PATENTWATCH

Court reversal in favour of Pfizer

The US Court of Appeals for the Federal Circuit has reversed the New Jersey District Court's dismissal of Pfizer's patent infringement action against Dr Reddy's Laboratories' generic version of the calcium channel blocker amlodipine besylate (Norvasc; Pfizer). The pharmaceutical industry has been closely monitoring this case, as Dr Reddy's used a novel approach to make its generic drug.

Pfizer's original patent on amlodipine besylate (US Patent 4,572,909) expired in 2003, but was extended until 2007 to compensate for a lengthy review process by the US FDA. At issue in this case was whether the patent extension was limited to Pfizer's marketed product or also applied to other chemical versions of the drug. As with many drugs, Pfizer's original patent protected both the chemical structure of amlodipine besylate and a host of sister compounds, or salts.

Dr Reddy's argued that Pfizer's patent extension did not apply to their version of the drug, amlodipine maleate. The district court agreed and held that the term extension was limited to amlodipine besylate. Although amlodipine maleate is covered by the claims, it is not subject to the extended term. The court reasoned that the 35 USC statute limits the term extension to the first permitted commercial marketing or use of the product and that this was relevant only for amlodipine besylate.

Two of the three Federal Circuit judges disagreed, and concluded that the active ingredient is amlodipine, so it is the same whether administered as the besylate salt or the maleate salt. The Act by its terms extended the term of the patent for the registered uses of the drug product including its salt esters. However, Judge Mayer dissented, arguing that to be eligible for a patent term extension, the product must have been subject to a regulatory review period before its commercial marketing or use. In this case, only amlodipine besylate was subject to regulatory review. The decision allows Pfizer to continue its infringement action in the district court.

Pfizer, Inc. versus Dr Reddy's Laboratories, Case No. 03-1227: http://www.fedcir.gov/opinions/03-1227.doc

Canada may need to review drug patent laws

In a decision that has surprised and disappointed many, Canada's Competition Bureau has told the Canadian government that although its drug patent laws are resulting in high expenditure for the country's burdened healthcare system, the bureau does not have the jurisdiction to probe controversies in the drug patent laws. The bureau was conducting an investigation into 'evergreening' — the practice of introducing minor variations in brand-name drugs to repeatedly extend their 20-year patent protection, thereby preventing generic copies from getting to market. The complaint against evergreening dates back to the spring of 2003, when a coalition of organizations, led by the National Union of Public and General Employees, alleged misuse of Canada's drug patent rules by brand-name pharmaceutical companies, complaining that evergreening is anticompetitive and drives up the costs of medicare. The competition watchdog maintains that the current rules need reviewing to ensure there is a balance between protecting intellectual property rights and advancing a competitive supply of pharmaceutical products. The Bureau lacks the power to take the matter further and says only federal politicians have the jurisdiction to handle the matter. However, the coalition that brought the complaint remains pessimistic as to whether politicians will deal with the issue, citing past failure to do so.

Competition Bureau response: http://cb-bc.gc.ca/epic/internet/incb-bc.nsf/vwGeneratedInterE/ct02803e.html

University of Rochester Cox2 patent invalid

The US Court of Appeals for the Federal Circuit in Washington DC has affirmed the district court decision invalidating a patent awarded to the University of Rochester (US Patent 6,048,850). Rochester's lawsuit is an example of a reach-through claim, which is a claim made by a patent holder in a patent or a patent licence asserting rights over a future product or process that might result from the use of a patent.

The University's patent is directed to a method of selectively inhibiting the COX2 enzyme by administering a non-steroidal compound. In April 2000, on the day the '850 patent was issued, Rochester University sued Pfizer, alleging that sale of Pfizer's COX2 inhibitors celecoxib (Celebrex) and valdecoxib (Bextra) infringed the '850 patent.

However, the Federal Circuit affirmed the patent invalidity for failure to comply with the written description requirement, because the compound recited in the claimed methods was defined purely by functional characteristics. Any specification must describe all elements of the invention in sufficient detail so that someone of ordinary skill in the art would recognise that the inventor was in possession of the invention when the application was filed. In this case, the only means provided for finding a compound was a trial-and-error process. The court concluded that, as a matter of law, the patent at issue clearly and convincingly proved its own invalidity because a required compound was not disclosed and there was no pre-existing awareness in the art of such a compound exhibiting the claimed activity.

In addition, a patent is only enabled when a person skilled in the art can use the invention without undue experimentation, and the district court found that the University's claims lacked enablement. A number of factors are considered in making such a determination, and in this case the judge concluded that a person skilled in the art would have to engage in undue experimentation. Although the '850 patent provided both an assay for identifying selective COX2 inhibitors and a use for such a compound once identified, it did not provide the necessary link between the two stages.

University of Rochester versus G.D. Searle & Co., Case No. 03-1304: http://www.fedcir.gov/opinions/03-1304.doc>