13 Abbreviated Approval Pathway for Biosimilars and Patent Policy: Balancing the Incentives of Innovation and Price Competition(*)

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Recently, there is a rallying cry for applying the ANDA to the biosimilars. Biologics are distinguishable in major technical ways from conventional drugs, which makes the provisions of the Hatch-Waxman legislation governing drugs simply cannot be incorporated into a regulatory scheme simply allowing for approval of follow-on protein products. IP is a critical intangible asset for biotech and pharmaceutical firms. But the distinction between biologics and small molecule drugs lead to substantive differences in how patent system operates in the condition of abbreviated approval pathway to provide market exclusivity for innovator biological products. To determine what kind of patent protection infrastructure is appropriate for regulating these "follow-on biologics", a thorough patent policy assessment, from the viewpoint of biotechnology environment, is necessary. With these points in mind, this research focuses on the legal and policy issues of patents in implementing an abbreviated approval pathway for follow-on biologics from different perspectives. At last, this research gives some recommended suggestions to these patent issues from the author's opinion.

Ⅰ Introduction

Due to the success of Hatch-Waxman Act in pushing forward the market entry of generic drugs, with several "blockbuster" biotechnology patents have reached, or are reaching the end of their patent protection, recently many people call for applying the Abbreviated New Drug Application ("ANDA") pathway, which was set up by the Hatch-Waxman Act, to the biosimilars. Biologics are distinguishable in major technical ways from conventional drugs, which makes the provisions of the Hatch-Waxman legislation governing conventional drugs cannot simply be incorporated into a regulatory scheme allowing for approval of follow-on protein products.(*1)

The patent issues are open policy questions that need to be resolved before any new regulatory approval system is set up.(*2) With these points in mind, this research focuses on the legal and policy issues of patents in implementing an abbreviated approval pathway for follow-on biologics.(*3) Chapter II offers a brief overview on the ANDA of Hatch-Waxman Act and why it should be applied to biological drugs; Chapter III explores the sticky patent issues arising when applying abbreviated approval pathway to biosimilars; Chapter IV explores how the patent system and regulatory approval scheme should interplay with each other optimally under the biosimilar pathway compared to how they operate today under the Hatch-Waxman framework for generic small molecule drugs; Chapter V explores these patent issues from Asian perspective, from China and Japan; Finally, some conclusions.

Ⅱ The Regulatory Approval Pathway in the Hatch-Waxman Act

1 The Approval Pathway for Generic Drugs Pursuant to the Hatch-Waxman Act

Prior to the enactment of the Hatch-Waxman Act, a generic manufacturer had to conduct the same clinical trials as the firm that was awarded marketing approval for the innovator drug, which

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(*1) *Bruce S. Manheim, Jr., Patricia Granahan and Kenneth J. Dow, 'Follow-on Biologics': Ensuring Continued Innovation in the Biotechnology Industry,* Health Affairs, 25, no.2 (2006): 394-404.

(*2) Henry Grabowski, Iain Cockburn and Genial Long, *The Market For Follow-on Biologics: How Will It Evolve?* Health Affairs, 25, no.5 (2006): 1291-1301.

(*3) The present paper will only examine the patent policy issues presented in crafting of the abbreviated regulatory pathway for follow-on biologics. Not to touch the other related issues, such as safety, efficacy and immunogenicity, although the others are too important.

greatly delayed the launch of more affordable generic drugs.(*4) Enacted in 1984, Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act (FDC Act), and established a kind of abbreviated new drug application (ANDA) to permit generic producers to rely on the innovator's clinical data.(*5) Any drugs approved under ANDA pathway are referred to as generic drugs.(*6)

2 The Patent Protection Provision in the Hatch-Waxman Scheme

In light of the ease with which generic manufacturers could free ride on the research and development conducted by innovator firms, there're also several additional provisions relating to patent protection included in the Hatch-Waxman Act.(*7)

The first one is the requirement of the active ingredient in any product approved through the ANDA process is the "same" as that in the innovator drug.(*8) "To be the "same" active ingredient, the generic product invariably must fall within the scope of the patent that the innovator holds for that compound. Thus, a generic drug manufacturer cannot have it both ways--it cannot gain FDA approval of its product by arguing "sameness" of the two products in an ANDA and then claim in the patent context that its product is different from the innovator's drug."(*9)

The second one is that the Hatch-Waxman Amendments established a kind of early patent resolution mechanism as an integral part of the ANDA, what is commonly known as "Patent Linkage".

The third one is that the Hatch-Waxman Act recognized that there would be no generic market without the products developed by innovators, and created a mechanism allowing for "patent-term extensions".

Even with the three kinds of patent bolstering protections mentioned above, the normal patent protection alone is still not sufficient to provide protection to innovators. Hatch-Waxman Acts established another mechanism called "data exclusivity" for innovators.(*10)

Under the Hatch-Waxman Act, generic firms also enjoy two enhanced patent related rights.(*11) (i) The Hatch-Waxman Act provides a special kind of patent infringement law, a statutory exemption called "Bolar exemption" provision; (ii) A180-day generic exclusivity for the first generic applicant to successfully challenge the patent for any approved drug.(*12)

3 The Statutory and Regulatory Regime for Biological Drugs

There are important differences between the regulation of biologics and that of non-biologic drugs. Due to the physical difference between the biologic and non-biologic drugs, presently, the ANDA is not applicable to the biosimilars.

(*4) *See* George Fox, Integra v. Merck: Limiting the Scope of the §271(e)(1) Exception to Patent Infringement, 19 Berkeley Tech. L. J. 193, 195 n.16(2004).

(*5) David M. Dudzinski, *Reflections On Historical Scientific, And Legal Issues Relevant To Designing Approval Pathways For Generic Versions Of Recombinant Protein-Based Therapeutics And Monoclonal Antibodies,* 60 Food and Drug Law Journal (2005), 143.

(*6) Donna M. Gitter, *Innovators And Imitators: An Analysis Of Proposed Legislation Implementing An Abbreviated Approval Pathway For Follow-On Biologics In The United States,* Florida State University Law Review (Spring, 2008).

(*7) Bruce N Kuhlik, *The Assault on Pharmaceutical Intellectual Property,* 71 U.Chi.L. Rev. 93, 96-97(2004).

(*8) Additional kinds of information, designed to show that the drug covered by the ANDA is the same in its indications and its effects as a previously approved drug (a "listed drug") or is so similar that use of the data on the previously approved drug is appropriate, must be included in the ANDA application documents. See FDCA Section 2.02 505(j)(2)(A), 21 U.S.C. 355(j)(2)(A). If the listed drug has only one active ingredient, the ANDA must show that the active ingredient of the product it covers is the same as that of the listed drug. See FDCA Section 2.02 505(j)(2)(A)(ii)(I), 21 U.S.C. 355(j)(2)(A)(ii)(I). If, however, the listed drug has more than one active ingredient, the information in the ANDA may show either that all of the active ingredients are the same as those of the listed drug or that FDA has approved an ANDA suitability petition to allow substitution of one such ingredient. See FDCA Section 2.02 505(j)(2)(A)(ii)(I), (II),21 U.S.C. 355(j)(2)(A)(ii)(I),(II).

(*9) Bruce S. Manheim, Jr., Patricia Granahan and Kenneth J. Dow, *'Follow-on Biologics': Ensuring Continued Innovation in the Biotechnology Industry,* Health Affairs, 25, no.2 (2006): 394-404.

(*10) *See* BIO: *A Follow-on Biologics Regime without Strong Data Exclusivity Will Stifle the Development of New Medicines,* available at http://www.bio.org, (accessed Oct 20, 2009).

(*11) Bryan A. Liang, *Regulating Follow-On Biologics,* Harvard Journal on Legislation (Summer, 2007).

(*12) 21 U.S.C.A. §355(j)(5)(B)(iv)(I)(2009).

Ⅲ The Patent Issues Arising When Applying Abbreviated Approval Pathway to Biosimilars

The application of the patent protection provisions of the Hatch-Waxman Act to the biosimilars may present complex issues. The followings are some major ones:

1 The Similarity Standard plus the Current Patent Practices in Biotechnology Causing a Large "Loophole" in Patent Protection

(1) The Similarity Standard Causing the Leeway to design around the patent scope

The No.1 measure in Hatch-Waxman scheme to effective protect of innovator's patents is the "sameness" standard for generic drugs. Due to the physical differences between small molecules and biological, it is virtually impossible for a follow-on company to show that its product is identical to an innovator's product. Under various statutory frameworks being considered for follow-on biologics, a biosimilar will not be required to be the "same" as the innovator product. Instead, the follow-on product will only have to be similar or highly similar to the innovator product. This similarity standard for follow-on biologics created a significant risk that a follow-on competitor will circumvent or "design around" the innovator's biotech patents. As a result, a biosimilar product may be sufficiently similar to the innovator biologic to rely on the safety and efficacy data of the innovator product and thus received abbreviated regulatory approval. Yet, it may be different enough from the innovator product to avoid a patent infringement claim and, thus, reach the market well in advance of innovator patent expiration.

(2) This Loophole Problem Exacerbated by Current Patent Practices in Biotechnology

Recently, there're a trend to heighten patentability of biotechnology patents and constraint of the scope of patent. This trend will create a wider gap that may enable a biosimilar to exploit more benefits of innovator's patents than previous generic chemical drugs.

2 Is There Any Necessity to Establish Hatch-Waxman Early Patent Resolution Mechanism for Biosimilar, and How?

(1) The necessity to Apply Hatch-Waxman Early Patent Resolution Mechanism to Biosimilar

Some believe in the context of biologics competition, the special early patent resolution mechanism, that is, the "Patent Linkage", is unnecessary. But the representatives of biologics hold the opposite. So, the need to apply Hatch-Waxman Early patent resolution mechanism to biosimilars is a big question should be solved firstly before extending the similar legislation to biologics.

(2) How to Apply Hatch-Waxman Early Patent Resolution Mechanism to Biosimilar

Usually, an early patent resolution mechanism should include two parts: (1) notification requirements, including when notification begins; and (2) identification of patents to be litigated in the pre-approval period, which could include only "necessary" patents.(*13) And, in addition, there is a problem of how to set up enforcement provision to deter abuse by the participants that seek to use the process to obtain competitive advantage.(*14) Most of the problems arise in the three aspects.

3 The Patent Term Extension and Safe Harbor Provision

There're a few limitations on the application of patent term extension provision, which prove to be too narrow for follow-on proteins. Whether a biosimilar product that differs from the innovator product, or is not even characterized, should be subject to the innovator's patent term extension? Whether a biosimilar product that does not show any analytical difference between the innovator drugs, but demonstrates a clinical difference, should be subject to the innovator's patent term extension?(*15) If the answer is no, such a scenario would severely undercut the purpose of patent restoration.

(*13) *Emerging Health Care Issues: Follow-on Biologic Drug Competition,* Federal Trade Commission Report, June 2009, available at http://www.ftc.gov (accessed Oct 20, 2009).

(*14) *Ibid.*

(*15) *The Difference with Biologics: The Scientific, Legal, and Regulatory Challenges of Any Follow-On Biologics Scheme,* BIO White Paper, April 25, 2007, available at http://www.bio.org, (accessed Oct 20, 2009).

"Although the legislative history show that Congress (the Bolar exception rule) was concerned with a very narrow class of infringers and range of activities, the language ultimately enacted is broader than necessary to allow pre-expiration studies of a patent product to obtain approval for generic version of the drug."(*16) In the context of abbreviated approval of biosimilar, there is an urgent need for clarification of the §271(e)(1) safe harbor to address these problems.

4 The Necessity of 180-day Exclusivity to Encourage Follow-On Biologic Applicants to Challenge Patents

Many people believe the competitive dynamics that justified the 180-day exclusivity period for small-molecule generic drugs are no longer present in the context of biosimilar drug.(*17) So, it is highly questionable whether the 180-day exclusivity still be necessary to encourage the biosimilar drug development or not.

5 Others

With the entry of biosimilars, those tactics proven successful for entry-deterring for innovator under the Hatch-Waxman Act will occur again. The much more and varied patents scattered in the biologic drugs field, and the complexity of biotechnology, especially the similarity standard, will make these tactics much harder to discern.

Ⅳ Recommended Solutions to the Patent Issues Might Rose in the Abbreviated Approval Process of Biosimilar

1 The Present Biosimilar Legislation Development All Over the World

Biosimilars guidelines and regulations are being developed all over the world nowadays, including EU, Japan, and so on. WHO developed two draft versions in 2008. Presently, there're two bills pending before the House of U.S.A., H.R. 1548 and H.R.1427, reflecting highly divergent perspectives on data protection and procedures for addressing patent conflicts.

2 The Recommended Solutions to the Patent Issues

(1) To the patent protection loophole issue brought by the similarity standard

There're two ways to solve this loophole problem. One way is to provide a substantial period of data exclusivity for the innovators, who conduct the necessary clinical testing to bring a new biological product to market; the other one is to harmonize the standard of equivalents between FDA approval procedure and Court patent infringement decision.

(2) To the pre-approval patent dispute resolution issue

The recently issued FTC Report(*18) has expressed many competition-related concerns over pre-approval patent litigation procedure and staked out a propose that a special procedures to resolve patent issues between pioneer and biosimilar drug manufacturers prior to FDA approval is unnecessary anymore. But the representatives of innovator drug believe this propose is based on flawed assumptions about patent litigation, and is totally unacceptable. In the author's opinion, though the proposal in FTC's Report is fair and rational in some degree, it is too radical to be acceptable. The patent resolution provisions should be retained, but it should be re-tailored in consistence with the inherent difference between small-mole drugs and biological drugs.

The pre-approval regulatory process used to be used repeatedly as a strategy to delay of generic entry by the innovator manufacturers. To solve these problems, the H.R.1427(*19) designs a process with no regulatory linkage for the assertion of a patent against a biosimilar applicant and some administrative sanctions on patent owners, which are attacked strongly by the innovator manufacturers.(*20) In contrast to

(*16) William S. Feiler & Paula L. Wittmayer, *The Section 271(E) "Safe Harbor"—A Proposal for Legislative Change, 25* Biotechnology Law Report, No 2, April 2006.
(*17) *Emerging Health Care Issues: Follow-on Biologic Drug Competition,* Federal Trade Commission Report, June 2009, available at http://www.ftc.gov (accessed Oct 20, 2009).
(*18) *See* FTC Report supra note 17.
(*19) *See* 111th US Congress, H.R.1427.
(*20) *See* Don Ware and Nick Littlefield, *Follow-on Biologics and Patent Reform: Will They Discourage Venture Capital Investment in the Biotechnology Industry?* 2009, Foley Hoag LLP.

H.R.1427, the H.R.1548,(*21) Pathway for Biosimilars Act (Eshoo), which is applauded by the innovator manufacturers, designs a procedure that enables that the BLA holder and third-party patent owners to identify relevant patents based on information provided by the biosimilar applicant under appropriate conditions of confidentiality is established. So, the H.R.1548, in the author's opinion, not as radical as H.R.1427, provides a more lenient and acceptable scheme to solve the above mentioned problems, may will be much easier to strike compromise between the opposite parties.

(3) To the patent term extension provision and safe harbor

The present method that the statute limits the scope of rights granted in a patent term restoration to a product's active ingredient will not applicable to the biologics due to the nature of protein products. That means the patent restoration statute needs making some adjustment to biologic to guarantee the same degree of effective protection as that for small-molecule drugs under the Hatch-Waxman. The solution to this problem once again comes to the similarity standard as above mentioned when deciding the scope of right granted in the patent term restoration for the innovator products.

In the context biosimilars, it is necessary to clarify the scope of article§271(e)(1), the safe harbor clause.

(4) To the 180-day exclusivity

Both H.R.1548 and H.R.1427 restrict this kind of exclusivity incentive only to "interchangeable" follow-on biologics, not other biosimilars, from coming to the market during that period of time.(*22) Maybe it's a better solution to this problem.

(5) Other suggestions

It's necessary to put more stringent enforcement of the disclosure requirement on biologic patent application. "It may be appropriate to focus on whether follow-on biologic drug producers are of "ordinary skill" in the art. Alternatively, patent claims may more productively be directed toward the biologic agent per se rather than to pharmaceutical compositions, avoiding any negative implications between claim scope and sufficiency of disclosure."(*23)

To the innovator's patent-blocking tactics, the government should consider more aggressive legal action against the violations of antitrust law.(*24) But any antitrust intervention needs to understand fully the risks to biotechnology innovation and intellectual property protection of an ill considered attack on the patent system.(*25)

Ⅴ Asian Perspective

1 China: Where are we heading?

In China, as for the generic drugs, there has an abbreviated approval pathway to get market approval without submission of clinical data,(*26) but as for the biosimilars, they can not apply for approval through the abbreviated approval pathway.(*27) In fact, when the safety and efficacy can be established, the SFDA will not refuse to apply the abbreviated approval pathway to the biosimilars.

(1) The present patent policy environment in the context of biosimilar

In China, there isn't special patent protection provision as those in Hatch-Waxman Act, but we do pay attention to the patent issues in the process of approval of generic drug. We do have the same active ingredient requirement for generic drugs and 6 years data exclusivity for innovator drugs. We don't have the patent extension provision, but the SFDA provides 5 years market exclusivity in a degree similar to that. We don't have patent linkage provision, but in the process of regulatory approval for generic drug, the SFDA indeed take heed of the existence of patent officially. We don't have the statutory provision in patent law about doctrine of equivalents, but the courts in various levels have tried cases involving the doctrine of equivalents.

(*21) *See* 111th US Congress, H.R.1548

(*22) *See* 111th US Congress, H.R.1548, Sec.101(k)(7) and H.R.1427, Sec.3(a)(k)(11).

(*23) Kevin E. Noonan, *Follow-on Biologic Drugs and Patent Law: A Potential Disconnect?* SINPPETS Review of Developments in Intellectual Property Law, May 2008, Volume 6, Issue 1.

(*24) *Arman H. Nadershahi & Joseph M. Reisman,* Generic Biotech Products: Provisions in Patent and Drug Development Law, BioProcess Int'l, Oct 2003, at 26.

(*25) Bill Batchelor, *Patent Attack—The EC Sector Inquiry's Interim Findings,* E.C.L.R., issue 5, 2009.

(*26) See *Chemical Products Registration Classification and Materials Required for Application,* Annex II of the Regulation of Drug Registration of SFDA, 2007.

(*27) Art.17, the Regulation of Drug Registration of SFDA, 2007.

Recently, the newly issued Draft Version of Several Regulations on Handling the Applicable Legal Questions on Patent Disputes by the Supreme Court of China adopted expressly the doctrine of equivalents. In fact, compared to the continuum of patent provision embodied in Hatch-Waxman Act, what is really missed in China, besides the patent linkage mechanism, is the 180-day exclusivity provision for the first generic drug applicant who challenges the patent.

(2) The future patent policy trend in the context of biosimilar products

In China, there's no possibility to establish the 180-day exclusivity in the context of biosimliar in the future, and there's a slim chance to extend the 6 years data exclusivity in the context of biosimiars too. But that doesn't mean China will not pay attention to the patent issues arising in the process of drug approval. Especially after the promulgation of Intellectual Property Strategy Outline and Third Amendment of Patent Law, China has stressed on the importance of patent protection.

Currently, the related authorities in China have different attitudes toward the Patent Linkage and Patent Term Extension provisions. To the patent linkage, they believe that it's a necessary process to protect the patent right and will not enhance the patent right inappropriately. But to the patent term extension, they believe that China has fulfilled the obligations specified in the TRIPs agreement, that is, 20 years patent protection for inventors, and no need to provide higher standard protection more than what is required by this treaty. In fact, presently, the SFDA is considering establishing the patent linkage mechanism, but not the patent term extension, in the near future, in China.

To China, some suggestions follow as: (1) In establishing the patent linkage institute, the issues debated in the Biosimilar Bill of USA should be taken into consideration; (2) In order to protect the benefit of patentee in the context of biosimilar, the complexity of the technology may necessitate a more sophisticated and specific guidance to the application of doctrine of equivalency other than present tripartite test, i.e. the FWR test adopted by the Draft Version; (3) It's necessary to make some adjustment of the provision Art.35 of Regulations for Implementation of the Drug Administration Law of PRC and the Art.18 of Regulation of Drug Registration 2007, which stipulate expressly the 6 years data exclusivity just apply to the drugs in question which contain new chemical entities; and (4) The actual scope of Bolar exception rule which was set up by the third amendment of Patent Law, also need clarifying by the case law as soon as possible.

2 Japan: Which way should Japan follow?

Japan issued a new guideline for the regulation of follow-on biologics in March 2009, which paved the way for a national biosimilars regulatory approval. The newly issued Guideline follows the European route, and takes a case-by-case approach based on the comparability of similar biological products.(*28) It is difficult to reduce the total development cost of biosimilar producers by a huge amount.

(1) The present patent policy environment for the biosimilar in Japan

In Japan, there's no special patent protection provision, such as patent linkage provision as that in Hatch-Waxman Act, but the authorities take heed of the existence of patents in unofficial manner in the process of drug approval. There are a same active ingredient requirement for generic drugs and a 8 years re-examination period acting as data exclusivity. Japan also provides for patent extension up to 5 years for regulatory delay. After 1998, the doctrine of equivalents became a basic legal principle applies in Courts of various levels subject to requirements issued by Supreme Court. Like China, compared to the continuum of patent provision embodied in Hatch-Waxman Act, what is really missed in Japan, besides patent linkage mechanism, is the 180-day exclusivity provision for the first generic drug ANDA filer who challenges the patent.

(2) The patent policy suggestions for Japan in the context of biosimilar

The present Japanese Guideline followed the European route, which was not a really abbreviated approval pathway for the biosimilar. If the Japanese Government does want to push the generic sector forward, the abbreviated approval pathway for biosimilar undergoing in USA should be followed. Anyway, proper patent policy should be set up in the context of biosimliar to keep the balance of innovation incentives and price competition.

(*28) *See* Guideline on Follow-on Biologics: Quality, Safety and Efficacy Issues, Art.8, March 4, 2009.

In Japan, the requirements for application of the doctrine of equivalence have been developed by case law. These requirements, especially the non-essential requirement, will come across problems when applying to biotechnology patent infringement dispute. This approach needs more specific guidance from the Supreme Court in the context of biosimilars.

Compared to USA, what Japanese Guideline adopted is not a really abbreviated approval pathway which free-ride a lot of safety and efficacy data of innovator drugs. In the context of biosimilar, extending data protection period in Japan, as long as, that in Europe or US, may not too persuasive.

Although the Japanese authorities appear to heed of the existence of patens in the process of new drug approval, it is still not enough to provide patent certainty to the biosimilar producers. Maybe it's right time for Japan authorities to set up the patent linkage mechanism in the context of biosimilars.

In order to fit the biologics context, some adjustments to the present Japanese patent term extension provision and precisely clarifying the definition of "testing and research" for Article 69 Paragraph 1 are needed.

It's unnecessary to introduce 180-day exclusivity into Japan. But the reverse payment should subject to stringent scrutiny by the anti-monopoly law.

Many Japanese companies engaged in developing biosimilars complained that it is difficult to obtain the original protein as standards and references for product evaluation. Maybe, it's time to the patent examination practice taking some actions, such as putting more stringent enforcement of deposit requirement, accepting the follow-on biologic drug producers as the "ordinary skill" in the art, and requiring patent claims directed toward the biologic agent per se rather than to pharmaceutical compositions.

Ⅵ Conclusion

The conclusions as follows:

Conclusion 1: In order to promot the biosimilars industry, when the safety and effectiveness can be established, the ANDA should be applied to the biosimilars application;

Conclusion 2: The Drug Agency should be fully aware the difference between similarity standards when approving a biosimilars application and when determining the scope of exclusivity;

Conclusion 3: The Court, Drug Agency and Patent office should keep an eye on each other's similarity standard from time to time. The doctrine of equivalents should play a larger role in offsetting the loophole problem of patent protection caused by the similarity standard.

Conclusion 4: The patent linkage mechanism is important not only for the innovator, but also for the biosimilars applicants, and should be retained. However, it should be re-tailored in consistence with the inherent difference between small-mole drugs and biological drugs. To the country like Japan, maybe it's right time to set up this mechanism in the context of biosimilars;

Conclusion 5: The data exclusivity is very important to protect the incentives of biologic manufacturers to innovate, but it not means the longer, the better.

Conclusion 6: The Patent Office should look closely at its own examination practices and make an adjustment timely. It could play a more positive role in the development of biosimilars industry;

Conclusion 7: The biopharmaceutical firms should use 'Patent life management' strategy, wisely and pro-competitively. They should not distort the research priority to patents labeled as "evergreen" patent, and use the patenting practices as deterring tactics with the sole purpose to delay the entry of biosimilars.

Conclusion 8: The Government Antitrust Agency should try to provide a clear guidance on the distinctions between the pro- and anti-competitive patent-blocking tactics. But any antitrust intervention needs to understand fully the risks to biotechnology innovation and patent protection of an ill considered attack on the patent system.