Mönchengladbach Regional Court
Mönchengladbach, Germany
Case Number: 6 O 470/20
Judgment date: January 26, 2024

Editor's note: This English translation was done by a third party. The original judgement can be accessed here.

REGIONAL COURT OF MÖNCHENGLADBACH
IN THE NAME OF THE PEOPLE

Judgment on the Basis of Liability and Partial Final Judgment

In the legal dispute between Mr. [redacted], plaintiff, represented by attorneys [redacted], and Mr. [redacted], defendant, represented by attorneys [redacted], the Sixth Civil Chamber of the Regional Court of Mönchengladbach, following the oral hearing of 22 November 2023, through the presiding judge at the Regional Court [redacted], a judge at the Regional Court [redacted], and a judge at the Local Court [redacted], has ruled as follows:

Operative part of the judgment

It is declared that the defendant, jointly and severally with [redacted party], is obliged to compensate the plaintiff for all material losses and further non-material harm that have arisen or may arise as a result of injury caused by taking the medicinal active ingredient finasteride, insofar as those claims have not passed, or do not pass, to social insurance institutions or other third parties.

In all other respects, the action is justified in principle. The decision on costs is reserved for the final judgment.

Facts of the case

The plaintiff seeks compensation for pain and suffering and a declaration that the defendant is liable for future material and non-material damage.

The plaintiff, born on [redacted date], had been treated by the defendant, a dermatologist in private practice, since 2010, initially for skin-cancer screening.

On January 31, 2012, the plaintiff sought advice about his increasing hair loss. The defendant prescribed Finapil (active ingredient: finasteride). After filling the prescription, the plaintiff saw that the package leaflet listed adverse effects relating to sexual dysfunction and psychological impairment. He initially decided not to take the medicine.

On February 14, 2013, the plaintiff told the defendant that he did not want to take Finapil; they agreed instead on long-term treatment with the non-prescription foam Regaine 5%. In January 2014, the plaintiff again asked the defendant about Finapil.

In 2014, the plaintiff also consulted a female dermatologist, Ms. [redacted], who prescribed Finapil again in August 2014. From the beginning of 2015 until December 2, 2015, on the defendant's prescription, the plaintiff took the original product Propecia 1 mg, manufactured by [redacted company], against which he is also pursuing damages before the Regional Court of Munich.

The professional product information for Propecia, from 2012 onward, stated: "The following has additionally been reported after marketing: persistence of sexual dysfunction (decreased libido, erectile dysfunction and ejaculation disorders) after discontinuation of PROPECIA."

The patient leaflet applicable from 2012 stated under “What side effects are possible?”: “Frequency not known” and, among effects persisting after discontinuation of treatment, difficulties with erections, reduced sexual desire, and ejaculation difficulties.

A German “Dear Healthcare Professional” safety letter (Rote-Hand-Brief) published on July 5, 2018 pointed out that adverse effects including sexual dysfunction and psychological symptoms or disorders had been reported during and after finasteride use. The professional and patient information had been amended to replace “depressed mood” with “depression” and to include “anxiety” as a new adverse effect.

Plaintiff’s allegations

The plaintiff alleges that in 2014 he asked critical questions about Finapil’s side effects and the defendant’s experience with it. The defendant allegedly said that he had prescribed it for years, that it was generally well tolerated, and that the plaintiff could take it without concern. The defendant allegedly mentioned only one patient who developed gynecomastia after changing the dose himself; the condition reportedly resolved after discontinuation.

The plaintiff further alleges that he began taking Finapil in mid-2014, soon developed testicular pain and increasing erectile problems, and independently stopped the medication in October 2014.

At his next skin-cancer screening in early 2015, he allegedly raised the side effects again. According to the plaintiff, the defendant reassured him that they could not really have been caused by the medication and that switching to the original Propecia 1 mg product should allow matters to normalize.

The plaintiff alleges that the adverse effects worsened after taking Propecia. He consulted a urologist, Mr. [redacted], who reportedly told him that these symptoms were typical of Propecia; on that doctor’s advice he stopped the medicine on December 2, 2015.

Nevertheless, the plaintiff alleges that he continues to suffer permanently from so-called post-finasteride syndrome, including: erectile dysfunction; loss of nocturnal, morning and spontaneous erections; complete or reduced loss of libido; no response to sexual stimuli; reduced and watery ejaculate; anorgasmia; penile pain; changes in penile structure; cold penis and scrotum; shrinkage of the penis and testicles; prostate pain; severe depression and suicidal thoughts; anxiety and panic attacks; anhedonia; severe mood swings; fatigue; listlessness; lack of motivation; short- and long-term memory problems; and severe sleep disorders.

The plaintiff accuses the defendant of failing to provide sufficient information about finasteride’s risks and adverse effects, particularly the possibility that symptoms could be irreversible. He alleges that the impairments prevent him from working in his profession as a business graduate, that he has lost social contacts and hobbies, and that his relationship has suffered.

He considers compensation for pain and suffering of approximately €100,000 justified.

Plaintiff’s requests

The plaintiff requests that the defendant, jointly and severally with [redacted party], be ordered to pay compensation for pain and suffering in an amount determined by the court, but at least €100,000, with interest at five percentage points above the base rate from December 14, 2019; that the defendant’s joint-and-several liability for all present and future material loss and further non-material harm caused by taking finasteride be declared, subject to transfer of claims to insurers or third parties; and that the defendant indemnify him against legal fees of €4,748.10 plus interest at five percentage points above the base rate.

Defendant’s response

The defendant requests dismissal of the action and denies any treatment error.

He alleges that on January 31, 2012, he thoroughly explained possible adverse effects, including reduced libido and gynecomastia, and therapeutic alternatives. He says he also explained that such impairments might be permanent. According to him, the prescription and counseling fully met specialist standards; publications on post-finasteride syndrome appeared only after treatment had ended.

The defendant maintains that the plaintiff could not have been surprised by side effects, since he was always very well informed. In January 2015, the plaintiff allegedly reported potency problems but wished to continue finasteride, placing great personal importance on avoiding hair loss and describing himself as vain.

The defendant says he discussed temporarily halving the Propecia dose and instructed the plaintiff to stop immediately if problems such as erectile dysfunction or loss of libido recurred. He disputes the impairments claimed by the plaintiff, pointing particularly to an alleged report in April 2016 of regular sexual intercourse without corresponding restrictions.

The Chamber took evidence by examining a witness and obtaining expert opinions. It refers to the records of hearings on October 20, 2021 (case-file pages 224 et seq.), November 23, 2022 (pages 651 et seq.) and November 22, 2023 (pages 803 et seq.), the expert report of March 29, 2022 (pages 315 et seq.), and supplemental opinions dated August 16, 2022 (pages 451 et seq.) and July 31, 2023 (pages 727 et seq.). The remaining submissions and exhibits are incorporated by reference.

Reasons for the decision

The admissible action is well founded with respect to the application for declaratory relief. In other respects, it is justified as to the basis of liability.

The plaintiff's declaratory application was ready for decision and could therefore be decided by a partial final judgment. The remaining claim could be decided by a judgment on the basis of liability pursuant to section 304 of the German Code of Civil Procedure (ZPO), because the parties dispute both liability and amount, but only liability is ready for decision. Further evidence will be needed concerning the amount of damages.

The plaintiff has a claim against the defendant under sections 630a and 280(1) of the German Civil Code (BGB), for breach of duty in the course of treatment, and under section 823(1) in conjunction with sections 249 and 253(2) BGB, for unlawful treatment, for compensation for pain and suffering and for a declaration of the defendant's duty to compensate material and non-material harm causally attributable to the treatment error.

Following the taking of evidence, the Chamber is satisfied that the plaintiff has proved that the defendant carried out treatment in breach of duty and unlawfully by prescribing Propecia. The Chamber is convinced that the defendant failed to provide sufficient information about the risks of finasteride, so that the plaintiff's consent was invalid under section 630d(2) BGB.

Under section 630d(1), sentence 1, BGB, the treating professional must obtain the patient's consent before carrying out a medical measure. Under section 630d(2), valid consent requires prior disclosure in accordance with section 630e(1)–(4). Section 630e(1) requires explanation of all circumstances material to consent, including the nature, extent, expected consequences and risks of the measure, and its urgency, suitability and prospects of success in relation to diagnosis and treatment.

Assessing risk requires consideration both of the seriousness of possible harm and of the probability that it will occur. Disclosure is required for risks whose combined severity and probability are not negligible. Frequency may be assessed using statistical information, but the seriousness of the potential harm must also be considered.

The duty of disclosure extends to risks sufficiently serious, in combination with their likelihood, that a reasonable patient would weigh the advantages and disadvantages of treatment. Rare risks must also be disclosed where the threatened harm is severe and would seriously burden the patient's future life. This is particularly true where an intervention offers comparatively little medical benefit or is not medically necessary, but exposes the patient to a risk of extremely serious harm, even if it occurs only very rarely (citing Münchener Kommentar zum BGB, Wagner, section 630e, marginal no. 18).

For cosmetic treatment, particular emphasis must be placed on disclosing even very rare harmful consequences because no health benefit offsets the risk. In such circumstances, risks must be presented clearly and without minimizing them (same commentary, marginal no. 26).

There is no duty to warn of a risk that was unknown at the time of treatment and that the physician neither knew nor was required to know, for example because it had not been discussed, or not seriously discussed, in medical science. Undifferentiated warnings about negligible risks may also overload a patient's ability to decide. Purely theoretical dangers unsupported by practical experience need not be disclosed (citing Martis/Winkhart and Münchener Kommentar zum BGB).

If disclosure is absent or inadequate, treatment is unlawful even if use of the medication itself complies with professional standards.

Measured against these principles, the defendant's disclosure was inadequate. He should have informed the plaintiff that impairments, particularly restrictions of sexual function, could persist after finasteride was discontinued and could be permanent or irreversible.

The expert had observed that possible irreversibility of side effects after finasteride discontinuation had not been addressed in the scientific literature until 2012 and that data on long-term or possibly lifelong side effects were unavailable. However, the 2012 Propecia professional information already recorded persistence of sexual dysfunction—decreased libido, erectile dysfunction and ejaculation disorders—after discontinuation.

The Chamber therefore does not share the expert's assessment that, at the time of treatment beginning in 2013, there were no indications of such possible adverse effects. The cited professional information itself supplied that indication.

The expert explained that he regarded the wording as referring only to individual case reports requiring verification. In the Chamber's view, that does not eliminate the defendant's duty to inform. The defendant was required to emphasize that permanent loss of erectile and ejaculatory capacity was at least possible, since such effects undoubtedly constitute serious impairment of a patient's future life.

The expert further noted that, because reliable data were lacking, no specific probability could be assigned to the usual frequency categories. In his view the risk was not "known" in the sense of scientifically established evidence, and disclosure was therefore not medically required.

The Chamber disagrees that this removes the legal duty to disclose. The absence of reliable data meant precisely that the eventual probability of the risk remained entirely open. The expert acknowledged that "frequency not known" could also mean that a risk might ultimately prove "common" once reliable data were available.

The Chamber also rejects the expert's analogy with fears of infertility caused by coronavirus vaccination. In that example, the court says, the concerns were wholly unsupported fears of worried patients, whereas the impairments at issue here had actually been "observed," that is, medically recorded.

Nor does the disclosure sought by the plaintiff resemble warning about everyday risks such as a rash or itching, because the potential impairment here is much more serious.

The Chamber regards it as important that there was no medical indication for drug treatment of the plaintiff's hair loss: it was a purely cosmetic treatment without medical benefit. That made it all the more necessary to explain even very unlikely or unquantifiable serious risks clearly and without minimizing them.

The defendant's duty was not removed by the plaintiff's own level of knowledge or his initial refusal to take Finapil after reading its leaflet. A physician generally may not rely on the patient reading the package leaflet but must personally provide information sufficient to make the risks clear (citing Federal Court of Justice, NJW 2005, 1716).

Moreover, when prescribing Propecia, the defendant again owed comprehensive disclosure. For the plaintiff, switching from the previously used generic to the original brand product represented a new treatment approach. The duty was particularly important because the frequency of the risk was unknown and the measure was not medically indicated. The defendant also did not know that the plaintiff had read the Propecia leaflet.

The defendant has not proved that he gave disclosure of the required scope.

The Chamber need not decide whether the treatment documentation meets the requirements of section 630f(1) BGB, including safeguards against untraceable later alterations, because it does not resolve the relevant issue. The record for January 31, 2012 notes counseling on "gynecomastia, impotence, reduced erectile capacity, reduced or lost libido, reduced ejaculate volume, possible fertility problems." It does not record disclosure of the decisive risk: that such impairments might persist after the medication was stopped.

No disclosure at all was documented when treatment was switched to Propecia. Nor did the evidence and personal questioning of the parties persuade the Chamber that the defendant had in fact disclosed this risk.

At his hearing, the defendant said that he had not placed any time limit on his warnings and had explained that no one could guarantee the side effects would disappear. He also said he had again explained all risks in 2015 before prescribing Propecia.

The plaintiff, by contrast, said none of those risks had been discussed. According to him, the defendant had only asked whether he currently wished to have children, which he denied, and said the original-product manufacturer had conducted studies showing that men could continue taking the tablets while their partner was pregnant.

Without further indications, particularly in the documentation, or other evidence, the Chamber cannot determine which account is true. The defendant therefore has failed to discharge his burden of proof on this issue.

Fault is presumed for contractual claims under section 280(1), sentence 2, BGB; the defendant has not rebutted that presumption. As to the tort claim, he was at least negligent. The unlawfulness of the tortious conduct is also established.

Accordingly, the defendant must compensate the plaintiff for harm causally attributable to the breach of the duty to inform.

The extent of damages depends on the specific health impairments actually suffered. Further evidence, potentially extensive, is necessary on that question. It is therefore appropriate to decide the basis of the claim first by judgment on liability.

The plaintiff is already entitled to a declaration that the defendant must compensate material and non-material harm caused by taking medication prescribed without adequate disclosure, to the extent stated in the operative part.

All further decisions are reserved for the final judgment.