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Datasheet for the decision of 16 March 2017

Case Number: T 0015/15 - 3.2.08

Application Number: 10009191.7

Publication Number: 2263599

IPC: A61C7/00

Language of the proceedings: EN

Title of invention:
Method for fabricating a dental appliance

Patent Proprietor:
Align Technology, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56, 76(1), 123(2), 83, 84

Keyword:
Inventive step - (yes) - after amendment

Decisions cited:

Catchword:

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Case Number: T 0015/15 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 16 March 2017

Appellant: (Patent Proprietor)	Align Technology, Inc. 2560 Orchard Parkway San Jose, CA 95131 (US)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 December 2014 revoking European patent No. 2263599 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	P. Acton
Members:	C. Herberhold
	I. Beckedorf

Summary of Facts and Submissions

I. By decision posted on 11 December 2014 the Opposition Division revoked European patent No. EP-B-2 263 599 on the ground for opposition according to Article 100(a) EPC in combination with Article 56 EPC.

II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

III. By withdrawing their oppositions during the appeal proceedings, both opponents ceased to be party to the appeal proceedings.

IV. Oral proceedings before the Board of Appeal were held on 16 March 2017. For further information concerning these proceedings, in particular the issues discussed with the appellant as the only (remaining) party to the appeal proceedings, reference is made to the minutes of the oral proceedings.

V. At the end of the oral proceedings the appellant requested

that the decision under appeal be set aside and
that the patent be maintained in amended form on the basis of claims 1 and 2 according to auxiliary request IVb filed during the oral proceedings.

VI. Independent claim 1 of that request reads as follows:

"A method for fabricating a dental appliance (100), said method comprising:

obtaining an initial digital data set representing an initial tooth arrangement for a patient;

augmenting a tooth component of said initial digital data set with a root template;

providing a digital data set representing a modified tooth arrangement for a patient;

controlling a fabrication machine (322) based on the digital data set to produce a positive model of the modified tooth arrangement; and

producing the dental appliance (100) as a negative of the positive model,

wherein the producing step comprises molding the appliance (100) over the positive model using a pressure molding technique."

VII. The following documents played a role in the present decision:

D5: Three Dimensional Model Building in Computer Vision with Orthodontic Applications; TR-CVIP 96, Elsayed E. Hemayed, Sameh M. Yamany, Aly A. Farag, November 1996;

E6: Orthodontic and Orthopedic Treatment in the Mixed Dentition, J. A. McNamara, Jr., W. L. Brudon, Needham Press, Sixth Printing July 1996, p. 347-353;

E12: N. Kawahata et al., "Trial of duplication procedure for complete dentures by CAD/CAM", Journal of Oral Rehabilitation **24**; 540-548, July 1997;

E30: US 5,338,198;

E38: P. A. Ehrl, "3-D-Diagnostik in der Zahnmedizin - aktuell"; ZWP **4** (2009).

VIII. The essential arguments of the appellant can be summarised as follows:

Articles 100(c), 76(1) and 123(2) EPC

The amendments in claim 1 were based on page 28, last paragraph - page 29, first paragraph and on page 29, line 37 - page 30, line 2 of the original PCT application. Furthermore, paragraph [0045] of the patent specification had been brought into line with the disclosure in the original PCT application on the basis of the content of Figure 2 as filed.

Articles 83, 84 EPC

Claim 1 defined the further method step of "augmenting a tooth component of said initial digital data set with a root template". The person skilled in the art was well aware that the term "root template" referred to something which "looked like a root" and "was added in order to get a sort of a root". There were thus no difficulties in putting the claimed augmentation step into practice.

Consideration of document E30

Document E30 had been submitted late in the proceedings by an opponent who was no longer party to the appeal proceedings. The Board should therefore not take it into consideration.

Inventive step

The closest prior art was document E6, which disclosed a conventional method of producing dental appliances by obtaining and modifying a common plaster work model and producing the dental appliance based on the modified positive model using a pressure molding technique.

The subject-matter of claim 1 differed from that prior art in obtaining a digital data set, in augmenting a tooth component of said initial data set with a root template and in controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement. Subsequently, the pressure molding was performed not over a conventional positive model but over the positive model produced by the fabrication machine from the modified digital data set.

These differentiating features facilitated the fabrication of the orthodontic appliance, thus solving the problem of improving fabrication of dental appliances.

In the present context, the person skilled in the art was an orthodontist, who - for years - had been working with conventional plaster models. They were thus not aware of any potential benefits of using CAD/CAM techniques in orthodontics, nor was there any co-operation between the fields. Suggesting that the skilled person was a team comprising an orthodontist and a CAD/CAM specialist involved knowledge of the invention and thus hindsight. Even if computer-aided manufacture was actually an option, the person skilled in the art would not consider document E30, which only dealt with scanning, model building and treatment

planning, whilst remaining silent on any fabrication aspects. There was thus no hint to apply the teachings of E30 in the context of the fabrication method disclosed in E6. Furthermore, the person skilled in the art would be reluctant to lose the information available from the sensitive finger tips involved when dealing with a physical model and thus not consider using a digital model. These reasons sufficed to render the subject-matter of claim 1 inventive.

Additionally, there was no disclosure in the prior art of augmenting an initial digital data set with a root template. This feature addressed situations where the impacting of teeth below the gumline was a concern, and - by taking the tooth root into consideration - solved the problem of further improving the design of the appliance.

Therefore, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. Articles 100(c), 123(2) and 76(1) EPC

1.1 Description

1.1.1 The description of the patent as granted has been amended over the earliest parent application (WO-A-98/58596):

At the end of paragraph [0045] of the patent specification it is stated that "...a plurality of intermediate digital data sets (INTDDS's) are generated to correspond to successive intermediate tooth arrangements. The system of incremental position adjustment appliances can then be fabricated based on the INTDD's, as described in more detail below."

There is no basis for the underlined part of the sentence in the earliest parent application (see page 16, last paragraph), in which these lines of text are missing.

1.1.2 In the description of the present request, the underlined text has been replaced as follows:

"successive tooth arrangements from initial to final. Incremental position adjustment appliances are produced based on INTDD's and FDDS."

This wording finds a basis in Figure 2 of the earliest parent application and of all members of the divisional chain (see the two last boxes of the Figure), with the penultimate paragraph on page 16 of the earliest parent, as well as the corresponding passages of the

other earlier applications (EP 1 369 091, EP 1 929 974) and of the application documents of the present patent (page 14, second paragraph of the respective descriptions as filed) explicitly creating the link to Figure 2 ("Referring again to Figure 2 ...").

The content of the description of the present request thus does not extend beyond the content of the application or the earlier applications as filed.

1.2 Claims

1.2.1 The step relating to "augmenting a tooth component of the initial digital data set with a root template" finds a basis on page 28, last paragraph - page 29, first paragraph of the earliest parent application, as well as in the corresponding passages of the other earlier applications (EP 1 369 091, EP 1 929 974) and of the application documents of the present patent (page 24, penultimate paragraph of the respective descriptions as filed).

1.2.2 Furthermore, the feature according to which "the producing step comprises molding the appliance over the positive model using a pressure molding technique" finds a basis on page 29, line 37 - page 30, line 2 of the earliest parent application, as well as in the corresponding passages of the other earlier applications and of the application documents of the present patent (page 25, line 30 - line 33 of the respective descriptions as filed).

1.3 The requirements of Articles 123(2) and 76(1) EPC are thus fulfilled and the opposition ground under Article 100(c) EPC does not prejudice the maintenance of the patent on the basis of the present request.

2. Articles 84 and 83 EPC

2.1 Claim 1 comprises the step of "augmenting a tooth component of the initial digital data set with a root template". The wording as such is considered clear: as argued by the appellant, the "root template" is no more than a - possibly quite abstract - representation of the root, i.e. something which "looks like the root" or is "sort of a root" and which is to be included in a tooth component of the digital model. Hence, the claim complies with the requirements of Article 84 EPC.

2.2 In view of the availability of commercial and customised solid modelling software packages before the filing date of the present patent, which also allowed for customised model segmentation (see e.g. E30, column 6, line 65 - column 7, line 10), the person skilled in the art was well capable of including such a root template in the tooth component of a digital data set. Moreover, digitisation of X-ray images - at least by manual segmentation of particular structures of interest - and subsequent model building was known to the skilled person. It may be that use of 3D diagnostics had not been established in daily dental/ orthodontic practice, as suggested by E38. This does not however imply that the skilled person was not able to carry out the invention.

Therefore, the requirements of Articles 83 EPC are fulfilled as well.

3. Consideration of document E30

The Board decided to take document E30 into consideration because of its *prima facie* relevance, and discussed this document with the appellant.

4. Inventive step

4.1 Document E6 uncontestedly represents the closest prior art. It discloses:

A method for fabricating a dental appliance, said method comprising:

producing a positive model of a modified tooth arrangement for a patient (E6, page 350, 351: "Minor Tooth Repositioning on Work Models") and

producing the dental appliance as a negative of the positive model,

wherein the producing step comprises molding the appliance over the positive model using a pressure molding technique (E6, page 351, 352: "Application of Acrylic" using Biostar pressure molding equipment).

4.2 The subject-matter of claim 1 differs from that prior art in the following method steps:

- obtaining an initial digital data set representing an initial tooth arrangement for a patient;

- augmenting a tooth component of said initial digital data set with a root template;

- providing a digital data set representing a modified tooth arrangement for a patient;

- controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement.

4.3 The technical effect of these differences is a transfer of model building and modification from the conventional plaster model realm into the "digital world", thus dispensing with the traditional study casts and their respective problems. By taking into account the tooth root, the claimed method further enhances the modelling capabilities. Hence, as submitted by the appellant, the invention solves the problem of improving the fabrication of dental appliances.

4.4 The skilled person

In the early nineties, use of computers in planning and manufacturing was spreading into basically every industry and field of technology. As evidenced by e.g. E30, column 2, line 64-68 or E12, page 540, first paragraph of the introduction, the field of dentistry and orthodontics was no exception. Thus, also the specialist in the field of dentistry and orthodontics was aware of the new technology and its potential for improved quality and cost efficiency.

In such a situation, where a new technology is about to spread into a traditional field, it is common practice to group people from both technical fields into a development team. The Board is thus of the opinion that the skilled person in the present case consists of a team of an orthodontist and an expert in CAD/CAM

technology. This conclusion is drawn from the situation in the field before the filing/priority date, without considering any specific invention. There is thus no element of hindsight involved.

4.5 In order to improve fabrication of dental appliances the "skilled person" defined above would consider document E30, which is from the field of dental modelling and explicitly addresses numerous problems with the traditional study casts as used in the closest prior art (E30, column 2, line 41-46 and 54-57). Indeed, overcoming these various problems at least balances out, if not outweighs, the alleged disadvantage of losing the tactile information available when using a physical model.

4.6 E30 suggests creating a digital data set representing an initial tooth arrangement for a patient (column 5, line 26 - column 6, line 59), in which changes in location or orientation of any tooth may be simulated (column 7, line 30-34), thus providing a digital data set representing a modified tooth arrangement for the patient. By simulating the effects of extracting specific teeth and realignment of the remainder of the arch, specific orthodontic appliance design is facilitated (column 9, l. 1-5).

Contrary to the appellant's belief, E30 is also not silent on the further use of 3D models in manufacturing. By overcoming problems in data acquisition, i.e. by overcoming the "principal deficiency of current CAD/CAM dental application" (column 3, line 3-7), the document aims at the application of CAD/CAM - and thus of computer-aided manufacturing - in dental applications, CAD/CAM technologies being explicitly acknowledged to have

"significant potential for improved quality and cost efficiency when applied to dentistry" (column 2, lines 64-68).

It is true that E30 does not give specific details about the application of the dental modelling simulator to dental appliance fabrication. However, the skilled person as defined above is aware of existing CAM techniques capable of transferring 3D digital models into corresponding physical objects (including the fabrication of complete dentures, see e.g. E12). They would thus immediately recognise that a corresponding physical object fabricated from the digital data set representing a modified tooth arrangement (as obtained by use of the E30 modelling simulator) is equivalent to the modified tooth arrangement for a patient obtained using the conventional method (as described in E6).

Combining the teachings of E6 and E30, the skilled person would thus arrive in an obvious way at a method comprising the following further steps:

- obtaining an initial digital data set representing an initial tooth arrangement for a patient;

- providing a digital data set representing a modified tooth arrangement for a patient;

- controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement.

4.7 However, claim 1 defines the further step of "augmenting a tooth component of said initial digital data set with a root template". None of the documents

on file discloses such a tooth model "augmented with a root template".

Moreover, the augmentation of a tooth component of the initial data set with a root template is only possible once the transfer of model building and modification into the digital world has been considered. The feature thus does not solve an independent partial problem with which the skilled person starting from prior art E6 was confronted, but comes into play once the conventional method has already been developed further by taking into account the teaching of E30 and the knowledge of the skilled person as discussed above.

Therefore, the Board comes to the conclusion that the subject-matter of claim 1 involves an inventive step.

4.8 It is noted that the teaching of document D5 does not exceed what has been acknowledged as having been made obvious by E30 in combination with the common general knowledge of the skilled person (see points 4.4 - 4.6 above). It can thus remain open whether or not the document was publicly available at the relevant date (be it the date of filing of the application or of the second priority document).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the following documents:

Claims:
Claims 1 and 2 according to auxiliary request IVb filed during the oral proceedings

Description:
Pages 1 to 27 of the "Druckexemplar" with handwritten amendments as filed during the oral proceedings

Figures:
1a to 11 of the patent as granted.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated