1. Patenting biosimilars

Claudia Mund*

1. INTRODUCTION

The title chosen for the present chapter might be surprising to some skilled experts and IP professionals. The two terms ‘patenting’ and ‘biosimilars’ are hardly ever used within the same context and it seems to be a contradiction in itself. True, the ‘classic’ approach to the concept of biosimilars is one of follow-on drugs or generics, which profit from the fact that patent protection of the original drug has already expired, and from simplified procedures for market authorization. This approach does not include any patent-related issues such as the scope of a patent claim, patent infringements, or the risk of being copied at all. However, patent-related questions do arise by slightly shifting the perspective and questioning whether a biotechnological invention, in which the pioneer manufacturer has invested high research costs, could – with minor changes or amendments – be brought to the market as a new product by an imitating competitor. The following chapter investigates this broader understanding of ‘biosimilars’ and presents some thought-provoking points without claiming to provide a final response to all the questions raised.

2. DEFINITION AND DELIMITATION OF TERMS

2.1 Conventional Generics as Follow-on Drugs

When defining and delimiting biosimilars from other conventional drugs or generics, it is essential to take a brief look at pharmaceutical history. Some centuries ago, most drugs and medications were composed of small molecules that were not too complex in their chemical structure. The pharmaceutical industry took advantage of patent protected drugs by being the exclusive holder of the intellectual property rights for up to twenty years.¹ After the drugs went off patent, other players began to enter the market by selling copies of the original chemical products at a lower price. These so-called ‘generic drugs’ are identical copies of the chemical molecular structure of the innovator product. They contain the same quantity of active substances² as the reference medicine. They are used

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¹ For up to 25 years, if a Supplementary Protection Certificate is additionally granted.

² The inactive ingredients, or ‘excipients’, may differ between the generic medicine and its reference.
in the same dosage to treat the same diseases and have an identical effect on the human body by being identical or nearly identical in their composition and manufacturing technology. Therefore, they are bioequivalent, which means the effects of the original chemical product and the generic product, with respect to both efficacy and consumer safety, can be expected to be essentially the same. Generic drugs are interchangeable and substitutable with the innovator product. They are, in general, cheaper than their originals since generic drug manufacturers do not develop a drug from scratch, meaning research costs can be reduced. In addition, most regulatory drug authorities apply a simplified authorization procedure for a medical product with known active pharmaceutical ingredients if the product meets the requirements for quality, safety and efficacy. These abbreviated approval procedures do not require the generic manufacturer to repeat costly clinical trials on ingredients or dosage forms that have already been approved for safety and effectiveness. Incremental development costs can be kept comparatively low. In this way, generic products can significantly contribute to reducing health care costs. Most regulatory authorities for drug market approval, such as the Food and Drug Administration (FDA) in the US or the European Medicines Agency (EMA), apply abbreviated drug application procedures for generic drugs.

2.2 Biosimilars in a Narrow Sense

A bio-generic (outdated terminology) or follow-on biologic is a generic product that is similar – but not identical – to an original biological product, also known as biologicals or biologics. Unlike most drugs or pharmaceutical products made through chemical processes, biologicals are in general made from human and/or animal material. They are isolated from living matter or produced in living cells using modern technologies, including recombinant DNA biotechnologies, controlled gene expression and antibody technologies. Biologicals differ from small-molecule drugs or products in several important respects. In comparison to small-molecule drugs or products, biologicals are large and complex molecules (1,000 times bigger) or mixtures of molecules. Moreover, biologicals are not

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3 Auxiliary products and formula.
7 Switzerland also applies abbreviated application procedures for generic products, but since 1 January 2014, the competent Swiss regulatory authority Swissmedic has no longer used the term ‘generics’ (<https://www.swissmedic.ch/> accessed 31 January 2016). The term has been replaced by the cumbersome term ‘medicinal product containing known active product ingredients, developed with or without innovation’. The reason for this change is a lack of legal basis for using the term generic in Swiss legislation on therapeutic products.
8 In recent years, many have discarded the term ‘bio-generics’ in favor of ‘follow-on biologics’ or ‘biosimilars’, saying that the word ‘generic’ unfairly implies a perfect replication of the reference medicine.
chemically synthesized. They are produced in living cells, which creates the potential for greater variability based on factors such as the precise host cells or organisms used to produce the biological, the growth conditions used to culture the host cells or organisms, and the methods of purification used to isolate the desired biological from host cell contaminants. During the manufacturing process, they can also react sensitively to changes in temperature or the composition of the culture medium. Manufacturing is technically demanding, complex and time-consuming. After patent expiry of biologicals, there is a market for generic biological products as is also the case with conventional chemical drugs. These generics are also known as ‘follow-on biologics’ or ‘biosimilars’. Contrary to conventional generics of chemical products, follow-on biologics or biosimilars are never entirely identical to the original active pharmaceutical ingredients, but only similar to the original. Therefore, unlike conventional generics made of chemical drugs, they show no bioequivalence. This is why their successful approval requires more elaborated and sophisticated procedures and monitoring methods prior to marketing authority, as is the case with conventional generics. A company needs to carry out studies to show that the drug is similar to the reference medicine and does not have any meaningful differences from the reference medicine in terms of quality, consumer safety or efficacy. As information on the reference medicine is already available, the amount of information on safety and efficacy, which is needed to recommend a biosimilar for authorization, is usually less than that needed to authorize an original biological medicine. To compensate this monetary disadvantage for the innovator of the original biological medicine, the reference medicine benefits from a period of exclusivity, during which biosimilars cannot be authorized for market approval. This period is ten years in Europe10 and 12 years in the US.11 Many questions regarding the market authorization of biosimilars have not yet been entirely answered.

2.3 Biosimilars in a Broader Sense

In a ‘narrow’ sense, biosimilars are generics of biological substances that are similar to the original active pharmaceutical ingredients but are never entirely identical. Conventional generics and biosimilars can be manufactured and launched on the market when the original product goes off patent and the exclusivity period has elapsed. Reference to the original product is an integral component of its approval. Reference shows that the market authorization of the original (identical or similar) product has already been approved. For this reason, both conventional generics derived from chemical compounds and biosimilars derived from biological substances benefit from less expensive market authorization procedures. No questions arise concerning patent protection – as patents have already expired – but regulatory questions for market authorization have to be answered. It should be noted that this definition of biosimilars is consistent with the definitions used by regulatory authorities such as the FDA, EMA and Swissmedic.


11 The 12-year period for biosimilars was introduced by the BPCI Act, see sub-section 7.1.
For the following discussion, the focus will be on biosimilars in a ‘broader’ sense. In this understanding, biosimilars are medicines that are made from biologicals and benefit from the innovator product in terms of effectiveness, consumer safety and efficacy. But unlike biosimilars in its common definition, these similar biological products could be accessible to patent protection depending on the extent of their similarity. Could similarity be so un-similar to be considered as new? Or in other words: Is it possible that a well-established and successful biological could be altered in such a way that there are changes in its sequential nucleotide arrangement and interference in the protein or DNA/RNA production process, which in turn could result in an invention that has to be accepted as a new invention by national patent offices? Could an imitator get patent protection for an altered process or product if the patent claims are different enough to fulfil the requirements of novelty and inventive step, yet still be similar enough to the original product to be equally successful on the market?

A quick glance at some figures taken from the biotech market shows the relevance of this question: The market for biologicals is a prosperous market witnessing enormous growth. In 2014, biologicals held – with a turnover of US$ 200 billion – a share of 20 percent within the global pharmaceutical market. Thomson Reuters\(^{12}\) suggest that the global biological market is expected to grow from US$ 38 billion in 2010 to US$ 253 billion by 2020. According to pharma market analysts GBI Research,\(^{13}\) the global biosimilars market value based on original biologicals will increase by up to US$ 55 billion or EUR 50 billion within the next five years. The reasons for this positive assessment are political efforts to cut costs in the health care system as well as the effectiveness of these drugs. Biologicals have revolutionized the treatment of numerous diseases. They can be used for therapies to treat severe diseases and health conditions such as arthritis, multiple sclerosis, diabetes and breast cancer. They also include a wide variety of products including vaccines, blood and blood components, tissues and proteins. Biologicals represent one of the fastest growing segments of the pharmaceutical industry. But manufacturing biologicals is challenging for the companies involved in terms of R&D costs and in terms of quality standards, safety and drug efficacy. As a result, biologicals are nowadays amongst the most expensive drugs available. While R&D costs for chemical drugs amount to CHF 2–4 billion, R&D costs for biologicals total CHF 120–140 billion.\(^{14}\)

As is commonly known, successful products easily attract imitating competitors. There are significant concerns reported by the Swiss industry that investing in biologicals could be a risk when competitors enter the market and try to apply for patent protection for similar biological products during the time the original patent is still valid. In this scenario, the main concerns from the pioneer manufacturer’s perspective are expressed in the following question: ‘How to draft the claims in the original patent broadly enough to prevent biosimilars from being patented and keep competitors from free-riding and entering the market?’ This question addresses issues like the scope of a patent claim. The claim should include a very broad covering of all sequences that are within a certain accepted range.

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of identity compared to the sequences of the original biological. On the other hand, a biosimilar manufacturer might be concerned about, ‘How to draft patent claims without infringing the pioneer manufacturer’s patent rights and how to ensure that regulatory authorities will grant the patent?’ This addresses questions of novelty and inventive step. Before answering these questions, patentability of DNA sequences and proteins should be explained using the example of Swiss patent law.

3. PATENTABILITY REQUIREMENTS UNDER SWISS PATENT LAW

3.1 Patentability of DNA Sequences

Under the Swiss Patents Act, a naturally occurring sequence or portion of a sequence of a gene as such (even if isolated) is not patentable. But a sequence deriving from a naturally occurring gene sequence or partial sequence is, in principle, patentable (cf. Article 1b PatA). It is important to note that under Swiss patent law, the scope of patent protection for derived sequences is limited to its function (= purpose). Although the function is not part of the patent claim, the function is part of the invention. This concept is also referred to as ‘function-limited protection’. As a consequence, derived gene sequences without a precise indication of a specific function connected with the sequence in question are not patentable inventions but discoveries. It is the technical manufacture and the indication of the intended function that makes a derived DNA sequence a patentable invention. Typical examples for ‘derived sequences’ are cDNA (complementary DNA), RNA (ribonucleic acid), proteins (macro molecules), and peptides (micro molecules; 100 amino acids or less). One of the first DNA sequences and its function ever patented was insulin (a peptide).

The effect of patents comprising derived nucleotide sequences is limited in Article 8c PatA. The protection conferred by a claim to a nucleotide sequence that is derived from a naturally occurring sequence or partial sequence of a gene is limited to the sequence segments that perform the function specifically described in the patent. If the sequence described in the patent claim will cover different effects in the future, the patent does not protect them. Only the relevant sequence parts should remain in the claim. It is important to mention that Article 8c PatA, contrary to article 1b PatA, includes only derived nucleotide sequences, but no amino acid sequences or proteins. Article 8c PatA has to be

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17 Filed on 1 January 1923 in Canada as application no. 273746, later granted as CA 234336.

18 So far, there is no practical experience in Switzerland concerning Article 8c PatA.

19 For the significance of this difference, see the following sub-section 3.2.
viewed in connection with Article 1b PatA, as, on its own, Article 8c PatA does not imply restricting the scope of protection to the specific function. Article 8c PatA aims to avoid speculatively broad claims for nucleotide sequences and leads to less dependent patents. This so-called ‘function-restricted compound protection’ under Swiss law differs from the so-called ‘absolute compound protection’, as is the case with chemicals, for example.

However, when biologicals are involved, this function-restricted compound protection under Article 8c PatA remains merely theory: with biologicals, you cannot clearly define the substance in the way that you would for a conventional molecule, and therefore a broader definition in terms of function may be needed. Additionally, the function-based approach is only possible if it is known exactly which sequence is encoding or responsible for what function. In reality, this is not always the case. The nature and function of large biomolecules in living organisms is determined by the order of the different amino acids or nucleic acids found in the sequences of these chain-like molecules. However, the sequence in these molecules is often slightly altered by nature. These small alterations might consist of a simple exchange of one link (amino acid or nucleic acid) in the chain with a different link. These exchanges create polymorph molecules that could show reduced or enhanced biological activity, or have no consequences on the activity of the chain-like biomolecules. This variability in the structure of biopharmaceuticals is often a result of the production process, depending on the type of organism or the culture conditions used for the generation of the drug. As a consequence, if a pioneer manufacturer of a biologic medical product wants to protect himself against competitors, he might need to define or describe his claims in a much broader manner. Pioneer manufacturers are well advised to also contemplate how their biologicals could be modified in future and should consider obtaining patent protection for these modifications.

3.2 Patentability of Proteins

As already mentioned, Article 8c PatA only includes nucleotide sequences, and not amino acids or proteins. As a result, the function-restricted compound protection is not valid for proteins. A pioneer manufacturer doing research in proteins can file a patent application with broader claims, as when researching in nucleotide sequences. So the effect of the patent for proteins can be broader. Considering that most biopharmaceutical drugs are based on proteins, the pioneer manufacturer can take advantage of this concept.

4. PRACTICAL EXAMPLES

The assumption that a pioneer manufacturer could have a vested interest in broadening his patent claims for obtaining maximal patent protection for his biologicals, and that a biosimilar manufacturer searches for patent claims which do not infringe the patent

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20 There is no equivalent regulation in European patent law for a (function-) limited effect of a patent claim when derived nucleotide sequences are involved. Article 5 section 3 indicates indirectly that a simple DNA sequence without indication of its function does not imply technical teaching and therefore is not an invention.
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rights of the pioneer manufacturer, raises the question of when similarity ends. This shall be illustrated by the following two scenarios (see Figure 1.1): first, we could assume that the biosimilar is only a small subsequence of the original sequence of the biological, but still has the same desired effect; second, the biosimilar could have a considerably longer sequence but contain the original sequence as a subsequence.

Thus, apart from the requirements for the patentability of DNA sequences and proteins, the questions of novelty and inventive step for biosimilar patent applications are also in focus. Again, a closer look at the requirements of novelty and inventive step shall be taken in the following section based on Swiss patent legislation.

5. NOVELTY REQUIREMENT UNDER SWISS LAW

One of the most important requirements for patent protection is the novelty of the invention. An invention is considered to be new if it does not form part of the state of the art (Article 7 para. 1 PatA). The state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way prior to the filing or priority date (Article 7 para. 2 PatA).21 The question of whether an invention is considered novel or not is much easier to answer for conventional chemical generics: a previous patent application with identical patent claims in the sense of identical chemical structures, in general, destroys novelty. The same applies if a drug with identical compounds has been used in any form previous to a patent application by another party: the use itself destroys novelty for any future patent application as the chemical compounds of

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21 This is also valid under European law, cf. Article 54 Section 1 and 2 of the Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.
the drug are considered as the state of the art (anything that is known and made public). If a research team at a university makes an invention and publishes it in journals such as *Nature* or *Science*, it belongs to the state of the art and patent protection is no longer possible for the same invention.

This rule seems to be easily applicable to conventional chemical drugs as their compounds are, in general, identical. The question of novelty is much more difficult to answer when dealing with biosimilars comprising nucleotide sequences, cDNA and proteins. What if a compound is not identical to an existing patent-protected compound, but only similar to the original patent-protected product or only similar to the state of the art? Or to put it another way: how ‘novel’ must a biosimilar be in order to be patentable? How much diversion is acceptable for a patent application for an invention to be considered as ‘new’? For example, if an invention differs by not more than 5 percent from a patent-protected original drug, will this application be considered as novel by IP offices? Or will this application be assumed to be identical to the original biologic and therefore not patentable? And what if an invention differs by more than 5 percent from a reference invention? Will the invention, in this case, no longer be considered as identical, but rather similar? The question to be raised is as follows: how much similarity is enough in order not to be identical, resulting in an invention being considered as novel?22

Apart from this question, it should also be mentioned that although an invention is considered new, it might lack an inventive step. Even if an invention differs in an acceptable way for IP offices from the original drug and is considered new, there is another hurdle to pass as the invention also has to be the result of an inventive step. This means that the invention must not be derived in an obvious way from the prior art (by a person skilled in the art). Unexpected characteristics of products or surprising effects of processes are indications that this criterion has been satisfied. An inventive step may also exist if a solution to the technical problem overcomes a prejudice or satisfies a pre-existing need.

6. SOLUTIONS TAKEN FROM CASE LAW (EPO LEADING CASES)

The following paragraphs quote a selection of decisions of the Technical Boards of Appeal of the European Patent Office,23 which deal with a number of issues that could help to answer the questions raised in the previous sections:

- In decision T 198/8424 a number of principles for a selection of invention in the field of chemistry were defined: according to this decision, a sub-range singled out of a

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22 It is not possible to answer this question conclusively. Some years ago, some IP offices were inclined to rule out novelty if sequences differed by not more than 20 percent from a previous patent application. Nowadays, there is a tendency by IP offices to accept much smaller alterations in sequences for an invention to be novel. Even the smallest deviations could justify ‘novelty’ and, provided that the invention is the result of an inventive step, lead to the granting of a patent.


larger range is not considered new by virtue of a newly discovered effect occurring within it, but must be new per se.

- In T 12/90\textsuperscript{25} a decision on the novelty of generically defined compounds including particular examples, the Technical Board of Appeals stated that an arbitrary selection cannot be considered novel.
- In T 133/92\textsuperscript{26} it was decided that a claimed group of compounds cannot be considered as selectively novel when it essentially resulted from omitting those parts of a larger group of compounds that a skilled person would have immediately considered as being less interesting than the remainder.
- As for the decision on the inventive step for enlarging the sequence by adding sequences that have virtually no function, T 72/95\textsuperscript{27} says that if a known device is modified by adding a feature which has no technical function, this modification cannot contribute to the inventive step.
- Furthermore, in T679/92\textsuperscript{28} it was held that the use of equivalent means can indicate lack of inventive step.

The question of whether or not a biotechnological invention involves an inventive step is especially interesting in connection with equivalents. As already mentioned,\textsuperscript{29} it is not always exactly known which sequence is encoding or responsible for a function. Besides the problems described regarding Article 8c PatA, it is commonly known that some minor changes in sequences could have no effect on the function of its function. Therefore, a strict consistency of sequences cannot be required.

As for the previously mentioned two examples of extracting or inserting sequences, the following must be considered: if the subject of a patent claim is sequence A, but the described function could also be exactly fulfilled by the middle part of this sequence A, then the middle part is also protected by the patent claim if: (a) this partial sequence fulfils the same function; and (b) this could be expected by a person skilled in the art. On the contrary, if a skilled person would not expect the partial sequence to fulfil the same function, this partial sequence is not protected by the original or older patent. The same applies for a sequence to which a new partial sequence is added. If the extended sequence fulfils the described function to a significant extent, and a skilled person could expect this effect, the extended sequence lacks an inventive step. This could also apply to sequences where only one nucleotide is replaced by another.

Due to the absence of decisions on cases involving biosimilars in Europe, case law dealing with other technical areas has to be used. Thus, there remains considerable uncertainty regarding biosimilar patent applications.

\textsuperscript{26} Unpublished in the OJ.
\textsuperscript{27} Unpublished in the OJ.
\textsuperscript{28} Unpublished in the OJ.
\textsuperscript{29} Cf. sub-section 3.1.
7. HANDLING BIOSIMILARS AND PATENT RIGHTS – THE US APPROACH

7.1 Obama’s ‘BPCI Act’ aka ‘Biosimilar Act’ of March 2010

On 23 March 2010, US President Barak Obama signed into law the Biological Price Competition and Innovation Act (BPCI Act) – or Biosimilar Act as it is commonly referred to. It provides a regulatory approval pathway for generic biologicals in close alignment with the generic drug pathway provided under the Hatch-Waxman Act of 1984.\(^{30}\) The Biosimilars Act\(^{31}\) is part of the health-care reform provisions included in the Patent Protection and Affordable Care Act.\(^{32}\) The act outlines the requirements for determining ‘biosimilarity’ and ‘interchangeability’, provides the timeline for engaging in infringement, and sets forth the exclusivity period awarded to the innovator biological as well as the first-filer biosimilar. But most interestingly, it contains provisions for a patent information exchange and patent dispute resolution scheme prior to the market approval of biosimilars by the FDA. Any patent infringement litigation should be avoided from the beginning in order to encourage the innovative industry to invest in biologic products and foster innovation. By establishing a new scheme to resolve patent disputes, pioneer manufacturers are likely to be protected from imitating competitors. In addition, abbreviated and simplified approval requirements, especially for pre-clinical and clinical trials, were introduced which aim at reducing prices on biologicals and biosimilars.

7.2 Patent Dispute Resolution Scheme in the ‘Biosimilar Act’

In subsection 262(l) of the Biosimilar Act, a new patent dispute resolution scheme involving biosimilar products was introduced. This scheme lays out a schedule of timed steps according to which both parties – the biosimilar applicant and the pioneer manufacturer – exchange certain information and respond to each other’s contentions about potential patent disputes. This scheme is also known among experts and in professional circles as the ‘patent dance’. The patent dance thus determines when patent litigation may begin, and how much information a party may have before initiating litigation.

According to these steps, the biosimilar manufacturer is required to submit his application to the pioneer manufacturer after having received notice from the FDA that his application has been accepted for review. He has to provide the pioneer manufacturer with an (unredacted) copy of his biosimilar application and manufacturing information for his proposed biosimilar within 20 days (step 1). The innovator can only use this application to determine whether a claim of patent infringement can be reasonably asserted. He must then – within 60 days – provide a list of all patents owned or licensed by him that cover his product, including those for methods or processes (step 2). The biosimilar manufacturer must then identify the patents that he is challenging as invalid, not infringed, or

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unenforceable, and provide a detailed statement in support for each assertion. He is also given 60 days to identify these patents (step 3). The pioneer manufacturer then indicates his counter-basis for validity of the patent and infringement – again within 60 days (step 4). Both parties then have 15 days to negotiate in good faith in order to develop a list of patents to be immediately litigated before the competent court (step 5). If the parties agree on that list, the pioneer manufacturer brings an infringement suit before the competent court. If the two parties fail to agree on that list, those patent disputes will be litigated upon notice of the biosimilar manufacturer’s intention to engage in the commercial marketing of his product in 180 days.

It is interesting to note that approximately 200–300 days elapse between the acceptance of the biosimilar application by the FDA and the filing of any patent infringement lawsuit. So far, four applicants for biosimilars have been accepted by the FDA based on the Biosimilar Act.\(^33\) One case has already challenged the patent dispute resolution procedures. In this case, *Amgen v. Sandoz*,\(^34\) two main questions were raised. The first was whether the statutory provisions for resolution of patents – the ‘patent dance’ – are mandatory or optional. Amgen said that the disclosure of the application was required, whereas Sandoz believed it had latitude here. Another matter is the question of timing. The Biosimilar Act requires the biosimilar manufacturer to give 180 days’ notice. Sandoz insisted that the 180 days start from the moment the application is accepted. Amgen believed that the biosimilar manufacturer cannot give notice until it has the FDA’s approval. The US Court of Appeals for the Federal Circuit sided with Sandoz in its interpretation that the Biosimilar Act does not force the biosimilar applicant to make these disclosures. As for the 180 days’ notice, the Federal Circuit agreed with Amgen that the law does not permit marketing notice until after a biosimilar applicant has received FDA approval.\(^35\)

8. CONCLUSION AND OUTLOOK

The question of if, and if so under what conditions, biosimilars might be subject to patent applications or could infringe existing patent rights of the pioneer manufacturer remains uncertain in Europe. The absence of decisions at the European level leads to the conclusion that existing leading cases dealing with other technical areas, such as biotechnological ones, have to be consulted. This unsatisfactory situation leaves pioneer manufacturers as well as biosimilar manufacturers in uncertainty regarding patent-related questions. In the US, the Biosimilar Act addresses the issue of possible patent infringements by a patent information exchange and patent dispute resolution scheme also known as the...
‘patent dance’. However, the decision of the Federal Circuit is casting doubt on whether the patent dispute resolution scheme as stated in the BPCI Act contributes to more legal certainty. If the new case law leaves it up to the parties involved as to whether they want to engage in this new (and time-consuming) scheme when biosimilars are involved, only the future will tell if the ‘patent dance’ becomes an effective and established procedure before the FDA. So far, the BPCI Act’s information exchange and patent dispute resolution scheme is the only procedure in which both parties, the pioneer manufacturer and the biosimilar manufacturer, are actively involved in the process of market approval. With the patent dance, the biosimilar manufacturer has certainty that his product is not infringing existing patent rights and the pioneer manufacturer has the possibility of pursuing alleged patent infringements. Could this also be a possible approach for Europe? The issue is open for discussion.