Legal and regulatory update

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Legal and regulatory update

UK REVIEW
Pharmaceuticals company fined £6.8m for abusive pricing

The Office of Fair Trading (OFT) has recently found Genzyme Limited guilty of abusing its dominant position in the market for the supply of drugs for the treatment of Gaucher disease, in breach of the 'Chapter II prohibition' of the Competition Act 1998. Genzyme supplies a drug called Cerezyme, which until recently was the only treatment for Gaucher disease, a rare inherited genetic disorder. Owing to the serious nature of the infringement, the OFT fined Genzyme £6.8m.

Genzyme was shown to have abused its dominant position by charging the NHS a price for Cerezyme that included home delivery of the drug and the provision of homecare services. This effectively ensured that only Genzyme, or an entity operating under contract with it, could provide such services, and thereby deprived the NHS and patients of a choice in delivery/homecare provider. The OFT also decided that Genzyme, as the dominant supplier, had further infringed the Competition Act by charging independent third party delivery and homecare providers an excessive price for the drug. Genzyme's price was so high that it prevented them from making a reasonable profit (conduct generally referred to as 'margin squeezing') and therefore from running a viable business in competition with Genzyme's own downstream operations. This excessive pricing also ensured that no new entrants in the market could viably begin to offer these services. Such behaviour guaranteed that Genzyme would retain its dominant position.

As well as imposing a substantial fine and ordering Genzyme to end its exclusionary pricing tactics immediately, the OFT also required Genzyme to offer to supply the drug to the NHS at a stand-alone price, ie exclusive of delivery and homecare services, and to supply it to independent parties at a price no higher than one to be agreed between Genzyme and the Department of Health for the stand-alone product only.

OFT recommends liberalisation of the UK pharmacy market

Earlier this year, the OFT reported that current regulations that limit the number and location of community pharmacies in the UK should be ended. The OFT found these regulations to be excessively restrictive on UK pharmacy markets, worth £8.6bn annually. This resulted in a restriction of consumer choice and convenience in terms of location of pharmacies and opening hours, a restriction in access to lower-priced over-the-counter medicines (meaning that consumers are paying £30m a year more than they would have to if the market was deregulated), and a reduction in incentives for pharmacies to compete on additional customer services. As well as stifling innovation and responsiveness to changing consumer needs, these regulations, the OFT estimated, cost businesses a staggering £16m a year in compliance, and the NHS £10m a year in administration costs alone.

Under the current regulations, pharmacists are permitted to dispense NHS prescriptions only where local health authorities are satisfied that this is 'necessary or desirable' for the adequate provision of pharmaceutical services in the local community. These rules have basically meant that while demand has grown steadily, and is set to continue, the number of pharmacies has remained static. Entry of new pharmacy businesses is effectively blocked. The OFT has recommended that these regulations

should be lifted, meaning that all registered pharmacies with qualified staff would be able to dispense NHS prescriptions.

The Government has since announced that it will bring forward proposals in response to the report before its summer recess, and in the interim will publish a progress report at the end of June.

Takeda Chemical Industries Limited *v* Comptroller of the Patent Office

Takeda was granted two patents concerning lansoprazole and was granted a marketing authorisation for lansoprazole for the treatment of the upper gastro-intestinal tract. Takeda carried out further research using lansoprazole in combination with antibiotics (clarithromycin, amoxycillin and metronizadole) which proved effective in eliminating *Helicobacter pylori*. On the basis of this research, Takeda applied for a further product licence in relation to the new indication. The Medicines Control Agency granted a product licence by varying the existing marketing authorisation to include the new indication. Following the grant, Takeda applied for supplementary protection certificates (SPCs) in relation to the combination of lansoprazole with each antibiotic and in relation to each patent.

This was an appeal on two points (both of which failed) from a decision of Mr Walker acting on behalf of the Comptroller of Patents, who refused to grant the six SPCs requested by Takeda. Jacob J considered Article 3 of the SPC Regulation (EEC/1768/92), which sets out the conditions for obtaining an SPC, and reached the following conclusion. Article 3(a) requires that the product is protected by a basic patent in force. Agreeing with Mr Walker, Jacob J took the view that the SPC system was designed to provide protection supplementary to that provided by the patent by extending the relevant part of the patent, and in this case it was only the lansoprazole element of the product that was protected by the patents and not lansoprazole in combination with an antibiotic. An SPC could not be used to widen the ambit of an applicant's monopoly. In this case, Takeda's monopoly was in lansoprazole and not lansoprazole in combination with an antibiotic.

The second issue on appeal related to Article 3(b) which provides a further condition for the grant of an SPC, namely that a valid authorisation to place the product on the market as a medicinal product must have been granted in accordance with Directive 65/65/EC. Jacob J held that the applications plainly did not satisfy Article 3(b). The current application related to the original product licence (23rd February, 1994), which was, even after variation, only a licence in respect of lansoprazole and no other chemical compound, as opposed to the later product licence (4th January, 1999), which was a licence for a combination of lansoprazole and a combination of two antibiotics.

It was suggested that, had the application succeeded with respect to Article 3(a), Takeda should have been given the opportunity to base its application for an SPC on the later product licence. Jacob J held that given his decision regarding Article 3(a), this was not relevant.

Case highlights the difference between loans and dividends

***First Global Media Group* v *Larkin* [2003] All ER (D) 128 (Apr)**

The defendant had been a director of First Global Media Group (the company). Having received tax advice, the defendant and another director were paid for their services by the company granting them dividends rather than paying them salaries. For this purpose, the company had a loan account from which the defendant and the other director withdrew funds as 'advance dividends'. Annually, the company would declare a dividend that would cancel out the 'advance dividends'. The company went into liquidation and

the liquidators issued a claim for £165,000. The money owed by the defendant had been drawn down by him as 'advance dividends' but the company had not declared a dividend to clear the debt. The defendant argued that the debt was in fact some form of interim dividend or remuneration. The liquidators applied to the court to have the defence struck out and for summary judgment. The key issue for the determination of the court was whether the moneys had been paid as a loan or as a dividend.

On 8th April, 2003, Jacob J in the Chancery Division held that funds passed to the defendant which had been called 'advanced dividends' were in fact loans made to the defendant by the company. The moneys were now owed as there had been no dividend declared by the company. The court found in favour of the liquidators, who applied to have the moneys repaid and the application for summary judgment was granted.

Company Directors (Health and Safety) Bill (Bill No. 82)

This Bill received its first reading in the House of Commons on 25th March, 2003. It is designed to introduce a statutory obligation to appoint a director as the health and safety director. This director and any other directors will have certain obligations in relation to health and safety. If passed, it is anticipated that this Bill would turn the principles behind existing guidelines into statutory obligations. The Bill was brought into being because of the increasing interest in raising corporate responsibility. The Rt Hon. Ross Cranston MP highlighted the Clapham and Paddington rail accidents and recognised that while some companies had high health and safety standards, every company's standards should be similarly high.

At the time of writing, no text of the Bill was available. We shall report on any details of the proposed change in the law relating to companies as it becomes available.

EU REVIEW

Proposed amendments to Directive 2001/83/EC on the Community Code relating to medicinal products for human use

This was a proposal sent to the Council and European Parliament[1] on 26th November, 2001. An Opinion was given by the European Economic and Social Committee[2] followed by the official Position of Parliament (first reading).[3]

The original draft of the Directive on medicines for human use[4] has thereby been extensively amended to take into account the objections of the European Parliament. Overall, more than 80 revisions have been proposed and argued. The most significant from the point of view of those in the commercial sector appear below.

In summary, the general objective of the proposal was to harmonise Regulation 2309/93[5] and Directives 2001/83/EC and 2001/82/EC on the Community codes relating to medicinal products for human and veterinary use.[6] This objective can be factored into four broad categories:

- To guarantee a high level of public health protection, particularly by providing patients as swiftly as possible with innovative and reliable products and by increasing market surveillance by reinforcing monitoring and pharmacovigilence procedures.

- To complete the internal market in pharmaceutical products while taking account of the implications of globalisation, and to establish a regulatory and legislative framework that favours the competitiveness of the European pharmaceuticals sector.

- To meet the challenges of the future enlargement of the EU.

- To rationalise and simplify the system, thus improving its overall consistency

and visibility and transparency of procedures.

Unannounced inspection

Amendment 125 on the possibility of unannounced inspections by competent authorities[7] states that competent authorities may also carry out unannounced inspections at the premises of manufacturers of active substances used as starting materials, or at premises of marketing authorisation holders, whenever it considers that there are serious grounds for suspecting non-compliance with GMP (good manufacturing practice). Such inspections may be carried out at the request of the member state, the Commission or the European Agency for the Evaluation of Medicinal Products (EMEA). This is obviously of concern to all pharmaceutical manufacturers.

Eight-year data exclusivity rejected

The Commission cannot accept **Amendment 16** as proposed, which is aimed to limit to eight years the data protection period for products containing new substances not previously included in veterinary medicinal products in the EU. This amendment has the knock-on effect of shifting the balance between protecting innovation and supporting generic competition and innovation.

Three-year limit on authorisations[8]

Following proposed **Amendments 57 and 58** on the invalidity of marketing authorisations where the authorised product is not effectively marketed, such authorisations should lapse according to the original proposal by the European Parliament. Unfortunately, 'effectively marketed' does not appear to be defined, although Articles 24(2) and (3) dictate that any authorisation that is not followed within three years of its issue by the actual placing on the market of the authorised product in the authorising member state, shall cease to be valid.

The Commission, however, has stipulated that any competent authority may, in exceptional circumstances and on public health grounds, grant derogation from these provisions when justified. Similar Parliament recommendations have been drafted for products already authorised but which have not been marketed for three consecutive years, but the Commission has proposed an analogous derogation.

No additional three-year protection

The Commission has refused to accept **Amendment 40**. This would potentially introduce an additional period of three years' data protection for data submitted with regard to authorising new indications for products that have already been authorised. This is objectionable because the provision would lead to an unacceptable extension of the data protection period already available for such products, the corollary of which is that it would interfere with generic circulation.

Salts, esters and other derivatives are to be considered equivalent

Amendment 156 intends to make the definition of generic products more precise. Article 10(2)(b) will be as follows:

> . . . generic medicinal product shall mean a medicinal product which has the same qualitative and quantitative composition in active principles and the same pharmaceutical form, and whose bio-equivalence with the reference medicinal product has been demonstrated by appropriate bioavailability tests. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered as the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. . .

Five-year renewal of marketing authorisation

The European Parliament has rejected in **Amendments 185 and 186** the Commission's proposal that the current need to renew marketing authorisations every five years should be abolished. The relevant proposed amendments attempt to change the period of validity of a marketing authorisation so that after a first renewal of the existing five-year authorisation, it should then be considered to be indefinite.[9] Recital 13 and Article 24(1) are therefore proposed to be amended as follows:

> Marketing authorisations for ***new*** medicinal products must initially be limited to five years' validity. After the first renewal, the marketing authorisation shall be considered to be valid indefinitely. Furthermore, any authorisation not used for three consecutive years, that is, it has not led to the actual placing on the market of a medicinal product during that period, should be considered invalid in order, in particular, to avoid the administrative burden linked to maintaining such authorisations.[10]
>
> [without prejudice to the above provision] . . . authorisations may be renewed after five years on the basis of a comparative reassessment of the risk/benefit balance. When, after five years, the marketing authorisation is renewed, the holder shall provide a consolidated version of the dossier on the quality, safety and efficacy of the medicinal product which includes all the modifications made during its five years of validity. . . after this renewal, the marketing authorisation shall be valid indefinitely.

Advertising and information

Amendment 99 attempts to distinguish advertising from the mere provision of information. The Commission has recommended rewording of the relevant provision[11] as follows:

> Advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. . .

In addition, **Amendments 106 and 191** propose that a rewording is necessary in relation to the provisions for non-proprietary names.[12] As such:

> Member States may decide that the advertising of a medicinal product to the general public may . . . include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark if it is intended solely as a reminder.

Amendment 108 allows reference to a trade mark under certain conditions but requires re-wording of Article 89(2) concerning the advertising of medicinal products. It proposes that:

> Member States may decide that the advertising of a medicinal product to persons qualified to prescribe or supply such products may . . . include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.

Bolar provisions refused

The Commission has rejected **Amendments 34, 39, 134 and 202.** These proposed to introduce the possibility of conducting trials for authorisations for generic products during the ten-year data exclusivity period. They also proposed that Bolar-type clauses be extended to cover generic submissions for authorisation and exports during patent term and/or SPC protection.

The Commission observed that such derogation from rights deriving from the protection of data and from intellectual property (IP) rights was detrimental and that it was important to maintain the balance between the ten-year period for

data protection for innovative products and Bolar-type clauses allowing tests and trials for generics during IP protection.

No to cloning and restrictions on stem cell research

Report on medicine: standards of quality and safety of human tissues and cells

On 10th April, 2003, the European Parliament adopted over 80 amendments to the Commission's proposal to set quality and safety standards for the donation, procurement, testing, processing, storage and distribution of human tissues and cells. The Parliament welcomed the proposal but also adopted amendments relating to the scope of the directive, compensation for tissue and cell donation, donor consent, donor anonymity and ethical issues.

Ethical issues

On ethics, MEPs insist that this directive expressly recognises the right of member states to maintain or introduce more stringent protective measures. As a minimum, member states shall prohibit research on human cloning for reproductive purposes and research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei. Cloned human embryos, and human/animal hybrid embryos produced by cloning, aggregation or any other procedure, and cells and tissues derived from them, shall be excluded as sources of material for transplant. MEPs also adopted an amendment saying that the procurement of tissues after abortion shall require special rules.

Donations to be voluntary and unpaid

MEPs welcomed the Commission's view that tissue and cell transplantation programmes should be based on voluntary and unpaid donation. Although MEPs do not want to keep the private sector out completely, an amendment was adopted demanding that member states encourage strong public and non-profit sector involvement in the provision of tissue and cell transplant services and related research. Another amendment calls for donations to be made with the donor's free will and without any payment except compensation, for example travel expenses. However, rules on compensation should be left to the member states.

Traceability and anonymity

MEPs also insist that EU-wide rules should be laid down to ensure the traceability of tissues and cells of human origin. Even though anonymity of donors was strongly supported, the Parliament adopted an amendment saying that in the case of gametes in particular, member states may waive anonymity in order to respect the right of children to know their genetic parents, but only in exceptional circumstances.

Donor consent

Another key issue is the procurement of human tissues or cells, which the Commission says should be carried out only after all mandatory consent requirements in force in a member state have been met. The Parliament wants to go considerably further by demanding that the EU member states take account of the minimum requirements set out below.

Before any procurement of tissues or cells, living donors must have given their prior, informed and express written consent or, in exceptional cases, such consent may be given orally in the presence of witnesses. Until the moment the donated tissues or cells are actually used, donors shall have the right to withdraw their consent without having to face any negative consequences. The donor must be informed about this right and must be given the opportunity, in a prior interview with a doctor, to understand the objectives, risks and inconveniences of retrieval, and the conditions under which the retrieval is to be conducted.

In the case of procurement of tissues and cells from deceased persons, donors must not have expressly refused their consent during their lifetime. In the absence of any declaration by donors during their lifetime, tissues or cells may be procured only if the relatives of the deceased have given their prior, express consent.

Cells and tissues may not be retrieved for the purpose of allogeneic donation from individuals who are not in a position to give informed legal consent. Exceptionally, regenerative tissue and regenerative cells may be retrieved under strict conditions, eg if the recipient is a brother or sister of a donor, the donation is potentially lifesaving for the recipient and the potential donor does not refuse.

Clarification of scope of the Directive

The Commission's proposal excludes blood and blood products, human organs as well as organs, tissues or cells of animal origin from the scope of the Directive. The Parliament clarifies the Directive's scope even further by including the research use of tissues, haematopoietic peripheral blood, placenta and bone marrow stem cells, reproductive cells, foetal tissues and cells, adult and embryonic stem cells. On the other hand, hair, nails and body waste products are excluded.

Although MEPs rejected amendments calling for organs to be covered by the Directive, they urged the Commission to bring forward before July 2003 a separate legislative proposal on human organ transplants, saying that the Commission should take into account the severe shortages that result in many patients going untreated. No proposal has been published at the time of going to press.

The Parliament also adopted an amendment saying that reprogrammed differentiated cells, and genetically modified cells or tissues for human therapy, are still in the research phase, but nevertheless pose different regulatory problems that will need to be addressed in due course.

Bodies managing a healthcare system not treated as an 'undertaking' and therefore not subject to Articles 81 and 82

The Court of First Instance (CFI) has decided that bodies, including three ministries of the Spanish Government, which run the Spanish national health system (the 'SNS Bodies'), do not constitute 'undertakings', and are therefore not subject to EC competition laws in relation to their purchase of medical goods and equipment necessary to operate the SNS. This matter of when healthcare bodies might be said to constitute undertakings, was previously visited in the November 2002 issue, in relation to the OFT decision in Bettercare.

FENIN, an association of the majority of the undertakings that market medical goods and equipment used in Spanish hospitals, complained to the Commission that the SNS Bodies were abusing their dominant position in the Spanish market for medical goods and equipment contrary to Article 82 of the EC Treaty, by taking 300 days on average to pay their debts to FENIN members, while settling their debts to other suppliers within a much shorter time period. The Commission had, in an earlier action, rejected the complaint on the basis that the SNS Bodies were not acting as 'undertakings' when they purchased medical goods and equipment from FENIN, a condition essential in order for Article 82 to apply.

The CFI confirmed that for EC competition law purposes, the concept of an undertaking covered any entity engaged in 'an economic activity', regardless of its legal status or the way in which it was financed. The Court decided that as it was the activity of offering goods and services on a given market, and not the mere fact of making purchases, that constituted the characteristic feature of 'an economic activity', one could not dissociate the purchasing of goods from their subsequent use. On this basis, therefore, an entity that purchased goods – even in

substantial quantities, and where it wielded considerable economic power – not for the purpose of offering them as part of an economic activity, but rather to use them in a different context, such as of a purely social nature, was not acting as an undertaking simply because it was a purchaser on a given market.

The Court went on to explain that where an entity fulfils a purely social function, its activities are based on national solidarity, and it is non-profit-making, it cannot be regarded as carrying on an economic activity. It considered that SNS was operating according to the principle of solidarity on the basis that it was funded from social security contributions and other state funding, and provided its services free of charge to its members on the basis of universal cover. In relation to the matter of non-profit making, FENIN interestingly argued that insofar as SNS hospitals on occasions provide private care for which patients not covered by the SNS (such as foreign visitors) are charged, the SNS Bodies are acting as undertakings in the provision of such services and in the purchase of medical goods and equipment in connection therewith. Unfortunately, the Court declined to rule on this point, as FENIN had neglected to bring this fact to the Commission's attention earlier in the proceedings.

Pharmacia: Acquisition permitted, but only subject to conditions

The European Commission has cleared the acquisition of Pharmacia Corporation by Pfizer, in a deal estimated to be worth US$60bn, and which creates the largest pharmaceutical company in the world, with a global market share of 10 per cent. However, approval was only granted subject to extensive commitments by the parties.

Following an investigation by the Commission, serious competition concerns were raised in various pharmaceuticals markets, in particular, G4B4 Urinary Incontinence, G4B3 Erectile Dysfunction and C2A Antihypertensives (Of Non-Herbal Origin), and in the animal healthcare sector, for Oral Penicillin for the treatment of cats and dogs.

To alleviate concerns that the merged entity would, as a result, be in a position to exploit its dominant positions in these markets, and in order that the Commission could allow the acquisition to proceed, the parties offered the following commitments. In the market for G4B3 Erectile Dysfunction, where Pfizer pre-merger held almost 100 per cent of the market across the European Economic Area (EEA) for its product, Viagra, the parties agreed to divest two products, a dopamine D2 receptor agonist and Apomorphine hydrochloride nasal spray, being developed by Pharmacia in cooperation with Nastech Pharmaceutical Company Inc. The addition of these two products to Pfizer's portfolio would have further strengthened Pfizer's already strong market position. In the market for Urinary Incontinence, Pharmacia's existing product, Detrusitol, had a market share in most EU member states of between 40 and almost 100 per cent; therefore, the parties agreed to divest Pfizer's worldwide interests in Darifenacin, a compound in Phase III development. Concerning the Antihypertensives market in the Netherlands, because the merger would have brought the numbers one and two market operators together, while the remaining competitors would have been very small, and as Pfizer had just introduced a new patent protected version of its leading product, the parties agreed to discontinue selling Ketensin and transfer the rights or assets to the original licensor or to third parties. Finally, regarding the market for Oral Penicillin antibiotics, where the merger would have removed Pfizer's second largest competitor from the German market, the parties agreed to divest Pharmacia's product Parkemoxin in Germany. The transaction was cleared only subject to full compliance with these undertakings.

EMEA study on innovation in the pharmaceutical area

In 2002, the EMEA noted that there had been a significant drop in the number of applications for marketing authorisations concerning new chemical entities.

In order to identify what lies at the root of this phenomenon, to measure the size of the problem and to propose measures to deal with it, the Commission has decided to launch a study to answer and to report on the following questions:

- Is there a worldwide crisis in innovation in the pharmaceutical sector?
- What are the reasons behind this crisis?
- What tools do we have available to kick-start innovation?

The Commission has yet to announce who has won the tender to undertake this study.

US REVIEW

In *University of Rochester v G.D. Searle & Co., Inc., et al.*, US District Court deals setback to patent protection under 'tools' patents by Cooley Godward

Summary

The US Federal District Court in New York issued a recent decision expanding the application of 35 USC §112 to biomedical methods. That section requires that the specification of a patent must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognise that the inventor possessed the claimed invention at the time of filing.[13] In *University of Rochester v G.D. Searle & Co., Inc., et al.*, the court ruled invalid a 'method patent' for treating the side effects of pain relievers on the grounds that it failed to adequately describe the compound used in the claimed method.

Background

This case involved US Patent No. 6,048,850 (the ''850 Patent'), which relates to a new generation of pain relief medication that does not produce certain undesirable side effects (such as stomach irritation) associated with many other pain relievers such as aspirin, acetaminophen, ibuprofen, etc. The invention arose from the discovery of the disparate activities of Cox-1 and Cox-2 enzymes by scientists at the University of Rochester in the early 1990s. The activity of Cox-2 is associated with inflammation, while the activity of Cox-1 can help protect the stomach lining. The scientists at the University of Rochester developed an assay for determining whether a particular compound inhibits Cox-2 activity but does not affect the activity of Cox-1. The '850 Patent claims a method for selectively inhibiting Cox-2 activity in a human host while not inhibiting the activity of Cox-1. Thus, a compound used in the invention would inhibit the inflammatory activity of Cox-2 while maintaining the protective activities of Cox-1.

Upon issuance, the University of Rochester immediately brought a patent infringement action against defendants G.D. Searle & Co., Inc., Pfizer, Inc., Monsanto Co. and Pharmacia Corp., seeking injunctive relief and damages for alleged infringement of the '850 Patent. Searle moved for summary judgment of patent invalidity on the ground that the patent does not comply with the written-description requirement of 35 USC §112, ¶1, because while the patent calls for the use of a compound that specifically inhibits Cox-2, the patent specification does not identify any such compound. In addition, Searle moved for summary judgment of patent invalidity for non-enablement.

In *Regents of the University of California v Eli Lilly & Co.*[14] and in *Fiers v Revel*,[15] the Federal Circuit held that adequate written description under 35 USC §112 of a DNA claim requires a precise definition, such as by structure, formula, chemical

name or physical properties of the DNA, not a mere wish or plan for obtaining the claimed chemical invention. The Federal Circuit again addressed the issue of written description of biotechnology inventions in *Enzo Biochem Inc. v Gen-Probe Inc.*,[16] in which the court adopted the standard set forth in the US Patent and Trademark Office Guidelines for Examination of Patent Applications Under 35 USC §112, Paragraph 1 'Written Description' Requirement, which states that the written description requirement can be met by 'showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics', including, *inter alia*, 'functional characteristics when coupled with a known or disclosed correlation between structure and function.'

Judgment on written description

Plaintiffs argued that the holding of *Lilly*, *Fiers* and *Enzo* are limited to claims directed to DNA or nucleic acid sequences, to which the court responded that such a conclusion is inconsistent with the language of the cases themselves. Plaintiffs further argued that the requirements for written description of chemical compounds are irrelevant to the patent-at-issue because the present claims are drawn to methods of treatment by targeting Cox-2 activity. The court rejected this argument stating that '[v]irtually any compound claim could be transformed into a method claim, however, simply by means of wording of the claim in terms of using the compound.' The court found that drawing a line between compound claims and method claims was little more than a semantic distinction without a difference.

The court agreed with the defendants' argument that claiming an invention without having possession of a compound essential to practising that invention is 'akin to ''inventing'' a cure for cancer by utilizing a substance that attacks and destroys cancer cells while leaving healthy cells alone.' The court stated that without possession of such a substance, such a cure is illusory, and there is no meaningful possession of the method itself.

The court concluded that, because the inventors failed to take the last critical step of actually isolating a compound, or even developing a process through which one of ordinary skill in the art would be directly led to such a compound, the patent provides 'little more than a research plan'. Hence, the patent claims a method that cannot be practised until one discovers a compound that was not in possession of, or known to, the inventors themselves. Accordingly, the court held that the inventors could not be said to have possessed the complete invention claimed in the patent. Thus, the court held that the University of Rochester patent was invalid for lack of written description of the claimed method of treatment.

Enablement

Applying similar logic, the court agreed with Searle's argument that the patent is invalid for failing to meet the enablement requirement of 35 USC §112. To be enabling, a patent specification must teach those of ordinary skill in the art how to make and use the full scope of a claimed invention without undue experimentation. Based on its previous determination that the patent essentially calls for the use of trial and error to attempt to find a compound that will selectively inhibit Cox-1 activity, the court held that '[t]o practice the invention claimed in the patent, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.'

Conclusion

The decision in *University of Rochester* is yet another blow to 'tools' companies. Like the '850 Patent, screening patents and patent applications often describe and claim compounds in terms of their methods of discovery as opposed to providing a description of the compound *per se*. Following the logic of *University of Rochester*, a description of a method of

identifying a compound, without more, will not support a claim to the compound or to methods of using the discovered compound. The *University of Rochester* opinion, along with the decision in *Bayer AG v Housey Pharmaceuticals Inc.*[17] shows the trend of US courts to limit the patent protection afforded by tools patents.

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2. 18th September, 2002.
3. 23rd October, 2002.
4. Directive 2001/83/EC.
5. Which makes provision for the evaluation of the Community procedures for the authorisation and supervision of medicinal products, and which entered into force in 1995.
6. In light of the Commission's report 'on the operation of the procedures for granting marketing authorisation for medicinal products' COM(2002) 606 final, 23rd October, 2001.
7. Article 111(1).
8. Article 13(1).
9. Recital 13, Article 24(1).
10. Recital 13.
11. Article 86(1).
12. Article 89(2).
13. *Vas-Cath, Inc. v Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991).
14. 119 F.3d. 1559 (Fed. Cir. 1997).
15. 984 F.2d. 1164 (Fed. Cir. 1993).
16. 296 F.3d. 1316 (Fed. Cir. 2002).
17. 61 USPQ2d 1051 (DC Del 2001), holding that a US patent was not infringed under the provisions of 35 USC §271(g) by the importation into the USA of a product discovered using the claimed screening method.