

additional coverage under the regime of paediatric extension.¹⁰² This was granted and brought the overall protection to 17 January 2012. For unknown reasons, no supplementary protection had been requested in Italy, where the patent term was due to expire in September 2009, 20 years after the patent application had been filed.

In the United States latanoprost was covered by the patent US 5,296,504 which had been filed in December 1992 and expired in March 2011. Patent term extension could not be requested because FDA approval was obtained in June 1996 and therefore the remaining patent term exceeded 14 years.¹⁰³

4. Conclusion

In the case of Latanoprost prolongation of patent protection was obtained through supplementary protection certificates and paediatric extension.

A substantial number of patents (93%) have been filed after the launch of the product in 1996 which were mainly (71% of these) directed to formulation, processes and delivery devices as can be seen from figure 4.¹⁰⁴ However, of these only few have been filed by the originator company. Of the reported patent families only 13 belong to Pfizer or its predecessors and the last application attributable to the originator dates to 2003.

A significant number of the patents directed to processes have been filed by Johnson Matthey (15%), a company specialized in catalyst and process development. Their patent filing activity started in 2001,

102 Council Regulation 1901/2006, Article 36, 2006 O.J. (L 378) 1, 12: according to the Regulation (EC) on medicinal products for paediatric use additional 6 month protection period may be obtained, when the holder of a patent or a supplementary protection certificate files study results in paediatric patient populations with the respective authorities.

103 35 U.S.C. § 156 (c)(3).

104 The graphics reports the number of families for priority date. If a specific patent refers to more indications, it has been counted for each category.

III. Case Studies-Facts

about five years after the launch of Xalatan when its success was presumably already evident. Regarding the patents directed to delivery devices, figure 4 shows that they were filed mainly from 2007 onward. However, various companies are active in this area and amongst them the more prolific is QLT Inc., a biotechnology company whose research is focussed on innovative ocular products.

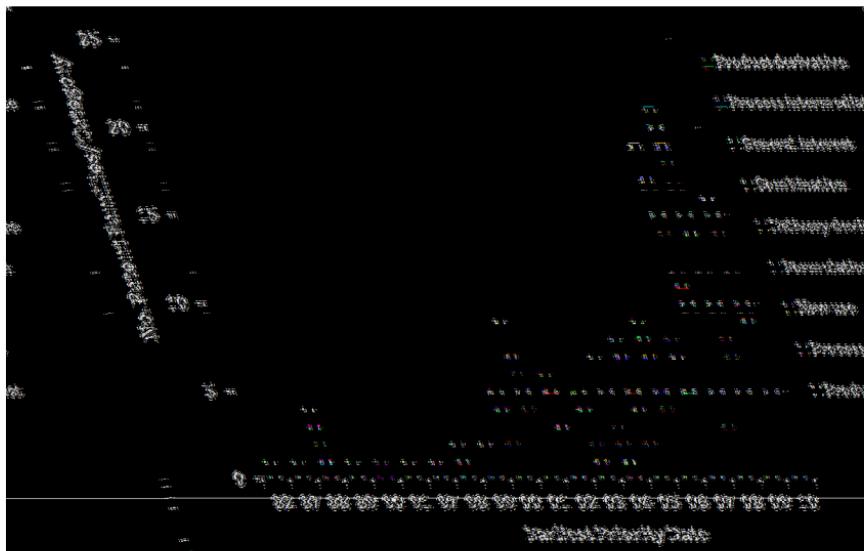


Figure 4: Patent filing trends: latanoprost¹⁰⁵

105 *Supra* note 73.

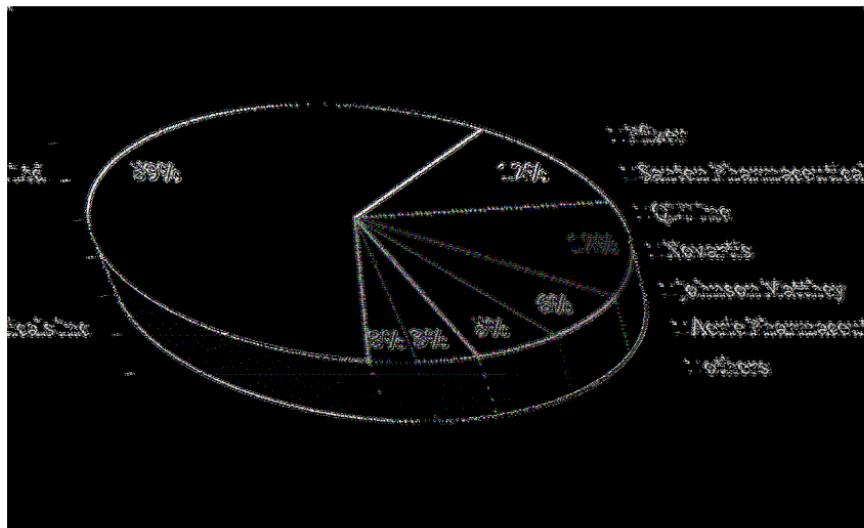


Figure 5: Top patent applicants for latanoprost (118 patents)¹⁰⁶

The third most prolific area of research covers formulations. This area is dominated by Santen Pharmaceutical (25%) which moreover is the major competitor of Pfizer (2.3%) (figure 5), as far as latanoprost is concerned, and which in 2011 announced the positive outcome of Phase II studies for Catioprost®. Catioprost is a preservative-free formulation of latanoprost with reduced side-effects and thus regarded as next generation glaucoma treatment.¹⁰⁷

106 *Id.*

107 Press release Novagali Pharma, Catioprost Phase II positive results (Sept. 8, 2011).