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.

does not imply lower quality, but are just filed after the basic patent.[214] The EU Commission feels confirmed when it quotes that almost 80% of all legal patent disputes involve secondary and not basic/primary patents.[215] *Ullrich* and others have joined into the EU Commission's perspective in alleging there would be something like 'patenting as necessary', which would allow a patent being granted not at the time of invention, but whenever required, i.e. ideally shortly before the first generation product's LOE.[216] This hypothesis was however falsified by evidence provided in the final report itself, which shows that secondary patenting is equally distributed over the lifetime of the first generation product and not cumulated towards its end.[217] It thus does not seem that easy to revitalize protection from a patent law perspective.

The EU Commission's concerns may be grounded in a policy perspective: Issues may arise in cases where follow-on innovations do not add (significant) benefits to patients over existing pharmaceutical therapies, but do meet patentability as well as comfortable pricing/reimbursement criteria.[218] In such cases, originators are granted 'fresh' exclusive rights for new but therapeutically non-superior drugs, which may allegedly be abused to shift demand to this second generation to maintain exclusivity. What is not considered by the sector inquiry though is that this scenario, which indeed may have negative social welfare implications, is not the standard but the exceptional case: Revitalizing exclusivity with a follow-on innovation is far from being a trivial exercise for an originator due to three important hurdles:

First, the follow-on innovation needs to meet patentability requirements of novelty and inventive step. The EU Commission indirectly criticizes that the EPO would grant patents on minor modifications too lightly, while generic companies have commented that EPO would overlook prior art and apply a rather loose 'inventive step' definition. Although one could argue whether too many weak patents are granted, a patent still must be analyzed

214 See supra note 10 at p. 51 and p. 100 and p. 509.
215 See supra note 10 at p. 164.
216 See supra note 59 at p. 37 referring to supra note 10 at § 1014, § 1016 as well as § 427, § 448 and § 473.
217 See supra note 10 at § 449, figure 55.
218 More effective therapeutic action is not assessed but alien to patent law, see supra note 10 at p. 100.

under the presumption that the invention has deserved it.[219] A granted patent per definition is an invention contributing to (medical) progress and thus deserves time-limited exclusionary rights, although the direct and immediate value to patients may be low. The *Actavis v Merck* decision in the UK for example has confirmed that dosage requirements are patentable even if the associated medical indication is in the prior art.[220] Leveraging other protection schemes beyond patents provides even fewer opportunities: Data exclusivity requires long and expensive new clinical trials. Without those, most product changes from first to second generation would fall under the marketing authorization of the first generation product.[221]

Secondly, European national pricing and reimbursement systems normally consider therapeutic benefits vis-à-vis therapeutic costs (i.e. drug prices) – often referred to as the 'fifth hurdle to market access'. Consequently, already at the beginning of this century, the days were gone "(*if, indeed, they ever existed) when pharmaceutical pricing was a case of thinking of a number and doubling it."*[222] Today, a patented follow-on innovation therefore is evaluated from both a cost and benefit perspective. If this cost-benefit profile is not superior to existing substitutes (i.e. also to the originator's own first generation product), this may lead to no or unfavorably low reimbursement.

Third, even if the follow-on product is patentable and receives reimbursement status, the existing demand for the first generation product still has to be shifted to the second generation product. This often requires immense marketing and sales efforts due to information asymmetries between originators and the physician. Thereby again, therapeutic and pricing attributes compete with comparable substitutes (i.e. the originator's own established first generation product, post-LOE generic versions of this product and eventually even existing alternative innovative therapies by competing originators). It would be naïve to assume that all successful demand shifts in the past were realized without any favorable cost-benefit arguments.

219 See supra note 10 at p. 100 and pp. 449-450.
220 See Actavis UK Ltd v. Merck & Co Inc, 2008 EWCA Civ 444, 2008 R.P.C. 26.
221 See supra note 10 at p. 358.
222 Neil Turner, Containing global pharmaceutical costs: supply versus demand, The Pharma Letter (Oct. 20, 2000) available at http://www.thepharmaletter.com/file/37084/containing-global-pharmaceutical-costs-supply-versus-demand-by-neil-turner.html.

Successfully maintaining revenues and profitability using follow-on innovations is therefore likely to be deserved if it really can be achieved by an originator. A starting point for limiting such behavior via competition law and proving abusive behavior lies more in unfair commercial practices of 'pushing' the second generation into the market rather than in IP or patent related aspects. Where marketing and sales practices are clean from fraud or any unprofessional behavior, e.g. do not include messages intended to denigrate generic products without objective arguments, originators are likely to be in safe harbors.[223]

The discretionary power of the EU Commission may thus focus their investigations rather on other identified conducts. Introducing restrictions for exclusivities of follow-on innovations could result in much lower incentives to innovation, which everyone agrees would be a 'false-positive', i.e. an intervention resulting into negative (dynamic) welfare effects.[224] *Arrow* however already suggested in the early 1970ies, that firms with less monopoly power have a higher incentive to behave in a dynamic and inventive manner compared to the ones with a dominant position.[225] Consequently, although the risk of a false-positive scenario is likely to hinder the EU Commission to strongly intervene in this area, there are also 'pro generic' arguments, which may be well received by legislators with a general 'evergreening' concern in mind.

4.2.3.2 Authorized Generic Entry and Dispute Settlement Agreements

Chapter 4.2.2.2. has shown that patent disputes and litigation are a frequently observable pattern and an integral part of generic defense strategies. Such litigation is either concluded by a final court decision, or settled with an *inter partes* agreement. The sector inquiry has raised strong concerns about the settlement practice of originators and generics, alleging that such deals may constitute restrictive business practices prohibited by Art. 101 TFEU. *Priddis* and *Constantine* observe that the final report *"calls into question nearly any circumstance in which patent litigation is settled"*[226]

223 See supra note 9 at p. 590.
224 See Id.
225 See Kenneth J. Arrow, Economic Welfare and the Allocation of Resources for Invention, in The Rate and Direction of Inventive Activity: Economic and Social Factors 609, 609-626 (Harold M. Groves ed., 1962).
226 See supra note 12 at p. 31.

between an originator patent holder and an allegedly infringing generic competitor in its effort to enter the market. Special concerns are articulated where a settlement agreement involves a value transfer, also known as reverse payment, from the originator to the generic company in exchange for refraining from invalidating the patent and entering the market prior to formal patent expiry.[227] The final report does however not provide a clear legal assessment which could serve as the basis for future guidance to avoid anticompetitive allegations.[228]

From an economic perspective, settlement agreements with the potential to delay generic market entry are related to information asymmetries and the principle-agent dilemma as described in chapter 3.2.2:[229] Disputing parties form independent opinions about whether static competition is likely to be initiated prior to LOE due to patent invalidity. They typically have diverging perceptions about the strength of the underlying patent and thus about the win probability of the case.[230] A settlement agreement therefore often is the (subjectively) better outcome for both parties as it reduces uncertainty: The originator is able to maintain its exclusive rights until LOE while the generic company receives parts of the profits instead of maybe losing the case and getting nothing. Consequently, the value of such an agreement for the parties involved is especially high in situations where the originator patent holder believes to hold a weak patent likely to be invalidated, while the generic patent challenger expects the patent to be stronger. The alternative to settling the case for the generic competitor would not only be more risky, but also shows characteristics of a public good: The generic competitor could not (fully) appropriate all benefit from an invalidation success, as this would clear the way also for any other generic company.

A settlement agreement compensating the generic for a delay in its entry and the maintenance of a weak patent right, which could have otherwise been invalidated, may therefore not extend the formal but very well the effective exclusionary power of that weak patent.[231] Whether such agreement would come at welfare loss to the public thus depends on the weakness

227 See e.g. supra note 10 at § 1573.
228 See supra note 10 at § 1573.
229 See also supra note 73 at p. 11.
230 A Patent holder may know more about the weaknesses and invalidation probability of its right while attacking parties may tend to overestimate its strength.
231 See supra note 10 at pp.456-457 (considering this issue as eliminating price competition).

of the patent, which the agreement itself avoids to conclusively assess. As former Competition DG Commissioner *Kroes* has put it, pharmaceutical patent settlements are agreed *inter partes "without the most effected [sic] stakeholders being present during the [...] negotiations, namely the consumer or the health schemes representing their interests."*[232]

Concerns and reasoning of the EU Commission seems to be inspired by the U.S. Federal Trade Commission (FTC), where the issue has been highly disputed already for years.[233] The U.S. situation is however much more concerning due to a specific regulatory issue: The U.S. Hatch-Waxman Act allows generics to file an Abbreviated New Drug Application (ANDA) including a 'paragraph IV' certification, which constitutes an 'artificial' act of infringement under 35 U.S.C. § 271 (e) (2). By establishing jurisdiction in federal courts, this automatically triggers a validity/infringement law suit. Thereby, the U.S. system facilitates settlement agreements as it has established a solution to the public good problem described above: Generic competitors are incentivized to invalidate patents early as the first ANDA filer winning the subsequent law suit receives generic exclusivity of 180 days according to 21 U.S.C. § 355. In the US, this has led to various antitrust investigations, such as the deal associated with *Bayer Healthcare's* blockbuster product *Cipro®,* which included a total value transfer to *Barr Pharmaceuticals* of almost 398 million US$.[234] The FTC estimates that prohibiting such agreements could generate cost savings of 12 billion US$ for the federal budget over a period of 10 years. In contrast to this, the European situation seems much less severe: The sector inquiry only lists 45 agreements (or only 8% of all disputes) within the period from 2000 to 2007, of which only 23 involved a value transfer. The consolidated value of transfer payments from all agreements amounts to 200 million EUR – almost half of what a single case in the U.S. (i.e. Cipro®) had produced.[235]

Agreements in general however are an expression of the doctrine of freedom of contracts between two parties, which does nonetheless legitimate such a contract to restrict competition.[236] In addition, settlements are just an alter-

232 Press conference at the EU Commission (July 8, 2009) quoted according to supra note 12 at footnote 15.
233 See supra note 12 at p. 31.
234 See In re Ciprofloxacin Hydrochloride Antitrust Litigation 363 F. Supp. 2d 514 (E.D.N.Y. 2005) and 261 F. Supp. 2d 188 (E.D.N.Y. 2003).
235 See supra note 10 at p. 208 and supra note 68 at p. 18.
236 See supra note 68 at p. 24.

native to achieve the originator patent holder's legitimate right to exclude competitors from profiting from its invention. But this also does not legitimate such conduct from being excluded from competition law scrutiny.[237] Most importantly, the economic bargaining function of such a deal can be regarded as a market-approach to reduce existing information asymmetries (similarly to license contract negotiations), which generally facilitate rather than restrict economically efficient solutions. *Inter alia*, procompetitive effects can be amplified in cases where agreements include 'early entry' opportunities for the generic competitor. In such constellations, authorized generics may enter the market based on an (exclusive) license, even months prior to LOE.[238] This produces welfare effects for patients, who can enjoy access to lower-priced drugs earlier, but also gives the 'preferred' generic a head start vis-à-vis other generic competitors in a temporary duopolistic setup together with the originator. It thereby may shield some market share from switching to other generic companies which may consider coming in post LOE and thereby reduces market attractiveness for further generic entry, which both parties benefit from.[239] Such 'side deals' can therefore also constitute a very effective 'buffer' to alleviate the pain from the inescapable LOE.[240]

According to the EU Commission – similarly to the U.S. FTC –, the role of value transfer in rendering a settlement agreement restrictive is especially important. The sector inquiry seems to imply that the size of value transfer may serve as a proxy for the weakness of the underlying patent and thus anticompetitive behavior. *Leibowitz* of the U.S. FTC goes even one step further: He argues, that value transfers do not only allow the parties of the agreement to share consumer wealth that would have resulted from lower prices following static competition,[241] but that such agreements would also lower dynamic competition: High value transfers by originators could have been invested into R&D instead of paying off generic competition.[242] In

237 See supra note 10 at p. 225 and p. 262 as well as supra note 78 at p. 12.
238 See supra note 10 at p. 89, § 236.
239 Compare supra note 10 at p. 297 with supra note 73 at p. 11.
240 See supra note 12 at p.31.
241 See supra note 10 at pp. 456-457.
242 See supra note 68 at p. 23.

other words, originators would *"most likely […] pay-off generic competitors when they have not innovated."*[243]

As parties buy off each other's litigation risk, any benefits granted in that course could basically be regarded as a value transfer – including the mere reimbursement of litigation expenses by the originator.[244] A license granted by an originator to its generic competitor as the result of a court settlement could, although having procompetitive effects as described above, also fall into the category of value transfer. In contrast, large cash payments may just signal the commercial importance of the underlying product and not necessarily the weakness of the patent right which it protects: As in the case of *Cipro*®, the value transfer was extraordinarily large, but the patent was evidentially proven rock-solid by two subsequent successful defenses against generic's invalidation attempts.[245] Value transfers in settlement agreements may thus occur not due to collusive intent, but risk adverse behavior of the originator: According to economists *Shapiro* and *Lemly,* every time a patent holder attempts to enforce its exclusionary power there is uncertainty and some sort of invalidation risk involved. This 'probabilistic patent theory' thus regards every patent to be 'a little bit invalid', as every patent would be a 'fuzzy' property right.[246] It thus seems evident how dangerous such a broad accusation is, when only focused on value transfer.

As an alternative, some authors, both in Europe and the US, have called for anticipating or 'second guessing' patent validity to determine anticompetitive effects in course of a competition law allegation of a settlement agreement.[247] Although this may theoretically be a clear cut solution to determine anticompetitive effects, it practically is an extremely complex issue in pharmaceuticals, which would require the expertise and experience of other

243 Jon Leibowitz, Chairman, U.S. Federal Trade Commission, speech at the Center for American Progress: 'Pay-for-delay' Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for health Care Reform (The $35 billion solution) (Jun. 23, 2009) (available at http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf).

244 See supra note 68 at p.15. and supra note 14 at p. 435 and supra note 12 at p.31.

245 Four generic companies filed ANDAs in subsequent years, i.e. Ranbaxy, Mylan, Schein and Carlsbad. See supra note 234.

246 See supra note 22 and Mark A. Lemley & Carl Shapiro, Probablistic Patents, 19 J. ECON. PERSP. 75 (2005).

247 For Europe, see supra note 73 pp. 11-12; for the U.S. see Asim Bhansali, Reverse-Payment Settlements After the Federal Circuit's in Re: Ciprofloxacin Decision, in Patent Law Institute 205, 211 (3rd annual patent law institute 2009).

specialized jurisdictions.[248] Moreover, national member states' courts have already exclusive jurisdiction for invalidity cases according to Art. 22.4 of the *Brussels Regulation* 2001/44/EC.

With respect to the current state of EU competition law, patent settlement agreements may on the one hand be easier to render anticompetitive compared to other issues identified and discussed above: In contrast to the abuse of a dominant position under Art. 102 TFEU, Art. 101 TFEU cases have a longer history with the EU Commission as their logic can be compared to well known patterns of (price) cartels (see chapter 2.2.2.).[249] Moreover, any of such allegedly restrictive practices would be based on a formal contractual agreement. Anticompetitive effects or intent may therefore be proven more easily by authorities.[250] On the other hand, as the burden of proof for showing restrictive effects lies with the EU Commission, a strong case probably may only be brought forth, when based on evidence that the underlying patent was invalid, which is hardly possible without a company-internal 'smoking gun' document at hand.[251]

With respect to potential legislative change, *Schnichles,* the head of the EU Commission's Task Force running the inquiry, proposes to follow the U.S. FTC perspective as reflected in some currently discussed reform bills. According to these, any settlement agreement including a reverse payment would presumably be *per se* illegal, whereas the parties to the agreement may rebut this presumption by providing clear and convincing evidence of procompetitive outweighing anticompetitive effects.[252] Such a practice could however be in conflict with the treatment of IP settlements in EU Commission's legislation outlined in Regulation 772/2004/EC regarding the application of Art. 81.3 EC Treaty (today 101.3 TFEU) to categories of technology transfer agreements, to which the final report explicitly refers

248 See supra note 68 at p. 25.
249 See supra note 68 at p. 23.
250 See supra note 9 at p. 585.
251 See supra note 7.
252 See Eric J. Stock, Patent Settlement Developments: California Court Dismisses Challenge to Patent Settlement as Legislation Moves Forward in Congress, 14 Hogan & Hartson Life Sciences Competition & Antitrust Update 2, 2 (2009).

as guidance.[253] *Gassner* however questions whether established legal opinions such as the *technology transfer* regulation could be applied at all in cases of patent settlements, as a resulting early entry agreement would follow different characteristics compared to traditional licensing agreements.[254]

One can conclude that out of the many issues discussed in the final report, patent settlement agreements have unambiguously reached the EU Commissions highest level of attention. Although the initial stage of the sector inquiry was very much focused on unilateral conduct under Art. 102 TFEU, the emphasis seems to have turned more towards restrictive agreements under Art. 101 TFEU due to easier proof finding associated with the difficulties in determining market dominance and abusive conducts under Art. 102 TFEU.[255] This was also confirmed by the first enforcement cases following the final report against *Lundbeck* and *Les Laboratoires Servier*.[256]

Although it may be harder for originators in the future to conclude favorable settlement agreements, the EU Commission admitted in the inquiry's final report to not yet be in a position of making policy recommendations.[257] It thus decided to gain more experience through a tailored monitoring exercise, the first annual report of which was published in July 2010, i.e. 18 months after its start.[258] This report unveiled that both originators and generics have already altered their behavior towards a much more risk-averse approach to patent settlements – most likely due to the strong allegations in the sector inquiry's final report and the above mentioned law suits initiated: Not only did the overall number of agreements with value transfer substantially decrease compared to the period analyzed in the sector inquiry,

253 Compare Commission Regulation 772/2004, 2004 O. J. (L 123) (EC) and supra note 10 at p. 508, § 1510 with Dominik Schnichels, The Application of European Competition Law to the Pharmaceutical Sector – Some Personal Thoughts 23 (Fordham Annual Conference on International Antitrust Law and Policy, discussion paper, Sept. 2009).

254 See supra note 73 at pp. 7-88.

255 See supra note 45 at p. 11.

256 See supra note 88.

257 Compare supra note 14 at p. 437 with supra note 10 at p. 458 and p. 524.

258 Compare Press Release IP/10/12, European Commission, Antitrust: Commission launches monitoring of patent settlements concluded between pharmaceutical companies (Jan. 12, 2010) with Press Release IP/10/887, European Commission, Antitrust: Commission welcomes decrease of potentially problematic patent settlements in EU pharma sector (Jul. 5, 2010).

but also the monetary values of such transfers declined substantially. Beyond this, the monitoring report again does not provide any further guidance. It however stresses that settlement agreements without value transfer may nevertheless also infringe competition law: Either when they are based on deceptive conduct (following the *AstraZeneca* example) or when they impose restrictions on generics beyond the territorial scope of the patent.[259]

The lack of transparency for competition authorities to even detect 'problematic' agreements had also triggered the proposal to (re)introduce a notification system.[260] *Gassner* has argued that it seems unlikely that the EU Commission will provide more reliable guidelines on the issue, as this would voluntarily reduce its power to intervene.[261]

4.2.3.3 Intervention into Generic Marketing Authorization

IP related generic defense strategies can be used to not only extend the exclusionary effect of a patent within the legal regime of patent law, but also beyond that to independent bodies of law and regulation. By intervening into the marketing authorization process of a generic product, originators may trigger delaying or even blocking effects. They benefit from the suspensory feature, which an originator's appeal typically has on a generic marketing authorization process, such as frequently practiced not only by the German Federal Institute for Drugs and Medical Devices (BfArM).[262] According to the sector inquiry, originators frequently intervene into the generic product's approval process by arguing either lack of equivalence, raising safety and/or efficacy concerns or patent infringement. [263]

The pharmaceutical marketing authorization process is – as emphasized by the EU Commission – a bilateral procedure between the applicant and the regulatory authority, which generally is not designed to consider 3rd party interventions. This means that interventions into such proceedings cannot

259 See Richard Eccles, EU: European Commission Reports on the Monitoring of Patent Settlement Agreements (Online News Update, Bird & Bird, Jul. 28, 2010).
260 See supra note 10 at pp. 456-457 and supra note 14 at p. 435.
261 See supra note 73 at p. 12.
262 See supra note 78 at p. 10.
263 See supra note 10 at p. 863 and p. 874.

be regarded *prima facie* as the exercise of a right.[264] Nevertheless, authorities would typically not simply ignore originator's articulated concerns where relevant to fulfill the authority's duty to ensure drug safety, efficacy and quality.[265] Launching an improved second-generation product and simultaneously unveiling new internal data to argue insufficient safety of the first-generation product and consequently also similar generic drugs, may be a potentially legal way to keep generics out.

Objectively more concerning are originator interventions with focus on patent-linkage arguments: Although generics *inter alia* require bioequivalence prove, authorities are not supposed to consider patent-related questions in the marketing authorization process according to Art. 8 of Directive 2001/83/EC. This is also true for questions related to patent infringement. Despite the patent's exclusionary right, such arguments are simply irrelevant in such decisions.[266] In this respect no U.S. FDA-like 'Orange Book' exists, which would provide a basis for infringement/invalidity discussions related to marketing authorization.

The same irrelevance exists with respect to patent-linkage interventions into national pricing and reimbursement decisions. Nevertheless, regulatory authorities of some EU member states still seem to be receptive for such arguments. *Postner* mentions the situation in Portugal as a good example.[267]

Similar to the EU Commission's perspective taken on blocking/defensive patents, also here a focus on the originator's 'primary' motivation behind such an intervention would be crucial to determine whether such an intervention is abusive under Art. 102 TFEU: Any *bona fide* concerns about a generic drug's safety or efficacy should indeed be raised even if that may block or delay generic entry. In contrast, pure intent to block or delay without substantive – or even irrelevant – arguments may be considered abusive under competition law. However, any intent-focused analysis immediately raises the problem of clear and convincing evidence, which seems to be very hard to generate for the EU Commission in any cases others than patent-linkage. The fact that safety or efficacy concerns are raised by the respective product's originator (and not any other 3rd party) should thereby not be easily interpreted by authorities as evidence against *bona fide* argu-

264 See supra note 9 at p.588.
265 See supra note 10 at § 1408.
266 See supra note 10 at p. 130 and § 874 and § 1408.
267 See supra note 78 at p. 10.

ments: "*Originators are often best placed to identify those concerns, given its access to the relevant scientific research.*"[268]

Although the *AstraZeneca* case seems to be an extreme and too specific case likely to be replicated,[269] it seems clear that *"[m]isleading regulators to gain longer protection acts as a disincentive to innovate and is a serious infringement of EU competition rules"*.[270] Originators can expect that competition authorities will continue to investigate allegedly deceptive conduct. This may not only relate to the acquisition of SPCs, as in the *AstraZeneca* case, but also to deceptive exercise of other property-like rights, such as patents, in the cause of marketing authorization or pricing/reimbursement proceedings.[271]

Actions by the EU Commission to counter unjustified generic marketing authorization interventions by originators are likely to be focused on a stricter and more effective harmonized enforcement of the existing regulatory regime rather than individual competition law cases.[272] The sector inquiry already announced the willingness of the EU Commission to monitor such interventions more closely and to push national regulatory bodies to work on the transparency of such interventions.[273] Individual actions against anticompetitive pricing and reimbursement interventions are likely to be addressed more effectively by national member state competition authorities rather than by the EU Commission, as such systems are not (yet) harmonized across Europe.[274]

268 Supra note 12 at p. 31 Fn. 25.
269 See supra note 5 at p. 7.
270 See Ansgar Ohly, Geistiges Eigentum und Wettbewerbsrecht – Konflikt oder Symbiose, in Geistiges Eigentum und Gemeinfreiheit 47, 47 (Ansgar Ohly and Diethelm Kippel eds., 2007) (quoting former EU Commissioner Competition DG Neelie Kroes commenting the AstraZeneca decision).
271 For a general discussion see supra note 43 at p. 138.
272 See supra note 10 at §§ 1581-1606.
273 See supra note 10 at p. 491.
274 See supra note 9 at p. 588.