4.2.2. Creation of Deterring Effects

As an originator's pharmaceutical innovation – if commercially relevant – opens up new and attractive market segments, it is important for defense strategies to deter generics from entering those markets. Generic defense strategies therefore aim at 'counterbalancing' market attractiveness by signaling '*this market is highly attractive, but entering and exploiting it will come at substantial costs'*.

The sector inquiry's final report has highlighted three areas, where it sees potential cases of foreclosure based on Art. 102 TFEU. As already generally expressed by the EU Commission prior to the sector inquiry, such a *corpus delicti* does not necessarily require forcing a competitor out of the market: Discriminating or disadvantaging competing undertakings is regarded to be sufficient. Cases where a dominant firm directly raises a rival's costs or reduces the demand for a competing product may already constitute a substantial economic disadvantage in conflict with Art. 102 TFEU.[175]

4.2.2.1 Patent Thickets

The sector inquiry suspects 'patent thickets' being built up by originators as market entry barriers against generics. Those thickets protect a 'basic patent' on a newly invented drug compound by additionally surrounding it with all kinds of other patents e.g. on dosage forms, galenic forms or manufacturing processes. Any of those patents are then again multiplied on a geographic dimension into 'patent families' due to the national character of those rights.[176] The resulting portfolio of rights protects different product features in the different EU member state markets of only one single medical product. The top third products with the most annual sales analyzed in the sector inquiry are on average protected by almost 30 patent families, while some products reach around 700-800 individual national patents.[177] *Schnelle* even speaks of approx. 1300 individual patents for a blockbuster product across Europe, which the European Patent Office (EPO) finds to

175 See supra note 65 at p. 101 as well as supra note 56 at p. 585.

176 The need for multiplication into a bundle of separate national patents is a systemic issue of EU patent law rather than of originator's strategic behavior. Normally, one would not count every individual national patent but group them into 'patent families'. See supra note 10 at p. 512.

177 See supra note 10 at pp. 171-172 and p. 188.

be a misleading and artificially inflated number counting national patents instead of EU-wide patent families.[178]

From a defensively motivated perspective, patent thickets significantly reduce originator's dependency on the invention's basic patent, which may be invalidated or circumvented easily otherwise.[179] The sector inquiry regards this as a strategy to build several different layers of defense ('multi-layer defense'), which thereby also serve an aggressive-offensive purpose by building the foundation for using other IP related generic defense strategies, especially when it comes to litigation (see chapter 4.2.2.2.).[180] For generic competitors, broad patent thickets reduce the ability to imitate an originator's product easily by increasing complexity and transaction costs for market entry: Generics would have to invalidate or circumvent each patent in every single country they target. The EU Commission therefore calls this 'trapping generics' and expresses its concerns on the one hand about effects from granted patents, but also about effects from intentional delays of a patent application's final decision, e.g. via filing multiple divisional applications. Even if those rights would later not necessarily be granted, they still increase risk and uncertainty for any generic competitor observing such behavior.[181]

From an economic perspective, the key determinant would be whether the negative effects on dynamic competition associated with the higher transaction costs for generics' market entry exceed the positive effects on dynamic competition from improved diffusion of new knowledge via the patent system's disclosure function. If negative outweigh positive effects, it would be advisable to render such behavior anticompetitive. It is obvious that such a test could not be reliably conducted in a competition law case. It is difficult for competition authorities to intervene into such behavior as any potential anticompetitive effects are created by the mere existence of such rights, which – as discussed above – is normally not sufficient to be abusive: Deterring effects do not necessarily require a conduct of exercising

178 See supra note 41 at p.169 as well as supra note 7.

179 See Dietmar Harhoff, Head of Institut für Innovationsforschung, Technologiemanagement und Entrepreneurship, Ludwig-Maximilians-Universität Munich, speech at the anniversary event '30 Jahre Monopolkommission': Innovationen und Wettbewerbspolitik – Ansätze zur ökonomischen Analyse des Patentsystems (Nov. 5, 2004).

180 See supra note 10 at pp. 184-188 and p. 373 and supra note 126 at p. 7.

181 See supra note 10 at pp. 187-193 and pp. 453-455 as well as p. 512 and supra note 13 at p. 91.

exclusionary power – the mere information asymmetries and potential effort involved in thinning out such thickets are sufficient.

An associated issue can be found in the Art. 102 TFEU prerequisite of a dominant position: At the point of applying for patents to build a thicket, originators most likely would not hold a dominant position yet. Consequently, the anticompetitive conduct would be maintaining a patent thicket rather than initially building it.[182]

So could competition authorities succeed by proving strong anticompetitive intent associated with maintaining the patent thicket, e.g. by accusing the originator to raise a generic rival's cost base? On a macro level, the sector inquiry suspects exactly such intentional behavior and provides evidence for a diverging trend between increasing pharmaceutical patent applications on the one side and a slowdown of granted marketing authorizations on the other side.[183] Besides substantial statistical difficulties with this evidence,[184] proof for such an allegation seems unrealistic on an individual company (micro) level: Pharmaceutical R&D does not search for individual patentable inventions, but for metabolic and clinical pathways, technologies and combinations of multiple pharmacological features which can be combined into a single new drug. Clustering different inventions, which are separately protected, into one single product thus lies in the nature of (bio)medical science, which may lead to something which might look like a 'thicket'.[185]

Also patent law itself does not change the picture, as patentability does and should not consider any criteria associated with anticompetitive effects of granting such rights.[186] In contrast to this, the inquiry's report is explicitly concerned about deterring effects from weak patent rights, where the patentee knows about the invalidation risk, but not the generic competitor. The EU Commission seems to imply anticompetitive conduct being associated with intentionally applying and exercising a knowingly weak patent.[187] Their understandable concern lies in deterrence purely associated with in-

182 See Hanns Ullrich, Professor emeritus, Max-Planck-Institute, speech at the MIPLC Trilateral Patent Law Conference (May 14, 2010).
183 See supra note 10 at pp.163-164.
184 The figures e.g. do not consider patent families but count them as separate ones and also considers those which are later invalidated.
185 See supra note 59 at p. 48.
186 See supra note 14 at p. 432.
187 See supra note 10 at §§ 503-505.

formation asymmetries. Nevertheless, such a perspective seems irritating as it would effectively use competition law to review the quality of patents, for which patent law already has own control measures.[188]

The above mentioned arguments as well as existing case law by the *Tetra-Pak II*[189] decision seems to allow the conclusion that patent thickets alone should normally not be in conflict with current EU competition law. *Ullrich* correctly remarks that a useful assessment of anticompetitive effects in such cases should anyways be only done considering building and maintaining thickets together with other procedural and/or patenting behavior of that undertaking.[190] The uncertainty associated with cumulative use of generic defense practices – as outlined in chapter 4.1 – may thus play a predominant role in assessing limitations of patent tickets. Furthermore, systemic change in patent law may limit future behavior in this key aspect of generic defense strategies.

4.2.2.2 Patent-Related Disputes and Litigation

Building on patent thickets, the subsequent step for generic defense is to offensively use such patent portfolios for infringement litigation against generics. The sector inquiry suspects that potential interim injunctions and damage claims against a generic entry acts as a significant deterrent.[191] Thereby, signaling to generic competitors that any infringement will not be tolerated can be achieved even if the patent at dispute may subsequently be revoked or amended in opposition.[192]

One needs to keep in mind, that it is the exact purpose of any enforcement action related to a property right, including IP, to protect a (legal) monopoly created in the first place – in a pinch through litigation. Litigation in general is rather – guaranteed by the *European Convention of Human Rights* – a legitimate and fundamental right.[193] The sector inquiry nevertheless suspects that originators may not always bring a court case against a generic

188 See supra note 12 at p. 31.
189 See Case C-333/94 P, Tetra Pak International SA v. Comm'n, 1996 E.C.R. I-05951.
190 See supra note 59 at p. 34.
191 According to the final report, a main infringement process on average takes 2,8 years whereas a generic's counterclaim for invalidity may not be enough to prevent interim measures. See supra note 10 at pp.205-220.
192 See supra note 10 at pp. 107-108 and p. 199 as well as p. 369.
193 See supra note 7.

competitor in pursuit of the merits of an individual patent claim, but rather (only) as a deterrent signal to potential entrants: By drawing generic competitors into 'unnecessary' legal disputes, originators would purposely raise – or at least threat to raise – their rival's cost base, even if the generic competitor ultimately succeeds in these disputes. According to the final report, this effect would be especially relevant where multiple parallel legal cases are brought against generics in different EU jurisdictions.[194] During the period under review by the sector inquiry, the number of patent disputes in the EU has quadrupled, which is however no indicator whatsoever without a substantial cross-industry comparison: Are 700 started litigations in relation to over 200 investigated drug compounds in eight years and 27 EU member states 'too much' or a signal for abnormal behavior? As demonstrated in previous chapters, the pharmaceutical sector is a highly competitive and aggressive industry, where legal disputes in a high frequency are likely to be expected.[195]

Originators to a certain extend are even required to bring similar cases in different jurisdictions when they effectively want to defend their IP rights. This is not necessarily due to abusive intent, but more due to the current imperfections of the judicial patent law system in Europe with respect to inabilities for consolidating cross-border litigation into a single case: Despite the theoretical possibility provided by Art. 6.1 of the 'Brussels Regulation' 2001/44/EC,[196] patent infringement since the *GAT v. LuK* decision requires individual court cases in different EU jurisdictions, even if they address the same patent family, parties and business conduct. As those cases normally do not qualify (anymore) as being 'closely related' due to the bundle of separate national patent rights, individual national courts have to decide based on *lex loci protectionis*. Multiple separate cases with conflicting decisions concerning the same facts are consequently no exception.

European competition law does however provide an established limitation to the pursuit of litigation for dominant originators qualifying as an Art. 102 TFEU abuse: The case of vexatious or frivolous litigation as established in the *ITT Promedia* decision, which allows interventions however only in 'wholly exceptional circumstances'.[197] According to *Lord Jus-*

194 See European Commission, supra note 60.
195 Compare supra note 68 at p.17 and supra note 59 at p.35. and supra note 11 at p. 54.
196 Also known as the 'spider in the web' doctrine.
197 See Case T-111/96, ITT Promedia NV v Commission, 1998 E.C.R. II-2937 as well as supra note 5 at p. 8.

tice Jacob, *"only if there is vexatious litigation should there ever be a competition law intervention"*.[198] Under this doctrine, clear cases to be avoided by originators are those where litigation's purpose would be solely to harass or hinder the generic competitor as part of a plan to block its market entry.[199] This situation normally is given where the litigation *"cannot reasonably be considered to be an attempt to assert what the plaintiff reasonably believes to be its right."*[200] The difficulty with this test in generic defense situations obviously lies in the complexity of pharmaceutical patents, where a genuine dispute about an infringement allegation will almost always exist.[201] The doctrine's application should thus – if it remains unchanged – likely play into the hands of originators, except for 'whistleblower' situations where authorities can present clear and convincing evidence (e.g. internal company documents) about the existence of anticompetitive plans and strategies.[202]

Although the issue in general is not flagged for follow-up by Competition DG, *Priddis* and *Constantine* nevertheless see a potential threat if the EU Commission would want to combine the vexatious litigation doctrine with its general problem associated to weak patents: Vexatious intent may be proven more easily where it can be shown that the underlying patent right was weak, so that the originator clearly only would have used litigation to raise rival's costs and deter market entry. It feels highly uncomfortable to imagine a situation where the alleged originator would not only need to show its genuine attempt to assess infringement, but that it also initiated litigation with good prospects of succeeding in court.[203]

4.2.2.3 Implications from Future Patent System Reforms

Besides the intent to enforce competition law against individual undertakings, the inquiry's final report articulates high hopes for a unitary pan-European patent law system as being the solution for many of the discussed issues – quasi a 'magic bullet' against abusive generic defense strate-

198 Quoted according to supra note 11 at p. 70.
199 See Case T-111/96, supra note 197 at § 55.
200 Supra note 12 at p. 31 referring to supra note 197.
201 See supra note 12 at p. 31.
202 See supra note 9 at p. 587.
203 See supra note 12 at p. 31.

gies.[204] Indeed, a single patent court as proposed by the European Patent Litigation Agreement (EPLA) for example could substantially reduce forum shopping and other litigation tactics, while the introduction of a Community patent would drastically reduce patent thicket building options.[205]

Major patent reforms have however been discussed since decades and many constructive proposals have not found their way through the political decision making process. Although the final report claims the contrary, it is still not evident that a unitary patent system in Europe is welcomed by all stakeholders involved. For originators seeking patent protection, the Community Patent indeed would e.g. eliminate costly and burdensome national patent validation and renewal procedures.[206] However, originators would also face a much higher risk of consolidating patent validity decisions for the whole European marketplace into one single court decision.[207] Legislation has recognized this perspective and is utterly concerned about potential chilling effects on innovation not only across the pharmaceutical but also many other patent-heavy industry sectors.[208]

Besides above mentioned large reform plans, incremental change is driven forward by the EPO. During the sector inquiry, the EPO had already confirmed that certain practices outlined above, such as defensive patenting, may not be in line with the patent system's policy objectives.[209] As a practical reaction to the inquiry's findings already in March 2009, the EPO triggered an EPC amendment limiting possibilities and time periods during which voluntary divisional patent applications can be filed. This demonstrates the impact the sector inquiry already had and will continue to have in shaping the European patent system, whereby EPO's 'raising the bar' initiative will continue to play a major role in fine-tuning certain aspects.[210] The EU Commission has already articulated that it would also like to see stricter procedural rules and shorter time limits in the area of patent opposition and appeal procedures.[211]

204 See supra note 10 at § 1578 as well as supra note 14 at p.437.
205 See supra note 10 at p. 164 and p. 443 and p. 525.
206 See supra note 10 at p. 442.
207 See supra note 54 at p.76.
208 See supra note 12 at p. 30.
209 See supra note 10 at p. 512.
210 See supra note 10 at p. 512.
211 See supra note 10 at § 1340.

4.2.3. Extension of Exclusivity Terms

Besides the creation of deterring effects, the maximization of the exclusivity term prior LOE, during which generic competitors cannot effectively compete, is at the heart of any IP related generic defense strategy. In this area, the sector inquiry identifies three practices, which the EU Commission finds concerning and allegedly anticompetitive. All of these strategies do include essential patent-related aspects; their potential future limitations are discussed below.

4.2.3.1 Revitalization through Follow-On Innovation

As outlined in chapter 3, originator business models require a constant introduction of new inventions to the market in order to commercialize products under exclusivity. Sometimes those inventions are radically innovative drugs with new treatment for a disease with high unmet medical needs. Inventions can however also constitute 'follow-on innovation', i.e. only incremental improvements of already existing drugs, e.g. by further improving the safety and efficacy profile. In most cases – as science often does develop incrementally by building on prior art and own previous inventive work – the therapeutic profile of such new products is very close to the existing 'first generation' product commercialized by the same originator.

The sector inquiry has articulated the well-known criticism that, should the follow-on innovation qualify for a patent, the originator would benefit from an 'unjustified' extension of its exclusivity term through 'evergreening'. Although no (legal) obstacles exist for a generic to imitate the first-generation product post LOE, incremental follow-on innovation would be used to switch patients to the new, arguably better product before LOE of the old one is reached. From the sector inquiry's perspective, this would often just be an 'overhaul' of the existing product.[212] The revitalization of exclusivity may be achieved by developing different formulations or physical forms of an existing product.[213] Patents, which protect this follow-on innovation, are referred to as 'secondary patents' in the final report, although it was acknowledged that this term is not technically established in patent law and

212 See supra note 10 at § 987ff. as well as supra note 9 at p. 589.
213 See supra note 10 at p. 165 and p. 357.