the UK legislation - employees can make claims at any time before patent expiry. It should be noted that the law was changed in 2005 whereby the court could take into account the benefit from the invention overall, not just the benefit arising from the patent.

Biotechnology Patenting before the U.S. Federal Circuit

By Serge Lapointe

On January 9th 2009, the U.S. Federal Circuit heard oral arguments in *re Kubin*, a case which concerns a patent application for isolated cDNA that encodes Natural Killer Cell Activation Inducing Ligand.

This case is significant for biotechnology patenting because the question at issue is whether the existence in the prior art of a purified protein combined with "routine" cloning methods renders obvious a claim to a nucleic acid encoding the protein¹.

The Court now must determine whether the U.S. Board of Patent Appeals and Interferences erred as a matter of law in finding Kubin's claims obvious. The Court also has to review substantial evidence used by the Board in its finding that the Appellants did not possess the full scope of their claimed invention under 35 U.S.C. § 112 (written description requirement). Interestingly, the Court will be asked to opine also on how the U.S. Patent and Trademark Office interpreted the frequently-conflicting written description jurisprudence. In fact, during presentation of the oral argument, the Court questioned whether the recently updated training materials (used by examiners to examine patent applications) themselves correctly apply the written description requirement of 35 U.S.C. § 112, first paragraph².

We will provide a complete analysis of the decision when it becomes available.

Validity of Selection Patents in Canada

By Philip Swain

Late last year, the Supreme Court of Canada (SCC) in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 upheld the validity of selection patents in Canada. In this case, Apotex failed in their attempts to both invalidate Sanofi's selection patent, which covers the anti-coagulating drug PLAVIX, and have the SCC render selection patents invalid in Canada altogether.

Sanofi held a patent in which the genus claim covered more than 250,000 compounds useful for inhibiting platelet aggregation. One such compound was a racemic mixture of two enantiomers. Sanofi discovered that one of the enantiomers, the dextro-rotatory enantiomer, had an unexpectedly high therapeutic effect and low toxicity when compared to the levo-rotatory enantiomer and the racemic mixture claimed in the genus patent. Sanofi subsequently filed for, and was granted, a patent based on the superior properties of the dextro-rotatory enantiomer. Sanofi argued that its patent was a "selection" patent. Apotex alleged the patent was invalid for anticipation, obviousness and double patenting.

The SCC affirmed a two-step approach to establish a claim of anticipation. The approach requires separate consideration of "prior disclosure" and "enablement", both of which if proven, establishes that the prior art anticipates the invention. If a person skilled in the art, when reading a genus claim in a prior patent, does not discover the special advantages of the selection, then there is no anticipation by way of "prior disclosure". No trial and error is allowed. Similarly, if that person has to perform the invention with undue burden, then there is no anticipation by way of "enablement". A skilled reader of the patent should arrive at the invention the first time they try it and each time after, with limited trial and error. In this case, there was no anticipation because Sanofi's former patent did not reveal which enantiomer was more active even if it was known that one enantiomer is often more active than another. Also, even if the methods of separation of enantiomers were known, the fact is that extensive investigation over a period of months was requested.

¹ The Court is confining its analysis to a single claim: "73. An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48. »

² A PDF copy of the revised training materials which issued in March 2008 can be found on the U.S.P.T.O. web site at <http://www.uspto.gov/web/menu/written.pdf>

In addressing obviousness, the SCC examined the circumstances under which it might be appropriate to use the “obvious to try” criterion. The SCC concluded that for an invention to be obvious instead of it being merely “obvious to try” it must also be “more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.” In this case, the SCC found that Apotex failed to establish that the selected isomer was “obvious to try” from the 250,000 other possibilities in the earlier genus patent because it was not self-evident from the prior art and common general knowledge. In particular, there was no evidence that a person skilled in the art would have known which of the established separation techniques would work to separate the racemic mixture.

Finally, Apotex argued that selection patents extend the lifetime of the original genus patent by allowing so-called “evergreening” or double-patenting. The SCC rejected this and pointed out that third parties can obtain selection patents, and that they encourage innovation by identifying hitherto unknown and useful properties in the original genus. In a double-patenting challenge, the focus is on the claims of the two patents rather than on the disclosure and because the claims of the genus patent are broader than those of the selection patent, there cannot be double patenting.

Comment: *The lower courts heard two selection patent cases last year and concluded that “sufficient representative testing” is required to establish a valid selection patent. It remains to be seen what exactly is meant by this term, but clearly, the more comparative data the patentee includes in an application for a selection patent, and the more the patentee articulates the selection’s advantages over the previous genus, the stronger the argument will be for a proper patentable selection. Now with the SCC weighing in, the Sanofi decision may pave the way for more selection patents in Canada. In the meantime, with the affirmation of the two-part test for anticipation; the apparent softening of the historically strict test for obviousness; and the requirement for “sufficient representative testing”, we can expect that selection patents and applications for selection patents will be scrutinized for compliance with this decision.*

Early Working Exemption

By Ralph Cox

In *Laboratoires Servier v. Apotex*, the Canadian Federal Court ruled on numerous issues relating to Servier’s drug, perindopril, which is sold in Canada under the trademark COVERSYL™, and which is used primarily to treat hypertension and cardiac insufficiency.

Importantly, Apotex successfully convinced the Court that it should not be liable for any infringement relating to some specific amounts of perindopril that were produced *during commercialization* because these amounts fell under the experimental and regulatory use exemption of section 55.2(1) of the Canadian *Patent Act*. The provision states that:

55.2 (1) *It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.*

Section 55.2 is the so-called “early working” exemption which permits early working of a patented invention by others, such as generic drug companies, during the drug’s approval process by Health Canada. In the past, this exemption had been used solely for purposes of developing submissions for regulatory approval of the drug *before* commencement of its commercialization. In the present case, the Court was satisfied that some of the amounts of perindopril that were generated *during* commercialization for submission, analytical testing and the like, as may be required by the regulatory authorities in Canada, the United States and other jurisdiction, constituted uses of perindopril which qualified under the statutory exemptions of the *Patent Act*.

Proposed Fee Reductions for Electronically Filed Sequence Listings

By Kevin Holbeche

The Canadian Intellectual Property Office (CIPO) is currently seeking feedback on a number of proposed amendments to the *Patent Rules*.

Until January 5 to February 28, 2009, CIPO is seeking comments on proposed changes to the *Patent Rules*.

Proposed changes in this package include amendments to the *Patent Rules* pertaining to authorised correspondents, requests for examination, and reinstatement periods. CIPO has stated that these amendments “seek to safeguard applicants’ rights in situations where their rights would have been expunged due to a failure to meet certain procedural requirements. The package also reduces some operational requirements by providing more flexibility as to who can pay a fee and reinstate an abandoned application. Finally, the package also [...] reduces the prescribed delay to request examination.”

According to CIPO’s website, these amendments waive “some of the fees related to sequence listings filed electronically”. Under the proposed changes, electronically filed sequence listings would be effectively discounted from the excess page fees which are presently payable at grant of a patent. Notably, therefore, such fees would be eliminated in respect of sequence listings filed electronically.

This package of proposed changes is the third in a series of five consultations planned for 2009, under which interested parties may comment on the various proposed changes. Two consultation periods were previously concluded in early 2009 concerning: (1) “generally housekeeping” changes to the *Patent Rules*; and (2) proposed changes to practice related to the title of the invention.

Comment: *Later this year, in what promises to be another busy season, CIPO plans to conduct two further consultations (over periods yet to be determined at the time of print) concerning other contemplated changes to the Patent Rules. These upcoming consultations will concern: (i) amendments to Patent Appeal Board and final action procedures;*

and (ii) disclaimers, Section 29 of the Patent Rules, and claiming practice.

COMMERCIAL

Definitions of Generic Competition in Contracts

By Gary Howes

In licensing and other collaborations the onset of ‘generic competition’ may be cause for renegotiation of certain aspects of the agreement or reductions in payments. Such clauses tend to be contentious. Below we review the US and EU rules which will inform when such competition can be said to arise.

In the US, there are two possible ways to define generic competition in contracts, reflecting the two available routes to bring generic drugs to market.

The first route falls under section 505(j) of the Food, Drug and Cosmetic Act (“the Act”). A section 505(j) application is made when a product is identical in active ingredient, dosage form, strength, route of administration, labelling, quality, performance characteristics and intended use, among other things, to a previously approved product. This is known as an abbreviated new drug application (ANDA) and is not accompanied by clinical studies or evidence of safety and efficacy but information establishing bioequivalence to an originator product. This route represents a “true” generic as it is a direct copy of a previously approved product.

The second route falls under section 505(b)(2) of the Act where an application is accompanied by full reports of investigations of safety and effectiveness of a drug where at least some of the information comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A section 505(b)(2) application may therefore be submitted for a new chemical entity or for changes to an originator product. Applications made under Section 505(b)(2) are therefore not considered to be “true” generics as they are not duplicates of an originator product but simply a modification of an approved product.

Different tactics are employed when defining generic competition in commercial contracts. In license agreements, licensors will seek to receive the maximum amount of royalties under the license by attempting to limit the definition of generic competition to the “true” generic under Section 505(j) of the Act, whereas a licensee would attempt to include a wide definition of generic competition (covering both possible routes) in order to reduce the amount of royalties payable to the licensee when such generic competition enters the market.

In the EU, the introduction of generic products to market is contained in Directive 2001/83/EC on the Community Code relating to medicinal products for human use (as amended by Directive 2004/27/EC) (“the Directive”).

Article 10(1) of the Directive provides that an applicant with a “generic medicinal product” of a reference medicinal product can dispense with providing results of pre-clinical and clinical trials. The reference product may be considered to correspond to the Section 505(j) type of generic as it provides for a route to market for a direct copy of a previously authorised product and is therefore a “true” generic.

In circumstances where a medicinal product does not fall within the definition of a generic medicinal product, Article 10(3) of the Directive provides that an applicant can rely on results of preclinical tests and clinical trials and in part on new data to support a modification of an existing product. Article 10(3) of the Directive is therefore broadly equivalent to section 505(2) (b) of the Act and covers variants of the reference products which are therefore not “true” generics.

The Directive is more comprehensive than the Act in and provides for further routes to market for generics than the US regime.

Article 10(4) of the Directive provides that where a biological product is similar to a reference biological product, results of pre-clinical tests or clinical trials can be provided in support of the application. Article 10(a) establishes a gateway where the results of pre-clinical and clinical trials can be replaced by reference to published scientific literature of a well established

product. Article 10(b) further covers substances used in the composition of authorised medicinal products where the results of new pre-clinical tests or new clinical trials relating to that new combination can be provided. Finally, Article 10(c) of the Directive allows a possible route where consent has been given by the originator to cross- refer to existing data possessing the same qualitative and quantitative composition.

Comment: Although the US regime has two gateways for generics, the EU has several (although many may not fall within the strict definition of a “true” generic). Definitions of generic competition in contracts should therefore be considered in light of the differences between the regime in the US and the EU. Under the EU regime, there are more scenarios of generic competition to exclude when acting for licensors, however, licensees will have more options to consider.

In any event, mere market entry alone of the generic should not be the basis of a licensor to submit to reduced royalties as the reasoning behind such clauses is a reflection that the licensee’s volumes will decrease as a result of sales of the generic.

Parallel Trade and Quota Schemes

By Antonina Cuffaro

The ECJ has ruled that a pharmaceutical company that is dominant in a national market for a product abuses its dominant position if it refuses to meet orders from wholesalers for that product that are “ordinary”. Such companies are however, permitted to refuse to fulfill orders from wholesalers that are “out of the ordinary in terms of quantity”.

On September 16, 2008, the European Court of Justice (ECJ) delivered its judgment in the joined cases C-468/06 to C-478/06, *C-Sot. Lélos Kai Sia EE (and Others) v. GlaxoSmithKline AEVE*.

Until November 2000 GlaxoSmithKline distributed its pharmaceuticals in Greece through wholesalers. Its products included Lamictal® for epilepsy, in which it was found to be dominant. In addition to supplying the local market some wholesalers exported the product into Germany and the United Kingdom. GSK limited

its supply to amounts required to meet their domestic needs, plus a safety margin.

The wholesalers complained to the Greek competition authority, which in turn asked the ECJ to interpret the underlying EU law on abuse of dominance—Article 82 of the EC Treaty. This reference to the ECJ resulted in its judgment in the *Syfait* case delivered in May 2005 [*Case C-53/03, Syfait and Others [2005] ECR4609*] (see previous Fasken Martineau newsletters) where Advocate General Jacobs delivered an opinion to the ECJ in 2004 that the conduct in question did not automatically constitute an abuse. The ECJ declared itself unable to rule for jurisdictional reasons.

Following a preliminary reference from the Athens Appeal Court to the ECJ, Advocate General Ruiz-Jarabo (contrary to Francis Jacobs' view in the *Syfait* case), on 1 April 2008 considered that a dominant company's refusal to meet wholesalers' order with a view to limit parallel trade amounts to abusive practice.

Advocate General Ruiz-Jarabo disagreed with Advocate General Jacobs and found that to justify refusing to meet the orders of wholesalers of pharmaceutical products, with a view to reducing the harm caused by parallel trade, regulation of the market must compel the dominant undertaking to behave in that manner in order to protect its legitimate business interests.

The ECJ decided that whilst price regulation in the EU pharmaceuticals sector cannot preclude the application of EU competition rules, state intervention in the pricing of pharmaceuticals cannot be ignored when assessing the abuse by a dominant pharmaceutical company because it is likely to contribute to the creation of opportunities for parallel trade. However, it went further to say that Article 82 cannot operate such that the only solution left to dominant pharmaceutical companies is to refrain from marketing its products in low-priced Member States and that they must be able to take reasonable and proportionate steps to protect their own commercial interests.

The conclusion was that a dominant company may protect its commercial interests by refusing to fulfill orders that are "out of the ordinary" (i.e. out of proportion to those previously sold by customers to

meet demand in the relevant member state) but not "ordinary orders" of an existing customer solely because that customer intends to parallel export some of the goods supplied.

Comment: The ECJ clearly states that an order would be "out of the ordinary in terms of quantity" if it is out of proportion to those previously sold by wholesalers to meet demands in the relevant Member State. Otherwise, the only guidance offered by the ECJ on what constitutes an "ordinary" order is that consideration must be given to the previous business relations of the parties and the size of the orders in relation to market requirements in the relevant Member State. Despite the lack of certainty as to what exactly constitutes "ordinary" the ECJ's decision is positive for dominant pharmaceutical companies who may be able to refuse to supply wholesalers quantities of its products that are out of proportion to those previously supplied to meet the market needs in that Member State.

TUPE and Outsourcing

By Cerys Williams

Outsourcing arrangements (whether involving clinical research, manufacture, logistics, sales and marketing or facilities) are highly prevalent in the life sciences sector. The current economic climate is already likely to exaggerate this tendency further; as businesses seek to trim overheads, many are looking to remove employment cost and risk by contracting out business services. In entering into outsourcing arrangements, both client and service provider will need to navigate the minefield of TUPE (the Transfer of Undertakings (Protection of Employment) Regulations 2006).

Broadly, TUPE means that whenever a business outsources a service or moves from one service provider to another, any employees assigned to performing that service have preferential rights including:

- automatic transfer of their employment to the new service provider (with all historic liabilities);
- protection from dismissal in connection with the transfer;

- rights to information and consultation with their elected representatives;
- invalidation of changes to their employment terms in connection with the transfer (with limited exceptions).

TUPE is good news only for employees. The consequences for unwary service providers can be disastrous. Whole teams of employees can be landed on their doorstep (physically and metaphorically) and their options for integrating or removing them severely constrained by law. Equally, the former employer may be dismayed to see valued staff leave, particular where a re-tendering exercise means they are joining a key competitor. The client of the services is also likely to be unhappy, as changing provider does not rid them of the very staff who may have prompted the change, albeit now under new corporate flag.

TUPE applies where the services are provided pre-transfer by employees based in England or Wales irrespective of where the client or new service provider is based. This can come as a real shock to North American service providers who win a contract only to find themselves on a crash course in English employment law. While the geographical shift may make dismissals lawful, the non-UK service provider will be responsible for the severance costs, which are often significant in the UK. Take heed also that TUPE derives from European law and similar protections apply in all EU countries.

While there is no way to stop TUPE applying, with careful planning, its worst consequences can be mitigated by the following practical measures:

- Where possible, structure services, whether provided internally or externally, so that employees are not dedicated or assigned to a particular business division, contract or customer.
- Consider using services contracts for specific events or projects on a short-term, case by case basis, which fall within a specific TUPE exemption, rather than using a general retainer.
- Consider using self employed contractors or temps provided through an agency, rather than retaining employees. Only employees are protected by TUPE (but bear in mind that de facto

contracts of employment can be created inadvertently).

- Most importantly, make sure that TUPE and its associated risks and costs form part of your negotiations and pricing structure up front. Whilst parties cannot contractually prevent employees claiming under TUPE, there is nothing to stop the parties agreeing to a division of risk and cost as between themselves. If you are the new service provider, try to pass some of the risk and cost to the client, who may well be able to pass this on to the former services provider under existing contractual provisions.

INDUSTRY AFFAIRS

European Commission Pharmaceutical Sector Inquiry

By Stuart Richards

We review below the background and current status of the landmark Commission enquiry into the pharmaceutical industry, particularly its patent expiry and generic entry practices.

In January 2008 the Commission announced that it had launched the inquiry in response to concerns that competition in the sector may be stifled other than by parallel trade restrictions, highlighting the fact that there had been a decline in the number of new products reaching the market and instances of delays in the launch of generic medicines. The Commission stated that it was eager to establish if there were agreements restricting competition or abuses of dominant position and particularly blocking patents or settlements in patent disputes being used to delay the entry of generics.

The Commission took the unusual step of conducting unannounced inspections (“dawn raids”) at several pharmaceutical companies, including GlaxoSmithKline, AstraZeneca, Pfizer and Sanofi-Aventis, the first time this instrument has been used in a Commission sector inquiry.

In addition, the Commission initially sent questionnaires to approximately 100 companies that produce originator and/or generic medicines and then

widened its inquiry to include other stakeholders. It also spoke to European industry associations, including the European Federation of Pharmaceutical Industries and Associations (EFPIA) (representing the originator companies) and the European Generic Medicines Association (EGA) (representing the generic companies).

The Report, published in November 2008, days after a second series of dawn raids, makes clear that it does not seek to identify wrongdoing, rather that it provides information for the Commission to decide what further steps might be taken. However, its findings will cause concern that further action can indeed be expected. Indeed, the Commission press release is headed "Preliminary report on pharmaceutical sector inquiry highlights cost of pharmaceutical companies' delaying tactics" (such delay was said to be on average six months from end of originator's exclusivity to generic launch, at a cost of €3 billion between 2000 and 2007 in respect of the sample of medicines investigated in the Report) and the FAQ page on the Commission's website states "The main findings are that competition in this industry does not work as well as it should. According to the preliminary report there is evidence that originator companies have engaged in practices with the objective of delaying or blocking market entry of competing medicines."

While this interim report gives no advice to the Commission as to how to proceed, it is clear that some of the findings will give considerable food for thought when the Commission considers the matter further. A further consultation period closed at the end of January, and the Commission will prepare a final report, expected in the spring of 2009. Competition Commissioner Neelie Kroes has said "the Commission will not hesitate to open antitrust cases against companies where there are indications that the antitrust rules may have been breached".

In addition, beyond the inquiry itself, it should be noted that, during her speech given when the report was presented, the Competition Commissioner read out quotes from a number of potentially damaging documents found in the course of the dawn raids, and specifically said that this type of evidence shows the importance of carrying out investigations in this way. This may well indicate that while this was the first

sector enquiry to be started in this way, it is unlikely to be the last.

Medicines Rationing

By Antonina Cuffaro

The UK High Court has recently reviewed a Primary Care Trust's exceptionality policy as applied to the cancer drug lenalidomide.

In *R (Ross) v West Sussex PCT [2008] EWHC B15 (Admin) (Admin Ct)* Mr Ross, the claimant, applied to the local PCT for exceptional funding under the PCT's Individual Cases Policy for a trial course of lenalidomide. Lenalidomide is not ordinarily available to patients in the area.

Under the PCT's terms of reference when funding is sought for non-routine treatments under the PCT's Individual Cases Policy, a patient is required to demonstrate his exceptional circumstances and the clinical efficacy and cost effectiveness of the treatment. The PCT's Review Panel and appeal body rejected the claim on both grounds.

The PCT's terms of reference for the Review Panel included guidance on exceptionality. The guidance provided that there was no comprehensive definition of an exceptional case but stated that:

"In order for funding to be agreed there must be some unusual or unique clinical factor about the patient that suggests they are:

- Significantly different to the general population of patients with this condition.
- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition."

The guidance also provided that the panel could **not** make a decision to fund "where by doing so a precedent would be set that establishes a new policy (because the patient is not, in fact, exceptional, but representative of a group of patients)."

The High Court held that the PCT's exceptionality policy was unlawful because it meant that a patient was not 'exceptional' if his condition had characteristics

similar to those of other patients, thus setting a requirement of uniqueness that was unattainable.

The judge also criticised the PCT's failure to distinguish patients who were resistant to their previous treatment or who experienced unfavourable side effects from those (as was the case with the Claimant) who suffered intolerable side effects. In the judge's view, this distinction was "of vital importance" to the proper determination of exceptionality.

Cost effectiveness and clinical efficacy - the judge further found that the decision-makers had erred when assessing the clinical efficacy and cost effectiveness of the treatment. In the context of determining clinical efficacy the initial Review Panel was criticised for failing to seek expert advice. As a consequence, they had failed to appreciate the strength of the evidence in favour of treating a patient like the claimant with lenalidomide.

The judge held that the panels' views were such that no reasonable authority could reach and therefore irrational. The panel had misunderstood or failed to take account of various matters. For example, the panel had failed to offset the cost of the alternative care that the Claimant would otherwise be receiving.

Comment: *It is well-established that the courts cannot interfere with the funding priorities of the health authorities, provided they are reasonable - the court's role is limited to reviewing the lawfulness of the decision. A public authority is entitled to set its own policy for making decisions, provided it does so rationally, logically and lawfully.*

This decision may encourage unsuccessful drug companies to challenge reimbursement and funding decisions on the basis that the decision makers have misunderstood the evidence, thus allowing the courts to give at least some consideration to factual matters. As the judge noted, the courts will generally be prepared to subject highly sensitive "life and death" decisions to particularly rigorous scrutiny but of course as with all grounds of challenge in judicial review, mistake of fact is also applicable in the context of decisions by public bodies.

CORPORATE FINANCE

Biotech Support

By Fran Boateng-Muhammad

With concerns about the survival of the biotechnology industry growing, calls are now being made for the UK Government to step in and significantly invest in the sector (by establishing a couple of super funds in partnership with the private sector) to ensure its survival. It is feared that a major cash injection is the only hope for the industry's survival. The hope is that a government-industry partnership would encourage private investors.

The Head of Biotech Fund Managers, Excalibur, Sir Christopher Evans, along with 21 other leading figures have put forward to the Prime Minister, Gordon Brown, and Business Secretary, Lord Mandelson, a dossier in which they demand that a national biomedical public-private partnership which involves the Government and UK investors, be set up. Two funds of £500/£750 million each are envisaged with the Government and the private venture capital community equally providing the funding.

A national Biomedical Consolidation Fund, the first investment resource, would aim at encouraging small, sub-optimal UK medical science companies in the UK to partner with similar sized companies, pool knowledge, customers' revenue and resources and present funding proposals. The second, a National Super Grown Biomedical Fund, would invest in the brightest high growth individual prospects.

Comment: *It remains to be seen whether the Government will buy into the proposals set out in the Dossier and its recommendations.*

REGULATORY

“Essential Similarity” and the Mutual Recognition Procedure

By Fran Boateng-Muhammad

In November 2008 in *Synthon v The Licensing Authority of the Department of Health* the European

Court of Justice (ECJ) was asked to address whether a Member State can refuse an application for mutual recognition on the grounds that the medicinal product is not essentially similar to the reference product.

Under Article 10(1) of the Directive 2001/83/EC ('Directive'), (under the terminology in force before the Directive 2004/27/EC revision) if a medicinal product were essentially similar to another medicinal product authorised within the Community for not less than six or ten years and marketed in the Member State for which the application is made, full toxicological and pharmacological tests and trial data are not required.

The reference to the ECJ arose out of Synthon BV's ("Synthon") action against the MHRA following the MHRA's decision to refuse Synthon's application for mutual recognition of a marketing authorisation for 'Varox'. Varox had already been approved in Denmark by the Danish Medicines Agency ("DMA") under the abridged procedure using GSK's 'Seroxat' as the reference product. Whilst Varox and Seroxat were different salts, they shared paroxetine as the active moiety.

Using the DMA approval, Synthon applied to the MHRA (as a concerned member state) for mutual recognition ('MR') under Article 28 of the Directive requiring concerned member states to recognise the reference member state marketing authorisation unless there is a risk to public health. In the event of such objection the matter is dealt with by way of arbitration under Article 29. The MHRA refused Synthon's application on the basis that medicinal products containing different salts from the same active moiety could not be considered to be essentially similar. The MHRA did not suggest a risk to public health or initiate the arbitration process under Article 29.

Even though the MHRA subsequently changed its policy and deemed products with different salts essentially similar and granted Varox a marketing authorisation considered Synthon continued with its action to determine:

1) Whether Article 28 of the Directive allows a concerned member state considering whether to grant a marketing authorisation granted by a

reference member state under the MR procedure to refuse that application on the basis that it is not essentially similar to the reference product?

- 2) Whether the only two options available to such concerned Member State, would be to (a) recognise the marketing authorisation granted by the or (b) use the Article 29 procedure.
- 3) Whether a concerned member state's failure to grant a marketing authorisation based on the question of essential similarity or its policy on different salts not being essentially similar gives rise to a claim for damages.

The ECJ held that where an application for mutual recognition meets the requirements of Article 28, it must be held to be valid and that it must either (i) to recognise the marketing authorisation granted by the reference member state or (ii) object to the recognition of a marketing authorisation granted on the sole basis that the product may present a risk to public health. A member state cannot refuse an application for mutual recognition on the grounds that the medicinal product is not essentially similar to the reference product. In addition the Court considered that such a failure to grant a marketing authorisation was capable of rendering that concerned member state liable in damages.

***Comment:** It is clear from the ECJ decision that only one ground is open to a Concerned Member State to refuse to recognise a marketing authorisation granted by Reference Member State, namely the risk to public health and in relying on this ground, the procedure in Article 29 must be followed. The rationale for this decision in part is that unless marketing authorisation granted by a Reference Member State are recognised in other Member States, the mutual recognition procedure would otherwise be deprived of its role in securing the objectives of the Directive, such as the free movement of medicinal products in the internal market. The ECJ was keen to emphasise that it based its ruling on the principle of mutual recognition and not on the concept of essential similarity. Consequently, irrespective of whether or not the application has been submitted under the abridged procedure, a concerned Member State will have very little power to depart from the reference Member*

State's position, save for where there is a risk to public health.

MHRA Guidance for Website Advertising of Medicines

By Tracy Ko

In November 2008, the UK Medicines and Healthcare products Regulatory Agency (MHRA) published guidance relating to the advertising of prescription only medicine (POM) on consumer websites to assist in compliance with the Medicines (Advertising) Regulations 1994.

The guidance is aimed at companies and organisations that provide medical treatment services that may lead to the prescription and supply of a prescription medicine, but is not intended to be for pharmaceutical companies and those who actually hold the marketing authorisations.

It applies to all consumer websites (rather than those aimed towards healthcare professionals) registered in the UK or aimed at the UK audience.

Permitted information includes that relating to:

- promotion of the medical services provided by the company/organisation
- information on a certain medical condition or disease and a balanced and factual overview of the available therapeutic options
- links and navigation aids for certain medical conditions or diseases
- indicative costs of a consultation and course of treatment
- icons to encourage people to undertake a medical consultation

Prohibited information includes:

- direct references to named POMs in relation to a medical condition
- links and navigations aids to specific POMs
- costs of specific POMs, except after a prescription has been issued

- icons or features encouraging the purchase of POMs
- mentions of unlicensed medicines
- using website addresses that name specific POMs in their core URL

A full copy of the MHRA's guidance can be found at the following link:

<http://www.mhra.gov.uk/home/groups/pl-a/documents/websiteresources/con031140.pdf>

New EU Pharma Package

By Yasmina Hadded

In December 2008, the European Commission unveiled the long-awaited pharmaceutical package, consisting of three separate legislative proposals and a political communication, together aiming to improve the safety, innovation and accessibility of prescription medicines within the EU.

The political communication ("the Communication") proposes 25 separate measures on various topics focusing on setting the scene for the three legislative proposals. In addition, the Communication suggests several non-legislative initiatives including pricing/reimbursement decisions and increased cooperation with current major and future emerging partners. The Communication also recognises that the EU has fallen behind in pharmaceutical innovation and aims to restore the position of the EU as a leader in pharmaceutical excellence.

The legislative proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 comprise three parts.

The first would allow marketing authorisation holders to provide information to patients on prescription-only medicines if rigid criteria are complied with. Currently Member States may establish their own approaches regarding the provision of such information as long as the prohibition on advertising is upheld. The Commission felt that this resulted in disparities in practice amongst Member States and have therefore sought to create uniformity within the community whilst continuing to uphold in principle the ban on

advertising. The proposal aims to establish harmonised conditions on the content of information which marketing authorisation holders are able to disseminate. Such information will be subject to strict conditions, ensuring that it is of high - quality and non-promotional. The Commission will both determine authorised channels of communication and establish monitoring rules including imposing an obligation on Member States to establish a monitoring system to ensure that the above mentioned legislative proposals are complied with.

The second proposal addresses the need for improving the EU's system for pharmacovigilance (the safety monitoring of medicines). The current system, which allows for fast removal of any drugs which have been authorised and have later needed to be taken off the market where adverse reaction to the product have associated it with an unacceptable level of risk, is complex and in need of harmonisation. The Commission therefore proposes to simplify the current rules and procedures in order to create better protection of public health. The EMEA's position as the coordinating body is to be "reinforced" by the creation of a new scientific panel called the Pharmacovigilance Risk Assessment Advisory Committee (PRAAC) designed to work alongside the Committee for Medicinal Products for Human Use (CHMP) and representatives from Member States. The Commission have also proposed an overhaul of the Eudravigilance database with the aim for it to be the single point of receipt of pharmacovigilance information and propose the introduction of a dedicated website to communicate safety issues within the EU.

The third of the legislative proposals aims at tightening safeguards for preventing the entry of false medicines which can be unsafe, inefficient or low quality and pose a risk to human health. The Commission proposes to create a number of safety features, including improving control at EU borders, which will allow all high-risk products to be easily traced and further monitor the quality and authenticity of the active pharmaceutical ingredients.

The legislative proposals will now come before the European Parliament and the Council of Ministers under the EU's co-decision procedure where the content and detail of the proposals will be debated.

Comment: The long-awaited package has been positively received by the pharmaceutical industry. Brian Ager, the Director General of EFPIA, said "now the challenge is to make sure that the provisions proceed with no further delays and no dilutions to the measures proposed".

The preemption doctrine and its impact on litigation in the Pharmaceutical industry

By Mathieu Gagné and Pascal Bouchard

The preemption doctrine, a legal theory developed by the American courts, finds its source mainly in the U.S. Constitution.³ Basically, it leads to the recognition of the supremacy of federal law over state law. Under the doctrine, any state law that conflicts with a federal law is void.

This doctrine takes on a whole new dimension in the area of pharmaceuticals due to the broad spectrum of federally-regulated activities and the vast quantity of state-based suits.

The Supreme Court of the United States recently applied the preemption doctrine in a lawsuit that a patient brought against the manufacturer of a class III medical device – an angioplasty catheter.⁴ The suit, founded on state common law, was dismissed because a pre-market approval system had been implemented under federal law and due to the presence of a clause ensuring the paramountcy of federal over state law.⁵

But what of health products – like prescription drugs – for which federal legislation does not claim paramountcy over state law? This is the question that the Supreme Court of the United States will hopefully answer in the next few months. In the matter of *Wyeth v. Levine*⁶ currently in deliberation, the Supreme Court will be determining whether Food & Drug Administration standards governing information that should appear on prescription drug monographs – standards that result from a complex and complete

³ U.S. CONST., Art. VI, § 2

⁴ *Reigel v. Medtronic Inc.*, 128 S.C. t. 999 [2008]

⁵ *Medical Device Amendments* (21 U.S.C. § 360 k(a) to the *Food & Drug Cosmetic Act* (21 U.S.C. § 301)

⁶ U.S. Supreme Court, No. 06-1249

normative set of federal jurisdiction – supersede state standards that impose additional or different risk disclosure requirements and render them inapplicable. If they do, this could result in the dismissal of all suits and actions based on such causes of action. While there are standards that apply to class III medical devices, federal legislation contains no specific provision regarding the paramountcy, over state law, of federal rules applicable to the prescription-drug approval mechanism. The manufacturer is therefore requesting that the action be dismissed on the grounds that there is an implied preemption doctrine.

The Canadian counterpart of the preemption doctrine is the doctrine of federal paramountcy, which holds that a provincial law of general application, like the Consumer Protection Act or the Civil Code of Québec, does not apply if its effects are incompatible with federal legislation and regulations on research, development, commercialisation, marketing,

advertising, packaging and drug sale activities that are governed by the Food and Drugs Act and its regulations. However, many actions in the pharmaceutical industry are based on provincial legislation, and seek to guarantee, among other things, a level of quality, safety and information.

Various actions currently pending before the Canadian courts might soon shed new light on the issue.

Latest news ... On March 4, 2009, the U.S. Supreme Court handed down a 6-3 decision in *Wyeth v. Levine*.⁷ Penned by Justice Stevens, this ruling from the highest court in the United States dismissed *Wyeth's* argument that the “preemption doctrine” is implied in the sale of prescription drugs. *Wyeth* was therefore ordered to pay Ms. Levine US\$6.7 million. Look for our detailed commentary on this decision in our upcoming Bulletin.

⁷ <http://www.supremecourt.us/opinions/08pdf/06-1249.pdf>

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