

BEMER FACTS

Scientific statement on BEMER studies and resulting advertising claims

- Healing and advertising claims
- Listing of studies
- Discussion
- Court decisions (short overview)
- Methodologically questionable
- Literature

Court rulings vs. BEMER

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Physical Vascular Therapy BEMER®: An option for at-home treatment? (A preliminary opinion)

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Introduction

Microcirculation includes all transport phenomena of substance exchange and humoral information between the "organ" blood and cells of other organs, including cellular and humoral immune response. All processes take place on the "transit pathways of substance exchange" in the fine tissue area of arterioles, venules, capillaries, and initial lymphatic vessels. Many diseases are caused by disturbances of the microcirculation or are at least influenced by its impairment (Abularrage et al. 2005). Within the microcirculation, it is the local regulatory mechanism of spontaneous, autorhythmic vasomotion in the arterioles and venules near the capillaries, which as a pulsatile component influences the separation between blood plasma and blood cells and thus the distribution of blood in the microvascular networks.

Since the first description of vasomotion by TW Jones in 1852 and its influence on the physiology of the human organism, the improvement of microcirculatory blood flow to supply cell structures as needed remains a major medical challenge.

Within the last 40 years, more than 10,000 publications have been published about pulsating electromagnetic fields (PEMF). In this context, different companies have developed diverse ways of using this technology or presented different explanations. Many of these explanations are controversial from a scientific point of view. This may be due to insufficient consideration of the electromagnetic properties responsible for the effect. Comparable to the active ingredient of the medication, this applies in particular to the temporal course of the intensity of the stimulating electromagnetic fields: because here, too, it is a question of where, how, when, and in what time, with which form of application, a physiological effect becomes apparent.

For more than 20 years, the "Physical Vascular Therapy BEMER®" (manufactured/distributed by BEMER Int AG / Liechtenstein) has been used with a biorhythmically defined stimulation signal to stimulate a restricted autorhythmic (specifically three times per minute) vasomotion.

In the present paper, the findings generated with this technology are analyzed and evaluated with regard to the scientific quality of the corresponding advertising, healing, and efficacy statements made on the clinical-vasomotion-related – relevance.

Claims of BEMER INT AG & Partner about healing and effect - Intended use

° Excerpt from the User Manual BEMER Pro & Classic Set:

The BEMER products are suitable, by means of weak, pulsed electromagnetic fields generated by a special multi-dimensional signal structure, to

- - stimulate vasomotion (rhythmic contraction movements) of small and smallest blood vessels of living organisms.
- Through a specific biorhythmic modulation, upstream and downstream, slightly larger vessels are also synergistically influenced.
- This results in a more favorable distribution of blood components in the area of microcirculation for the treated organisms.
- The improved functionality of natural regulatory mechanisms,
- Boosting the immune system,

- improved production of endogenous radical scavengers
- and an influence on protein synthesis are the consequences of this.
- BEMER technology can be used both in prevention and complementary in the treatment of all diseases where improvement of microcirculation with the resulting effects in living organisms has therapeutic significance.

° **Note: The basis for these translations are excerpts from the German website and German press publications.**

Claims

They relate to broad indications primarily related to improvements in vasomotion, microcirculation, and the resulting increase in cellular supply, acceleration of wound healing, and reduction of pain (Appendix 2).

Claims about healing and effects:

- Physical vascular therapy BEMER®
- specific and reproducible effect on improved blood flow in the microcirculation (74%) through stimulation on restricted or disturbed vascular movement (vasomotion)
- the BEMER therapy meets the requirements for a prophylactic and complementary therapeutic use
- therapeutic efficacy – the efficacy has been scientifically researched and tested over many years and has been confirmed by studies several times
- Improvement of vasomotion
- Improvement of microcirculation
- Promotion of blood circulation and thus improved supply of cells
- Wound healing
- Diseases for which BEMER has been proven to help
- Chronic wound healing disorder
- Chronic degenerative disease of the musculoskeletal system
- Chronic metabolic disorder (e.g. diabetes mellitus, dyslipidemia)
- Improvement/Maintenance of blood distribution in micro vessels: The BEMER devices stimulate blood circulation in the small and very small vessels. This so-

called microcirculation is responsible for the distribution of blood and the supply of cells as needed.

- The signal in turn can stimulate the restricted pumping movement of the smallest vessels. Thanks to the improved blood circulation, the cells can be supplied with more oxygen and nutrients, your entire organism is now better supported.

Study results on the influence of physical vascular therapy *BEMER®* on vasomotor function (examples)

I. Chronic wound healing disorder

a)

In 2013, Klopp et al. showed whether and to what extent the complementary application of a biorhythmically defined physical stimulation of the deficient spontaneous arteriolar vasomotion can contribute to increase the therapeutic success of established concepts. 24 diabetes patients with wound healing disorders and skin lesions were assigned to the following treatment arms: 12 patients in the control group received only conventional therapy, 12 patients in the other group additionally received BEMER® Physical Vascular Therapy. The treatment and observation period were 30 days. The success of the therapy was checked by noninvasive, high-resolution investigations of related microvascular networks in the subcutaneous tissue region and in the marginal area of the wound. It involves (i) white light spectroscopy in combination with laser Doppler microflow measurement, (ii) reflection spectrometry, and (iii) intravital microscopy. The aim of these procedures was to examine whether and to what extent the arteriolar stimulation and thus the microcirculation were improved in the control and verum groups. Differences between the two study arms were found for all examined features. Specifically, patients who received BEMER® Physical Vascular Therapy showed improved spontaneous vasomotion (AVM), increased oxygen depletion (ΔpO_2) and an increase in blood cell perfused nodes in the target network (nNP) in the examined tissue. Another measured parameter was the venous flow (Q_{ven}) - this was also increased in the verum group. Disorders in microcirculation usually start in the

venules, so that this study result is of therapeutic relevance. The total length of all capillaries in a defined tissue volume (Iges) had also improved in the tissue of the verum group examined. The same is true for the number of adherent white blood cells on a defined venule inner wall surface. This reflects an increase in immunological activity in the tissue of the wound margin and is accompanied by an improved wound healing. The wound area had decreased by 63.5% in the verum group at the end of the study and by only 40.7% in the control group. Therefore based on Klopp et al., the results of this study demonstrate an improvement in the functional state of the subcutaneous microcirculation and cellular immune defense in the marginal area of the foot wound as well as a corresponding reduction in the area of the wound in patients with diabetic foot syndrome.

b)

In another placebo-controlled study by Klopp et al., 18 male patients with diabetic neuropathy, foot ulcers, and skin changes were randomly assigned to the following two therapy arms: the control group received only conventional therapy and the verum group additionally received BEMER® Physical Vascular Therapy. The treatment and observation period covered 30 days. The therapeutic success was evaluated by noninvasive, high-resolution investigations of related microvascular networks in the subcutaneous tissue region in the marginal wound area. A (i) laser doppler microflow measurement with white light spectroscopy, (ii) a reflection spectrometric examination unit, and (iii) a vital microscope examination unit in the combined incident-transmitted light method with secondary computer-assisted image processing were used to demonstrate an improvement in arteriolar stimulation and microcirculation. Relevant differences between the drug and control groups in all parameters were examined. The vasomotive activity (AVM), the venol-side oxygen depletion (ΔpO_2), the number of adherent white blood cells on a defined venule inner-wall surface A (nWBC / A - number of white blood cells per area) and the concentration of the intracellular adhesion molecule ICAM-1 were increased in the verum group, whereas no relevant increase was observed in the control group. Regarding the size of the wound area over the treatment period, no changes were observed in the control group, whereas the wound area in the verum group had decreased (Figures 1, 2) (Klopp et al. 2013 b).

II. Chronic Metabolic Diseases – Type 2 Diabetes

Klopp et al. examined whether physical vascular therapy with BEMER® device can improve the functional state of microcirculation in patients with type 2 diabetes. 60 patients with type 2 diabetes were randomly assigned to the following three therapy arms: The control group (n = 20) completed a 60-minute daily workout on a treadmill with moderate exercise for 30 days. Group 1 (n = 20) completed a corresponding training on the treadmill, but under conditions of hypoxia (oxygen content in the room air of 25 percent by volume). Group 2 (n = 20) trained under the same hypoxic conditions as group 1, however, they also received the BEMER® Physical Vascular Therapy. Microvascular networks (arterioles, capillaries, and venules) in a tissue volume of approx. 3,000 μm^3 were recorded in all subjects. The following changes in characteristics were measured: (i) the number of blood cell-perfused nodes (nNP) in a defined microvascular network as a measure of the state of distribution of the blood, (ii) the venol side oxygen depletion (pO₂), (iii) the QRBC value as a parameter for the distribution of the blood (flow force of microcirculation). The statistical evaluation was carried out using the Wilcoxon rank sum test. Patients in group 1 (with training under hypoxic conditions but without BEMER® Physical Vascular Therapy) showed an improvement in the above-mentioned measured parameters. The patients in group 2, however, who had also been treated with the BEMER® Physical Vascular Therapy, showed a greater improvement in the measured parameters. The oxygen consumption in the target tissue in the group with BEMER® Physical Vascular Therapy increased by 40%, the distribution of the capillary network had improved by 30%, and the QRBC value by 50% (Figures 3,4) (Klopp 2015).

III. Skeletal Disorders

In a randomized, controlled, double-blind follow-up study, Gyulai and Bender showed the effectiveness of BEMER® Physical Vascular Therapy in 50 patients with knee osteoarthritis and 50 patients with chronic lower back pain. The subjects of both groups were randomly assigned to the following two study arms: The verum group received 3-week physiotherapy followed by BEMER® Physical Vascular Therapy. The placebo group received treatment with an ineffective placebo device after the 3-week physiotherapy. The following parameters for the effectiveness of BEMER® Physical Vascular Therapy were examined. In all patients, pain intensity was assessed using a VAS (Visual Analog Scale), quality of life using the quality-of-life

questionnaire (SF 36), and the extent of fatigue using the Facit Fatigue Scale (FFS). The influence of pain on coping with everyday life was determined in patients with lower back pain using the Oswestry Index and in patients with knee osteoarthritis using the WOMAC Index. To compare the effectiveness in the two study arms (verum vs placebo), the covariance analysis ANCOVA with a significance threshold of $\alpha = 0.05\%$ was used. Patients with lower back pain in the verum group had a significant improvement in resting pain and fatigue symptoms upon termination of treatment compared to the placebo group. The improvement in stress pain was close to the significance limit. The Oswestry and Quality of life scores showed no change. Patients with knee osteoarthritis had no significant improvement at the end of therapy for all measured parameters (Gyulai et al. 2016).

III. Fibromyalgie

Fibromyalgia is a syndrome with a prevalence of around 5% in women and 1% in men (Vincent et al. 2013). This disease causes the condition of soft tissue pain, subjective muscle stiffness, sleep disorders, and cognitive dysfunction. Numerous possible mechanisms causing or influencing the disease are discussed, such as hypersensitivity to pain (Gracely et al. 2002), hormonal influences (Sadreddini et al. 2008; Cuatrecasas 2009), inflammation (Kadetoff et al. 2012) or mitochondrial dysfunction (Pieczenik and Neustadt 2007; Gardner and Boles 2011). Various studies suggest that the arteries of patients with fibromyalgia do not provide the connective tissue with nutrients efficiently (Lee et al., 2011). However, the exact pathomechanism of this disease based on a reduced blood supply is not known. A specific treatment setting does not exist. Therefore, the randomized controlled trial on pulsed electromagnetic field therapy for the treatment of pain and other symptoms of fibromyalgia from the group of Juhani Multanen and Jari Ylinen from the Department of Physical Medicine and Rehabilitation of the Central Finland Central Hospital was of particular interest. A group of 108 women with fibromyalgia underwent a 12-week treatment period with BEMER® Physical Vascular Therapy. Pain and stiffness were assessed on a visual analog scale (VAS scale). The functional status was determined with the Fibromyalgia Impact Questionnaire (FIQ). In the first treatment period, 57 patients assigned to active treatment and 51 patients assigned to sham treatment were instructed to use BEMER® Physical Vascular Therapy for 12 weeks.

The first treatment period (week 1-12) was followed by 4-week washout phase (study weeks 13-16). During this time, the participants went to the hospital to exchange the application devices. The second treatment period was carried out in weeks 17-28. The participants kept a daily diary in which they documented both the application of the supplied vascular therapy device and the medical treatment concerning fibromyalgia symptoms. In addition, all patients answered the Finnish version of the validated Fibromyalgia Impact Questionnaire (FIQ) (Gauffin et al. 2012). The FIQ is a multidimensional self-administered questionnaire with 10 questions assessing physical function, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and well-being.

The 108 patients had an average age of 47 years (range 24–61) and an average body mass index of 29.5 (range 18–44). The mean duration of fibromyalgia disease, determined as the time since fibromyalgia was diagnosed, was 7.7 years (range 0–31). At the start of the study, 86 patients took either prescription or over-the-counter analgesics. Ninety-two patients had one or more comorbidities. The most common concomitant diseases were various musculoskeletal problems such as arthrosis, back pain and spondylosis (47%), lung and respiratory diseases (29%), cardiovascular diseases (22%), thyroid disease (19%) and neurological disorders (15%), mild mental disorders (12%), allergies (8%) and type 1 or 2 diabetes (7%). Of the 108 patients who started treatment, nine (8%) dropped out during the study, and 92% of the included patients completed the study. The treatment was well tolerated with no serious side effects. Average treatment compliance, measured as attendance at all 168 planned 8-minute treatment sessions, was 80% when using active devices and 78% when using the placebo devices. After the experiment, both active and sham treatment showed improvement in pain, stiffness, and FIQ. However, there were no significant differences in the results between active and sham treatment. This study demonstrated that treatment with pulsed, low energy electromagnetic fields was not more effective than treatment with an accelerator to reduce pain, stiffness, and function in patients with fibromyalgia. This study could not prove that BEMER® Physical Vascular Therapy is effective in reducing pain or improving stiffness in patients with fibromyalgia. Therefore, treatment with BEMER® Physical Vascular Therapy is not recommended for the treatment of fibromyalgia symptoms (Multanen et al. 2018).

IV. Coronary heart disease

In another study conducted with regard to the efficiency of BEMER® Physical Vascular Therapy in the summer of 2022 by Zita Kreska and co-workers, with the support of Harkány Spa Hospital, the Institute of Translational Medicine (Faculty of Medicine, University of Pécs), the Department of Public Health Medicine (Faculty of Medicine, University of Pécs) and the Heart Institute (Faculty of Medicine, University of Pécs) in Hungary (Kreska et al., 2022), there was again no significant, clinically relevant result. This approach, published under the name "Physical Vascular Therapy (BEMER) Influences Heart Rate Asymmetry in Patients with Coronary Artery Disease," was set up as follows. The aim of this study was to analyze the acute effects of Bemer physical vascular therapy on the autonomic nervous system by analyzing heart rate variability (HRV) and heart rate asymmetry (HRA) with a low-frequency pulsed electromagnetic field ($<35 \mu\text{Tesla}$). A total of 48 patients undergoing inpatient rehabilitation with coronary artery disease (CAD) were enrolled in the study. Bemer physical vascular therapy was performed with a B.Box Professional and a B.Body Pro applicator. After 15 minutes of postural adjustment, 6-minute electrocardiograms (ECGs) were recorded immediately before, during the first, and during the last 6 minutes of the 20-minute application of Physical Vascular Therapy Bemer, or one hour after treatment. Of the 48 patients, the last twenty patients received therapy with a nonfunctional device (placebo) for application of Bemer physical vascular therapy according to the same protocol. The offline analysis was blinded. A linear mixed statistical model was used for evaluation to compare both HRV and HRA parameters. Thereby, the time domain parameters at the end of the study showed no statistically significant difference between the changes in the group with a functional device for the application of physical vascular therapy Bemer compared to a non-functional placebo device (sham treatment) (Kreska et al., 2022).

Discussion

According to Klopp et al., the following changes in microcirculation are observed through the use of BEMER® physical vascular therapy with the additional signal to stimulate vasomotion: An increase in a previously reduced frequency of spontaneous vasomotion oscillations, an increase in arteriolar and venular flow, an increase in the number of capillaries through which blood cells flow, an improvement in blood

distribution in the microvascular network, increased venous oxygen consumption, and a relevant influence on immunological behavioral characteristics, such as increased adhesion and transmigration of leukocytes (Klopp et al. 2013a,b).

In contrast to the statements of Klopp et al., however, Schuhfried and colleagues from the Department of Physical Medicine and Rehabilitation at the Medical University of Vienna were not able to positively influence the microcirculation by using PEMF technology in a randomized double-blind crossover study (Schuhfried et al. 2005). The aim of this study was to investigate whether a low-dose pulsed low-frequency magnetic field or a high-dose pulsed low-frequency magnetic field changes the cutaneous microcirculation in the outer extremities. Twelve healthy volunteers (five women, seven men) with an average age of 25.8 years participated in the study. One of the following three interventions was applied over a 30-minute period via a cushion placed under the foot: either a pulsed, low-dose magnetic field (100 μ T, fundamental frequency 30 Hz with frequency modulation), a pulsed, high-dose magnetic field (8.4 mT, 10 Hz), or a sham treatment. Individual treatment sessions were performed at one-week intervals at the same time of day. Cutaneous microcirculation (laser Doppler flowmetry) and temperature (infrared thermography) were measured on the dorsum of the foot and the big toe every 5 minutes and 5 and 10 minutes after the procedure. A two-way analysis of variance with repeated measurements revealed no significant difference between the three groups for any parameter. It was concluded that the local application of pulsed low-frequency magnetic field is not able to improve microcirculation.

All relevant data regarding vasomotion/microcirculation and the resulting healing and efficacy statements of BEMER® physical vascular therapy are based on the work of Klopp et al. In addition, until 2011, the results of BEMER® physical vascular therapy were only published by the company itself and not in renowned scientific journals (Klopp 2007, 2008). Therefore, there is no opinion-forming publication on the physiological basis of the mode of action of BEMER® physical vascular therapy that has been reviewed by independent experts from the same field according to scientific criteria and the procedure for quality assurance of a scientific paper. In addition, all the fundamentals regarding targeted vascular therapy to influence vascular movement have never been presented for discussion by Klopp personally to experts in the field of microcirculation at a scientifically recognized and relevant congress.

Not even the use of the extremely sensitive laser Doppler method with regard to a positive influence on vasomotion was reproduced by other scientists.

Ala-Nissila and colleagues (Ala-Nissila et al., 2013) further demonstrated that the BEMER® Physical Vascular Signal did not result in any physiologically detectable interaction with biological. Tapio Ala-Nissila (Chair of the Interdisciplinary Centre for Mathematical Modelling, School of Science, Loughborough University, UK), processes even declared the proposed treatment mechanism for BEMER® Physical Vascular Therapy invalid.

This finding is also supported by the scientific study (Multanen et al. 2018). In this placebo-controlled study conducted by the Institute of Physical Medicine and Rehabilitation of Central Finland Hospital, BEMER® Physical Vascular Therapy was found to be useless in fibromyalgia patients. In detail, 108 patients with fibromyalgia were randomized according to the criteria of the American College of Rheumatology (ACR). 57 patients were assigned to active treatment and 51 patients to sham treatment.

They used the BEMER devices for 12 weeks according to the manufacturer's instructions. Then the groups were crossed, i.e. each participant had an active and a sham treatment at some point. At the end of the study, there was no difference between sham and real treatment with BEMER® Physical Vascular Therapy. The data obtained here demonstrate that the magnetic field of BEMER® Physical Vascular Therapy has no direct influence on vasomotion/microcirculation.

Unlike the research by Klopp and colleagues, which was 100% funded by Bemer International AG, this independent study was largely supported by Finnish public funding and published in a prestigious scientific journal (Multanen et al. 2018).

In the long term, the negative result of this placebo-controlled crossover study fundamentally calls into question the effectiveness of BEMER® Physical Vascular Therapy. It is even possible that Physical Vascular Therapy BEMER® does not produce any effect beyond the placebo effect or clinical relevance in other important diseases either. Based on these studies, it can therefore not be ruled out that the positive effects expressed by the company for various painful or inflammatory diseases such as cardiovascular, rheumatism or the improvement of the recovery of

tumor patients are overall irrelevant with regard to the clinical relevance of BEMER® Physical Vascular Therapy.

In this respect, the question of whether BEMER® physical vascular therapy can influence microvessels, microcirculation, or vasomotion via precapillary arterioles in order to improve the autoregulation of microcirculatory blood flow has therefore remained unresolved to date according to scientific criteria.

Thus, due to the small number of studies with very small numbers of patients, and thus a lack of statistical validation and discussion in expert groups, and in particular due to the fact that they are mainly published by the company itself, all of the main statements regarding the clinical relevance and justification of the claims made about the efficacy and healing properties of BEMER® physical vascular therapy cannot be seen at this point in time in the sense of a technology that demonstrably has a positive influence on the vasomotion of the microcirculation.

Even if not decisive for the scientific statements, it has to be added that the investigations of Klopp and colleagues - contrary to what is presented (Klopp and Niemer 2007, Klopp 2007) - were not carried out according to the rules of Good Clinical Laboratory Practice (GCP), i.e. not in compliance with the obligatory approval of an ethics committee, because these would have to be mentioned in scientific publications.

Thus, while this technology could be used as an adjunctive use of individual home therapy for the purpose of general wellness or a holistic wellness approach, the claims that the application of BEMER® Physical Vascular Therapy results in 1) improvement of previously impaired spontaneous vasomotion oscillation, 2) improvement of arteriolar and venular flow, 3) improvement of blood distribution in the microvascular network, 4) an increase in venous oxygen consumption or a clinically relevant influence on immunological behavioral characteristics, such as increased adhesion and transmigration of leukocytes are not applicable.

The rulings of German courts (Appendix 3), which have prohibited the advertising statements of BEMER® AG int. in this respect as being misleading, also go in this direction.

- Berlin Regional Court, judgment dated February 10, 2016, ref. no.: 97 O 89/15 (Cease and desist from statements on effects of Bemer therapy due to misleading statements)
- Frankfurt a.M. Higher Regional Court, ruling of December 19, 2018, Ref.: 6 W 97/18 (Omission of statements on the effects of Bemer therapy if these are scientifically disputed)
- Koblenz Higher Regional Court, judgment of January 20, 2016, Ref.: 9 U 1181/15 (omission of effect statements on magnetic field therapy because of misleading)

Methodological questionability

As shown below, the statements made by BEMER INT AG regarding vasomotion/microcirculation are also highly questionable from a physical and technical point of view:

1. Based on the methods described in the book edition (Klopp 2008) from page 133 and in Klopp et al. (2013), in particular the image and video representation of the vasomotion/microcirculation obtained via 35 mm ARRI high-speed camera and the multistage, two-step film processing, a recovery in the online procedure is practically impossible for reasons of time alone.
2. In addition, the recovery of a specific microcapillary region in the micro-meter range described in Klopp and Niemer 2007 (page 62, figs. 2 and 27d) still seems impossible after 60 days without special additional mechanical devices (e.g. micromanipulators) for technical reasons. It is also curious that after this period of time no positional changes of the cell nuclei in a dynamic organic system can be seen.
3. With reference to an autonomously running vasomotion in the frequency range of approx. 3 per minute, Klopp and Niemer (2007) further claim that the function of the microcirculation in the target tissue is already significantly improved by a slight change in the form of stimulation of approx. 30 pulses /s, which is adapted to this autonomously running, by additional 3 times (i.e. every 20 seconds) repeating (altogether 6x5) additional pulses with higher intensity (patent WO 2008/025731 A1).

These changes could be clearly demonstrated already 2 minutes after the start of the irradiation, i.e. after only 6 such additive impulse series by pictorial before and after comparisons (Klopp, Niemer 2007). This is also highly questionable for physical reasons because at the given pulse repetition rate of 30 pulses/s (i.e. $30 \times 120 = 3600$ pulses in 2 min), these additional 30 pulses would only provide an energy contribution increased by approx. $(3600 + 2 \times 30) / 3600 = 1.01$, i.e. approx. 1%, even at double intensity. However, with this small additional energy contribution, the described improvement of vasomotion/microcirculation is physically hardly comprehensible.

4. This is especially true because an effective transmission requires that it occurs in resonance with the vasomotion, i.e. - comparable to the push of a swing - at exactly the right moment. For statistical reasons, it is more than improbable to hit the right moment if the intended support of the vasomotion is started randomly.

5. Furthermore, in the book (Klopp 2008) a range of the vital microscopic recording technique of approx. 0.8 cm is described. In connection with this, the (Klopp and Niemer 2007) pictorially depicted, non-invasive influence on the microcirculation in the central organ of the liver (distance of several cm) is in stark contradiction.

6. Above all, however, there is no proof that the differences in the illustrated before and after comparisons in the microcapillary range can actually be attributed to the electromagnetic stimulations. Because, measured against the autonomous process of vasomotion, the images could also be based on recordings that were made at a "favorable", i.e., autonomously controlled, point in time. However, even if BEMER exposure actually took place here, there is still no proof of the temporally correlated relationship between cause and effect. Apart from that, it is questionable why only video recordings for before-and-after comparisons but not for corresponding transitions were used for documentation.

scientific criteria, the efficacy and healing claims made on the basis of BEMER INT AG's influence on microcirculation are neither justifiable nor admissible.

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Court rulings vs. BEMER

- Landgericht Berlin, Judgment from 10.02.2016
- Oberlandesgericht Frankfurt a.M.,
Judgment from 19.12.2018
- Oberlandesgericht Koblenz, Judgment from 20.01.2016

Berlin District Court
In the name of the people
Verdict

Reference no: 97 O 89/15

Delivered on Feb. 10, 2016, Neumann, Justice Supt.

In the legal dispute

= Plaintiff

a g a i n s t

BEMER International AG,
represented by the Chairman of the Board Detlef Nitsch,
Austrasse 15, FL-9495 Triesen,
Liechtenstein,

= Defendant

Attorney-at-law:
Attorney Christoph Unrath,
Nymphenburger Strasse 154, 80634 Munich, Germany

the Chamber for Commercial Matters 97 of the Berlin Regional Court in Berlin - Mitte, Littenstrasse 12-17, 10179 Berlin, at the hearing on February 10, 2016, by the Presiding Judge at the Regional Court Krumhaar and the Commercial Judges Rohrer and Winter

f o u n d i n f a v o r o f t h e l a w:

- I. The defendant is ordered to refrain from advertising magnetic field therapy, in particular so-called „Bemer Therapy“ (Bemer treatment system „B. Body Professional“), in the German market in the course of business, on pain of an orderly fine of up to €250,000.00 or imprisonment in lieu of an orderly fine, to be imposed for each infringement, or imprisonment in lieu of an orderly fine of up to six months, to be carried out on the Chairman of the Management Board:

1.

„for prevention“,

2.

„complementary therapy of diseases and complaints“,

3.

„Indication areas:

- Chronic Deg. Diseases Musculoskeletal System
- Chronic Fatigue (e.g. chronic stress/MS)
- Chronic Metabolic diseases (e.g. diabetes, fat metabolism)
- Chronic Wound healing disorder
- Acute and chronic pain
- Suffering with reduced quality of life
- Organ insufficiency (e.g. liver, multiple organ dysfunction)
- Peripheral arterial occlusive disease
- Polyneuropathy resulting from diabetes or after cancer treatment,

and/or

for one, several, or all of the above-mentioned fields of application,

in each case when this is done, as described in the journal „CO. Med“, April 2015 issue on page 47, charge K 3.

- II. The defendant is ordered to pay the plaintiff €178.50 plus interest at 5 percentage points above the prime rate since September 18, 2015.
- III. The defendant shall bear the costs of the legal dispute.
- IV. The judgment is provisionally enforceable in the operative part under I. against security in the amount of €40,000.00 and in all other respects against security in the amount to be recovered in each case.

Krumhaar

Winter

Rohrer

The foregoing copy, which is consistent with the signature, is issued to the plaintiff for execution. The foregoing decision was served ex officio on the plaintiff for the attention of his counsel, Rechtsanwaltskanzlei Buchert & Partner, on March 17, 2016, and on the defendant for the attention of his counsel, Rechtsanwalt Christoph Unrath, on March 23, 2016.

Berlin, 04.04.2016

Vollstreckbare Ausfertigung



Landgericht Berlin

Im Namen des Volkes

Urteil

Geschäftsnummer: 97 O 89/15

verkündet am : 10. Februar 2016
Neumann
Justizhauptsekretärin

In dem Rechtsstreit

Klägers,

g e g e n

die BEMER International AG,
vertreten durch den Vorstandsvorsitzenden Detlef Nitsch,
Austraße 15, FL-9495 Triesen,
Liechtenstein,

Beklagte,

- Prozessbevollmächtigter:
Rechtsanwalt Christoph Unrath,
Nymphenburger Straße 154, 80634 München -

hat die Kammer für Handelssachen 97 des Landgerichts Berlin in Berlin - Mitte, Littenstraße 12-17, 10179 Berlin, auf die mündliche Verhandlung vom 10. Februar 2016 durch den Vorsitzenden Richter am Landgericht Krumhaar sowie die Handelsrichter Rohrer und Winter

f ü r R e c h t e r k a n n t :

- I. Die Beklagte wird verurteilt, es bei Meidung eines für jeden Fall der Zuwiderhandlung zu verhängenden Ordnungsgeldes bis zu 250.000,00 €, ersatzweise Ordnungshaft, oder einer Ordnungshaft bis zu sechs Monaten, zu vollziehen am Vorstandsvorsitzenden, zu unterlassen, im geschäftlichen Verkehr auf dem deutschen Markt für eine Magnetfeldtherapie, insbesondere

für eine so genannte „Bemer Therapie“ (Bemer-Behandlungssystem „B. Body Professional“) zu werben:

1. „Zur Prävention“,
2. „ergänzende Therapie von Krankheiten und Beschwerden“,
3. „Indikationsbereiche:
 - chron. Deg. Erkrankungen Muskel-Skelettsystem
 - chron. Müdigkeit (z. B. bei chron. Belastung/MS)
 - chron. Stoffwechselerkrankungen (z. B. Diabetes, Fettstoffwechsel)
 - chron. Wundheilungsstörungen
 - akute und chronische Schmerzen
 - Leiden mit eingeschränkter Lebensqualität
 - Organinsuffizienz (z. B. Leber, multiple Organdysfunktion)
 - periphere arterielle Verschlusskrankheiten
 - Polyneuropathie infolge von Diabetes bzw. nach Krebsbehandlung“,

und/oder

für eines, mehrere oder alle der vorstehend genannten Anwendungsgebiete,

jeweils wenn dies geschieht, wie in der Zeitschrift „CO. med“, Ausgabe April 2015 auf Seite 47, Anlage K 3.

- II. Die Beklagte wird verurteilt, an den Kläger 178,50 € nebst Zinsen in Höhe von 5 Prozentpunkten über dem Basiszinssatz seit dem 18. September 2015 zu zahlen.
- III. Die Beklagte hat die Kosten des Rechtsstreits zu tragen.
- IV. Das Urteil ist im Tenor zu I. gegen Sicherheitsleistung in Höhe von 40.000,00 € und im Übrigen gegen Sicherheitsleistung in Höhe des jeweils beizutreibenden Betrages vorläufig vollstreckbar.

Krumhaar

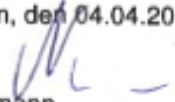
Winter

Rohrer

Vorstehende, mit der Urschrift übereinstimmende Ausfertigung wird dem Kläger zum Zwecke der Zwangsvollstreckung erteilt.

Vorstehende Entscheidung ist dem Kläger zu Händen seiner Prozessbevollmächtigten, Rechtsanwaltskanzlei Burchert & Partner, am 17.03.2016 und der Beklagten zu Händen ihres Prozessbevollmächtigten, Rechtsanwalt Christoph Unrath, am 23.03.2016 von Amts wegen zugestellt worden.

Berlin, den 04.04.2016


Neumann
Justizhauptsekretärin
als Urkundsbeamtin der Geschäftsstelle
ZP 550



Reference

1. An application for an injunction to prohibit health-related claims of efficacy that are challenged as misleading is successful if the applicant credibly demonstrates that the efficacy of the advertised product or procedure is scientifically disputed and the defendant makes use of the opportunity given to him to comment.

2. On the question of what requirements are to be placed on the prima facie case within the meaning of Item 1.

Tenor

¹ On the appeal of the applicant, the order of the 6th Civil Chamber of the Regional Court of Frankfurt am Main dated November 29, 2018 is partially amended.

² The defendant is prohibited by way of an interim injunction on grounds of urgency without an oral hearing, upon avoidance of a fine of up to € 250,000.00 or imprisonment for up to 6 months, to be determined by the court for each individual case of infringement, from advertising magnetic field therapy, in particular, „BEMER® therapy“, in the course of business: „Well-functioning healing and regeneration processes are important for maintaining and restoring your health. These unfold best in tissue with a good blood supply because the removal of nutrients and oxygen with the blood allows the energy required for healing to be formed in the cell on site. The physical vascular therapy BEMER® ensures that the fine blood circulation in the whole body, but above all in the injured tissue, is effectively increased and that the natural healing processes can take place to the maximum.“ In all other respects, the complaint is rejected.

³ The costs of the summary proceedings in both instances shall be borne by the parties in equal shares.

⁴ The amount in dispute in the appeal proceedings is set at €15,000.00.

Reasons

⁵ I.

⁶ The applicant is an association with legal capacity. The defendant is a physiotherapist. It advertised on the Internet for various treatments, including a „Bemer therapy“ and a „Kinesio Tape“ treatment with the information shown in Exhibit A3. Defendant did not respond to Applicant's warning letter.

⁷ The Regional Court dismissed the applicant's application for a temporary injunction by order dated October 29, 2019. It did not intervene in the applicant's appeal against this by order dated November 20, 2018.

⁸ The applicant requests,

⁹ to amend the order appealed against and to refrain from issuing the following interim injunction:

¹⁰ The defendant is prohibited, upon avoidance of a fine of up to € 250,000.00 or in lieu thereof imprisonment for up to six months, to be determined by the court for each case of future infringement, from advertising in the course of business.

¹¹ to advertise magnetic field therapy, in particular, „BEMER® therapy“: „Well-functioning healing and regeneration processes are important for maintaining and restoring your health. These unfold best in tissues with a good blood supply because the removal of nutrients and oxygen with the blood enables the energy required for healing to be formed in the cell from the site. The physical vascular therapy BEMER® ensures that the fine blood circulation in the whole body, but especially in the injured tissue, is effectively increased and the natural healing processes can proceed to the maximum.“,

¹² 2.

¹³ to advertise a „Kinesio Tape“ treatment with the field of application:2.1.

¹⁴ „Pain“,

¹⁵ 2.2.

¹⁶ „Lymphoedema“,

¹⁷ in each case if this is done as on the Internet at [www\(...\).de](http://www(...).de), retrieved and printed on September 25, 2018 between 19:12:26 to 19:12:51, according to printout Annex A 3.

¹⁸ The Senate granted the defendant the opportunity to comment by sending the notice of motion, the notice of appeal and the orders of the Regional Court of 29.10. and 20.11.2018. It has not made use of this opportunity.

¹⁹ II.

²⁰ The admissible appeal is also partially successful on the merits.

²¹ 1. The urgency is presumed according to §12 II UWG.

22 2 The applicant is entitled to injunctive relief against the defendant to the extent tenured under §§3, 3a, 8, I, II No. 2 UWG, 3 No. 1 HWG.

²³ a) The applicant is entitled to bring an action pursuant to Section 8 II No. 2 UWG. It is an association with legal capacity for the promotion of commercial or independent professional interests of its members. The Federal Court of Justice has repeatedly acknowledged that it is actually able to perform its statutory duties according to its personnel, material, and financial resources. This is supported by a presumption (cf. BGH GRUR 1997, 476 [BGH 14.11.1996- I ZR 164/94] - Geburtstagswerbung II; Köhler/Bornkamm, UWG, ed., § 8 Rn. 3.49).

²⁴ b) The applicant has credibly shown that the information advertised in the applications under 1. is scientifically unsubstantiated. They are therefore inadmissible.

²⁵ aa) According to § 3 No. 1 HWG, it is inadmissible to attribute effects to medical treatments which they do not have. As is generally the case with health-related advertising, strict requirements are to be placed on the accuracy, unambiguousness, and clarity of the advertising claim, since misleading health-related claims may be associated with considerable risks for the high level of protection of the individual as well as the population. The advertising is only permissible if it corresponds to established scientific knowledge.

²⁶ bb) The „BEMER therapy“ treatment method advertised on the defendant's website is to be assigned to the field of so-called magnetic field therapies. The applicant has made this credible by submitting Annex A 14, the website of BEMER Int. AG. According to this, it is a physical vascular therapy that works with the help of electromagnetically transmitted stimulation signals and is intended to normalize blood flow.

²⁷ cc) By submitting an excerpt from the „Manual - X“ of the Stiftung Warentest, the applicant has made it credible that magnetic field therapy is scientifically unproven (Annex A5). According to this, studies on the therapeutic efficacy of magnetic field treatments come to contradictory results. A substantial effect of the offered devices is not observable. The proof that a static magnetic field promotes bone healing has not yet been provided. It is certain that it has no influence on the healing of muscles or wounds on the skin. However, it is precisely for the healing of „injured tissue“ that the defendant advertises the therapy. Contrary to the opinion of the district court, the manual of Stiftung Warentest, even if it is not itself a scientific publication, can certainly be used to establish the credibility of a lack of scientific substantiation or scientific controversial nature of treatment procedures. The study by Stiftung Warentest is ultimately based on an evaluation of scientific studies. Also, the lack of topicality of the manual does not fundamentally lead to its unusability. This would only be different if the results published in the handbook had been explicitly described as non-exhaustive or if there were already more up-to-date studies. It would be up to the defendant to bring forward such findings.

²⁸ 3. The applicant is not entitled to injunctive relief against the defendant with regard to the statements challenged by the applications under No. 2. In this respect, the complaint had to be rejected. The defendant advertises on its website for a so-called „Kinesio-Tape treatment“. The applicant has not succeeded in making it credible that this treatment method is still scientifically unproven or controversial at the time of the advertising. Without success, he refers to the textbook excerpt submitted as Annex A7, which refers to the therapeutic method of „kinesiology“. This is a therapy with natural remedies and massages. A connection with the tape treatment advertised by the defendant is not recognizable. As annex A8, the applicant has submitted an article from the *Ärztezeitung* from 2012. This article avoids a clear statement. It certainly describes positive effects of the tape treatment and only criticizes the appearance of „tangible scientific evidence“. Contrary to the view of the applicant, a possible effect is also not attributed to a mere placebo effect. The corresponding statements refer only to the coloring of the various tapes. In addition, the article mentions a certain massage effect. All in all, the article is not sufficient to substantiate the lack of scientific evidence. The „abstract“ submitted as Exhibit A9, which is supposed to be a summary of the study submitted as Exhibit A8, is also not a suitable means of establishing credibility.

²⁹ The decision on costs follows from Section 92 (1) ZPO.

Fundstelle

openJur 2019, 36184

Rkr: ☐ AmtlSlg: ☐

1. Ein auf die Untersagung gesundheitsbezogener, als irreführend angegriffener Wirksamkeitsaussagen gerichteter Verfügungsantrag hat Erfolg, wenn der Antragsteller glaubhaft macht, dass die Wirksamkeit des beworbenen Mittels oder Verfahrens wissenschaftlich umstritten ist, und der Antragsgegner von der ihm eröffneten Möglichkeit zur Stellungnahme keinen Gebrauch macht.

2. Zur Frage, welche Anforderungen an die Glaubhaftmachung im Sinne von Ziffer 1. zu stellen sind

Tenor

¹ Auf die Beschwerde des Antragstellers wird der Beschluss der 6. Zivilkammer des Landgerichts Frankfurt am Main vom 29.11.2018 teilweise abgeändert.

² Der Antragsgegnerin wird im Wege der einstweiligen Verfügung wegen Dringlichkeit ohne mündliche Verhandlung bei Meidung eines vom Gericht für jeden Einzelfall der Zuwiderhandlung festzusetzenden Ordnungsgeldes bis zu € 250.000,00 ersatzweise Ordnungshaft, oder Ordnungshaft bis zu 6 Monaten, untersagt, im geschäftlichen Verkehr für eine Magnetfeldtherapie, insbesondere für eine "BEMER®-Therapie" zu werben: "Für die Erhaltung und Wiederherstellung Ihrer Gesundheit sind gut funktionierende Heilungs- und Regenerationsprozesse wichtig. Diese entfalten sich am besten in einem gut durchbluteten Gewebe, weil durch den Abtransport von Nährstoffen und Sauerstoff mit dem Blut die für die Heilung benötigte Energie in der Zelle vor Ort gebildet werden kann. Die physikalische Gefäßtherapie BEMER® stellt sicher, dass die Feindurchblutung im ganzen Körper, vor allen Dingen aber im verletzten Gewebe, wirksam gesteigert wird und die natürlichen Heilungsprozesse maximal ablaufen können." Im Übrigen wird die Beschwerde zurückgewiesen.

³ Die Kosten des Eilverfahrens beider Instanzen haben die Parteien je zur Hälfte zu tragen.

⁴ Der Streitwert des Beschwerdeverfahrens wird auf € 15.000,00 festgesetzt.

Gründe

⁵ I.

⁶ Der Antragsteller ist ein rechtsfähiger Verband. Die Antragsgegnerin ist Physiotherapeutin. Sie warb mit den aus der Anlage A3 ersichtlichen Angaben im Internet für verschiedene Behandlungen, unter anderem für eine "Bemer Therapie" sowie für eine "Kinesio Tape"-Behandlung mit den im Verfügungsantrag dargestellten Angaben. Auf die Abmahnung des Antragstellers hat die Antragsgegnerin nicht reagiert.

⁷ Das Landgericht hat den Antrag des Antragstellers auf Erlass einer einstweiligen Verfügung mit Beschluss vom 29.10.2018 zurückgewiesen. Der dagegen gerichteten Beschwerde des Antragstellers hat es mit Beschluss vom 20.11.2018 nicht abgeholfen.

⁸ Der Antragsteller beantragt,

⁹ den angefochtenen Beschluss abzuändern und folgende einstweilige Verfügung zu erlassen:

¹⁰ Der Antragsgegnerin wird bei Vermeidung eines vom Gericht für jeden Fall der künftigen Zuwiderhandlung festzusetzenden Ordnungsgeldes bis 250.000,00 € ersatzweise Ordnungshaft, oder einer Ordnungshaft bis zu sechs Monaten, untersagt, im geschäftlichen Verkehr 1.

¹¹ für eine Magnetfeldtherapie, insbesondere für eine "BEMER®-Therapie" zu werben: "Für die Erhaltung und Wiederherstellung Ihrer Gesundheit sind gut funktionierende Heilungs- und Regenerationsprozesse wichtig. Diese entfalten sich am besten in einem gut durchbluteten Gewebe, weil durch den Abtransport von Nährstoffen und Sauerstoff mit dem Blut die für die Heilung benötigte Energie in der Zelle vor Ort gebildet werden kann. Die physikalische Gefäßtherapie BEMER® stellt sicher, dass die Feindurchblutung im ganzen Körper, vor allen Dingen aber im verletzten Gewebe, wirksam gesteigert wird und die natürlichen Heilungsprozesse maximal ablaufen können.",

¹² 2.

¹³ für eine "Kinesio Tape"-Behandlung mit dem Anwendungsgebiet zu werben: 2.1.

¹⁴ "Schmerzen",

¹⁵ 2.2.

¹⁶ "Lymphödem",

¹⁷ jeweils wenn dies geschieht wie im Internet unter [www\(...\)de](http://www(...)de), abgerufen und ausgedruckt am 25. September 2018 zwischen 19:12:26 Uhr bis 19:12:51 Uhr, gemäß Ausdruck Anlage A 3.

¹⁸ Der Senat hat der Antragsgegnerin unter Übersendung der Antragschrift, der Beschwerdeschrift und der Beschlüsse des Landgerichts vom 29.10. und 20.11.2018 Gelegenheit zur Stellungnahme eingeräumt. Davon hat sie keinen Gebrauch gemacht.

¹⁹ II.

²⁰ Die zulässige Beschwerde hat auch in der Sache zum Teil Erfolg.

²¹ 1. Die Dringlichkeit wird nach §12 II UWG vermutet.

²² 2. Dem Antragsteller steht gegen die Antragsgegnerin ein Unterlassungsanspruch im tenorierten Umfang aus §§3, 3a, 8, I, III Nr. 2 UWG, 3 Nr. 1 HWG zu.

²³ a) Der Antragsteller ist nach § 8 III Nr. 2 UWG klagebefugt. Er ist ein rechtsfähiger Verband zur Förderung gewerblicher oder selbständiger beruflicher Interessen seiner Mitglieder. Der BGH hat immer wieder anerkannt, dass er nach seiner personellen, sachlichen und finanziellen Ausstattung imstande ist, seine satzungsgemäßen Aufgaben tatsächlich wahrzunehmen. Hierfür spricht eine Vermutung (vgl. BGH [GRUR 1997, 476](#) [BGH 14.11.1996 - I ZR 164/94] - Geburtstagswerbung II; Köhler/Bornkamm, UWG, 33. Aufl., § 8 Rn. 3.49).

²⁴ b) Der Antragsteller hat glaubhaft gemacht, dass die mit den Anträgen zu 1. beworbenen Angaben wissenschaftlich ungesichert sind. Sie sind daher unzulässig.

²⁵ aa) Gemäß § 3 Nr. 1 HWG ist es unzulässig, medizinischen Behandlungen Wirkungen beizulegen, die sie nicht haben. Wie allgemein bei gesundheitsbezogener Werbung sind strenge Anforderungen an die Richtigkeit, Eindeutigkeit und Klarheit der Werbeaussage zu stellen, da mit irreführenden gesundheitsbezogenen Angaben erhebliche Gefahren für das hohe Schutzgut des Einzelnen sowie der Bevölkerung verbunden sein können. Die Werbung ist nur zulässig, wenn sie gesicherter wissenschaftlicher Erkenntnis entspricht.

²⁶ bb) Die auf der Internetseite der Antragsgegnerin beworbene Behandlungsmethode der "BEMER Therapie" ist dem Bereich der sog. Magnetfeldtherapien zuzuordnen. Dies hat der Antragsteller durch Vorlage der Anlage A 14, der Internetseite der BEMER Int. AG, glaubhaft gemacht. Danach handelt es sich um eine physikalische Gefäßtherapie, die mit Hilfe elektromagnetisch übertragener Stimulationssignale arbeitet und den Blutfluss normalisieren soll.

²⁷ cc) Der Antragsteller hat durch Vorlage eines Auszugs aus dem "Handbuch - X" der Stiftung Warentest glaubhaft gemacht, dass die Magnetfeldtherapie wissenschaftlich ungesichert ist (Anlage A5). Danach kommen Studien zur therapeutischen Wirksamkeit von Magnetfeldbehandlungen zu widersprüchlichen Ergebnissen. Eine wesentliche Wirkung der angebotenen Geräte sei nicht feststellbar. Der Nachweis, dass ein statisches Magnetfeld die Knochenheilung fördere, sei noch nicht erbracht. Sicher sei, dass es keinerlei Einfluss auf die Heilung von Muskeln oder Wunden an der Haut habe. Gerade für die Heilung "verletzten Gewebes" bewirbt die Antragsgegnerin die Therapie aber. Entgegen der Ansicht des Landgerichts kann das Handbuch der Stiftung Warentest, auch wenn es sich nicht selbst um eine wissenschaftliche Veröffentlichung handelt, durchaus zur Glaubhaftmachung einer fehlenden wissenschaftlichen Absicherung bzw. einer wissenschaftlichen Umstrittenheit von Behandlungsverfahren herangezogen werden. Die Untersuchung der Stiftung Warentest beruht letztlich auf einer Auswertung wissenschaftlicher Studien. Auch die mangelnde Aktualität des Handbuchs führt nicht grundsätzlich zur Unverwertbarkeit. Dies wäre nur dann anders, wenn die im Handbuch veröffentlichten Ergebnisse ausdrücklich als nicht abschließend bezeichnet worden wären oder es bereits aktuellere Untersuchungen gäbe. Es wäre Sache der Antragsgegnerin, solche Erkenntnisse vorzutragen.

²⁸ 3. Dem Antragsteller steht gegen die Antragsgegnerin kein Unterlassungsanspruch hinsichtlich der mit den Anträgen zu Ziff. 2. angegriffenen Angaben zu. Insoweit war die Beschwerde zurückzuweisen. Die Antragsgegnerin wirbt auf ihrer Internetseite für eine sog. "Kinesio-Tape-Behandlung". Dem Antragsteller ist es nicht gelungen glaubhaft zu machen, dass diese Behandlungsmethode zum Zeitpunkt der Werbung noch wissenschaftlich ungesichert bzw. umstritten ist. Ohne Erfolg beruft er sich auf den als Anlage A7 vorgelegten Lehrbuchauszug, der sich auf das therapeutische Verfahren der "Kinesiologie" bezieht. Hierbei handelt es sich um eine Therapie mit Naturarzneimitteln und Massagen. Ein Zusammenhang mit der von der Antragsgegnerin beworbenen Tape-Behandlung ist nicht erkennbar. Als Anlage A8 hat der Antragsteller einen Artikel aus der Ärztezeitung aus dem Jahr 2012 vorgelegt. Dieser Artikel vermeidet eine eindeutige Festlegung. Er beschreibt durchaus positive Effekte der Tape-Behandlung und bemängelt lediglich das Ausstehen "handfester wissenschaftlicher Beweise". Entgegen der Ansicht des Antragstellers wird eine mögliche Wirkung auch nicht nur einem bloßen Placebo-Effekt zugeschrieben. Die entsprechenden Ausführungen beziehen sich lediglich auf die Farbgebung der verschiedenen Tapes. Darüber hinaus ist in dem Artikel von einem gewissen Massageeffekt die Rede. Der Artikel reicht insgesamt zur Glaubhaftmachung der fehlenden wissenschaftlichen Absicherung nicht aus. Kein taugliches Glaubhaftmachungsmittel ist auch das als Anlage A9 vorgelegte "Abstract", bei dem es sich um eine Zusammenfassung der als Anlage A8 vorgelegten Studie handeln soll.

²⁹ 4. Die Kostenentscheidung folgt aus §92 Abs. 1 ZPO.

Title:

Right of action of a competition association in the case of advertising medicinal products

Chain of norms:

UWG § III No. 2

HWG § 3

Decision Keyword:

Observation in medical practice

Editorial Guidelines:

1. The factual requirement of „goods of the same or related kind“ in Sec. 8 III No. 2 UWG is to be interpreted broadly and therefore already fulfilled if the mutual goods are similar in kind to such an extent that the sales of one may be affected by any anticompetitive conduct of the other.

2. In the case of a technically controversial treatment method (here: magnetic field therapy), the reference that the effect has not yet been scientifically confirmed is not sufficient if this statement is qualified with the addition „I observe gratifying therapeutic successes in my practice on a daily basis“. (Editorial guidelines)

Keywords:

Legal standing, competition association, health-related advertising, advertising of remedies, medical device, magnetic field therapy

ECLI:

ECLI:DE:OLKOBL:2016:0120:9U1181.15.0A

Legal force:

Legally binding

Tenor:

1. On the appeal of the applicant, the judgment of the 4th Chamber for Commercial Matters of the Koblenz Regional Court of 27.19.2015 is amended and reworded as follows:

2. The costs of the legal dispute shall be borne by the defendant.

3. The amount in dispute is set at 18,000 euros.

Reasons:

1 The appeal is admissible and well-founded.

2 In its order of February 20, 2015, the 4th KfH of the Koblenz Regional Court rightly prohibited the Ag. by way of an interim injunction from advertising in the course of business for a „magnetic field therapy“ with the statements objected to by the applicant.

3 The application is admissible.

4 The defendant has the right to sue according to § 8 III No. 2 UWG.

5 Pursuant to § 8 III No.2 UWG, the right to injunctive relief is granted to legally capable associations for the promotion of commercial or self-employed professional interests, insofar as a considerable number of companies belong to them, which sell goods or services of the same or related kind on the same market.

6 In this context, the term „goods of the same or related kind“ is to be interpreted broadly (cf. Köhler/Bornkamm, UWG, 32nd ed., § 8 marginal no. 3.38ff. with further references). This refers to companies that are competitors of the infringer on the same relevant product and geographic market, i.e. which can compete for customers (cf. BGH, GRUR 2000, 1084 - Unternehmenskennzeichnung). The mutual goods or commercial services must be so similar or close in nature that the sales of one may be affected by any anti-competitive conduct of the other. The existence of an abstract competitive relationship is required, for which it is sufficient that a not entirely insignificant potential detriment can be considered with a certain, even if only slight, probability. Belonging to the same or a related industry is sufficient but by no means a necessary criterion (cf. Köhler/Bornkamm, UWG, 22nd ed., § 8 para. 3.38 et seq.; BGH, GRUR 2006, 778 - Sammelmitgliedschaft IV; BGH, GRUR 2000, 438 - Gesetzeswiederholende Unterlassungsanträge).

7 Therefore, in the present case, with regard to the required competitive relationship, the focus is not exclusively on physicians and non-medical practitioners. Rather, at least also pharmacies, clinics, and manufacturers/distributors of medical devices and pharmaceuticals are potential competitors. Because from the point of view of a patient, these come into consideration as an alternative to the treatment offered by the accused by means of magnetic field therapy. Patients who see a need for magnetic field therapy could choose other treatment approaches as an alternative, e.g., medicinal, or surgical treatments.

8 By submitting its list of members, the applicant has made it credible that its members include 89 healthcare service providers, 43 healthcare service providers including physicians, alternative practitioners and pharmacists, as well as 114 manufacturers/distributors of therapeutic products including medical devices and pharmaceuticals, and that a not inconsiderable number of these are also active in the geographically relevant market. These include the pharmaceutical manufacturers, such as the companies A-Arzneimittel GmbH & Co. KG, B-GmbH, C-AG or D-GmbH, and the Federal Association of German Mail Order Pharmacies with its members.

9 The asserted claim for injunctive relief is also not abusive within the meaning of Section 8 IV 1 UWG.

10 Such an abuse exists if the claimant, by asserting the claim, predominantly pursues interests and objectives that are extraneous and not worthy of protection in themselves, in particular, if it is predominantly a matter of creating a claim for compensation for applications or costs of legal prosecution. The existence of abuse is to be assessed in each individual case, taking into account the entire circumstances, which include the nature and extent of the competition infringement, the conduct of the infringer after the infringement, the conduct of the claimant in pursuing this and other infringements, the nature and gravity of the infringement and the conduct of the debtor after the infringement (cf. Köhler/Bornkamm, UWG, 33rd ed., § 8 para. 4.10 et seq.).

11 Circumstances that speak for the abusive behavior of the defendant in the present case are neither sufficiently presented nor evident. In particular, abusive conduct does not result from the declaration of discontinuance form submitted by the applicant to the defendant with the warning of July 26, 2015. It is expressly included therein that a contractual penalty is only to be paid in the event of culpable infringement of the cease-and-desist obligation. A contractual penalty of 5100 euros for each case of culpable infringement also does not allow the conclusion that the applicant is only interested in obtaining fees in the present case.

12 The asserted request for injunctive relief is also well-founded.

13 Pursuant to § 920 II, 936 ZPO, the applicant has made a credible claim for an injunction pursuant to §§ 8 I 1, III No. 2, 3 I, 4 No. 11 UWG, § 3 S. 2 No. 1 HWG.

14 The defendant's statements in dispute on his website regarding the magnetic field therapy offered him to suggest the therapeutic effectiveness of this therapy. This is not changed by the statement „Even if the effect has not yet been scientifically confirmed“, especially since in the continuation of this sentence „I observe gratifying therapeutic successes in my practice every day“ the claimed effectiveness is expressed once again. The therapeutic effectiveness of the advertised magnetic field therapy the accused did not make however plausible. Therefore, his advertising violates § 3 HWG and is therefore unfair and inadmissible according to §§ 3 I, 4 No. 11 UWG, 3 S. 2 No. 1 HWG (see also OLG Braunschweig, GRUR-RR 2012, 431 - Kernspinresonanztherapie; OLG Frankfurt a. M., MD 2006, 1179; OLG Koblenz, MD 2007, 307; OLG Munich, MD 2002, 924).

15 The existence of a ground for injunction follows from the presumption of § 12 II UWG, which has not been refuted.

16 The assumption of a risk of repetition is not precluded by the fact that the defendant issued a cease-and-desist declaration to the applicant on July 9, 2015. This declaration to cease and desist, which was made subject to conditions subsequent, does not eliminate the risk of repetition.

17 Strict requirements are set for the cessation of the risk of repetition. If there is even the slightest doubt about the seriousness of the accepted obligation, it is generally not suitable to eliminate the concern of future infringements (cf. Köhler/Bornkamm, UWG, 33rd ed., § 12 marginal no. 1123).

18 The resolving conditions under point 3.2 of the cease-and-desist declaration, „that the therapeutic efficacy or respectively described the effect of the procedure magnetic field therapy becomes established knowledge of science“ and under 3.3, „that it is judicially determined that the association X e. V. is not entitled to the cease-and-desist claim concretized under No. 1“, do not meet these strict requirements, especially since the defendant has also announced a negative declaratory action in the event that it considers the claimant's standing to sue to be insufficiently proven.

19 The decision on costs results from § 91 of the German Code of Civil Procedure (ZPO).

OLG Koblenz (9. Zivilsenat), Urteil vom 20.01.2016 - 9 U 1181/15

Titel:

Klagebefugnis eines Wettbewerbsverbandes bei Heilmittelwerbung

Normenketten:

UWG § 8 III Nr. 2

HWG § 3

Entscheidungsstichwort:

Beobachtung in ärztlicher Praxis

Redaktionelle Leitsätze:

1. Der tatbestandliche Voraussetzung der „Waren gleicher oder verwandter Art“ in § 8 III Nr. 2 UWG ist weit auszulegen und deshalb bereits dann erfüllt, wenn die beiderseitigen Waren sich ihrer Art nach so weit gleichen, dass der Absatz des einen durch irgendein wettbewerbswidriges Verhalten des anderen beeinträchtigt werden kann.

2. Bei einer fachlich umstrittenen Behandlungsmethode (hier: Magnetfeldtherapie) reicht der Hinweis, dass die Wirkung bisher wissenschaftlich nicht bestätigt ist, nicht aus, wenn diese Aussage mit dem Zusatz „beobachte ich in meiner Praxis täglich erfreuliche Therapieerfolge“ relativiert wird. (Leitsätze der Redaktion)

Schlagworte:

Klagebefugnis, Wettbewerbsverband, gesundheitsbezogene Werbung, Heilmittelwerbung, Medizinprodukt, Magnetfeldtherapie

ECLI:

ECLI:DE:OLGKOB:2016:0120.9U1181.15.0A

Rechtskraft:

rechtskräftig

Tenor:

1. Auf die Berufung des Ast. wird das Urteil der 4. Kammer für Handelssachen des *LG Koblenz* vom 27.10.2015 abgeändert und wie folgt neu gefasst:

Die einstweilige Verfügung der 4. Kammer für Handelssachen des *LG Koblenz* vom 20.7.2015 bleibt aufrecht erhalten.

2. Die Kosten des Rechtsstreits trägt der Ag.

3. Der Streitwert wird auf 18.000 Euro festgesetzt.

Gründe:

1Die Berufung ist zulässig und begründet.

2Die 4. KfH des *LG Koblenz* hat mit Beschluss vom 20.7.2015 dem Ag. zu Recht im Wege der einstweiligen Verfügung untersagt, im geschäftlichen Verkehr für eine „Magnetfeldtherapie“ mit den vom Ast. beanstandeten Angaben zu werben.

3Der Antrag ist zulässig.

4Der Ast. ist nach § 8 III Nr. 2 UWG klagebefugt.

5Nach § 8 III Nr. 2 UWG steht der Unterlassungsanspruch rechtsfähigen Verbänden zur Förderung gewerblicher oder selbstständig beruflicher Interessen zu, soweit ihnen eine erhebliche Zahl von Unternehmen angehören, die Waren- oder Dienstleistungen gleicher oder verwandter Art auf demselben Markt vertreiben.

6Dabei ist der Begriff der „Waren gleicher oder verwandter Art“ weit auszulegen (vgl. *Köhler/Bornkamm*, UWG, 32. Aufl., § 8 Rn. 3.38 ff. mwN). Damit sind solche Unternehmen gemeint, die dem Verletzer auf demselben sachlich und räumlich relevanten Markt als Wettbewerber begegnen, also um Kunden konkurrieren können (vgl. *BGH*, GRUR 2000, 1084 – Unternehmenskennzeichnung). Die beiderseitigen Waren oder gewerblichen Leistungen bzw. Dienstleistungen müssen sich ihrer Art nach so gleichen oder nahestehen, dass der Abs. des einen durch irgendein wettbewerbswidriges Verhalten des anderen beeinträchtigt werden kann. Erforderlich ist das Vorliegen eines abstrakten Wettbewerbsverhältnisses, wofür es ausreicht, dass eine nicht gänzlich unbedeutende potenzielle Beeinträchtigung mit einer gewissen, wenn auch nur geringen Wahrscheinlichkeit in Betracht gezogen werden kann. Die Zugehörigkeit zu derselben oder einer verwandten Branche ist dabei zwar ein ausreichendes, aber keineswegs notwendiges Kriterium (vgl. *Köhler/Bornkamm*, UWG, 33. Aufl., § 8 Rn. 3.38 ff.; *BGH*, GRUR 2006, 778 – Sammelmitgliedschaft IV; *BGH*, GRUR 2000, 438 – Gesetzeswiederholende Unterlassungsanträge).

7Daher ist vorliegend hinsichtlich des erforderlichen Wettbewerbsverhältnisses nicht ausschließlich auf Ärzte und Heilpraktiker abzustellen. Vielmehr sind zumindest auch Apotheken, Kliniken und Hersteller/Vertreiber von Medizinprodukten und Arzneimitteln potenzielle Mitbewerber. Denn aus Sicht eines Patienten kommen diese als Alternative zu der vom Ag. angebotenen Behandlung mittels Magnetfeldtherapie in Betracht. Patienten, die einen Bedarf für eine Magnetfeldtherapie sehen, könnten als Alternative andere Behandlungsansätze wählen, zB medikamentöse oder operative Behandlungen.

8Der Ast. hat durch Vorlage seiner Mitgliederliste glaubhaft gemacht, dass zu seinen Mitgliedern 89 Dienstleister des Gesundheitswesens, 43 Dienstleister des Heilwesens einschließlich Ärzten, Heilpraktikern und Apothekern sowie 114 Hersteller/Vertreiber von Heilmitteln einschließlich Medizinprodukten und Arzneimitteln gehören und dass auch eine nicht unerhebliche Anzahl davon im räumlich relevanten Markt aktiv sind. Dazu zählen vor allem die Arzneimittelhersteller, wie zB die Firmen *A-Arzneimittel GmbH & Co. KG*, *B-GmbH*, *C-AG* oder *D-GmbH*, sowie der Bundesverband deutscher Versandapotheken mit seinen Mitgliedern.

9Der geltend gemachte Unterlassungsanspruch ist auch nicht missbräuchlich iSd § 8 IV 1 UWG.

10Ein solcher Missbrauch liegt vor, wenn der Anspruchsberechtigte mit der Geltendmachung des Anspruchs überwiegend sachfremde, für sich gesehen nicht schutzwürdige Interessen und Ziele verfolgt, insbesondere wenn es überwiegend darum geht, einen Anspruch auf Ersatz von Aufwendungen oder Kosten der Rechtsverfolgung entstehen zu lassen. Das Vorliegen eines Missbrauchs ist jeweils im Einzelfall unter Berücksichtigung der gesamten

Umstände zu beurteilen, wozu Art und Umfang des Wettbewerbsverstoßes, Verhalten des Verletzers nach dem Verstoß, Verhalten des Anspruchsberechtigten bei der Verfolgung dieses und anderer Verstöße, Art und Schwere des Verstoßes und Verhalten des Schuldners nach dem Verstoß gehören (vgl. *Köhler/Bornkamm*, UWG, 33. Aufl., § 8 Rn. 4.10 ff.).

11 Umstände, die für ein missbräuchliches Verhalten des Ast. im vorliegenden Fall sprechen, sind weder ausreichend dargelegt noch ersichtlich. Ein missbräuchliches Verhalten ergibt sich insbesondere nicht aus dem vom Ast. dem Ag. mit der Abmahnung vom 26.7.2015 vorgelegten Unterlassungserklärungsformular. Darin ist ausdrücklich aufgenommen, dass eine Vertragsstrafe erst bei schuldhafter Zuwiderhandlung gegen die Unterlassungsverpflichtung zu zahlen ist. Eine Vertragsstrafe von 5100 Euro für jeden Fall der schuldhaften Zuwiderhandlung lässt auch nicht den Schluss zu, dass es dem Ast. vorliegend nur um ein Gebührenerzielungsinteresse geht.

12 Der geltend gemachte Unterlassungsantrag ist auch begründet.

13 Der Ast. hat gem. § 920 II, § 936 ZPO einen Verfügungsanspruch nach §§ 8 I 1, III Nr. 2, 3 I, 4 Nr. 11 UWG, § 3 S. 2 Nr. 1 HWG glaubhaft gemacht.

14 Die streitgegenständlichen Angaben des Ag. auf seiner Internetseite betreffend die von ihm angebotene Magnetfeldtherapie suggerieren eine therapeutische Wirksamkeit dieser Therapie. Daran ändert auch nichts der Hinweis „Auch wenn die Wirkung bisher noch nicht wissenschaftlich bestätigt ist“, zumal in der Fortsetzung dieses Satzes „beobachte ich in meiner Praxis täglich erfreuliche Therapieerfolge“ die behauptete Wirksamkeit noch einmal zum Ausdruck gebracht wird. Eine therapeutische Wirksamkeit der beworbenen Magnetfeldtherapie hat der Ag. jedoch nicht glaubhaft gemacht. Daher verstößt seine Werbung gegen § 3 HWG und ist somit nach §§ 3 I, 4 Nr. 11 UWG, 3 S. 2 Nr. 1 HWG unlauter und unzulässig (vgl. ua auch *OLG Braunschweig*, GRUR-RR 2012, 431 – Kernspinresonanztherapie; *OLG Frankfurt a. M.*, MD 2006, 1179; *OLG Koblenz*, MD 2007, 307; *OLG München*, MD 2002, 924).

15 Das Vorliegen eines Verfügungsgrundes folgt aus der Vermutung des § 12 II UWG, die nicht widerlegt worden ist.

16 Der Annahme einer Wiederholungsgefahr steht nicht entgegen, dass der Ag. am 9.7.2015 gegenüber dem Ast. eine Unterlassungserklärung abgegeben hat. Denn diese unter auflösenden Bedingungen abgegebene Unterlassungserklärung lässt die Wiederholungsgefahr nicht entfallen.

17 Für den Fortfall der Wiederholungsgefahr werden strenge Anforderungen gestellt. Bestehen an der Ernsthaftigkeit der übernommenen Verpflichtung auch nur geringste Zweifel, ist sie grundsätzlich nicht geeignet, die Besorgnis zukünftiger Verstöße auszuräumen (vgl. *Köhler/Bornkamm*, UWG, 33. Aufl., § 12 Rn. 1123).

18 Die auflösenden Bedingungen unter Punkt 3.2 der Unterlassungserklärung, „dass die therapeutische Wirksamkeit oder jeweils beschriebene Wirkung des Verfahrens Magnetfeldtherapie gesicherte Kenntnis der Wissenschaft wird“ und unter 3.3, „dass gerichtlich festgestellt wird, dass dem Verband X e.V. der unter Nr. 1 konkretisierte Unterlassungsanspruch nicht zusteht“, werden diesen strengen Anforderungen nicht gerecht, zumal der Ag. auch eine negative Feststellungsklage für den Fall angekündigt hat, dass er die Klagebefugnis des Ast. für nicht ausreichend nachgewiesen erachtet.

19 Die Kostenentscheidung folgt aus § 91 ZPO.

Ruggell, 08.05.23

**Interessenkollisionserklärung zur wissenschaftlichen Stellungnahme zu BEMER-Studien
und daraus resultierenden Werbeaussagen**

Die Autoren Prof. Dr. Dr. Fred Harms und Prof. Dr. Wolf A. Kafka erklären, dass sie keine konkurrierenden Interessen haben.



Prof. Dr. Dr. Fred Harms



Prof. Dr. Wolf A. Kafka

For your information (translated text)

Conflict of interest declaration regarding the scientific statement on BEMER studies and resulting advertising claims

The authors Prof. Dr. Dr. Fred Harms and Prof. Dr. Wolf A. Kafka, declare that they have no competing interests.