V. Final Remarks

The purpose of this work was to highlight a few points concerning lifecycle management which is very often considered an issue and sometimes labelled as "evergreening".[261] First, critics of this business model argue that secondary patents prolong the monopoly the originator holds on a drug at a cost for society.[262] In both the cases at present analysed this could not be confirmed. Also in cases of examples where secondary patents led to commercial success, like the protection of Symbicort (Asthma treatment: combination of budesonide/formoterol), it needs to be stressed that such a patent does not constitute a unilateral advantage for the originator company.[263] This is for two reasons: first, society has the choice between the classical and the improved treatment and second, any third party, desiring to provide the original drug not anymore covered by a patent, is free to offer it to the market and to compete with the originator or others.

The second argument voiced against lifecycle management is that the originator companies put their efforts only on maintaining exclusivity on old blockbusters and not invest in NCEs. However, this argument fails to acknowledge that a successful product has to generate revenue for a multitude of unsuccessful projects.[264] In this context it has also been remarked: "A study by the U.S. Federal Trade Commission indicates that brand-name companies currently file more patents to protect market exclusivity of their products. However, a few companies are using these frivolous patenting [strategies] to ob-

---

261 John R. Thomas, *Patent "Evergreening": Issues in Innovation and Competition*, Congressional Research Service, (Nov. 13, 2009): this article highlights the debate on lifecycle management.

262 Kristof Roox, Julia Pike, Andrew Brown, Stefan Becker, *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*, 12 (Kristof Roox ed., 2008): publication of the European Generic Medicines Association.

263 See AstraZeneca *supra* note 187.

264 See Jacob *supra* note 13.

tain market exclusivity to such an extent that these strategies may be referred to as abuse."[265, 266] While there are surely exceptions, one needs to keep in mind that also small increments might constitute innovation, and address so far unmet needs as was demonstrated throughout this thesis.

Another criticism raised is that the further filing increases costs as these might cover essential aspects of the marketed product such as a specific formulation or manufacturing process, for which substitutes need to be developed. However, this argumentation falls short of its target.[267] Emphasis should be placed on the research and development cost. The development cost of a new drug is very high, the development of a new use still has a considerable cost also if reduced (due the clinical trials needed to prove efficacy), while on the other hand the costs of simply reproducing the drug is very low.[268]

On the other side, it must be conceded that if such granted secondary patents are of low quality this creates additional strain on resources. This cannot be considered a specific issue of secondary patents in the field of pharmaceuticals but in principle regards all patents also if data reported might sustain such arguments.[269]

As has been shown by performing the two case studies it oftentimes is a major problem to overcome own prior art and secondary patents are more vulnerable due to the increased knowledge in the public do-

265 V. N. Bhat, The Challenges of the new EU Pharmaceutical legislation Pharmaceuticals Policy and Law, Volume 6, 109-122 (J. L. Valverde, P. Wassenberg eds., 1st ed. 2005) at 118.

266 The "frivolous" patents mentioned in this context refer for example to pill boxes or computerized dispensing systems for specific drugs.

267 If a drug product could only be protected *via* the coverage of its active ingredient, any investment into the identification of an efficient process of production or a "patient-friendly" formulation could be considered to be without return and therefore not worth making. If on the other hand such an investment is made but not incentivised or protected, then the use of the results of such research would constitute a form of "free-riding", which may not be considered to be a competition on the merits.

268 See Bhat *supra* note 265.

269 See sector inquiry *supra* note 120.

main. Therefore, more care is needed in drafting such patents. In addition, they might not be the best way to incentivise research on improvements of existing drugs. Other instruments like an additional market exclusivity period for a proven real benefit might be an option.[270]

The two case studies demonstrate that the originator companies concentrate their filing activities mostly during the premarketing period when there is not yet any guarantee of an impending commercial success, in some cases not even of a successful passing of the clinical trials. The spread of the patents over a period of many years also reflects the fact that the basic patent must be filed as early as possible when not all the research has been already done. The patent filing after the successful marketing of the drug derives from a multitude of entities of which the originator is only one. In addition, the large number of patents applications withdrawn by the originator company or not granted, demonstrate that the patent system works to effectivly filter the applications, as desired by the Commission in its Pharmaceutical Sector Inquiry.[271]

In summary, it is believed, that the case studies do not indicate the presence of "evergreening" strategies, but reflect the normal course pharmaceutical research is taking, where one step follows the other, and investment into a certain aspect or another is done according to the needs of the project until it arrives at the stage of marketing authorisation. While this filing strategy may be partially attributed to an interest in not losing a market position gained, at the same time the research done is a benefit to the public and may not be meaningfully carried out at an earlier point in time. In stating this however, it must not be neglected that sometimes the strategies used stretch the limits of competition on the merit.

---

270 A similar conclusion has been reached in: Manfred E. Wolff, *Drug Discovery Market Exclusivity After KSR: The Challenge to Pharmaceutical Scientists and the US Congress*, 100 J. Pharm. Sci. 3044, 3052-3053 (2011).

271 See sector inquiry *supra* note 120.