the patents connected to it stem very often by more specialized companies as shown in the Xalatan case study. As already mentioned,[215] QLT inc. was one of the more prolific players regarding patent filing in this field of research. QLT's patent application (WO 2007/115259) on nasolacrimal drainage system implants has been granted in U.S. and Japan while it is still pending in Europe. Phase II clinical studies of this device showed promising results.[216]

Patents that cover such delivery devices can only further protect the use of the concerned drug in connection with the patented system and do not create any market entry barrier. They do not impede the administration to the patient of generic version of the traditional drug or the use of other versions belonging not to the originator company. The economic success of such delivery device is more dependent from the marketing strategy.

2. Xalatan SPC Request: a Case for Competition Law?

The patent protection (EP 0364417) for Xalatan based on obtained SPCs was due to end in July 2011. This however was not the case in Italy where the expiry date was still September 2009 and generic companies could enter the Italian market already on that date. To maintain its market position also in Italy, Pfizer in 2002 (13 years after the parent patent) filed a divisional patent application of the basic patent (EP 1225168). The patent on the divisional application granted[217] in January 2009 was then validated only in Italy. Successively, an SPC based on the divisional patent could be requested. This conduct fell under scrutiny of the Italian competition authority which

215 See section II B 2 f) of this thesis.

216 Press release, QLT inc., QLT shows positive 4 week efficacy in phase II study for glaucoma using latanoprost punctual plug delivery system, (Aug. 29, 2011).

217 EP 1225168 was revoked in October 2010 because new findings were added.

defined it as a complex strategy to avoid generic entrance.[218, 219] According to the authorities such strategy allowed to artificially prolong Xalatan's protection in Italy from September 2009 to July 2011 and moreover, due to an additional paediatric extension in various European countries including Italy, to January 2012.

The conduct of Pfizer was strongly criticised by the Italian Competition Authority (ICA). The ICA sustained that this situation determined a climate of legal uncertainty with respect to the possibility of commercializing equivalent drugs based on latanoprost. This uncertainty was further increased by numerous warnings sent to the generic companies concerning an administrative and civil dispute in case of commercialization of the corresponding generic before July 2011.[220] This behaviour was said to have delayed by seven months the commercialization of generics (Ratiopharm applied later due to this legal uncertainty) causing a big economic loss to the Italian State health system (NHS). On the other hand this delay for Pfizer meant a profit of approximately 17 million Euro (ICA calculation). In a press release the ICA stated: "Thanks to its strategy, Pfizer managed to: 1) increase the effective market entry costs for the manufacturers of generic drugs; 2) delay the market entry of Xalatan-equivalent specialty drugs by at least 7 months; 3) maintain the *de facto* exclusive commercialization of medicines based on latanoprost even after patent coverage had expired; 4) cause an estimated 14 million Euro in lost savings by the NHS. These elements led the Authority to classify the sanctioned competitive violation as very serious."[221]

The Italian authorities objected also to the request of paediatric extension stating that glaucoma is a disease which typically affects old

218 See AGCM *supra* note 96.

219 Michele Giannino, *Patents: Beware of competition law! Relying on patents to extend protection for medicines may be anticompetitive*, 7 J. Intell. Prop. L. & Pract. 391, (2012).

220 Press release, AGCM, Drugs: Pfizer sanctioned with 10.6 million Euro fine for abuse of a dominant position (Jan. 17, 2012).

221 *Id.*

people and therefore this request was also an action with the only purpose to extend patent protection.[222]

The ICA relied on the General Court's judgment in AstraZeneca[223] and argued that such use of administrative procedures by a dominant company is outside the competition on the merit. However, some authors comment that Pfizer behaviour is "[...] nothing more than attempt to rely on the patent and SPC system to protect its innovative glaucoma treatment across the European Union for the maximum period allowed by the legislation."[224] Such legislation is intended to foster innovation and if the available measures of protection are arbitrarily reduced by competition law incentives to develop new drugs will be reduced.[225] This argument was also raised in the AstraZeneca case but the then Competition Commissioner Neelie Kroes commented "[m]isleading regulators to gain longer protection acts as a disincentive to innovate and is a serious infringement of EU competition rules."[226] While this statement was objected as being without support[227] it might be remarked that innovation cycles might be prolonged.

Pfizer appealed the decision and interestingly the Italian administrative court overruled in its entirety the findings of abuse of a dom-

222 See AGCM *supra* 96 at ¶ 214.

223 European General Court, T-321/05, AstraZeneca v Commission, July 1, 2010, E.C.R. II-02805.

224 Christopher Stothers, Marco Ramondino, *Aftermath of AstraZeneca and the Pharmaceutical Sector Inquiry: The Big Chill?*, 12 Eur. Comp. L. Rev. 591, 594 (2011).

225 *Id.*

226 Press release, IP/05/737, (Jun.15, 2005).

227 Johanna Müller-Graff, Filipe Fischmann, *Der Fall AstraZeneca: "Tool boxes" im Arzneimittelsektor – wer hat die besseren Werkzeuge und welche sind erlaubt? Zum Urteil des Gerichts der Europäischen Union vom 1. Juli 2010, Rs. T-321/05*, 792 GRUR Int 1, (2010) at 10.

inant position.[228, 229] The court found that, by relying on the provisions of the EPC and the SPC regulation, Pfizer had been using legal measures available to it and not carried out procedural abuses or misrepresentations. In particular, the court stated that the ICA, by finding the divisional application abusive with the intent to exclude generic companies, had not considered that the divisional had been filed seven years before the supposed generic market entry.[230] The Court also commented that the ICA seemed to have based its decision on the revocation of the divisional patent by the EPO ignoring that such revocation could be appealed and it was not final.[231] The Court's decision may still be appealed.[232]

With its actions (the divisional patent application and the SPC request based on the divisional) Pfizer tried to remedy a former mistake and as a consequence to obtain more protection in Italy. Such strategy used instruments allowed by patent law[233] and by the SPC regulation[234]. From a commercial point of view this behaviour is legitimate, and the Italian administrative court held that it has also legal bases.

Nonetheless, the AstraZeneca case and the Pfizer case should warn dominant companies that, by making use of the patent and/or regulatory system to delay generic entry and to avoid profit erosion, they

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228 Pfizer v AGCM, Tribunale Amministrativo Regionale [Regional Administrative Court] per il Lazio Sezione Prima, 07467/2012 REG.PROV.COLL., Sept. 4, 2012 available at http://www.giustizia-amministrativa.it/DocumentiGA/Roma/Sezione%201/2011/201109968/Provvedimenti/201207467_01.XML (last visited Sept. 12, 2012).

229 For a summary of the decision in English see Micaela Modiano, *Italian u-turn on latanoprost abuse of dominant position dispute,* The SPC blog, (Sept 7, 2012) available at http://thespcblog.blogspot.de/2012/09/italian-u-turn-on-latanoprost-abuse-of.html (last visited Sept. 11, 2012).

230 See Pfizer *supra* note 228 at 58.

231 *Id* at 61.

232 See Modiano *supra* note 229.

233 R. 25(1) EPC 1973: Filing of divisional application was possible for any pending application. The rule has since been amended introducing a time limit for filing divisional applications (R. 36 EPC 2000).

234 The SPC regulation does not draw any distinction between parent and divisional patent, see Stothers *supra* note 224.

might fall under scrutiny of competition law and incur a fine. The use of certain ways of action permitted by other branches of law[235] does not preclude the application of competition law.[236, 237]

Finally, a comment needs to be made regarding the objection on Xalatan paediatric studies.[238] Although the percentage of children who need such drug is low (around 1%) it is duty of the health system to guarantee that a safe drug is available to them. The scope of paediatric extension is to give an incentive to companies to provide such drugs, therefore the ICA point of view cannot be shared and Pfizer's use of paediatric extension should have not been penalized.

C. Patent Strategy and Innovation

The main criticisms on pharmaceutical R&D are directed to the reduced number of NCEs approved by the FDA and the EMA and to the reduced number of new breakthrough drugs compared to "me-too drugs'' (follow-on drugs). Nonetheless, drugs based on new biological mechanisms continue to be discovered (e.g. Isentress the first HIV-integrase inhibitor introduced by Merck in 2007).[239] The reasons for the apparent reduction of NCEs are various.[240] However, these are not within the scope of the present study.

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235 E.g. AstraZeneca deregistered a Marketing Authorisation, which *per se* is not forbidden by the regulations guiding the pharmaceutical market.

236 See AstraZeneca *supra* note 223 at ¶677.

237 Josef Drexl, *Astra Zeneca and the EU Sector Inquiry: when do patent filings violate competition law?,* Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02, 21 (2012).

238 Vanessa Peden, Imti Choonara, Brian Gennery, Hilary Done, Recruting Children to a Clinical Trial, 4 Paed. Perinat. Drug Ther. 75, (2000): "In children, one can only study those children who are to undergo a clinical procedure and may benefit from a medicine.".

239 John E. Calfee, White Paper on Pharmaceutical Market Competition Issues, June 2, 2008, available at http://62.102.106.100/content/default.asp?PageID=559&DocID=4894 (last visited Aug. 3, 2012).

240 See Chapter I of this thesis.