edge with respect to ease of application, this method of administering the drug to the eye would not have created any market entry barrier as there is a sufficient number of generic ways to do so. In any case, these applications have not been pursued and are deemed withdrawn.[91]

f) Packaged Product

In 2005, Pharmacia & Upjohn filed two patent applications[92] in the United States exclusively which are directed to a special method of packaging latanoprost into plastic vials, as well as to the plastic vials filled with the drug *per se*. It appears, that there existed a need to stabilise the packaged drug and that the company had identified a solution for this. However, both applications were objected to by the USPTO under the aspect of unity of invention[93] and the company by that time must have had decided not to pursue the issue any further, as both patent applications result abandoned by mid-2008.

A further patent application has been filed with respect to the packaging of a combination of the drugs timolol and latanoprost, which is sold under the trade name Xalacom.[94] Also this application has been refused due to lack of unity and was then abandoned.[95]

3. Use of Procedural Provisions

a) Divisional of Basic Patent

The basic patent EP 0364417 B1 gave rise to 9 divisional applications filed between 1993 and 2003 which are directed to more specific embodiments comprised in the parent application. In particular, EP

91 *Supra* note 89.
92 Published as US 2005/0049311 A1 and US 2005/0287325 A1.
93 See USPTO *supra* note 68.
94 Published as US 2005/0048122 A1.
95 See USPTO *supra* note 68.

1225168 B1 filed in 2002 covers various prodrugs including Xalatan. This patent was revoked by the EPO in 2011 and fell under the scrutiny of the Italian competition authority (ICA)[96]. Pfizer appealed the decision of the EPO. In the course of the procedure Pfizer filed a new main request and further auxiliary requests. With regard to the new main request, the opponents to the patent withdrew their opposition. In May 2012 the Board of Appeal remitted the case to the first instance with the order to maintain the patent on the basis of the main request as presently on file.[97] Instead of being directed to latanoprost and its ester analogues, the patent now claims the use of Xalatan in speficic amounts for a specific indication.[98]

b) Supplementary Protection

The basic patent protection for latanoprost in Europe is derived from EP 0364417 which has been filed in September 1989. Said patent was to expire after a patent term of 20 years in September 2009. The regulatory obligations to be able to commercialize latanoprost had been fulfilled within seven years after filing and thus first marketing approval for Xalatan could be obtained in Sweden on 18 July 1996[99] and subsequently in other EU countries. Based on the SPC regulation, extension of the patent term up to 15 years after the first MA could be requested nationally.[100] Further protection of latanoprost was thus obtained in various EU Member States and gave additional coverage until July 2011.[101] In addition, Pfizer in early 2011 was able to request

96 Autorità Garante della Concorrenza e del Mercato (AGCM) (Italian Competition Authority), Jan. 30, 2012 Bollettino 5 (XXII-2) (It.).
97 T 2402/10 available in the EPO register under the number of the patent in suit.
98 EPO register, set of claims of 9.3.2012.
99 See European Patent Register s*upra* note 76.
100 Council Regulation 469/2009, 2009 O.J. (L 152) 1.
101 In Switzerland as non-EU country until September 2011, based on the Swiss MA.

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,

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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.