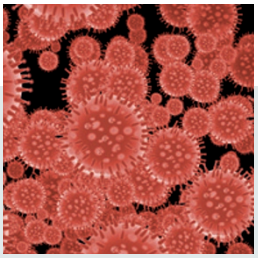
PATENT WATCH



Aloysius Patrimonio/Alamy

Court sides with generics company over Tamiflu patent

A US appeals court has ruled that the expiration dates of two patents owned by Gilead that protect Tamiflu (oseltamivir) are important when determining whether they overlap with each other. If the generics manufacturer Natco is successful in the next stage of the dispute, the company may be able to file for regulatory approval of generic oseltamivir 22 months earlier than originally anticipated.

Natco asserted that Gilead had committed so-called obviousness-type double patenting (OTDP) with regard to two Tamiflu patents (US 5763483 and US 5952375). This doctrine prevents an unjust extension of the length of patent protection by stating that the claims of one patent must be distinct from the claims of a second patent (that shares a common inventor). Normally, the reference patent on which OTDP is based issues before and expires before the second patent. But in the current case, the court had the unusual task of deciding whether a patent (the '375 patent) that expires before yet was issued after another patent (the '483 patent, which expires 22 months after the '375 patent) qualifies as a reference for OTDP.

In agreeing with Natco, the court said that expiry dates as well as issuance dates should be taken into account when deciding OTDP; therefore the '375 patent could serve as a double patenting reference for the '483 patent even though it was issued later. Relying only on the issuance date, said the court, could create quirks in the patent system, meaning that a patentee could then circumvent the intended purpose of OTDP and obtain an unwarranted patent extension.

The appeals court remanded the case to a district court to decide whether the '483 patent overlaps with the '375 patent.

Gilead *et al.* versus Natco: http://www.cafc.uscourts.gov/images/stories/opinions-orders/13-1418.Opinion.4-18-2014.1.PDF

Lamb chopped: Dolly not patent eligible

Dolly, the first mammal to be cloned using somatic cell nuclear transfer, would not have been eligible for patenting, according to a US appeals court. This was because she was genetically identical to her donor parent.

The current appeal was based on the rejection of a patent application for Dolly the sheep (US 09225233) by the US Patent and Trademark Office. (A method of cloning mammals using somatic cell nuclear transfer (US 7514258) was not part of the current case.)

The Roslin Institute, which cloned Dolly, argued that mammalian clones were eligible for protection because they are the product of human ingenuity. But the appeals court drew on the recent Myriad case (see *Nature Rev. Drug Discov.* **12**, 570–571; 2013) to emphasize that discoveries must have "markedly different characteristics from any found in nature" to be eligible for patent protection.

In response to this, the Roslin Institute asserted that several features of mammals produced by somatic cell nuclear transfer make them patent eligible. For example, it said that environmental factors lead to phenotypic differences that make clones distinct from their donor. In addition, it said that mammalian clones are distinguishable from donor mammals because of differences in mitochondrial DNA.

But the court highlighted that these differences were not claimed in the patent application, and held that Dolly and other mammals cloned using the same technique would be exact genetic copies of an animal that exists in nature, and as such were not eligible for patent protection.

In re: Roslin Institute: http://www.cafc.uscourts.gov/images/stories/opinions-orders/13-1407.Opinion.5-6-2014.1.PDF

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