PATENTWATCH

Lack of intracellular definition

The Federal Circuit has upheld a New Jersey district court's ruling against Immunomedics that Cytogen did not literally infringe a patent (US 4,460,559) relating to tumour detection and localization by targeting intracellular marker substances, but disagreed with the ruling that there was no infringement according to the doctrine of equivalents.

Immunomedics sued Cytogen for patent infringement over their prostate cancer diagnostic product ProstaScint, which relies on the marker prostate-specific membrane antigen (PSMA). PSMA is a transmembrane antigen, with intracellular and extracellular domains, and the molecule binds to the interior side of the cell wall.

In considering the literal infringement, the court dismissed Cytogen's proposed broad-claim construction interpretation that an intracellular marker substance is "an antigen *or a portion thereof* that is located inside a cell", arguing that the prosecution history of the patent showed that the inventor associated the term with a fully intracellular antigen. By a majority ruling, the appellate court agreed with the district court that the marker substance must be fully internal to the cell. Judge Prost disagreed with the majority's claim construction and, siding with Immunomedics, believed that 'marker substance' bears a broader meaning.

Although the Federal Court agreed with the district court that PSMA is not an intracellular marker substance, they criticized the lower court for viewing the world of antigens as consisting of either intracellular or cell-surface antigens. This assumption led the district court to conclude as a matter of law that antigens falling in two halves could not be equivalents as a matter of law. The Federal Court reversed the judgement on no infringement of equivalents and remanded the issue back to the district court because the factual dispute of categorizing transmembrane antigens remains to be resolved.

Goldenberg versus Cytogen, Inc.: www.fedcir.gov/opinions/03-1409

All-elements rule

The Federal Circuit has upheld a Delaware district court's judgement as a matter of law that Abbott did not infringe two of Novartis' patents (US 5,342,625 and 6,007,840) relating to pharmaceutical compositions of the drug cyclosporin. Although the appellate court disagreed with the district court's claim construction in determining whether Abbott infringed the patents under the doctrine of equivalents (a concept employed to prevent someone from getting the benefit of the invention by making a minor change that avoids literal infringement), it upheld the decision in favour of Abbott after applying the all-elements rule.

Cyclosporin is a drug that prevents organ rejection in transplant patients. The drug is highly lipophilic and it is consequently difficult to administer in a convenient form that provides the desired bioavailability. Novartis' patents cover oil-in-water micro-emulsion compositions that facilitate human absorption of cyclosporin, which include lipophilic components. Novartis sued Abbott for patent infringement over their product Gengraf, which is a cyclosporin formulation that contains hydrophilic excipients and the surfactant Span 80, which reduces the surface tension of water at appropriate concentrations and increases drug solubility. The parties disputed whether the term 'surfactant', as it is used in the patents, encompasses both hydrophilic and lipophilic molecules.

Although the Federal Circuit stated that the district court's construction of 'lipophilic component' as excluding the function of a surfactant was too narrow, it determined that, even with a broader construction, there would still be no infringement by Abbott. This is because application of the doctrine of equivalents in this case would violate the all-elements rule, which requires that the determination of equivalency proceed on an element-by-element basis, rather than comparing the overall similarity of the accused invention as a whole to the claims. This ensures that the application of the doctrine is not allowed such broad coverage as to effectively eliminate every similar invention.

Novartis Pharm Corp. versus Abbott Labs.: www.fedcir.gov/opinions/03-1367

Antitrust case can proceed

The US Court of Appeals has overturned a district court's dismissal of Xechem International's 2003 paclitaxel lawsuit against Bristol-Myers Squibb (BMS), enabling Xechem to reinstate its claims against BMS. Generics manufacturer Xechem alleged anticompetitive action by BMS in delaying competition of generic versions of the anticancer drug paclitaxel (marketed by BMS as Taxol). The lawsuit was initially dismissed by the District Court on the grounds that the statute of limitations barred the action. Xechem's antitrust suit against BMS seeks damages of US $150 million.

The Hatch–Waxman amendments to the Food and Drug Act entitle pharmaceutical companies that first bring a drug to market to a five-year period of exclusivity. BMS was first-to-market with paclitaxel, the exclusivity period of which was due to expire in July 1997. Shortly before its exclusivity was to end, BMS listed in the FDA's Orange Book (approved drugs and the patents which protect them) two patents covering the administration of paclitaxel. It sued all manufacturers that filed Abbreviated New Drug Applications (ANDA) for that drug, so the automatic 30-month deferral of generics manufacturing allowed by the amendment took effect. Courts ultimately determined that all the important claims of both patents are invalid. Just before the 30-month deferral was to expire, BMS listed a third patent in the Orange Book. This reset the 30-month clock, which continued to run until 17 January 2002, at which point BMS withdrew this listing after the third patent had also been declared invalid.

Xechem makes and sells paclitaxel all over the world, but not in the United States. The company began the antitrust suit in 2003, claiming that the activities described above excluded rivals and exposed consumers to elevated prices. The district court dismissed the complaint because Xechem did not file an ANDA in 1997, and also the four years allowed by the statute began in 1997 and therefore expired before Xechem's litigation started. The Appeals Court, however, explained that although it might be too late to complain in 2003 about what BMS did in 1997, it is not too late to complain about what they did in 2000 or 2002. Each discrete act with fresh adverse consequences starts its own period of limitations.

Xechem versus Bristol-Myers Squibb: http://caselaw.lp.findlaw.com/data2/circs/7th/034292p.pdf