Gewerblicher Rechtsschutz und Urheberrecht
INTERNATIONALER TEIL

GRUR Int

Zeitschrift der Deutschen Vereinigung für gewerblichen Rechtsschutz und Urheberrecht
In Zusammenarbeit mit dem Max-Planck-Institut für Innovation und Wettbewerb

2/2016
Seiten 109–208
65. Jahrgang – Februar 2016

Herausgegeben von Josef Drexl und Reto Hilty
in Gemeinschaft mit Joachim Bornkamm und Ansgar Ohly

AUFSÄTZE

MARKUS MEYER*/ALEXANDER G. ALBRECHT**/CHRISTIAN A. KILGER***

Patentability of Known Medical Devices with a New Medical Use – Case Law of the European Patent Office

Is a medical device with a new medical use patentable before the European Patent Office (EPO)? In some cases it is. But when? A new and inventive device is clearly patentable. When the device *per se* is known, but the medical indication for which it is applied is new, the issue becomes more complicated. The article provides an overview of the evolution of case law relating to the patentability of devices with a new medical use and an attempt to formulate the criteria that devices need to fulfil in order to benefit from novelty of their new medical use.

I. Background

Medical devices are becoming increasingly important in medicine, as they take on diverse and specialised functions in medical treatments. Their development is of paramount importance for the medical profession as they allow for better therapies and assist medical practitioners in delivering complex new treatments. As a consequence, patentability of medical devices before the EPO has a big influence on the availability of medical treatments to European populations.

Medical devices can be patented before the EPO, provided they are new and inventive. What happens, though, if the invention relates to a known medical device with a novel medical use? Contrarily to substances and compositions, medical devices can as a rule not directly derive novelty from a new medical indication. Despite this, the EPO does under certain circumstances grant patents for known medical devices based on their new use. We attempt to define the parameters a medical device has to fulfil in order to be patentable based on its novel use.

Contrarily to substances and compositions, which can derive novelty from a novel use in a method of treatment, surgery, or diagnosis (Art. 54 (4) and (5) EPC), there is no equivalent provision in the EPC to allow medical devices to derive novelty from a new medical use. In the United States, the new medical use of a device can be patented in the form of a method of treatment claim using the device. This possibility does not exist in Europe, as methods of treatment *per se* are not, at least up to now, patentable subject matter before the EPO (Art. 53 (c) EPC).

The exclusion from patentability of methods of treatment before the EPO has historical reasons. Inventions relating to methods of treatment were considered not to be industrially applicable under the EPC 1973 (Art. 52 (4) EPC;[1] § 5(2) PatG) and were barred from patentability for this reason. The intention of the legislator was to maintain medical and veterinary professions free of any limitations imposed by patents. The German Federal Court of Justice decided in 1967 in its *Glatzenoperation*[2] decision that any method by which a physician is provided the means to remove a pathological condition is excluded from patentability as a physician's profession is not industrially applicable.

However, a few years later, the two decisions *Benzolsulfonylharnstoff*[3] (1978) and *Sitosterylglykoside*[4] (1983) made by the German Federal Court of Justice held that

* MSc Biochem., Ph.D., European Patent Attorney trainee, Berlin.
** Dipl. Chem., Dr. rer. nat., European Patent Attorney trainee, Berlin.
*** Dipl. Biol., Dr. rer. nat., Patentanwalt and European Patent Attorney, Berlin.

1 EPC in its version of 1973.
2 GRUR 1968, 142 – *Glatzenoperation* (Bald spot operation).
3 GRUR 1977, 652 – *Benzolsulfonylharnstoff*.
4 GRUR 1982, 548 (549) – *Sitosterylglykoside*.

contrarily to methods of treatment, the use of substances to treat an illness was susceptible of industrial application. These decisions therefore paved the way for making substances for the treatment of an illness patentable in Germany.

At the EPO level, the Enlarged Board of Appeal was asked in 1983 (G 5/83) to decide whether a patent with claims directed to the use of a substance or composition for the treatment of the human or animal body by therapy is allowable subject matter.

In its decision, the Board agreed in principle with developments in the German case law that was in effect considering making claims for substances for use in medicine patentable in Germany. However, it reasoned that since patent infringement questions were dealt with by national courts according to Art. 64(3) EPC 1973, and since Germany was the only contracting state of the EPC which now allowed protection for substances for use in medicine, it could not for the time being follow the decision of the German court. It therefore ruled that claims for substances for use in a treatment were not allowable under the EPC because they would be in direct contradiction with the exclusion of medical treatments from patentability stipulated by Art. 52(4) EPC 1973.

The Board, however, also decided that claims in the format "use of a substance or composition X in the manufacture of a medicament for the treatment of condition Y" were allowable, provided the claimed use was novel and inventive. Such claims are known as Swiss-type claims because they were allowed by the Swiss Federal Institute of Intellectual Property, before being deemed acceptable by the EPO by decision G 5/83. With this type of claim, a known substance and compositions could in effect derive novelty from the intended new medical use of the substance in the treatment of a disease.

Swiss-type claims thereby became the standard type of claim for protecting known compounds with a new medical use and only became obsolete upon entry into force of the revised EPC 2000 on December 13, 2007. The revised convention deals with the question of patentability of substances and compositions for medical use essentially as specified by the German Federal Court decisions *Benzolsulfonylharnstoff* and *Sitosterylglykoside* cited above. Methods of treatment are still unpatentable under the EPC 2000, as they are explicitly mentioned as an exception to patentability in Art. 53(c) EPC 2000. However, Art. 53(c) EPC 2000 specifies that products, in particular substances and compositions for treatment are not excluded from patentability. Furthermore, Art. 54(5) EPC 2000 explicitly states that a substance or composition can derive novelty from its intended new specific use in a method of treatment. Together, these two provisions make it possible to obtain a patent with claims for a known substance for a purpose-limited novel and inventive first, second or further medical use.

In contrast to compositions and substances, medical apparatuses and devices do not benefit from such special provisions. From the time between the G 5/83 decision allowing Swiss-type claims and their abrogation by decision G 2/08, patenting of known medical devices for which there was a new medical use was therefore also often attempted through Swiss-type claims. Theoretically, nothing precluded medical devices from receiving protection through this type of claim, provided that the devices could be equated to medicaments. However, arguing that a device is in fact a medicament, or part of a medicament, is not always straightforward to say the least. The point of contention was often the exact definition of the properties that characterise a medicament and whether a particular device fulfils these characteristics. For example, can a scalpel be considered a medicament? What about a catheter coated with an antibiotic agent? And, what about a progesterone-releasing intrauterine device? Or a laser used in eye surgery?

Answers to these questions came about through the decisions of the Technical Boards of Appeal that repeatedly had to determine whether a particular device, or at least parts thereof, could be equated to a medicament, in order to be patentable for its new medical use. With entry into force of the EPC 2000 the question shifted towards determining when a medical device can be regarded as a substance or a composition. Since a medicament is by definition a substance or composition, the pre-EPC 2000 case law remains relevant to determine whether a medical device can drive novelty from its new medical use. We look at some of the most relevant case law that brought answers to these questions.

II. Case law relating to patentability of medical devices for a new indication

1. The device has to be consumed

The part of decision T 227/91[5] relevant to the patentability of medical devices relates to claim 1 of the auxiliary request. The Applicant appealed the decision of the Examining Division refusing the patent application on the grounds that the claims were neither novel nor inventive in view of the prior art. The claim of interest was in the Swiss-type format and the Applicant argued that the particular medical use of the device was novel. It reads as follows (emphasis added):

> "*Use, in the manufacture of a laser surgical instrument for intercepting an incident laser beam* having a particular wavelength after the laser beam has energised a desired surgical target site but before the laser beam energises material adjacent to the surgical target site, *of:*
> *substrate means (16) adapted to transmit energy received from said laser beam away from said surgical target site*, said substrate means having a high thermal conductivity and an exterior surface; and coating means (18) adapted to absorb laser energy at said wavelength, said coating means covering substantially the entirety of the exterior surface of the substrate means, having a high absorptivity for energy at that wavelength and having a thickness in excess of one quarter of the wavelength of the laser beam;
> characterized by said coating means having a thickness substantially equal to 0.1 (a.t)0.5,
> where
> a = thermal diffusivity of the coating means
> t = effective pulse time of the laser beam."

The Appellant argued that since the instrument was to be used in surgery, it could be equated to a medicament. The laser should therefore be able to derive its novelty from its new medical use, just as medicaments can derive novelty from a second or further medical use.

The Board did not concur (point 5.2 of the Reasons):

5 T 227/91, OJ 1994, 491 = GRUR Int. 1994, 848.

> "The indication of purpose, i.e. intercepting the laser beam, is a characteristic of the surgical use of the instrument and is not affecting the structure of composition of the entity itself. This kind of functional reference cannot normally impart novelty to an otherwise known article, unless the function implies a necessary modification of the article itself. The only exceptions so far recognized are based on Art. 54(5) EPC and on a new therapy for a known medicament when the manufacture of the same is also characterised by the new use of the product (i.e. second or further therapeutic indication – G 5/83)."

The Board further explained that the surgical use of an instrument could not be equated to a therapeutic use since contrarily to the medicament, the surgical instrument is not consumed during the treatment and can therefore be reused after it served its surgical function, including for a different purpose. Contrarily to a medicament, a surgical device can therefore not derive its novelty from its use in a method of treatment, even if this use is novel.

Decision T 227/91 sets a fundamental condition that a medical device must fulfil to derive novelty from its intended medical use. It requires that the device, analogously to a medicament, must be consumed during the treatment. A device that is not consumed can therefore not derive novelty from a medical use, even if this use is novel.

2. The device has to be a finished product ready for use without surgical insertion into the body

In decision T 775/97, the Board had to decide whether an endoprosthesis could be protected by a Swiss-type claim and thereby derive novelty from its new medical use. An endoprosthesis is an artificial device that replaces a missing body part. Such a device is not recycled for another use after serving its function and is therefore undeniably consumed by application to the patient. It thereby fulfils the requirement specified by decision T 227/91 (see section II.1.). However, in order to carry out its function, the prosthesis has to be surgically inserted into the patient, as described in the relevant claim 29 (emphasis added):

> "*Use of a mutually connected first tube (160A) and first tubular member (166A) and a mutually connected second tube (160B) and second tubular member (166B),* as defined in any one of claims 1 to 26, *for the manufacture of a device for use in a surgical method in which the tubular members and tubes are intraluminally delivered* in the first diameter condition of the tubular members into a body passageway (152) to be repaired , to be disposed therein substantially even and on the same level as each other, and the tubular members are subsequently expanded and deformed, by the application from the interior of the tubular members of a radially outwardly extending force, from the first diameter to the second, expanded and deformed, diameter with portions of the first and second tubular members being in a substantially flat adjacent relationship, whereby the adjacent portions are substantially flattened towards each other to substantially close off and substantially remove any gaps that may otherwise be present within the body passageway between the tubular members; to form a bilateral passageway in the body passageway to repair the body passageway."

The board argued (point 2.6 of the Reasons) that a medicament resulting from the manufacturing process is a finished product that is ready to serve its therapeutic function. The medicament is therefore solely responsible for the therapeutic effect. In contrast, the functionality of repairing the body passageway by the known endoprosthesis is only possible after its insertion into the body by a new surgical method. The board therefore ruled that the claim is not *in fine* for a medicament, but rather "actually directed to a surgical method which is characterized by the use of known endoprotheses in a new way" (point 2.7 of the Reasons). It found that it is the surgical treatment that confers to the device the properties needed for its intended use. Since this category of claims is explicitly excluded from patentability, the claim was deemed not to be allowable. The board therefore confirmed that European patents could not be granted for new ways of using materials or devices involving a treatment by surgery. This would be equivalent to patenting a surgical method, which is not possible under the EPC.

3. The device has to be in contact with the patient's body when it carries out its function

The definition of what constitutes a medicament was further refined by decision T 138/02. This case discussed the patentability of a material for the manufacture of an absorbant that allows removing undesirable substances from bodily fluids to treat a certain number of diseases. Specificly, the absorbant is added to a bodily fluid and later removed by centrifugation before the treated fluid is readministered to the patient, as explained in claim 1 of the main request (emphasis added):

> "*Use of a material* comprising a porous water-insoluble carrier and a compound covalently immobilized onto said carrier, wherein the compound to be immobilized onto said carrier satisfies a value log P of at least 2.50, in which P is the distribution coefficient in an octanol-water system, and the total of hydrophobic fragmental constants f of fragments of said compound covalently immobilized into said carrier is not less than 2.50, in which the hydrophobic fragmental constant f shows the hydrophobicity of various fragments which are determined by statistical management of many found values of log P, *for the manufacture of an adsorbent for the treatment of a disease* selected from the group consisting of rheumatoid arthritis, systemic inflammatory response syndrome, sepsis, systemic lupus erythematosus, Lyme disease, osteoporosis, Kawasaki disease, gouty arthritis, endometritis, premature labor, Castleman's disease, chronic disease with proliferation, contact dermatitis, idiopathic fibroid lung, adult respiratory distress syndrome, inflammatory bowel disease, immune angiitis, glomerular nephritis, urinary tract infection, cardiac infarction, asthma, respiratory tract infection, perinatal infectuous disease and rejection in organ transplantation, by removing at least one cytokine selected from the group consisting of interleukin-1, interleukin-2, interleukin-6 and interleukin-8 from body fluid, wherein the distribution coefficient P is determined by dissolving the compound in octanol (or water), adding an equal volume of water (or octanol)

thereto, shaking for 30 minutes, centrifuging for from 1 to 2 hours at 2000 rpm and measuring the concentrations of the compound in the octanol and water layers, and said carrier has at most 60 degrees contact angle with water."

The absorbant was for all intents and purposes considered by the Board to be "consumed" during the treatment, because it is "changed" by the treatment of a patient and is not recycled. The absorbant is also a finished product that carries out the therapeutic effect, and is not applied to the patient by a surgical method. Both hurdles that hindered patentability in cases T 227/91 (section II.1.) and T 775/97 (section II.2.) did therefore not apply here.

However, in its decision the Board stated that every tool, substance or composition which is consumed during its therapeutic use is not necessarily a medicament. The board considered that "an essential characteristic of a medicament is that it be administer to a patient's body in order to treat a disease".[6] It further explained that a medicament has to come into contact with the patient's body to carry out its therapeutic function. The Board found that the absorbant in question does not fulfil this criterion because it is added to a bodily fluid outside of the body, and is not administered to the patient. Novelty could therefore not be derived from its new medical use, as it would have been had the absorbant been found to be a *bona fide* medicament.

A practical example in which this principal was applied is the opposition against the unrelated European Patent 0 862 444. This case dealt with the use of a ligand in the manufacture of a column used in the treatment of dilated cardiomyopathy by removing specific antibodies from plasma.

Claim 1 of the first auxiliary request is the following (emphasis added):

"*Use of a specific ligand for human immunoglobulin in the manufacture of a column* having said ligand coupled thereto *for the treatment of a patient suffering from dilated cardiomyopathy,* said treatment comprising passing plasma of the patient over the column under conditions which effect the binding of said specific ligand to immunoglobulin in the patient's plasma, thereby removing a significant portion of the immunoglobulin from the patient's plasma, and reinfusing the plasma to the patient."

The Opposition Division decided that this claim was allowable as a second medical use claim, because in contrast to case T 138/02 (same section above), the blood was treated in a closed circuit connected with the body. Despite the ligand not being administered into the patient's body, it was brought into contact with the blood of the patient through the closed circuit. This blood was deemed to be part of the body even though it was outside of the body because it remained in contact with the body at all times. Thereby, the column was considered to have all the characteristics of a medicament based on the case law. The new use was deemed novel and inventive and the patent was maintained on the basis of the cited first auxiliary request.

This decision of the Opposition Division was appealed both by the Patentee and the Opponent and was thereby brought before the Technical Board of Appeal as case number T 2003/08. The Board concurred with the decision of the Opposition Division, but for different reasons. This decision by the Board introduced another criterion a device has to fulfil in order to be able to derive novelty from its new medical use and is therefore reviewed in the next section (section II.4.).

4. The medical device can derive novelty from the new use of its active ingredient

In case T 2003/08, the Board had to rule on the allowability of the claim for the use of a ligand in the manufacture of a column that was deemed novel and inventive in the opposition against EP 0 862 444 (section II.3., second part). The Board also came to the conclusion that the novel medical use conferred novelty to the claims and that they were therefore allowable. However, although the conclusion was the same, the reasoning was different. The Board reasoned that it was not the column *per se* that was instrumental in achieving the therapeutic effect, but rather, the ligand inside the column. As a result, the means for achieving the treatment is not the column but the ligand. The Board also stated that the Enlarged Board of Appeal in decision G 5/83 had in fact intended to allow products that are substances and compositions to derive novelty from their second medical use, not in fact medicaments. The Board therefore concluded that it was (Reasons 14)

"… of pivotal importance to establish whether or not the means used in the treatment of DCM [dilated cardiomyopathy] according to the present claims constitute a 'substance or composition', rather than to establish whether or not it constitutes a 'medicament'".

The key question in this case therefore became to determine whether the ligand could be seen as a substance or a composition. This change in perception regarding the second medical use was well in tune with the developments in patent law introduced by the coming into force of the EPC 2000, as seen in the introduction. The Board found that even though the exact definition of a substance or a composition was not entirely clear, it should be assumed that at least a "chemical entity" would qualify. Since the ligand is undeniably a chemical entity, it is also a substance or a composition.

With this reasoning, the board came to the conclusion that the medical function of the device is carried out by the ligand in the column, which is a substance or a composition. It ruled that the claim for the medical device was allowable because ultimately the object of the claim was for the new use of a substance or a composition. This decision therefore established that a claim for a medical device can derive novelty from a second or further medical use, provided the therapeutic effect is carried out by an active ingredient (a substance or a composition) of the device.

5. The function of the device is based on an active compound, not on its position or shape

In essence this is also the position of the Boards in decisions T 1099/09 and T 1069/11. In the first case, the Board had to decide whether a known strip ("bandelette") made of a biocompatible material and used in a new treatment of urinary incontinence could be deemed to be a composition that could derive novelty from its novel medical use. Patentee argued that since the strip was inserted into the body and had a physiolo-

6 T 138/02, point 2.6 of the Reasons.

gical interaction with the body it should be considered to be a composition. Since a composition can derive novelty from its new medical use, the strip should also be able to.

In case the Board did not agree with this reasoning, the Patentee also set forth the following argument. Since Art. 53 (c) EPC 2000 does not exclude the patentability of products used in medical treatment, products, which could be devices, should also not be excluded from deriving novelty from a new further medical use under Art. 54 (5) EPC 2000, despite not being explicitly mentioned in this article. The argument of the Patentee was that otherwise there would be a legal grey area where a product (i.e. the strip) was at the same time patentable under one article (Art. 53 (c) EPC 2000), but barred from patentability under another (Art. 54 (5) EPC 2000). Therefore Art. 54 (5) EPC 2000 should not be applicable only to substances and compositions but also to products.

The Board was not convinced. It rejected the argument by ruling that a strip was a finished product with a given shape and dimensions, and could therefore not be seen as a substance or composition. It also ruled that products not being excluded from patentability by Art. 53 (c) EPC 2000 did not imply that they should also be considered as novel on the basis of their new use under Arts. 54 (4) and (5) EPC 2000. The claims were therefore considered to lack novelty and the strip with its new medical use not patentable.

In T 1069/11, the new use of another medical device, in this case a stent, was again the subject of the decision. The relevant claim (claim 1 of the main request) was the following (emphasis added):

> "*Stent for use in prevention of restenoses* of a wall (3) of a blood vessel having atheromatous plaque consisting of a multilayer braided framework (13) wherein the framework, devoid of any cover layer, comprises a plurality of stabilized layers (14, 15, 16) of biocompatible metal wires (17), which are interlaced, forming a lattice, a plurality of wires (17) of a given layer (14, 15, 16) being integrated in the lattice of at least one of the adjacent layers;
> characterized in that:
> the mechanical characteristics of the stent are so that, when deployed in the vessel, an outermost layer (14) is able to rest against the vessel wall (3) and the other layers are able to extending [sic] substantially along cylindrical surfaces distinct from the outermost layer (14), so as to form a multi-layer mat so designed that the combined effect of the various layers locally affects the haemodynamic of a flow of blood passing along said mat, the flow of blood being deviated towards an inner face of an innermost layer and [sic] provoking a drop of the pressure exerted on the vessel wall, thus preventing the growth of plaques on said vessel wall and promoting the growth of a new layer of endothelial cells."

Patentee argued that the stent is used up during the treatment, and can therefore not be reused, just as a medicament, or a substance or composition used for a medical purpose. By analogy, the stent is therefore to be seen as a substance or composition, and should thereby be able to derive novelty from its new medical use. The Board countered by pointing out that the criterion of only a single use is by no means an exhaustive definition of what defines a substance or a composition. Therefore a product should not be classified as a substance or a composition on this basis alone. The Board went on to state in the Reasons for the Decision point 3.3.5 that:

> "… the novelty of the product of claim 1 can be acknowledged on the basis of its medical indication only if that product qualifies as a substance or a composition. However, the claimed product is a stent consisting of a multilayer braided framework devoid of any cover layer. Accordingly it is a finished product having a certain shape and certain dimensions and which does not comprise any active ingredient. Hence, the claimed stent does not qualify as a substance or a composition."

The Board therefore reasoned that the stent derives its function entirely from its mechanical properties and does not comprise an active ingredient that carries out the medical function. In turn, the Board argued, since the stent could not be likened to a substance or a composition it could not gain novelty from its new medical use.

III. The present status

As exposed above, a known medical device has to fulfil a set of criteria to be able to derive novelty from its new medical use, and therefore be patentable. The various rulings reviewed here show that medical devices, or at least parts thereof, had to be likened to a medicament under the Swiss-type claim regime, and later to a substance or composition. The changes in the law brought about by the introduction of the EPC 2000 and decision G 2/08 did not dramatically change the patentability of medical devices for a second or further medical use. This is mainly because a medicament is in most cases a substance or a composition. The criteria for patentability derived from the pre-EPC 2000 era therefore remain valid today. The criteria that have been extracted from the case law can be summarised as follows. In order to derive novelty from its new medical use, a device, or parts thereof, must

- be consumed during the treatment,
- be a finished product that on its own carries out its function,
- be in contact with the body during the treatment,
- have an active ingredient that carries out its function, and
- not derive its function from its shape and position.

Having defined these criteria, we are now in a position to evaluate whether the devices cited in the introduction would be able to derive novelty from their new medical use. A scalpel is almost certainly not patentable for a second or further medical use, because it hardly fulfils any of the criteria. A single-use scalpel may be consumed during the treatment, but is not able to carry out its function on its own as it is the act of surgery that is the basis of the treatment.

A catheter coated with an antibiotic agent comes closer to patentability for its new use because it comprises a substance or composition that has a certain function in the treatment. However, the action of the antibiotic is merely ancillary to the mechanical action of the catheter in the treatment. An attempt to patent the catheter for a new use would therefore most likely also founder.

A progesterone-releasing intrauterine device with a new medical use however likely does fulfil all the criteria to derive novelty from its new use. It is a finished product that is consumed during the treatment. The treatment is carried out by the action of an active substance, the

progesterone, which is by definition a substance or composition. This device would therefore have good chances to derive novelty from its new medical use.
In contrast, a laser used in eye surgery can be reused after treatment, and does not rely on an active ingredient. It would therefore likely not be patentable for a new medical use.
Patentability before of the EPO of medical devices for a second or further medical use has evolved and was refined over the past few years. The cases relayed here have shaped rules of patentability for such devices. One clear point that emerges from this survey of cases is that patenting of medical devices with a new medical use is arduous compared to patenting of substances used in medical treatments. Indeed, since no mention is made directly about medical devices and their further medical uses in the EPC, patenting in such cases always has to be carried out by proxy. In all the cases exposed here, the devices had to be equated to a medicament up until the advent of the EPC 2000, or to a substance or a composition since then, for being patentable for a second or further medical use. The question logically arising from this observation is, as medical devices become ever more omnipresent and important in medicine, whether this tortuous way of patenting devices for which new uses are found is adequate. It is entirely possible, as medical devices evolve, that the current law becomes obsolete and is finally deemed to be stifling innovation in the medical device sector. In such a case, the EPC has shown that it is able to adapt to new medical realities. Insufficiencies in the law were duly rectified in the past, as for example when the ban on patentability of substances in medical treatment for lack of industrial application was abolished by the EPC 2000. We argue that a similar evolution should follow for medical devices, and make their use in medical treatment *per se* patentable. In fact, the allowability of method of treatment claims would solve these problems. As other jurisdictions prove on a daily basis the medical profession is not hindered by the allowability of such claims.

GÜNTHER MARTEN*

Die Reform des Unionsmarkensystems 2016

Im März 2016 wird die neue Unionsmarkenverordnung (UMV, bisher Gemeinschaftsmarkenverordnung, GMV) in Kraft treten. Am 28.10.2015 veröffentlichte der Rat einen Text, der vom Europäischen Parlament am 15.12.2015 in zweiter Lesung bestätigt und am 24.12.2015 im Europäischen Amtsblatt veröffentlicht wurde. Dieser ist Gegenstand des vorliegenden Artikels, der vor allem Aspekte der neuen Verordnung hervorheben will, die für die Rechtsanwender von Bedeutung sind. Vorschriften der Durchführungsverordnung zur GMV[1] wurden teilweise in die Verordnung eingearbeitet, womit auch Änderungen an der GMDV vorgenommen wurden. Daneben wurde folgerichtig auch die Markenrichtlinie 2008/95/EG überarbeitet, die jedoch nicht Gegenstand des Artikels ist.

I. Vorgeschichte der Reform

Die GMV ist seit ihrem erstmaligen Inkrafttreten im Jahr 1994 schon mehrmals geändert worden. Allerdings waren dies punktuelle Änderungen, die mit der hier diskutierten nicht vergleichbar sind. Im Mai 2007 beauftragte der Rat der Europäischen Union die Kommission, das Gemeinschaftsmarkensystem sowie nationale Markensysteme einer allgemeinen Überprüfung zu unterziehen. Nach einer allgemeinen Ausschreibung im Jahr 2008 beauftragte die Kommission das damalige Max-Planck-Institut für Immaterialgüter- und Wettbewerbsrecht (jetzt: MPI für Innovation und Wettbewerb) im Jahr 2009, in einer Studie das Funktionieren des Gemeinschaftsmarkensystems und der Markenrichtlinie zu untersuchen und Vorschläge zu unterbreiten, wie die Systeme einheitlicher, günstiger, schneller und zuverlässiger gemacht werden können. Die umfassende Studie des Max-Planck-Instituts, der unter anderem auch eine Umfrage von Benutzern der Markensysteme zugrunde lag, wurde im Jahr 2011 erstellt.[2] Die gesammelten Erfahrungen seit Einrichtung des Gemeinschaftsmarkensystems haben nach dieser Studie gezeigt, dass Benutzer innerhalb der Union und in Drittstaaten das bestehende duale Markensystem angenommen haben. Das Gemeinschaftsmarkensystem stellt namentlich eine erfolgreiche, tragfähige Ergänzung und Alternative zum Markenschutz auf mitgliedstaatlicher Ebene dar. Die Kommission nahm diese Studie als Basis zur Erstellung eines Vorschlags einer Verordnung zur Novellierung des europäischen Markenrechts, die im März 2013 veröffentlicht wurde. Damit setzte sie das Gesetzgebungsverfahren der Europäischen Union in Gang. Das Europäische Parlament, der Europäische Rat und die Europäische Kommission haben sich Ende April 2015 grundsätzlich über die offenen Punkte der seit über zwei Jahren diskutierten Reform des europäischen Markenrechtssystems verständigt. Am 28.10. 2015 veröffentlichte der Rat einen Text,[3] der vom Europäischen Parlament am 15.12.2015 in zweiter Lesung bestätigt und am 24.12.2015 im Europäischen Amtsblatt veröffentlicht wurde. Dieser ist Gegenstand des vorliegenden Artikels.

II. Inkrafttreten

Die Verordnung wurde am 24.12.2015 im Amtsblatt veröffentlicht und tritt 90 Tage danach, also am 23.3.2016,

* Ass.iur., Mediator, HABM, Alicante. Der Artikel basiert lediglich auf der Meinung des Autors und repräsentiert nicht die Position des HABM.

1 Verordnung (EG) Nr. 2868/95.

2 Studie Max Planck Institut, abzurufen über http://ec.europa.eu/internal_market/indprop/docs/tm/20110308_allensbach-study_en.pdf.>

3 <http://www.consilium.europa.eu>, 28.10.2015; <http://www.consilium.europa.eu/register/en/content/out/?RESULTSET=1&i=LD&ROWSPP=25&ORDERBY=DOC_DATE%20DESC&DOC_LANCD=EN&typ=SET&NRROWS=500&ARCHIVEDATE=15-10-2015:29-10-2015>.