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D E C I S I O N
of 13 July 1999

Case Number: T 0139/98 - 3.4.2

Application Number: 89902619.9

Publication Number: 0398984

IPC: G02C 7/04

Language of the proceedings: EN

Title of invention:
Improved contact lens design

Applicant/Patentee:
Igel International Limited

Opponent:
Wesley-Jessen Corp.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56
EPC R. 29(1)

Keyword:
"Novelty and inventive step (confirmed)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0139/98 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 13 July 1999

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 9 December 1997 concerning maintenance of the European patent No. 0 398 984 in amended form.**

Composition of the Board:

Chairman: E. Turrini
Members: A. G. Klein
V. Di Cerbo

Summary of Facts and Submissions

I. European patent No. 0 398 984 (international publication No. WO 89/07 303) was maintained in amended form by an interlocutory decision of the Opposition Division, on the basis of a set of claims of which claim 1, the only independent claim, reads as follows:

"1. A soft contact lens having a concave posterior surface for fitting to the eye of a wearer, a convex anterior surface for exposure from the eye of a wearer, and stabilising means (4,8,10) to impart rotational stability to the lens when in use, said soft contact lens providing a correction with an astigmatic component for the eye, said posterior surface having a back toric optic zone (1,9,11) configured for at least some of the correction of the eye of a wearer and being juxtaposed to the central portion of the eye of the wearer when in use, wherein a peripheral area (2) is located about the back toric optic zone (1,9,11) for fitting the soft contact lens to the eye of the wearer and wherein the curvature of the back toric optic zone (1,9,11) is configured with a refractive correction independent of the topography of the eye of the wearer, the stabilising means comprising stabilising wedges (4,8,10) on the anterior surface of the lens, the thickest portions of the stabilising wedges being in the lower half of the lens so as to be located over the sclera when in position on the eye of the wearer whereby eyelid irritation during blinking of the eye of the wearer is minimised."

The Opposition Division in its interlocutory decision in particular held that the subject-matter of claim 1

was novel and that it involved an inventive step within the meaning of Articles 54 and 56 EPC in view of the contents of document

D8: M. J. Remba "Evaluating the Hydrosoft Toric" in Contact Lens Forum Vol. 12, No. 3 (March 1987), pages 45-51,

which it had introduced into the opposition procedure of its own motion and which it considered to disclose the nearest prior art, and of the remaining documents on the file, of which the following will be referred to also in the present decision:

D2: US-A-4 095 878.

II. The appellant (opponent) filed an appeal against the interlocutory decision. In his Statement of the Grounds of Appeal he **inter alia** referred to five new citations, numbered D9 to D14, of which

D13: Andrew Gasson, "A Clinical Appraisal Of The Zero 6 Toric Soft Lens", Optician, Contact Lens Monthly, 4 September 1987, Pages 19-22

was cited against the novelty of the claimed subject-matter.

III. In a communication pursuant to Article 11(2) of the Rules of Procedures of the Boards of Appeal the Board informed the parties that document D13 appeared to be the sole document on the file to disclose stabilising wedges similar to those disclosed in the patent. Since the feature of the stabilising wedges was not

introduced into claim 1 by the respondent (proprietor of the patent) until about one month before the oral proceedings in the opposition procedure, at which the appealed interlocutory decision was taken, the late filing of this relevant citation appeared to be excusable and document D13 should therefore be duly considered in the appeal procedure.

The Board also informed the parties of its intention to disregard late filed documents D9 to D12 under Article 114(2) EPC.

IV. Oral proceedings were held on 13 July 1999 at the end of which the appellant requested that the patent be revoked.

The respondent for his part requested that the appeal be dismissed and that the patent be maintained according to the decision of the Opposition Division (main request).

As his first and second auxiliary requests he requested that the patent be maintained on the basis of the claims filed as his first and third auxiliary requests, respectively, with his letter dated 2 October 1998.

V. The appellant's arguments in support of his request can be summarized as follows.

The drafting of the claim in the one-part form does not correctly reflect the actual contribution of its subject-matter to the art. Since according to the appealed interlocutory decision all the features of the claim excepted the stabilising wedges were disclosed in

document D8, the claim should have been drafted in the two-part form with the characterising portion comprising the latter feature only.

Document D2 discloses a soft contact lens which fully anticipates the subject-matter of claim 1. This lens can in particular be provided either with an inner or an outer toric surface to correct astigmatism (see column 3, lines 42 to 45). The lens is stabilized by means of flattened regions 2,4 provided on the anterior surface which at their junction with the central region also form wedges in the sense of claim 1 (see column 2, lines 29 to 43). Finally, the feature of claim 1 that the curvature of the back toric optic zone is configured with a refractive correction independent of the topography of the eye of the wearer does not provide any structural distinction over the lens of document D2.

The claimed soft contact lens does not involve an inventive step in view of document D8, considered as disclosing the nearest prior art. The only distinction consisting of the provision of stabilisation wedges is known from document D13. The claimed lens thus results from the obvious implementation in the lens of document D8 of the stabilisation technique disclosed in document D13.

The claimed soft contact lens is obvious also in view of document D13 considered alone, from which it is distinguished only by the localisation of the toric zone on the posterior surface rather than on the anterior surface as in document D13. Such toric zone can however as a matter of routine be provided on

either side of a lens, as indicated on page 19, lines 2 to 6 of document D13, and confirmed e.g. by the above-mentioned passage in column 3 of document D2.

Anyway, due to its flexibility, a soft contact lens will always configure to the shape of the eye of the wearer, so that whether its toric surface is on its anterior or posterior side can no longer be determined once it is in position on the eye.

The claimed soft contact lens therefore also provides an obvious alternative configuration of the lens disclosed in document D13, in respect of the location of the toric surface.

VI. These arguments were contested by the respondent who stressed in particular that the claimed soft contact lens comprised four closely interrelated technical features, namely a back toric surface juxtaposed to the centre of the lens, a peripheral area for fitting the lens to the eye of the wearer, the independency of the curvature of the back toric optic zone of the topography of said eye, and the stabilising wedges. The one-part form of the claim adequately reflected the interrelationship of these features.

According to an essential aspect of the invention, the back toric optic zone being configured independently of the topography of the eye of the wearer provided correction of the overall astigmatism of the eye, including the astigmatism of the external and internal corneal surfaces and of the eye lens. When adapted to the configuration of the eye, the back toric optic zone only provided for correction of the external corneal

astigmatism, whilst only the total astigmatism was measured by the optician. This problem was not addressed by any of the pieces of prior art on the file.

The stabilising wedges for their part compensated for any tendency of the lens to misalign in case the cylinder axes of the toric surface and of the cornea extended in angularly offset directions.

Document D8 in this respect disclosed a soft contact lens which as a result in particular of the broad radial extension of the toric zone in the horizontal direction wrapped around the cornea to match its shape so as to achieve maximum stability.

The soft contact lens disclosed in document D13 comprised a toric surface on its front side, so that it had no tendency to misalign. The front side for the toric surface was selected on purpose, to achieve a lens with a spherical back surface correlating with the geometry of the spherical lenses of the same manufacturer, so that the skilled person would certainly not have inverted the locations of the toric and spherical surfaces.

Document D13 also explicitly emphasised that stabilisation was achieved there by prism ballast rather than by eye wedge effects.

Reasons for the Decision

1. The appeal is admissible.

2. Compliance of the patent documents in accordance with the respondent's main request with the requirements of Article 123(2) and (3) EPC was not contested by the appellant, and the Board is satisfied that no objection arises in this respect.

3. The question of whether the feature of claim 1 of the respondent's main request, according to which the curvature of the back toric optic zone is configured with a refractive correction "independent of the topography of the eye of the wearer", actually limits the scope of the claim has given rise to considerable discussion both in the opposition and in the appeal procedures.

The description of the patent in this respect states that in the past, soft contact lenses had been designed according to the corneal shape to afford maximum stability, fit and comfort for the wearer such that there was an optimum relationship between the corneal and/or scleral profiles and the back surface of the contact lens. Designing contact lenses primarily by back surface comfort criteria had a number of attendent disadvantages which arose with the aim to gain close proximity between the lens and the corneal/sclera profile. The invention sought to overcome these disadvantages without compromising a close comfortable proximity between the lens and the eye of the wearer, the amount of refactive correction being independent of the topography of the eye (see page 2 of the specification, lines 6 to 10, 15 to 18 and 28 to 34).

Thus, the feature at issue as interpreted in compliance with the description to the effect that the topography

of the eye of the wearer is not taken into account in the designing or manufacturing of the soft lens, provides an essential technical limitation which in the Board's view cannot be simply left out of consideration when assessing the patentability of the claimed invention.

The Board in this respect is well aware of the fact that the above feature actually defines an aspect of a method for designing or manufacturing a soft contact lens, rather than a structural characteristic of a soft contact lens considered **per se**. This method feature was already recited in the device claim 1 as granted. Since possible non-compliance of the claim with the requirement of clarity set out in Article 84 EPC would not constitute a valid ground for opposition, the Board has no power to investigate this question. The claimed invention nonetheless comprises the feature, which shall be taken into account for the assessment of its patentability in view of the prior art available on the file, accordingly.

4. *Novelty of the subject-matter of claim 1 of the respondent's main request*

Document D2 discloses a soft contact lens having a flattened region to cooperate with eyelid movement of a user to dynamically stabilise the angular position of the lens on the cornea (see claim 1 in conjunction with Figures 1 to 4). The lens may be provided with an inner or an outer toric surface (see column 3, lines 40 to 47), but the shape of the posterior surface in case it comprises a back toric optic zone is not specified in the document. In respect of the correction of

astigmatism, the document states that usually a soft contact lens will adhere almost completely to the cornea thus transferring the existing astigmatism of the cornea to the front surface of the lens without correcting it. An exact correction can however be achieved by providing both a toric front surface and a toric inner surface (see column 3, lines 48 to 55).

Thus, document D2 in the Board's view fails to disclose the claimed arrangement of a back toric optic zone configured for at least some of the astigmatic correction and independently of the topography of the eye of a wearer, with a peripheral area located about said back toric optic zone for fitting the soft contact lens to the eye. In addition, stabilisation of the soft lens of document D2 is explicitly said there to be achieved by the cooperation of the flattened region with eyelid movement of a user. The document does not disclose that the edge at the junction of the flattened portion and the reminder of the lens in any way contributes to lens stabilisation. In contrast, in the claimed soft contact lens, stabilisation results from substantial interaction of the lid with wedges in the sense of peaks with a sharp increase in thickness for loading the pressure gradient of the upper lid during the blinking phase (see page 2, line 58 to page 3, line 4 of the specification in conjunction with the section illustrated in Figure 7).

Document D8 undisputedly discloses a soft contact lens having a concave posterior surface for fitting to the eye of a wearer, a convex anterior surface for exposure from the eye of a wearer, and stabilising means to impart rotational stability to the lens when in use,

the contact lens providing a correction with an astigmatic component for the eye, the posterior surface having a back toric optic zone configured for at least some of the correction of the eye of a wearer (see page 45, right-hand column, line 2 to page 46, left-hand column, line 13 and the drawing on page 45).

In this soft contact lens, the back toric optic zone in the Board's view is also "juxtaposed" to the central portion of the eye of the wearer when in use, with a peripheral area being located about the back toric optic zone for fitting the soft contact lens to the eye of the wearer (see paragraph 1 of the right-hand column of page 45: "Back (posterior) curve toricity, which is confined to the central optic zone only..." and the right-hand illustration on page 45 which shows a peripheral base curve designed for fitting the cornea as indicated on page 46, left-hand column, lines 15 to 22).

The respondent in this respect submitted that the claimed lens was distinguished from the one illustrated in the drawing on page 45 of document D8 in that the toric zone was confined to the central optic zone whilst in the known lens it substantially extended beyond that zone in the horizontal direction. However, the claim only requires the toric zone to be "juxtaposed to the central portion of the eye" the only further limitation being that some space be left about it for the peripheral fitting area. In addition, as correctly stressed by the appellant, the lateral extension of the toric zone will depend on its correction power. From the above-mentioned explicit requirement in document D8 that back curve toricity be

confined to the central optic zone only, it would anyway be clear to the skilled person that for low correction powers the lateral extension of the toric zone would be less than in the illustrated embodiment.

Document D8 also expressly stresses that the soft lenses disclosed there are available in all possible prescription combinations in three base curves only, of which one or two fit most normal corneas toricities and eccentricities (see page 46, left-hand column, lines 15 to 22 and the first paragraph of the right-hand column; and the second point of the summary of advantages in the right-hand column on page 51). The document also discloses that the incomplete flexure of the soft toric lens creates a slight minus tear power effect and that it partly masks some of the corneal toricity (see the second paragraph in the left-hand column on page 51). These indications, together with the fact that the only lens parameters evoked in the document are sphere powers, cylinder powers and cylinder axis, in the Board's view clearly demonstrate that the disclosed soft contact lenses, and in particular their toric optic zones, are not designed to exactly meet the topography of the eye of the wearer, so that they also anticipate the claimed feature of the back toric optic zone being configured with a refractive correction "independent of the topography of the eye of the wearer", within the meaning of this feature as discussed above under point 3 of this decision.

Stable orientation of the lens disclosed in document D8 is insured by two or more diopters of prism ballast (see page 45, right-hand column, lines 2 to 5 and page 46, left-hand column, point 3 of the first

paragraph). The back curve toricity is also said in the document to aid proper orientation by wrapping around the central cornea (see page 45, right-hand column, point 1).

Thus, the subject-matter of claim 1 is distinguished from the soft contact lens disclosed in document D8 in that its stabilising means comprises stabilising wedges on the anterior surface of the lens, the thickest portions of which being in the lower half of the lens so as to be located over the sclera when in position on the eye of the wearer whereby eyelid irritation during blinking of the eye of the wearer is minimised.

Document D13 discloses a soft contact lens which has its toric optic zone on the anterior surface, rather than on the posterior surface as is set out in claim 1. This can be deduced from the reference in point 2 of the centre column on page 19 to possible interaction of the lids with the toric surface, which can only occur if the toric surface is on the anterior surface, as was accepted by the appellant.

The lens is stabilised by prism ballast in the peripheral zone (see page 19, left-hand column, the first sentence of the last paragraph). Figure 1 on page 19 indeed shows symmetrically located main prism zones in the lower half of the anterior surface of the lens, but these would not in the Board's opinion form "stabilising wedges" within the meaning of claim 1. As a matter of fact there is no suggestion in the document that the prism ballast zones are sufficiently thick and sharp to cause stabilising interaction with the eyelid, and the section illustrated on the left side of

Figure 1 does not reveal any adequate stabilising wedge configuration either.

Thus, the subject-matter of claim 1 of the respondent's main request is distinguished from the soft lens disclosed in document D13 by both the back toric optic zone and the stabilizing wedges set out in the claim.

The other documents on the file do not come closer to the claimed invention.

The subject-matter of claim 1 of the respondent's main request therefore is considered to be novel within the meaning of Article 54 EPC.

5. *Inventive step*

5.1 The nearest prior art in the Board's opinion is constituted by the soft toric lens of document D8, which is the sole to comprise a back toric optic zone configured independently of the topography of the eye of the wearer, with the attendant difficulties in terms of its angular stabilisation, in particular when the cylinder axis of the toric zone, corresponding to a total astigmatism correction, is angularly offset from the axis of the corneal astigmatism.

5.2 Whilst in the soft contact lens of document D8 stabilisation is achieved by prism ballast and is aided by wrapping of the lens around the central cornea (see point 3 above), the claimed contact lens is provided with stabilising wedges as set out at the end of claim 1.

There is no evidence on the file, nor has it been alleged by any party, that the stabilising technique disclosed and praised in document D8 may not provide satisfaction. Thus, the technical problem underlying the claimed subject-matter, as objectively defined from a comparison with the nearest prior art, essentially consists in proposing an alternative technique for stabilising the lens.

5.3 A number of passages in document D8 stress the importance of reducing the thickness and weight of the lens and of minimising lens-lid interaction (see in particular the paragraph numbered 2 bridging pages 45 and 46 and the third and fourth points of the summary of the advantages in the right-hand column of page 51: "lens-lid interaction is minimised; the lid glides over the lens and surface without blunt obstruction" or "good quality of vision with minimal blink-related disruption of vision" or "comfortable edge design, minimal lid-eye interaction").

These repeated statements in the Board's view cannot be considered as an encouragement to provide stabilising wedges, i.e. thickened portions for substantial engagement with the lids. Moreover, such stabilising wedges are not disclosed in any of the available citations.

In particular the lens of document D13 comprises a spherical back surface, so that its stabilisation is easier than in cases where a toric back surface directly faces the cornea. The stabilising structures shown on Figure 1 of the document merely form prism ballasts in the peripheral zone (see page 19, left-hand

column, the first sentence of the last paragraph).

In respect of the appellant's lines of argumentation as starting from document D13, the Board agrees that the document states in its first paragraph that soft contact lenses may have a toric curve on either the front or back surface. This general statement indeed correctly summarises the state of the art, as is illustrated e.g. also by document D2 (see point 4 of the reasons above). The further description in D13 is however specifically directed to a lens with a front toric curve, which has been expressly designed to correlate with the spherical geometry of spherical lenses produced by the same manufacturer with the aim of achieving simpler and more reliable fitting and over-refractions (see page 19, left-hand column, lines 28 to 43). Accordingly, the Board cannot endorse the appellant's submission that a skilled person starting from the lens disclosed in document D13 would in an obvious way have contemplated inverting the sides of its toric and spherical surfaces. Anyway, such inversion would still have left him with the stabilising prism ballast structures disclosed in document D13, rather than with the claimed wedges which, for the above reasons, have not been made available to him by any of the cited pieces of prior art.

5.4 For these reasons, the subject-matter of claim 1 of the respondent's main request in the Board's view involves an inventive step within the meaning of Article 56 EPC.

6. The two-part form of claim 1 as granted was dropped by the respondent in the course of the opposition

procedure in favour of the one-part form now criticised by the appellant.

Rule 29(1) EPC only requires use of the two-part form "where appropriate", and the respondent in this respect submitted that his invention had to be considered as a whole, and that presenting it as an aggregation of features taken from different pieces of prior art would not properly reflect its actual nature.

The Board can give credit to the respondent's position. The fact also that the appellant based his novelty attack on document D2, and that, for his respective arguments on inventive step, he selected either the lens of document D8 or that of document D13 as the closest prior art, tends to confirm that there is no undisputable prior art embodiment from which the invention could be considered as a further development. Accordingly, and in view also of the fact that document D8, which the appellant considered should have been defined in the preamble of a two-part claim, is correctly summarised in the amended description, the two-part form of the claim recommended "were appropriate" by Rule 29(1) EPC is not considered mandatary in the present circumstances.

7. Thus, claim 1 of the respondent's main request meets the requirements of the Convention.

This equally applies to the dependent claims, by virtue **inter alia** of their appendency to claim 1, and to the remaining patent documents in accordance with the respondent's main request.

The respondent's auxiliary request need not therefore be considered further.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Beer E. Turrini