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IP STRATEGIES AND POLICIES FOR AND AGAINST EVERGREENING

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IP strategies and policies for and against evergreening[1]

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Abstract

Evergreening is the strategic extension of the duration of a temporary monopolistic or market dominant position by means of IP strategies, and in practice patent strategies particularly. This paper explores the evergreening phenomenon. After an introductory description of evergreening and its associated innovation and IP policy issues, the paper provides a literature review. We further present one case of the pharmaceutical blockbuster drug Losec (Omeprazol) that became the world's best selling drug from 1996 to 2000. The case is accompanied by short evergreeing examples based on other IPRs such as trade marks. A theoretical part discusses different types of evergreening approaches along with simple models. The paper ends with a discussion of implications for managerial counter-strategies and innovation and IP policies.

Keywords: Evergreening, intellectual property, patents, Losec, innovation policy

[1] The financial support from the Wallander foundation is gratefully acknowledged

1 Problem background

The tragic 9/11 events in 2001 implied a delay in the court proceedings in Boston that dealt with a case involving AstraZeneca and its blockbuster drug Losec (Prilosec in the US, with generic name omeprazol, with its key basic patent received by the Swedish company Astra in the US in 1981 (US patent # 4.255.431, issued March 10, 1981), later merged with Zeneca in 1998-9. This delay implied in turn that competitive entry into the Losec market was delayed.

At this time media circulated an undemented estimate of 200 MUSD as the monthly profits reaped by AZ from this drug, profits that were to be heavily reduced by competitive entry which was sure to take place asap as the key patent expired as generic drug manufacturers had prepared their ”springboards” for entry into this lucrative market.

Right or wrong, the sales, profits and profit margin of a blockbuster drug towards the end of its effective patent protection usually is very large, which incentivizes pharma firms to employ a myriad of means /tactics/strategiesto delay entries by competitors, ie means to maintain a competitive position and sustain any temporary competitive advantages, such as patent protection. In the case of AZ and its pre-merger constituent Astra, the expiration of this key patent, i e the ”patent cliff ”, together with Astra’s anticipated overdependence upon Losec had early on been perceived in Astra to have such dramatic consequences on its financial performance that it became an argument in favor of Astra’s merger with Zeneca in 1998-9. Astra had then since the 1980s tried to generate more radical innovations in its R&D pipeline but essentially without enough successes to be perceived as providing a business portfolio sufficiently diversified to pick up the company’s expected financial drop from the patent cliff, perceived by some as suicidal while disputed by others. Thus all in all, extending the effective patent protection of Losec and its successor Nexium in a second product generation, ie what is referred to as evergreening, bridging the patent cliff had become a strategic issue for AZ with powerful incentives to invent various strategies to that effect.

AZ is not a unique case in this respect and many firms engage in various forms of evergreening. This is troublesome for competitors, not the least manufacturers of generic drugs in the pharmaceutical industry, who try to invent counterstrategies. Evergreening is also particularly troublesome at IP policy level since the statutory duration of IPRs, being a key policy variable for fostering dynamic competition, is in effect circumvented or invented around strategically by IPR users.

2 Aims and outline of this paper

2.1 Aims

Evergreening in a general sense refers to the extension of the duration of an existing temporary monopolistic or market dominant position by various means or strategies. We can then talk more specifically about evergreening of sales or profits from products, technologies, services and equity. Evergreening can then be accomplished by erecting entry barriers of all sorts or delaying entries or weakening competition and/or strengthening own competitive advantages when the dominant position is threatened. Typically evergreening has been practiced in pharmaceutucal industry when an IP-based temporary monopoly is about to expire, and then IP strategies for evergreening of IP as well as other means have been used to evergreen product sales.

This paper aims to explore the phenomenon of evergreening by means of IP strategies in general, and patent strategies in particular. If, e.g. , an innovation which through wide-spread adoption and diffusion has led to a high growth rate in a market with a low rate of technological substitutions and with a steep learning curve, then any prolongation of a dominant market position pays off handsomely. Traditionally evergreening involves follow-up patenting of product and process improvements and new and non-obvious applications or medical indications of the basic invention. Evergreening could also be accomplished by launching a series of product generations with overlapping technology or resource bases, where a strong patent position in the technological overlap is leveraged to a strong market position for the subsequent product generation.

Evergreening is well recognized in industry, especially in the pharmaceutical industry, and in some policy circles, but it is not well researched by academia. Firms are clearly incentivized to engage in evergreening, and the patent system is also designed to encourage dynamic competition and the provision of innovations by granting innovators legal means for achieving a temporary or time limited monopolistic position sufficient to recover their investments in return for disclosure of their trade secrets. However, such an institutional design carries the seeds to counter its purpose when the time limits are not set right or could be strategically surpassed by its users, incentivizing them to become abusers. Policy responses are then called for, but as the paper will show such a call and response is difficult to get in tune.

2.2 Outline

The paper provides a review of the scholarly literature on evergreening and its conceptualizations. As operationalizations of evergreening are by and large missing the paper will also provide some tentative ones for further empirical research, which is clearly and dearly needed.

The paper then presents one empirical case of the pharmaceutical blockbuster drug Losec or Prilosec (with the generic name Omeprazol) launched with its first year of sales in 1988. Losec became the world's best selling drug from 1996-2000 towards the end of the term of its strategic patent. The case also covers its second generation follow up drug Nexium, both developed and sold by the Swedish company Astra, later merged into Astra-Zeneca (partly because of fear for the Losec patent cliff). We provide evidence on the case and report insights based on extensive interviews with numerous key informants involved in the development process and subsequently following litigation activities. This case is particular rich in many aspects of evergreening based on an ever extended portfolio of IPRs, patents and follow up patenting in particular, but also trademarks and trade dress, within and across two product generations, and finally a successful global patent litigation strategy. The case moreover illustrates how a couple of IP policy developments substantially aided evergreening. The case in addition contains some unexpected drama, which is useful in getting attention to the evergreening phenomenon.

The Losec case is accompanied by short examples of evergreening based on other IPRs such as trade secrets, trade marks, copyright, and database rights. The main case and the examples in the empirical part of the paper altogether illustrate different types of evergreening being based on different types of IPRs and IP strategies as well as on combinations of different types of IPRs into multi-protection strategies used within (intra-generational) and across product generations (inter-generational).

Some of the examples of evergreening are accompanied by some simple theoretical models in an appendix, provided in order to somewhat formally illustrate different types of complementary and substitute intellectual assets corresponding to some of the empirically identified evergreening strategies.

The paper ends with a discussion of implications of evergreening strategies for managerial counter-strategies as well as for innovation and IP policies in an innovation system context. Showing the feasibility and profitability of various proven and perhaps as yet unproven evergreening strategies then serves the purpose to direct managerial efforts to counter-

strategies and policy efforts to counter-policies in order to improve the innovation system on the whole to the extent that evergreening constitutes problems for dynamic competition, which it likely does. A number of policy issues are raised and a few policy options are analyzed in more detail in the paper. However, problems related to evergreening are not easily fixed by policy measures, given the inherent problems to finetune the patent system in light of the changing nature of technological change, changing modes of innovation and increasing risk of political capture. Given the meagre state of art regarding evergreening much of this endeavor must be left for experimentation and further research in the hope of evergreening research on evergreening.

In summary, this paper aims at making six types of contributions: A review of small but steadily growing academic literature on evergreening by IP strategies, a discourse of evergreening for each of the various IPR types, a case study particularly rich in various strategies for evergreening, a conceptual review with a proposed definition, typology and operationalization of evergreening by IP strategies, some simple formal modelling and a discussion of the strategy-policy game or dilemma.

3 Conceptual review

3.1 Defining evergreening

In our literature review we found six definitions or definition-like descriptions of evergreening. The most recent definition was provided by Alkhafaji, Trinquart et al. (2012), defining evergreening as a way that allows "owners of pharmaceutical products using numerous strategies, such as patent laws and minor drug modifications, to extend their monopoly privileges with their products". Rathod (2010) defines evergreening as a "strategy by which technology producers, using serial secondary patents and other mechanisms, keep their product sales protected for longer periods of time than would normally be permissible under the law". According to Bansal, Sahu et al. (2009), evergreening "refers to different ways wherein patent owners take undue advantage of the law and associated regulatory processes to extend their IP monopoly particularly over highly lucrative 'blockbuster' drugs by filing disguised/artful patents on an already patent-protected invention shortly before expiry of the 'parent' patent." Thomas (2009) defines evergreening as "strategy of obtaining multiple patents that cover different aspects of the same product, typically by obtaining patents on improved versions of existing products." In a multinational study of causes and consequences of a low inventive step requirement for patenting Granstrand (2003: 247)) describes evergreening as a strategy by which "effective

patent protection is prolonged from a continually renewed patent portfolio", as illustrated in Figure 1.

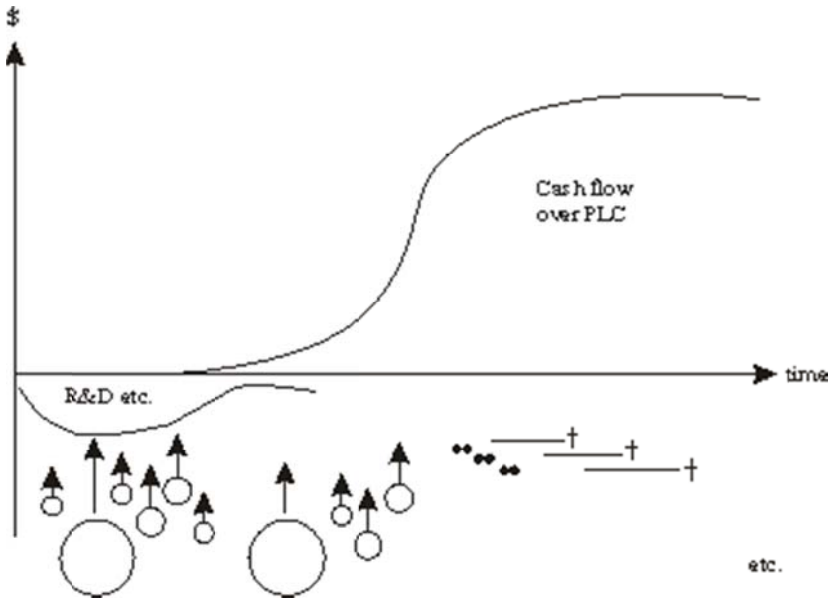

Figure 1- Continous patenting and build-up of patent portfolio over time

Source: Granstrand (1999)

Finally, according to Rathod (2010), the European Generics Association (2010) describes evergreening, as a "common form, occurs when the brand-name manufacturer literally 'stockpiles' patent protection by obtaining separate 20-year patents on multiple attributes of a single product… To evergreen their products, the originator company will develop what are euphemistically called 'life-cycle management plans' composed not only of patent strategies, but an entire range of practices aimed at limiting or delaying the entry of a generic product onto the market."

3.2 Proposed definition of evergreening

As seen these definitions and descriptions are non-contradictory and have several elements in common that then can be taken as definitional characteristics of evergreening as being a business strategy for extending/prolonging IP/patent/sales protection/monopolistic advantage(position, privilege) typically through taking out multiple/serial minor patents on product improvements and features/aspects, typically on pharmaceutical products. Some authors also add a judgment in their definitions.

For our purposes in this article we want to link the definition of evergreening more clearly to the duration of IPR protection for all types of IPRs and do so without value judgment since the statutory duration of various temporary IPRs constitute key policy variables that

are not necessarily set right in the first place, especially since they are interdependent and companies in different industries use different mixes of multiple IPRs and IPR types in form of multiprotection strategies for their businesses. Consequently we do not want to confine evergreening neither to patents alone nor to the pharmaceutical industry alone in order to keep focus on the more generic policy issue of assessing the proper (optimal) duration of IPR protection in light of the strategic gaming of the IPR system by companies, which possibly could lead to losses of not only static efficiency but also losses in dynamic efficiency, thereby making the IPR system counteract its basic purpose. On the other hand we do not want a too broad a definition of evergreening that would confuse and cloud this policy issue with other ones such as abuse of market power and market leveraging in general and protection of product sales and profits through delayed entries and competition from other practices unrelated to IPRs as referred to in the EU description above. This means that e.g. reverse settlements will fall outside our preferred definition of IP-based evergreening or evergreening of IP protection but inside a more general concept of evergreening of product sales. Thus we propose the following (tentative) definition of IP based evergreening:

> *IP based evergreening is the business strategy to extend the duration of the effective protection derived or derivable from a portfolio of IPRs in order to increase the appropriability of an innovation or a set of business related innovations or technologies.*

Some commentary to this definition is called for. First evergreening is a business strategy but not confined to a strategy employed only in an individual company, but the strategy could also be employed e.g. in a corporate innovation system or in open innovation with several collaborating organizations. Second, evergreening is not confined to companies and purely commercial entities but could possibly be used in a business environment by universities, R&D institutes, NGOs and non-profit or not-for profit organizations as long as they are concerned about appropriability of an innovation or a technology, e.g. in terms of capturing societal value rather than commercial value, e.g. by limiting the latter. Third, evergreening is tied to using a portfolio of IPRs as a means for increasing appropriability, thereby excluding the use of non-IPR means for the same purpose. Alternatively one could broaden the concept of evergreening and then distinguish between IPR based and non-IPR based evergreening. Fourth, the relevant IPRs for evergreening could be of any type, not

only patent rights, and they are not confined to ownership rights only but they also include usage rights or licensing rights. Fifth, the definition is chosen so the concept of evergreening can be operationalized and measured, at least in principle. This will be returned to later..

4 Literature review

Our literature review identifies 33 publications, with the oldest one being from 2001 (see Figure 2). They include 21 peer reviewed academic papers, seven kind of academic style working papers or unpublished manuscripts (including one white paper of the US Congressional Research Service), two reports (each one by the European Commission and the US Federal Trade Commission), one book chapter, one PhD thesis and a few short magazine-like articles or published only online.

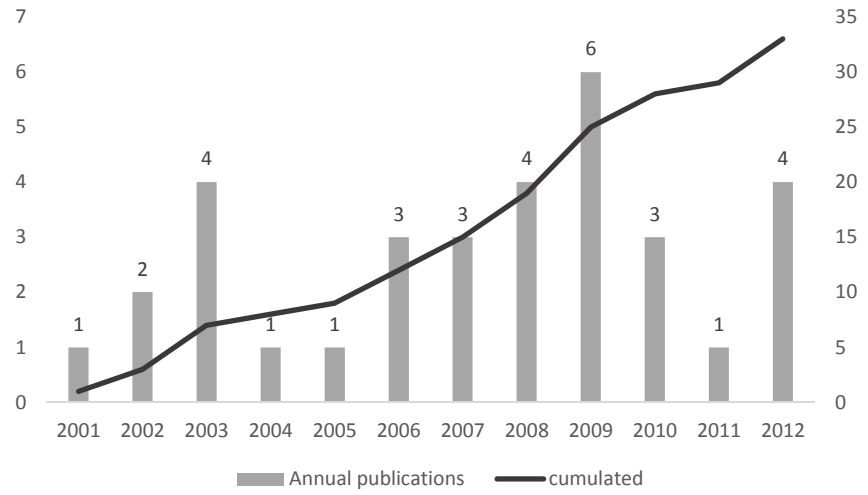

Figure 2 - Annual and cumulated evergreening publications; Source: Own research

Among the papers, one appeared in NATURE Biotechnology (Gaudry 2011) and one was published in Science (Higgins and Graham 2009), indicating a certain level of relevance for the topic. By far the top cited paper is Lemley and Moore (2003) with a total of 266 citations, hence an average of 27 annual citations since its publication, followed by Hemphill & Sampat (2012) with 20 annual citations and the EU report (European Commission 2008) with 18 annual citations. All other papers have less than 10 annual citations.

Very few papers appeared in business related journals. Rathod (2010) was published in a journal of business professionals in the generic medicine sector, Kesselheim (2007) published in a journal that is edited by the American Association of Pharmaceutical Scientists (AAPS) that also aims at business professionals, and Parker and Carruth (2007)

was published in the Journal of Commercial Biotechnology. Rather, papers were published in general law journals such as Darrow (2010) published in Harvard Law Review, Chalmers (2006) published in Melbourne University Law Review, Lemley & Moore (2003) published in the Boston University Law Review, Paine (2003) in Seton Hall Law Review, and Parchomovsky and Siegelman (2002) in Virginia Law Review. Three papers were published in dedicated medical journals, such as Alkhafaji, Trinquart et al. (2012) published in BMC Medicine, Gaudry (2011) published in Nature Biotechnology (being a lawyer) and Hollis (2004) in the Journal of Pharmacy & Pharmaceutical Sciences. Two articles appeared in health related economic journals, such as Hemphill & Sampat (2012) published in the Journal of Health Economics, and Faunce and Lexchin (2007) in the Australia and New Zealand Health Policy. The paper by Faunce, Vines et al. (2008) appeared in the Journal of Law and Medicine, a cross-disciplinary journal publishing contributions related to legal, medical or bioethical content arising at the intersection of law and health. Apparently, not any of the published papers appeared in a mainstream, peer reviewed management journal or even a journal associated with technology and innovation management. One recent working paper was however published by colleagues at INSEAD with a managerial focus on IP (Jain and Conley 2012).

Most articles are concerned with the topic on national policy level / legislation, for instance addressing questions of whether evergreening has a negative impact on costs for the health insurance system of a specific country e.g. , (Alkhafaji, Trinquart et al. 2012). Chalmers (2006) discusses evergreening in the context of the Australia-United States Free Trade Agreement. Authors of other papers are concerned with how legislation impacts firm's evergreening behavior. Other papers focus on the impact of international regulatory treaties such as TRIPS on the functioning of a patent systems and the pharmaceutical companies within a specific country, e.g. , in India (Amin 2007, Nair 2008). Other papers are concerned with how generic manufacturer enter the market of patented drugs.

Some papers take the perspective of society and the generic producer arguing against evergreening strategies. In contrast, Higgins and Graham (2009) argue in SCIENCE not in favor or evergreening, but rather against too much possibilities to enter the market despite patent protection through generic producers. The authors report cases where due to chapter IV exemptions firms were allowed to bring generic drugs on the market, even before the original inventor has recouped its R&D spendings, hence this raising societies awareness for the incentives for an innovative pharmaceutical system. The analysis of Gaudry (2011) presented in NATURE Biotechnology is one of the few empirically support study and

argues in a similar line. The author concludes that "current R&D efforts are in part supported by the additional exclusivities offered by this approach", meaning the additional possibilities of exclusivity periods in combination of patenting, even showing that the efforts seemed to have declined along the studied decade (2000-2010).

Most papers focus on the north-American situation. Seven papers focus specifically on the US (Federal Trade Commission 2002, Lemley and Moore , Paine 2003, Kesselheim 2007, Thomas 2009, Darrow 2010, Hemphill and Sampat). Two papers focus on Canada (Grootendorst 2009, Crowley and Lybecker 2012). Addressing the Asian situation, we only found five papers addressing particularly the situation in India (Amin 2007, Nair 2008, Bansal, Sahu et al. 2009, Kumar, Shukla et al. 2009, Nair 2009). When it comes to the European situation we found two papers that focus on the UK (Burdon and Sloper 2003, Parker and Carruth 2007), one paper that uses data from France (Alkhafaji et al., 2012) and one report by the European Commission addressing the consolidated EU situation (European Commission, 2008).

Several papers discuss evergreening across two or more countries. The paper by Rathod (2010) has a specific focus on the comparison of evergreening practices across different countries covering Canada, Australia, India, Philippines, and Thailand. Crowley and Lybecker (2012) compare the situation in Canada, US, EU, South Korea, Japan, Australia, and Brazil. Faunce and Lexchin (2007) compare evergreening in Canada with the Australian situation. Hollis (2004) compares drug prices in Canada and the US. A brief comparison of exclusivity regimes of the EU, Canada, Japan, and the US is also included in Higgins & Graham (2009). Mueller and Chisum (2008) compare the situation in the US and UK.

Some papers, particularly those that do not deal with specific national legislation but rather focus on managerial or theoretical aspects do not have a specific country focus, such as Jain and Conley (2012), and Parchomovsky and Siegelman (2002).

The literature review identified five papers in which either one specific or multiple evergreening strategies are discussed (Lemley and Moore 2003, Paine 2003, Raasch 2006, Rathod 2010, Jain and Conley 2012). The typology suggested by Raasch (2006) appears to be the most comprehensive one covering relatively well the different evergreening strategies that were discussed by other authors. Also, the typology is probably most helpful for managers as being designed to be used on firm level. Additionally, the strategies briefly discussed by Granstrand (1999) and Granstrand (2003) are also valuable for firm level IP

management. However, the state of the art in the academic literature must still be seen as meagre in terms of lacking systematic empirical studies.

Additionally, two publications should be mentioned. First, the report by the Federal Trade Commission (2002) should be mentioned that focuses particularly on the Hatch-Waxman Act and it implications for firms' evergreening behavior. The Hatch-Waxman should balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers. Several amendments have been made to the act to facilitate generic drug entry. The share of generic drugs on the US market increased from 19 percent in 1984 to 47 percent in 2001. The study examines whether the conduct that the FTC challenged represented isolated instances or is more typical, and particularly whether the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products. The study concludes deriving two major and a few minor recommendations for additional amendments.

Table 1: Evergreening cases covered in prior literature

Authors (year)	**Case studies**
Jain and Conley (2012)	AstraZeneca (Prilosec[2] and Nexium)[3] and Eli Lilly (Prozac and Zyprexa)
Dwivedi, Hallihosur et al. (2010)	Bristol-Myers Squibb and Taxolc; Pfizer and Viagra; AstraZeneca and Prilosec/ Omeprazole
Faunce, Vines et al. (2008)	Apotex vs. Servier; Alphapharm vs. Lundbeck
Raasch (2006)	Eli Lilly, Pfizer, Merck, and Schering-Plough
Parchomovsky and Siegelman (2002)	Roundup, Nutrasweet, Tagamet, Zovirax, Bayer Aspirin
Paine (2003)	Several firm and drug examples

Second, the paper by Conley and Szobocsan (2001) should be mentioned, who discuss the complementarity of different IPRs and characterized the proactive management of multiple IP regimes across the life cycle of an offering in a manner that sustained the value of the initial innovation as value transference. However, their discussion remains to be superficial. Furthermore, Parchomovsky and Siegelman (2002) focus on "leveraging

[2] Also mentioned in Federal Trade Commission (2002). Generic drug entry prior to patent expiration: An FTC study, Federal Trade Commission..

[3] Also briefly mentioned in other papers, such as Rathod, S. K. (2010). "Ever-greening: A status check in selected countries." Journal of Generic Medicines **7**(3): 227-242..

patents though trademarks" and to some limited extent discuss how also trade secrets and copyrights can be used as complements to prolong market exclusivity. They identified two main benefits for a firm: the exclusivity secured by the patent might lower the marketing costs of creating a strong brand and simplify the establishment of brand loyalty by locking out competition.

All papers with an industry focus or that provide case studies draw on the pharmaceutical industry and then almost solely on patent strategies. None of the papers we identified draws specifically on another industry or on other IPRs. Several papers include case studies to illustrate and substantiate their arguments, respectively present evergreening strategies. Very little quantitative data is available about evergreening strategies and no operationilization of evergreening was found, nor any typology of IPR based evergreening per se[4] Except some papers that use quantitative, primarily secondary empirical data, such as systematized patent statistics where the analyses remains descriptive. Notably papers include Alkhafaji, Trinquart et al. (2012), Hemphill and Sampat (2012), Gaudry (2011), European Commission (2008), and Lemley and Moore (2003). The data used by Hemphill and Sampat (2012) is probably the most extensive and solid quantitative study on evergreening. The report by the Federal Trade Commission (2002) should be mentioned additionally as it presents some limited descriptive data (e.g., on litigation cases, settlements, usage of later-issued patents).

5 Methodology

5.1 Literature review

For the literature review we used keywords to search iteratively in Google Scholar and ISI Web of Knowledge to identify papers related to the concept of evergreening (Cronin, Ryan et al. 2008). Essentially besides "evergreening" we used three notions "extension of market exclusivity period", "continuation patents" and "patent prosecution tactics". These synonyms emerged gradually from reading papers that we were able to find. We however did not search for broad terms like "life cycle management" or "life cycle management plans".

Since we did not focus specifically on the pharmaceutical industry and drug development, we did not search specifically for papers related to the life cycle management of drugs,

[4] Evergreening in the general sense has been operationalized as the time gap between patent expiration of a drug and the first entry of generics. This gap then depends also on the use of other strategies for evergreening such as reverse settlements ("pay-for-delay " deals).

although it appeared that by far most of the papers we identified are related to the pharmaceutical business.[5]

5.2 Case study

The singly case study Losec is based on multiple, extensive semi-structured, open-ended interviews involving almost all key stakeholders that were deeply involved in developing Losec, such as the top management of Astra at that time and persons heading the litigation team against generic companies. The data collection spans multiple years from the early to the mid 2000s. Multiple key respondents thus ensure result validity (Jick 1979, Van Bruggen, Lilien et al. 2002, Homburg, Klarmann et al. 2012). Additionally, the available literature was reviewed (e.g. Östholm, Wood et al. 1995, Sundling 2003) and secondary data was provided by the interviewees as was collected through desk research via a web search (e.g. annual reports).

6 Pharmaceutical case study of evergreening

"Five times we were told we should terminate the project… That it survived despite all these set-backs is an exciting tale of dedication and the efforts of very capable scientists." [6]

Back in 1956, the first idea was born to develop a drug that would neutralize hydrochloric acid in the stomach. After a symposium in 1966, a small group of researchers at Astra Hässle turned the acute need for the treatment of peptic ulcers into a research project at the small research subsidiary of Astra AB in Mölndal. The project turned out to be more challenging than ever could be expected.

"Everyone spoke against the project. The substances we had chosen for tests were either toxic, had potential side effects, or had absolutely no effect on humans. We had no chemical structure from which to start our renewed effort. It was easy to find arguments to end the project." [7]

[5] We acknowledge the support of Tobias Röth for his support in collection the papers.
[6] Östholm, I., et al. (1995). Drug discovery : a pharmacists story. Stockholm, Swedish Pharmaceutical Society (Apotekarsocieteten).
[7] Ibid, p.171

1956	Initial idea for a peptic ulcer drug
1966	Initation of research project after symposium
1981	First record of Omeprazole in annual report
Jul 82	Agreement with Merck signed to market products in the US
1983	Omeprazole in comprehensive clinical trials
Mai 84	Interruption of clinical trials
Nov 84	Testing relaunched
1984	Trademark for Losec filed
1986	Losec registration application filed in 20 countries
end of 1987	FDA registration with Merck carrying out clinical trials
1987	Approval in France
early 1988	Approval in Sweden (and 17 countries)
Okt 89	Approval in US, sales started by Merck
Apr 91	Launch in Japan
Apr 91	Losec approved for long term treatment in the US and UK
1993	Losec available in "all major markets"
Jul 98	Restructuring Astra, Merck agreement changed
1998-1999	Merger AstraZeneca
Jul 00	Nexium approval in EU

Figure 3: Losec development chronology

Driven by believe in the medical need of a small group of people, after more than twenty years the project resulted in approval of a drug called Losec, by the Swedish authorities (corresponding to the US FDA) for sales on the Swedish market in 1988. Estimates of total R&D costs for Losec range between 200 and 300 m$, i.e. depending on what costs are taken into account. In 1996, Losec became the world's largest selling drug for four consecutive years.

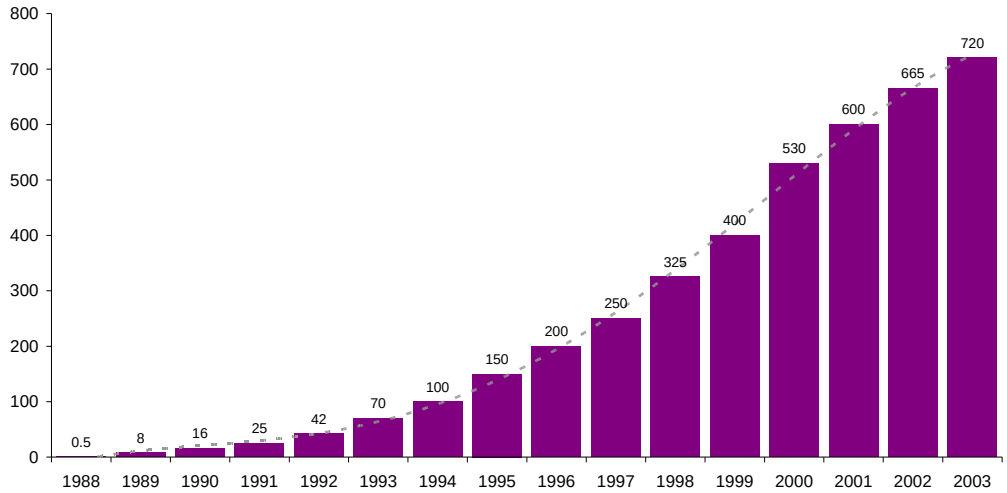

Figure 4: Accumulated worldwide patient treatments with Losec [mio]

6.1 Inventions and patents that led to Losec

During the twenty years of research to develop Losec, several patents were filed by Astra, essentially on new substance-classes that were discovered. However, finally Losec was essentially protected by two patent families as illustrated by the patent-to-product map illustrated in Figure 2. One patent family covered the invention of the active substance (Omeprazole), while the other covered the formulation, i.e. the way the drug is packaged for controlled release. While the substance patent was filed in 1979, the formulation patent was filed as late as in 1987. The substance Omeprazole proved to be very difficult to handle as it does not tolerate light, heat or water and even worst, hydrochloride acid. Astra had to manage the transport of this unstable substance through the acid environment of the stomach in order to reach the duodenum where the substance is released and transported via the blood to the stomach's acid producing cells. Once inside the cells, Omeprazole is transformed into an active proton pump inhibitor[8]. Astra managed this complicated 'transportation' problem by inventing a double coating system and filed for patent protection for this invention as shown.

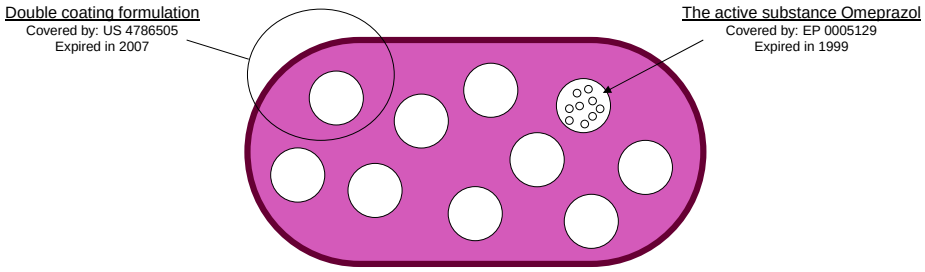

Figure 5: Product-to-patent map of Losec

6.2 Evergreening Losec

After Losec (Omeprazol) for stomach ulcers was developed at Astra-Hässle in Mölndal, Sweden, and launched with its first year of sales in 1988, it quickly became a commercial success and for several years was the world's annually bestselling drug. The basic patent on the active substance (EP 0005129) was applied for in 1979 in Europe and the US, among other countries, and was granted in 1981 in the US - which meant that its validity in the US expired in 1999 (although subsequently prolonged for three years). The basic patent can be regarded as a very strong one with a substantial inventive step and strategie blocking effect in terms of restricting possibilities for inventing around. Losec represented a whole new biological mechanism based on proton pump inhibitors, and was thus a technologically

[8] Compared to competing medications, Losec affects only the particular enzyme responsible for pumping H2 in the stomach, while competing medications function the way as they are named, H2 blockers.

radical innovation that also became economically very large since it attained huge growth and its value has been estimated to lie in the interval of 15-30 b$.

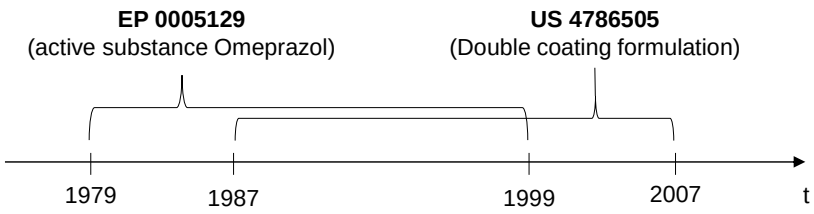

Figure 6: Evergreening of Losec

This innovation contributed more than any other of Astra's radical innovations to making Astra one of the 15 largest global pharmaceutical companies, from having been among the 40 largest before Losec. In 1999, annual sales of Losec increased for one more year up to its climax of 6.3 b$. In 2004, AstraZeneca was the sixth largest such company and had sales of prescription drugs amounting to 21.4 b$, ranked after Merck and before Novartis.

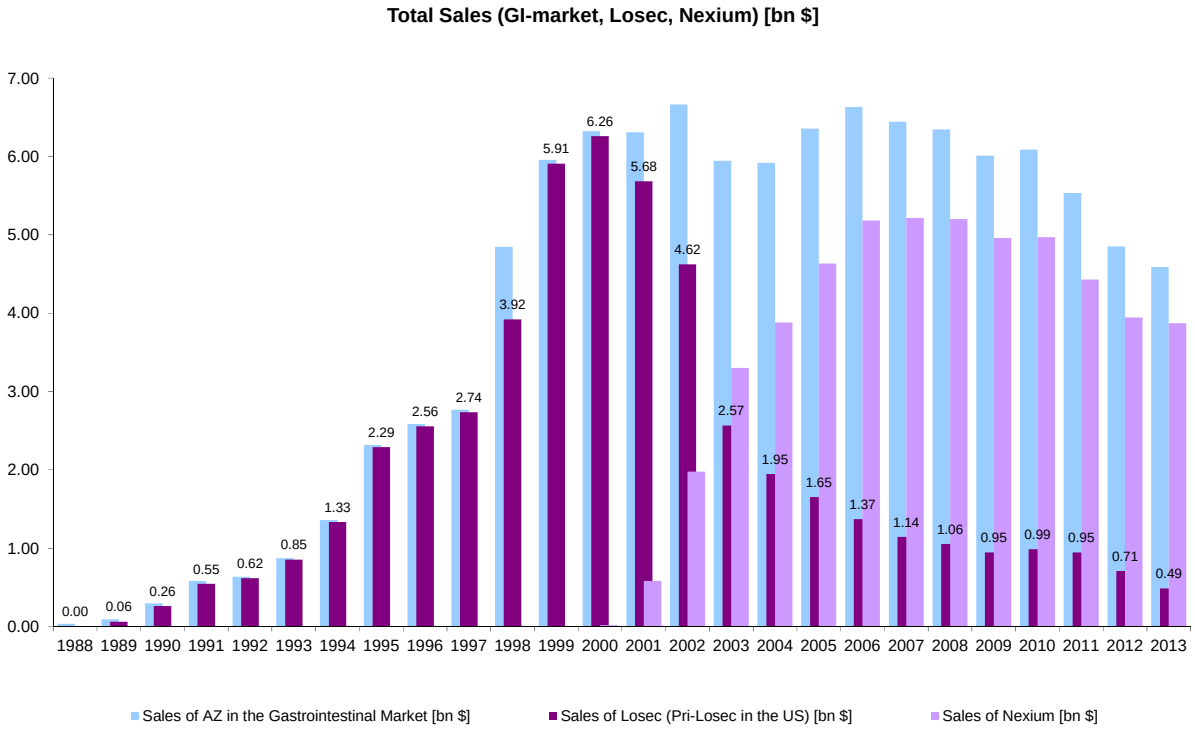

Figure 7: Evergreening of Losec by Nexium

After its initial launch, R&D efforts continued to develop an improved form of encapsulation for the active substance, which yielded a so-called formulation patent (Figure 4). This type of patent did not have the same high inventive step as the original

substance patent. An essential step in the commercialization of Losec was precisely the development of a well-functioning pharmaceutical preparation. Astra sought and thus received a patent on the preparation, which proved to be very valuable in preventing competition with generic companies. An extra month without generic competition was to be worth at least 100 million US dollars for Astra. If a patent, or a series of several such patents; delayed generic entry by, say, 8 years, which is not unrealistic in the case of Losec, it means roughly almost 10 b$ in (undiscounted) patent value.

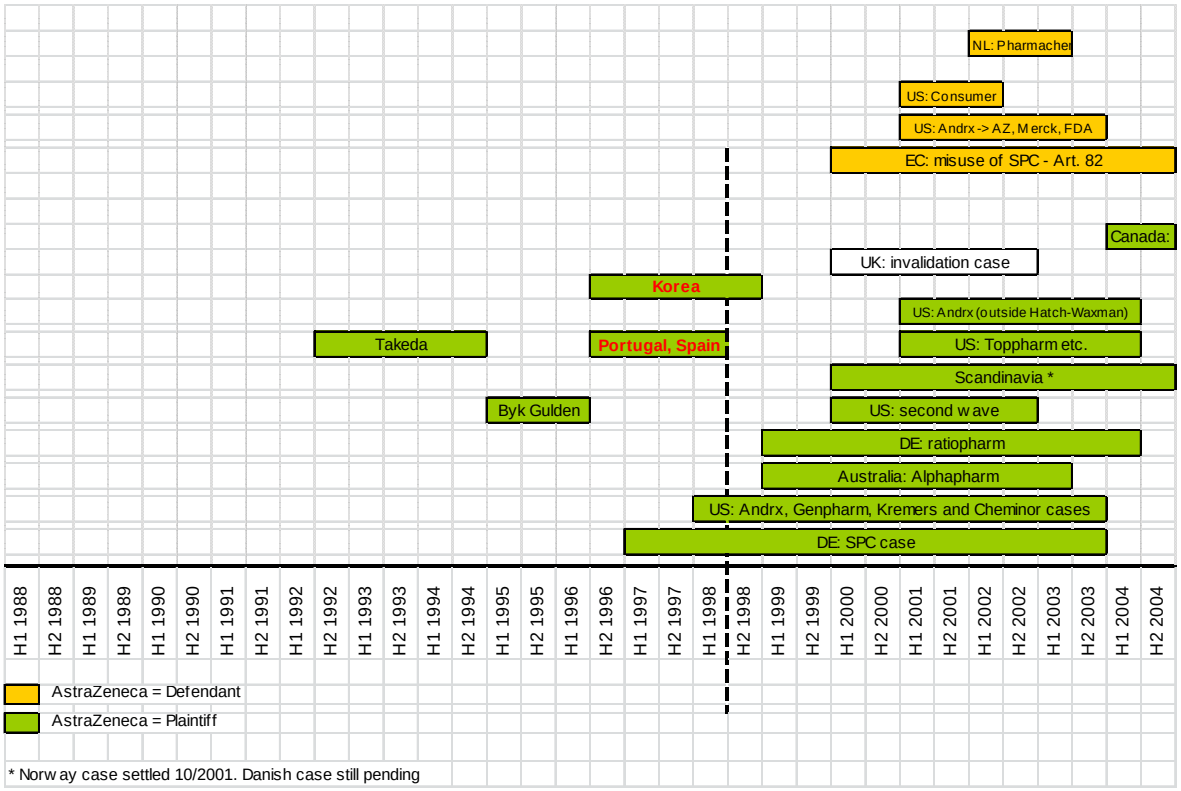

Figure 8: Litigation history of Losec patents

The case of Losec thus illustrates how patents with both large and small inventive steps in combination contribute to enormous growth in value, although not without patent enforcement efforts (see Figure 8). The fundamental prerequisite for the improvement patent to yield great growth of sales, value and welfare, however, was a radical basic innovation.

The case thus illustrates that a so-called "evergreening" strategies, with follow-up patenting of more incremental inventions following upon a large or generic one, can be extremely economically successful. The drug Nexium, a descendant of Losec (the second product generation), further illustrates the economic importance of more - in technical and

scientific terms - modest progress and constant improvement work along a "growth path". These cases altogether demonstrate the important interplay and synergies between radical and incremental innovations.

6.3 Summary of the Losec case of evergreening

The Losec-Nexium case as illustrates at least five major strategy types for evergreening. First is the use of a technically minor improvenment in form of a reformulation and repackaging. Second the development of a successor product as a second product generation with an overlapping technology base. Third the combination of patent protection with multiple trade mark protection (of product name, color, etc) and other brand building efforts and then aggressive marketing of the successor product. Fourth the use of aggressive litigation to fend off or delay entries. Five, the use of reverse settlements. All the time various patents and other IPRs were registered in addition to trade secrets together with various other more minor means.[9]

7 Cases of evergreening by IPR type

The traditional and still dominant form of evergreening uses patents. However, although patent strategies were central to evergreening in the Losec-Nexium case other IPRs were important as well as were evergreening by other means than IPRs. As will be illustrated below all other types of IPRs lend themselves to different forms of evergreening, with the common feature that the duration of the temporary competitive advantage a single IPR provides by IPR laws and regulations at policy level is extended by various IP strategies using multiple IPRs of the same type (single type protection) or multiple IPRs of different types (multi-protection[10]).

7.1 Patents

As for patents, the most common form of evergreening uses patents on subsequent improvements or different features of the original innovation, mostly then a product innovation. These follow-on patents are often minor technically seen (but not necessarily

[9] In fact, during the R&D phase of Losec in the Astra subsidiary Hässle outside Gothenburg kept a low profile since the reigning blockbuster in the area
was Smith-Kline-Beckman's Tagamet, the world's best selling drug for several years at the time, a drug that was likely to be evergreened with strategies directed at the much smaller company Astra at the time. This issue was covered in a joint study with late Edwin Mansfield by one of the authors of leakage rates of new technologies. The Astra subsidiary also encountered resistance against the Losec project internally in Astra and thus kept a low profile for that reason to allow a o gerilla R&D.

[10] Multiprotection refers more generally to the synergistic use of multiple IPRs of different types, see Granstrand (1999, pp.247-251).

economically seen) and could be taken out almost continually in the business development process. A case in point is the use of continous improvement processes (”Kaizen”) in Japanese industry which could result in a trail of cumulative or differentiating patents not only for products but also for processes as companies drive down the learning curve. New applications, e.g. new medical applications, could also be discovered and patented. Thus complementary serial patents will be instrumental for evergreening. Also substitute patents are instrumental for evergreening in that they limit invent around possibilities for competitors. A case in point (out of many) is the DuPont attempt to protect its innovation nylon by a fence of substitute patents (an attempt that failed, however, see Granstrand1999). Thus continually building and maintaining a patent network with series of complementary strategic patent fences for different applications, processes and improvement trajectories would be an effective patent strategy for evergreening a product innovation.[11] However other spatial patent configurations such as patent blankets could also be effective (although costly and perhaps not cost-effective) in blocking or delaying entries, not the least since they create entry deterring legal uncertainty. The important point for evergreening effectiveness is the temporal configuration, i e how the blocking or delaying patent portfolio is built up and maintained over time.

This in turn presents several complex optimization problems for the prospective evergreener. One problem is simply the overall cost-effectiveness of evergreening. Another is how much to speed up R&D and patenting of complementary and substitute patents in the overall racing and waiting game with competitors, since waiting to apply for a subsequent serial patent increases the evergreening effect while the probability to lose out in the patent race with others increases (see Appendix for a simple model illustration. The optimization is moreover complicated by several factors and uncertainties. The essentiality of patents and patent fences is normally not known beforehand and neither is the validity of a patent when challenged for example.

7.2 Trade secrets

Products with long life cycles and technical imitation difficulties (e g due to high reverse engineering costs), like certain recipes in the food and drink industry, are likely to be protected by trade secrets. A trade secret can leak out or become non-unique by independent invention or simply be lost, e.g. by death or bit rot. Various secrecy strategies

[11] A strategic patent fence is a patent fence (set of substitute patents) that altogether effectively blocks competing innovations. A single strategic (=essential) patent could then be seen as a reduced strategic patent fence.

are available. Leakage risks can e.g. be lowered by fragmentation of key knowledge into pieces and dispersing them across knowledge holders with limited access to each others' knowledge. [12]

This is essentially fragmentation of complementary resources in order to increase the duration of the entire trade secret, in other words a form of evergreening. Loss of knowledge can be countered by redundancy, which in turn increases leakage risks however. Redundency can then be seen as an aggregation of substitute resources.

An example of the use of such strategies for evergreening is what we can call the Benedictine scheme, inspired by an unvalidated story about how the Benedictine monks protected their secret recipe for the Benedictine liqueur.[13] The scheme (or evergreening strategy) was set up so only the abbot knew the whole secret, while two selected monks knew different halves of it. When the abbot died, one of the two monks was promoted to abbot and thereby was informed by the other monk while informing a new monk selected to replace him. This evergreening scheme then uses both knowledge fragmentation and knowledge redundancy but in a minimal way.

7.3 Copyright

The duration of copyright is very long but with a narrow scope, protecting only expressions and not ideas, as patents protect. Copyrighted products can have very long life cycles with substantial sales and are in general not particularly difficult to imitate and distribute technically (some paintings apart). The incentives to evergreen can thus be very strong despite the already long statutory duration but the narrow scope of protection limits the room for strategizing through portfolio extensions, instead incentivizing companies in the typical copyright industries to lobby for extensions of statutory duration of single copyrights. A case in point is the Disney protection of the Mickey Mouse character. Nevertheles there are possibilities to work with copyright portfolios for evergreening, e.g. by giving birth to new complementary or possibly also substitute characters over time in a family of cartoon or movie or game or ad characters, such as in Donald Duck. Derivative works with also play an important role for evergreening in the copyright area, comparable to but still different from patenting of product improvements.

[12] This is then at the expense of lower knowledge productivity and creativity in an organization, see e g Granstrand 1999.
[13] See Granstrand 1999, pp.253-54.

7.4 Trademarks

Trademark protection already allows for eternal evergreening since they do not expire by statutory law as long as they are properly maintained (and not diluted or degenerated). Still portfolios of complementary and even substitute trademarks could be built up and used for evergreening purposes, e.g. in form of dual marks such as Sony Walkman and Sony Discman where the product mark may lose its protective value over time but then has made a contribution to the company name which could be carried over to a subsequent product.[14] New forms of trademarks, protecting special colour combinations, sounds and 3D shapes, open up more possibilities of this sort.

7.5 Designs

Design rights are time limited as well. In many respects they are similar to ”small” patents or utility patents and could be used for evergreening in somewhat similar ways. Case in point is Apple’s series of smart phones in which certain icons and shapes are kept as well as added throughout different product generations. The lower inventive or creative step requirement actually facilitates evergreening at the same time as the risk of losing a patent race is lower since there are more possibilities to design around.[15] The possibilities to fence off substitutes are then more limited on the other hand.

7.6 Data base rights

Data base rights as existing in Europe have a 15 year statutory duration by law but are open to evergreening in that they are limitlessly renewable as long as new investments are made in the database. This is in contrast to other IPRs.[16]

7.7 License rights

License rights are as usage rights different from ownership rights but can be used as a complement to the latter in evergreening. In the case of patents a grant-back license on all improvements made by licensees broadens the set of controllable improvements and lessens the risk of losing a technological lead. The same outcome may be achieved in case of licensing trade secrets in form of know-how licenses. A by now classic case is the sharing of production secrets in the VHS family of video cassette recorder producers held

[14] This has been described in the literature as CI/BI building, commonly used in Japan originally, see Granstrand 1999.
[15] In the smart phone case the inventive step requirement for a design patent in the US was allegedly so low that it would not qualify even for copyright protection (Ralph Oman, personal communication).
[16] There is an investment related requirement in the maintenance of a trade secret right in that the rights holder has to make demonstrable efforts to protect the secret that moreover has to have commercial value so a pure investment is not sufficient.

together by JVC as licensor. A similar arrangement could be found in e.g. the copyright area where software developers and/or users feed back their improvements or applications to an original source code developer or a software community. Viral contracts or copylefting could then serve to extend the duration of a specific IP protection regime rather than the duration of IPR protection per se. Arrangements for user led innovation or producer led innovation similarly could be used for evergreening in a more general sense.

7.8 Summary

As seen all the different IPR types lend themselves to evergreening although with different strategies and different effectiveness. The strategies have some elements in common, however. IPR protection of fragmented complementary resources facilitates evergreening as does aggregation of substitute resources. Fragmentation is moreover facilitated by a low inventive or creative step requirement, which on the other hand facilitates invent or design around, in turn lessening the blocking or delaying of competition.

Finally the various evergreening strategies for the different IPR types could with a few exceptions be combined into multiprotection, as illustrated in our case study of Losec. Thus they are by and large complementary, with a major exception being patent rights and secrecy rights which for the same scope of protection cannot be combined. However, at the level of an innovation they can, e.g. by combining a product patent with secrecy protection of the production process as is well known. (See Appendix for a simple but illustrative formalization.)

8 Analysis and discussion

8.1 Operationalizing evergreening

The first step in operationalizing the phenomenon of evergreening is to typologize it in order to use nominal scales and perhaps also ordinal measurement scales.

As seen from conceptual review, the literature review, and the case studies we can distinguish between the following types:

- Evergreening of a dominant market position on the product/technology/service/equity market by IP/non-IP strategies where the dominant position in the first place may have been derived by IP/non-IP strategies.

- Evergreening by IP –strategies may in turn be based on single/multi -type IPRs for intra/inter-generational evergreening, using different types of IP-strategies (e g strategic /follow-on/ sequential patenting in form of fences, blankets etc. for products, processes and applications).

The case of inter-generational evergreening with three product generations may be illustrated as in Figure 9 below.[17]

The next step in operationalizing evergreening is to introduce some metrics. Here we will link a first kind of the metrics to the duration of an IPR portfolio in some time units. A second kind of metrics is linked to the time gap between the possible entry by competitors but for evergreening and the actual entries by competitors. If IP based evergreening is effective in delaying entry, then the first kind of metrics provide a lower bound on evergreening and the latter an upper bound. Needless to say the necessary counterfactual analysis for the latter kind of metrics involves uncertainty and subjective assessments, as does in fact the first kind as well.

[17] A good case of intergenerational evergreening is the Gillette sequence of razors with 1-2-3-4-5 razor blades, and each generation covered by numerous patents of which some read on more then one generation. The use of backward and forward compatibility of razors and razor blades and standards further contributes to evergreening.

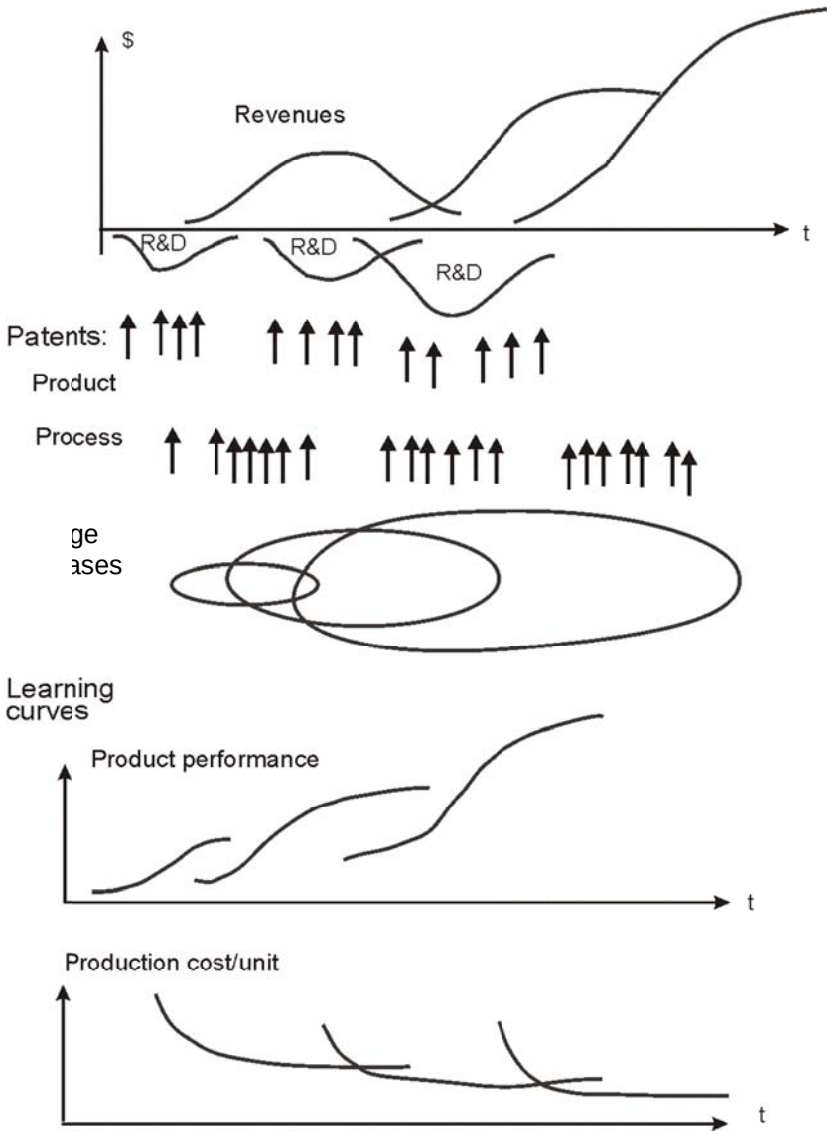

Figure 9. Patent based inter-generational evergreening for three generations

Operationalizing the duration of a single IPR is simple as to its statutory lifetime and as to its actual duration once it has expired (with the exception of trade secret rights). The duration of a single IPR ex ante its expiration is not clear since it could be unrenewed or invalidated. Its duration or life-time could thus be treated as a random variable with a probability distribution and an expected duration value.

The duration of a portfolio of IPRs is more difficult to operationalize. Two approaches will be proposed here. The first is based on the joint life time distribution function for the IPRs arranged in vector form, which gives a vector of expected duration values for the duration of the various individual IPRs. These duration values could then form the basis for an aggregate duration value for the whole portfolio. This approach does not take the economic value of the IPRs explicitly into account but could do so implicitly. The approach is related

to the approaches in systems reliability theory used to determine the expected life time of a functioning technical system.

The second approach proposed here is related to financial theory and takes the economic values explicitly into account (but still yields a measure of duration in time units). The portfolio of IPRs is then looked upon as a portfolio of (indivisible, intellectual) assets, each with a revenue stream associated with it (although more difficult to assess than for bonds or other securities). The different duration measures for financial asset portfolios could then be generalized to apply to IPR portfolios, which in contrast to "normal" financial asset portfolios have random revenue streams in continuous time (see Appendix 1).

Finally, once the duration of an IPR portfolio is operationalized in form of a one-dimensional measure in time units then the difference in duration resulting from additional IPRs added to the portfolio could be calculated and taken as a measure of the extent of evergreening in time units.

8.2 The strategy-policy game

Many of the problems with the patent system derive from the fact that the system can be strategically gamed by its users in ways that are difficult to counter by policy makers, including law makers. This leads to a meta-game between strategists at industry level, who are involved in a competitive game with each other, and policy makers at the government level, who needless to say might be involved in games with each other as well. We will refer to this meta-game as the strategy-policy game.[18]

This kind of meta-game is more or less omnipresent in any decentralized governance system and it should come as no surprise that it is present in the patent system in general. Evergreening by exploiting the rules in the patent system then provides a good illustration of the strategy-policy game as strategists want to increase the duration of effective patent protection in order to increase monopolistic rents while policy makers want to limit it in order to increase competition. At the same time viewing evergreening as a strategy –policy game provides useful analytical tools for coping with evergreening. One such tool is a strategy-policy matrix as shown in Table 1, considering the three categories policy-makers (without a competing category), evergreeners and their competitors.

As seen from table 1 there are many elaborate strategy options for evergreening and a fair amount of response strategies, while the standard patent policy variables are relatively few, i e duration, inventive step (non-obviousness), scope of protection, patentable subject

[18] This type of game can be looked upon as being played in simple cases at two levels with two competing categories of collaborating players at each level- a rule-making level and a subordinate rule-playing level.

matter and patenting fees. It is outside the scope of this exploratory paper to make an economic policy analysis of evergreening and suggest policies to cope with it, but a few observations and reflections are in order. First it is a daunting task to assess the economic consequences of evergreening that operates in increasingly complex technologies with significant prospects as well as costs for improvements with unclear counterfactuals. Evergreening defendants may argue somewhat in line with Kitch's prospect theory and the standard critique of that theory is difficult to empirically verify.Nevertheless evergreening is widespread and probably increasingly so and it runs counter to the basic idea of limiting the duration of IPRs, patents in particular. This clearly calls for policy analysis and research, which in turn requires clear definitions, operationalizations and typologies, to which end this paper hopefully has made some contributions. Second, even if evergreening is found to be detrimental to innovativeness, growth and welfare, at least certain types of it, it is difficult to find effective policy remedies that can add to the countering effects of strategies against it, i e add to the market forces.[19] This is so much due to the compounded effects of changes in terms of the parameters or policy variables in the patent system with its one-size-fits-all features and the industry specific nature of evergreening. More restrictions on the use of patent term restorations upon application are possible.

Raising the inventive step requirement is also possible but with mixed effects upon evergreening since possibilities to patent minor sequential improvements are reduced but so are invent around possibilities. [20] Third, policy remedies are perhaps more called for and also more easy to find for some other forms of evergreening, not being based on patents, as practiced in the pharmaceutical industry (including Astra Zeneca in the Nexium case), reverse settlements and branding post-patent drugs. The latter form of evergreening is based on IPRs, trade marks in particular, and could be surprisingly effective and profitable, not the least in countries as China with generics of poor quality, a fair amount of corruption, weak government price controls and a foreign-is-better syndrome among buyers, prescribers and users, promoted by various means by foreign producers.

[19] The Federal Trade Commission (FTC) in the US has voiced concerns, emanating in a legal brief in a special case in 2012, that reformulations of a pharmaceutical, dubbed a "product hopping" strategy by the FTC, in effect can be detrimental to competition by helping to keep generics out of the market rather than providing useful medical innovations (The Economist, June 21st 2014, p.72).

[20] Raising the inventive step requirement could be justified on other grounds such as the need to reduce transaction costs, see Granstrand 2003, Ch 10 for an empirical and theoretical study with this conclusion.

Table 4. The strategy-policy matrix for patent based evergreening[21]

Evergreening policies	
For[22]	Against[23]
• Patent term restoration • Injunctions • Delaying licenses, concessions, approvals, litigation etc.	• Reduction of statutory duration • Reducing the scope of protection • Reducing patentable subject matter • Increasing the inventive step requirement • Increasing patenting fees for sequential and/or substitute patents • Market power abuse intervention • Compulsory licensing • Abandoning the patent system

Evergreening strategies	
For	Against[24]
• Search and research for strategic patents and patent fences • Fragmentation and patenting of complementary resources and elements in the business innovation system, typically by • follow-on/ continous sequential patenting of product/process improvements, features and applications for the innovation and its related complements • Aggregation and patenting of substitute resources and products/ technologies, typically by blocking patents and patent fencing outside the own product area (cf ”offensive patenting”[25]) • Sequential patent blanketing and patent flooding • Multiprotection, combining patents with other IPRs • Grant-back licensing • Deterring litigation and litigation threats, possibly using NPEs and privateering[26] • Lobbying	• Invalidation[27] • Invent around • Patent or license acquisition • Patent pooling and cross-licensing • Partnering • Use of general bargaining power, e.g. purchasing or procurement power • Ignore and/or infringe • Delay entry until patent expiration • Abandon entry and related commercial operations and R&D Patent racing to foreclose evergreening patents, e.g. by surrounding a strategic patent with application patents or invent around or racing for strategic improvement patents.

[21] The table gives important and common examples of patent-based evergreening but is not exhaustive. Non-patent based means for evergreening of product sales also exist such as marketing of branded products after patent protection has expired (”off-patent” products) and reverse settlements (”pay-for-delay” of entry).
Moreover, policies as well as strategies for and against evergreening could be regarded as opposites and included in the matrix as such. Similarly policies aimed at strengthening or weakening the propensity to employ a certain strategy could be included. Such examples that are easy to derive logically are excluded here, however.

[22] Policies are taken in a broad sense here and includes laws, regulations, agency decisions and interventions. Policies in a narrow sense explicitly designed to promote evergreening in general are fairly rare in practice as to be expected. In theory they are conceivable, however, e g in line with the arguments in Kitch’s prospect theory, claiming that a broad and durable protective scope in emerging technologies allows for more coordinated subsequent improvement processes by the rights holder.

[24] Response strategies to blocking patents in general apply here, see Granstrand 1999, pp.232-234 in addition to patent strategies to foreclose evergreening patents.

[25] The dichotomy defensive/offensive patenting is avoided here since it is both unclear and value-laden.

[26] See especially Ewing (2011) on privateering. The use of privateering specifically for evergreening is likely although unclear, however.

[27] Invalidation of patents, especially by digging up prior art, is more common than generally recognized and could possibly affect a major share of all patents, see in particular Henkel et al. (2014).

9 Summary and conclusions

Evergreening is a strategy practiced since long in industry, particularly in the pharmaceutical and chemical industry, for extending a dominant market position, typically derived from and based on IPRs,typically patents. The academic literature and research on evergreening has lagged behind this practice with a small but steadily growing literature since the early 2000s, mostly case studies with almost no quantitative studies and almost exclusively dealing with the use of patents for evergreening in the pharmaceutical industry, fending off generics, and often then from advanced developing countries. A handful of definitions and descriptions have been forwarded but no operationalizations of evergreening.

In summary, this paper aims at making a number of contributions: First the small but steadily growing academic literature on evergreening by IP strategies is reviewed. Second a case study of the pharmaceutical Losec and its successor drug Nexium is provided in some detail. This case is particularly rich in various strategies for evergreening and illustrates at least five major strategy types for evergreening.

First is the use of a technically minor improvenment in form of a reformulation and repackaging. Second the development of a successor product as a second product generation with an overlapping technology base. Third the combination of patent protection with multiple trade mark protection (of product name, color, etc) and other brand building efforts and then aggressive marketing of the successor product. Fourth the use of aggressive litigation to fend off or delay entries. Five, the use of reverse settlements. All the time various patents and other IPRs were registered in addition to trade secrets together with various other more minor means. A third contribution is a discourse of evergreening for each of the various IPR types, followed by a conceptual review with a proposed definition, typology and operationalization of evergreening by IP strategies, accompanied by some appended simple formal modelling. Finally, the strategy-policy game or dilemma with strategies and policies for and against evergreening is discussed. At this stage of research on evergreening few strong conclusions can be forwarded except a standard one that more research is needed in the spirit of evergreening research on evergreening.

Appendix 1. Operationalization of evergreening

As mentioned above, we use two approaches for operationalizing evergreening in terms of an increase in the duration of protection of the relevant IPR portfolio due to the addition of further IPR portfolios to it. Essentially evergreening then extends the expected market lead time for the innovator.

If additional IPR portfolios are added repeatedly over time in such a way that the expected duration of the cumulated portfolios has no upper bound, then we could say that perfect evergreening has been achieved in theory. This concept could be formally stated but is omitted here.

Approach I

Given a portfolio M of intellectual resources or assets (e.g. technologies), protected by m IPRs with deterministic or random life expiration times $L_1,...,L_m$, ordered in some way, the pure time duration dur(M), unweighted by any associated revenues, of the portfolio is a mapping of the joint probability distribution of $L = (L_1,\ldots,L_m)$ to a one-dimensional random variable in time units such that it reflects the legitimate access time for competitors to the commercial user of the resources (cf market lead time), accounting for the structure of them in terms of being complementary and substitute resources (assets). See Appendix 2 for some examples of such a mapping.

Approach II

Given a portfolio of m IPRs with a random revenue stream $R_1,\ldots,R_n$ at deterministic or random times $t_1,\ldots,t_n$, a value weighted duration durw(M) accounts for the value or revenue consequences of the expiration of the IPRs in the portfolio in a manner that allows for competitors to enter the relevant market. The value weighting procedure is similar to duration concepts for general asset portfolios in finance. The one suggested here corresponds to the Fisher-Weil type for fixed securities, which is defined as:

$$durw(M) = \sum_{i=1}^{n} t_i \, R_i \, e^{-r_i t_i} \Big/ \sum_{i=1}^{n} R_i \, e^{-r_i t_i}$$

where r_i is the discount rate at time t_i.

We extend this definition to continuous time with instantaneous revenues R(t) occurring continuously over time t with a piece-wise constant or continuously varying discount rate r(t):

$$durw(M) = \int_0^\infty tR(t)e^{-r(t)t}dt \Big/ \int_0^\infty R(t)e^{-r(t)t}dt$$

Evergreening

The evergreening effect evg(M, ΔM) of adding a portfolio ΔM of further IPRs to the existing portfolio could then be operationalized as:

$$\text{evg}(\text{M}, \Delta\text{M}) = \text{dur}(\text{M} \cup \Delta\text{M}) - \text{dur}(\text{M})$$

where durw could also be used. Note that the duration and evergreening effect in general are random variables, and if ΔM is added later in time, evg could turn negative.

Appendix 2. Some simple models of IP portfolio duration and evergreening of IP.

If m patents are essential with life expiration times L_i, then the duration of the corresponding portfolio could be defined as the time L it takes until all patents have expired and competitors have legitimate access in principle to all necessary or essential technologies. Then L = maxL_i with probability distribution function F(x) = $\prod_i^m F_i(x)$ if all life times are independent. The life expiration times L_i could be seen as random in case the corresponding patent is possibly invalidated or unmaintained. In case a patent i applied for at time T_i is granted, maintained and valid for a fixed time of 20 years, its life expiration time probability distribution function is simply a condition function:

$$F_i(t) = \chi(t \geq T_i + 20)$$

If the m patents are perfect substitutes the duration L of the corresponding portfolio could be defined as the time it takes until any one patent expires, which is then the technology access time for competitors. Then L =minL_i with probability distribution function

G(x) = 1- $\prod_i^m G_i\,(x)$ if all life times are independent, where $G_i = 1 - F_i$.

Patent portfolios with essential and substitute patents mixed could in principle be broken up in essential and substitute patent modules, which in turn could be treated in similar ways for calculating the duration of the entire portfolio, reflecting the technology access time for competitors, in turn influencing the imitation time for competitors and in turn the market lead time and the revenue stream for the innovator. This could be done for other IPRs as well, since duration is defined for IPRs in general. An example is the Benedictine case of evergreening the protection of a trade secret as described in the text.

The Benedictine case

Denote by L_1 the random life expiration time of the abbot's whole secret, which is a substitute for the two complementary monk halves of the whole secret with random life expiration times L_2 and L_3 respectively. Then the duration of the (L_1, L_2, L_3) portfolio lasts as long as L_1 has not leaked out or has been destroyed or independently discovered or not both L_2 and L_3 have leaked out or have been destroyed or independently discovered. Thus the portfolio life time or duration is dur (L_1, L_2, L_3) := min(L_1, max(L_2, L_3))

Suppose for the sake of illustration that L_1, L_2 and L_3 are independently exponentially distributed with expected values $1/\lambda_1$, $1/\lambda_2$ and $1/\lambda_3$ and probability distribution functions

F_1, F_2, and F_3. Then the distribution function for dur(L_1, L_2, L_3) = 1- (1-F_1)(1-F_2·F_3)=: F. The expected duration of the portfolio is then = $\int xdF(x)$=:E(D)

The expected evergreening effect of adding the portfolio of the secret halves of the monks to the abbot's total secret is then

$$E(D)- E(L_1) = E(D)-1/\lambda_1$$

which is calculable once λ_1, λ_2 and λ_3 are known.

A more refined model (not shown here) takes the life expiration times of the secrecy holders, i e the individuals, into account as well, so that the repeated addition of new secrecy holders as described in the text leads to an embedded martingale and almost perfect evergreening under certain conditions (such as almost surely simultaneous deaths do not occur).

One can note that a societal or community system for secrets in return for patents with a limited duration exceeding the expected duration of trade secret protection would represent a policy for (limited) evergreening.

The reverse Benedictine case

Suppose an IPR portfolio M consists of a product patent and two substitutable trade secrets for the production process and the life expiration times are L_1, L_2 and L_3 respectively. Then the unweighted duration dur(M) = max(L_1, min(L_2, L_3)) which formally is a kind of reverse situation to the Benedictine case. For independent L_1, L_2 and L_3 with probability distributions F_1, F_2, and F_3 the probability distribution function for dur(M) is:

$$Prob(dur(M) \leq t) = F_1(t)(1 - \big(1 - F_2(t)\big)\big(1 - F_3(t)\big))$$

which can be used to calculate expected duration and evergreening effects e.g. of adding the secrets to the patent.

Optimal evergreening

The economic effect from evergreening could be maximized by optimizing the timing of acquisition of additional IPRs. This is a complex optimization problem in general, which will be illustrated here in a very simplified case for analytical tractability. To that end, assume a patentable product invention is invented at time zero (i.e. a technical success occurs then in the R&D process) and a market launch of the corresponding new product is

planned for time M. The probability that the secret is uniquely kept at time t is assumed to drop linearly from one at t=0 to zero at t=M. A patent is applied for at time T ∈ [0,M] and is necessary (i e essential) and sufficient for the innovation during the patent life time of 20 years. The patent gives a constant profit level during its effective protection time on the market as a patent premium V. Delaying patent application gives a longer market monopoly or market lead time, while speeding up patent application increases the probability to get the patent protection, so there is an optimization problem. It is then straightforward to show that the optimal T = min(0, M-10) and the value weighted duration of the patent durw = T + 20 - M for a zero discount rate (with a slightly more complicated expression for a constant non-zero discount rate).

In concluding it may be noted that Losec was marketed close to 10 years after the application of the basic patent, that later turned out to be essential. The R&D and patenting people at Astra-Hässle at the time did not consider this optimization problem in full, however. They never accounted for the impact of an application delay upon the profit level towards the end of the product innovation life cycle (which could be as much as 200 MUSD as described in the text), but only accounted for the risk that a competitor could win the patent race. At the same time they were unknowing about the essentiality of their patentable invention at the time of the application, a fact that was hardly knowable at the time but gradually became clear as the ensuing R&D unfolded. If the basic patent application could have been postponed, say 2 years, almost 5 BUSD in profits could have resulted (ceteris paribus), a kind of calculation that are remote from the ordinary calculus of R&D people.

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