

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ERNEST BEUTLER, RICHARD BRUCE,
SCOTT A. ELROD, JOHN STUART FITCH, HUANGPIN BEN HSIEH
ERIC PEETERS and RICHARD A. LERNER

Appeal No. 2006-0227
Application No. 10/121,264

ON BRIEF

Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a device comprising genomic DNA. The examiner has rejected the claims as anticipated by or obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 134. Because we agree with the examiner that the claims are broad enough to read on devices in the prior art, we affirm.

Discussion

1. Claim construction

Claims 23-28, 31-34, and 40 are on appeal. Claims 14-22 and 35-39 are also pending but have been withdrawn from consideration by the examiner.

The claims subject to each rejection stand or fall together, because Appellants have not argued them separately. See 37 CFR § 41.37(c)(1)(vii). Claims 23, 24, and 40 are representative and read as follows:

23. A device comprising
 - a) a substrate comprising
 - 1) a matrix;
 - 2) one or more separate transfer agent spaces; and
 - 3) one or more transfer agent layers contained in one or more of the separate transfer agent spaces; and
 - b) genetic material deposited on or in one or more of the transfer agent layers, wherein the genetic material on each of a majority of the transfer agent layers comprises purified genomic DNA comprising more than one chromosome of the genomic DNA from at least one cell of an individual within a defined population.
24. The substrate of claim 23, wherein at least one of the transfer agent layers comprises a saccharide selected from at least one of sucrose and glucose.
40. A device comprising:
 - a) a substrate;
 - b) a transfer agent layer; and
 - c) a first genetic material position and a second genetic material position on or in the transfer agent layer that each comprise genetic material, wherein the genetic material of the first genetic material position comprises purified genomic DNA comprising more than one chromosome of the genomic DNA from at least one cell of an individual within a defined population and the genetic material of the second genetic material position comprises purified genomic DNA comprising more than one chromosome of the genomic DNA from at least one cell of an individual within a defined population, and wherein the genetic material of the first genetic material position is separate from the genetic material of the second genetic material position.

“[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

The specification expressly defines most of the terms of the claims:

- a “substrate” is defined as “an object onto which genetic material may be deposited” (specification, page 16);
- a “matrix” is defined as “a material that includes transfer agent spaces” (id., page 14);
- a “transfer agent space” is defined as “a region capable of containing at least one transfer agent” (id.);
- a “transfer agent” is defined as “a substance onto or into which genetic material may be deposited, which can transport the genetic material when the transfer agent is moved” (id., page 13);
- a “transfer agent layer” is defined as “a layer comprising a transfer agent” (id.);
- “purified” is defined as “substantially separated from at least one other material with which it had been intermingled” (id., page 16);
- an “individual” is defined to include “vertebrate, invertebrate, plant, and prokaryotic sources” (id., page 19); and
- a “defined population” is defined as “any group of individuals . . . In certain embodiments, a defined population may include a random group of individuals that may or may not share at least one common characteristic” (id., page 11).

Thus, when we interpret claim 23 in light of the definitions in the specification, we conclude that it is directed to a device comprising “an object onto which genetic material may be deposited,” that object comprising “a material that includes” “a region capable of

containing” “a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved,” where the region also contains a “layer comprising” “a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved.”

In addition, the layer comprising a substance that can transport the genetic material when the substance is moved has deposited on or in it genomic DNA comprising more than one chromosome from a “vertebrate, invertebrate, plant, and prokaryotic” individual that belongs to “any group of individuals.”

When we give the terms of claim 23 their broadest reasonable interpretation consistent with the definitions in the specification, we interpret claim 23 to be directed to a device comprising an object that includes a region having a layer of a substance that can transport genetic material when the substance is moved, and that has deposited on or in it at least two chromosomes from the genomic DNA of any organism.

Claim 24 is directed to the same device, wherein the layer of a substance that can transport genetic material when the substance is moved comprises “a saccharide selected from at least one of sucrose and glucose.” (Although the preamble of claim 24 recites the “substrate of claim 23,” we interpret the claim as being directed to the device defined by claim 23; a dependent claim must incorporate all of the limitations of the claim from which it depends. 35 U.S.C. § 112, fourth paragraph.)

Claim 40 is directed to a device comprising “an object onto which genetic material may be deposited,” and a “layer comprising” “a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved,” where the layer comprises two separate positions at which there

is deposited genomic DNA comprising more than one chromosome from a “vertebrate, invertebrate, plant, and prokaryotic” individual that belongs to “any group of individuals.”

When we give claim 40 its broadest reasonable interpretation consistent with the specification, we interpret it to be directed to a device comprising an object onto which genetic material can be deposited and a layer of a substance that can transport genetic material when the substance is moved, where the layer has deposited on or in it, at two separate positions, at least two chromosomes from the genomic DNA of any organism.

2. Anticipation

The examiner rejected claim 40 under 35 U.S.C. § 102(b) as anticipated by Chu.¹ (Since the present application was filed in 2002 and Chu issued in 2004, the examiner’s citation of 35 U.S.C. § 102(b) appears to be a mistake. However, the application that issued as the Chu patent was filed in 1998, so Chu appears to qualify as prior art under 35 U.S.C. § 102(e). Appellants have not disputed that Chu is prior art.)

The examiner reasoned that

Chu discloses a device comprising a substrate (tray)[,] a transfer agent layer (slide) and a first genetic material position and a second genetic material position . . . comprising more than one chromosome from at least one individual within a defined population (chromosome spread whereby the chromosomes are removed from the cells[;] i.e.[,] purified) and wherein the first material position is separate from the second material position (i.e.[,] different wells) (Column 32, line 35-Column 34, line 14).

Examiner’s Answer, pages 5-6.

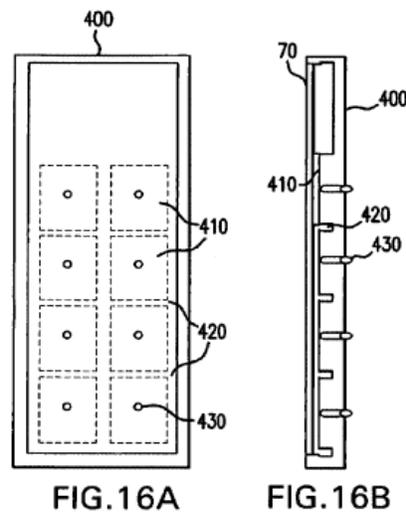
We agree with the examiner that Chu’s Example 9 anticipates instant claim 40. Chu states that “[c]hromosomes can be examined for gross abnormalities such as

¹ Chu, U.S. Patent 6,703,247, issued March 9, 2004 (application filed Dec. 23, 1998).

translocations by a technique known as whole chromosome painting.” Col. 32, lines 37-39. Chu states that the method typically involves staining multiple chromosomes at a time, with dyes that fluoresce in different colors: “For example, chromosomes 1, 2 and 3 can be stained simultaneously by using probes which fluoresce orange for one chromosome, probes which fluoresce green for a second chromosome, and probes which fluoresce red for a third chromosome.” Col. 32, lines 47-51.

Since human cells have a total of 24 chromosomes, “one test would typically use 8 slides of cells to examine the complete nuclear genome of a human. This test would include . . . placing the 8 slides onto 8 wells of a tray.” Col. 32, lines 52-54. That is, the same three (orange, green, and red) labels would be attached to different probes and used to label three different chromosomes on each slide, allowing all twenty-four chromosomes to be examined using eight slides.

Chu discloses an apparatus designed to allow all twenty-four chromosomes to be examined on a single slide. Chu’s Figure 16A and Figure 16B are reproduced below:



As described by Chu, these figures show:

A chip or tray **400** designed to allow the analysis of all 24 chromosomes on a single slide **70** The tray **400** is one which can snap on to or otherwise be attached to a microscope slide **70**. The chip or tray **400** contains 8 wells **410** with each well **410** separated from neighboring wells **410** by a gap or a trough **420**. Such a tray **400** is illustrated in FIG. 16A.

Col. 32, lines 57-63. "FIG. 16B is a side view of the 8 well tray **400** shown in FIG. 16A."

Col. 10, lines 14-15. "In a preferred embodiment, the probes are predried onto the 8 wells **410** of the tray **400** with probes for 3 different chromosomes in each well **410**. . . .

Metaphase or interphase cells are fixed across a slide **70** and the slide **70** is placed in contact with the tray **400**. Then buffer is added to the openings **430** to each well **410**."

Col. 33, lines 18-24.

Chu also describes a "more preferred embodiment [in which] the slide **70** includes positive and negative controls in the regions **440** which are those which are in contact with the hybridization fluid in each of the 8 wells **410**. Using microarray technology . . . , nucleic acids which are complementary to the probes being used to paint the chromosomes are coated and immobilized onto the slide **70** One example of an array is shown in FIG. 16E in which all 24 nucleic acids are arrayed around the edges of each region **440** which will contact each of the 8 wells **410**." Col. 33, lines 46-60.

Chu's Figure 16E is reproduced below:

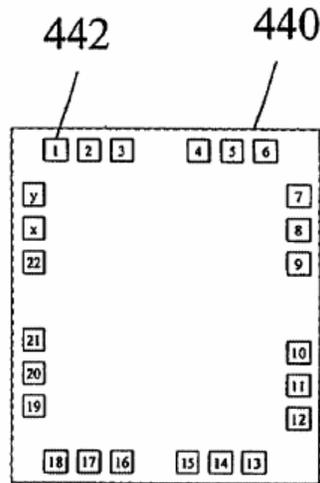


Figure 16 E

The figure shows one of the regions **440** having twenty-four smaller regions around its perimeter; the smaller regions are labeled with the numbers 1 through 22, x, and y, corresponding to the twenty-four chromosomes in the human genome. Chu describes the function of the smaller regions as follows: "If[,] for example, a first region **440** is one which will contact a well **410** containing probes for chromosomes 1, 2 and 3, then the control nucleic acids for these chromosomes should light up after staining (each showing only a single color) while the remaining 21 controls should not hybridize and should not fluoresce. In this manner there are both positive and negative controls and labels for each of the 8 wells **410**." Col. 33, lines 60-67.

Thus, as we interpret the reference disclosure, Chu teaches a microscope slide to allow chromosome painting of all twenty-four human chromosomes on a single slide. In a preferred embodiment, each of eight regions on the slide has samples of each of the twenty-four human chromosomes (1-22, X, and Y) arrayed around its edge; the

chromosomes serve as positive and negative controls for hybridization of the chromosome-specific probes to the target chromosomes in the sample.

We agree with the examiner that Chu's disclosure anticipates claim 40. The device disclosed by Chu comprises a substrate (i.e., "an object onto which genetic material may be deposited"). Specifically, Chu teaches that the eight wells of the tray can have probes predried in them (col. 33, lines 18-20). Thus, the tray is an object into which genetic material may be deposited – a substrate.

Chu's device also comprises a transfer agent layer (i.e., a "layer comprising" "a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved"). Specifically, Chu teaches a microscope slide having samples of all twenty-four human chromosomes immobilized at each of eight regions. The chromosomes would be transported when the microscope slide is moved. Thus, the microscope slide meets the definition of a transfer agent layer.

Finally, Chu teaches that the microscope slide (transfer agent layer) has all twenty-four human chromosomes immobilized on it at each of eight separate locations. Thus, the microscope slide comprises eight genetic material positions, each of them comprising more than one chromosome of genomic DNA. Genomic DNA by definition comes from a cell, and all cells are ultimately derived from an individual. According to the specification, a "defined population" is any group of individuals; thus, all individuals belong to some defined population.

Claim 40, in its broadest reasonable interpretation, reads on the device disclosed by Chu. Therefore, claim 40 is anticipated by Chu.

Appellants argue that Chu's microscope slide is not a transfer agent layer:

At best, the slide is a substrate. In fact, Appellants' specification defines the term "substrate" as "an object onto which genetic material may be deposited. . . . [I]n certain embodiments, the substrate may be, but is not limited to, a multiwell plate, a glass slide, a filter membrane. . . ." Specification at page 16, paragraph [047] (emphasis added). Therefore, the slide of Chu does not serve as a transfer agent layer.

Appeal Brief, page 22 (emphasis and alterations in original).

We disagree with Appellants' proposed claim construction. The specification defines a "transfer agent layer" as a "layer comprising" "a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved." A microscope slide is a layer of glass, and glass is a substance onto which genetic material may be deposited, which can transport the genetic material when the glass is moved. Therefore, a microscope slide is a "transfer agent layer" when that term is given its broadest reasonable interpretation consistent with the specification. While it is true, as Appellants argue, that the specification states that a glass slide can be a substrate in certain embodiments (Appeal Brief, page 22), that does not mean that a microscope slide cannot also be a transfer agent layer in other embodiments.

Appellants also argue that "the tray of Chu is not a substrate. . . . The specification defines a substrate as 'an object onto which genetic material may be deposited. . . . The genetic material of Chu is . . . always directly adhered to the slide, and is never deposited onto the tray. Thus, the tray of Chu is not a substrate as defined by Appellants' specification." Appeal Brief, page 23 (emphasis in original).

We also disagree with this proposed interpretation of the claim. As Appellants note, the specification defines a substrate as “an object onto which genetic material may be deposited.” Chu states that probes (genetic material) can be predried on the wells of the tray. See col. 33, lines 18-20: “In a preferred embodiment, the probes are predried onto the 8 wells **410** of the tray **400** with probes for 3 different chromosomes in each well **410.**” Thus, the tray is an object onto which genetic material may be deposited, and the tray meets the specification’s definition of a substrate.

We affirm the rejection of claim 40 as anticipated by Chu. The examiner also rejected claim 40 under 35 U.S.C. § 102(b) as anticipated by Kausch.² However, since we have already found that the claim is anticipated by Chu, we need not consider whether it is also anticipated by Kausch.

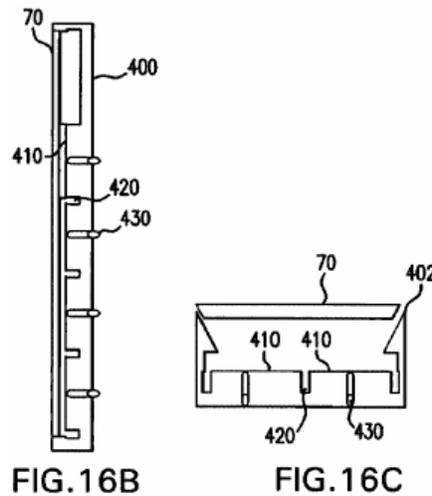
3. Obviousness based on Chu and Sabatini

The examiner rejected claims 23, 25-28, and 31-34 under 35 U.S.C. § 103 as obvious in view of Chu and Sabatini.³ We agree with the examiner that claim 23 is unpatentable in view of the cited references. In fact, we find that Chu anticipates claim 23.

Given its broadest reasonable interpretation, claim 23 is directed to a device comprising an object that includes a region having a layer of a substance that can transport genetic material when the substance is moved, and that has deposited on it or in it at least two chromosomes. Such a device is shown in Chu’s Figures 16B and 16C:

² Kausch et al., U.S. Patent 5,665,582, issued September 9, 1997.

³ Sabatini, U.S. Patent 6,544,790, issued April 8, 2003 (application filed Sept. 18, 2000).



Chu describes the figures as follows:

FIG. 16B is a side view of the 8 well tray **400** shown in FIG. 16A. A slide **70** is shown on the tray **400**. . . . FIG. 16C is an end-on view of the slide and tray of FIGS. 16A and 16B. . . . Slide **70** is shown resting above sides of tray **400** showing optional clips **402** to hold slide **70** to tray **400**.

Col. 10, lines 14-22.

As discussed above with respect to claim 40, Chu's microscope slide meets the instant specification's definition of a transfer agent layer that has deposited on it at least two chromosomes. Supra, pages 9-10. The device disclosed by Chu also comprises a transfer agent space; i.e., "a region capable of containing" "a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved." Such a space is shown in Chu's Figure 16C: the space between the two clips **402** is a region capable of containing a microscope slide, which is a substance onto which genetic material can be deposited, which can transport the genetic material when the slide is moved. Thus, Chu's device comprises a transfer agent space.

The device also comprises a matrix; i.e., “a material that includes transfer agent spaces.” The tray onto which the microscope slide is fitted includes transfer agent spaces, and therefore the tray (or more properly, perhaps, the material the tray is made of) meets the definition of a matrix.

Finally, the device comprises a substrate that comprises all of the above elements. The specification defines a substrate as “an object onto which genetic material may be deposited.” The assembled device shown in Chu’s Figure 16B includes all of the above elements and can have genetic material deposited on it (specifically, probes can be deposited on the tray part of the device and chromosomal DNA controls can be deposited on the microscope slide; see Chu at col. 33, lines 18-20 and lines 46-67).

As with the rejection of claim 40, Appellants argue that Chu’s slide is not a transfer agent layer as defined in the instant specification. See the Appeal Brief, page 26. We have already addressed this argument. Supra, page 10.

We find that Chu discloses a device meeting all the limitations of claim 23. We therefore affirm the examiner’s rejection based on obviousness in view of Chu and Sabatini: “[A]nticipation is the epitome of obviousness.” Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Appellants have not separately argued claims 25-28 and 31-34. Therefore, those claims fall with claim 23. See 37 CFR § 41.37(c)(1)(vii).

We affirm the rejection of claims 23, 25-28, and 31-34 under 35 U.S.C. § 103 as obvious in view of Chu and Sabatini. Our reasoning, however, differs from that of the examiner. Therefore, we will designate our affirmance a new ground of rejection in

order to give Appellants a fair opportunity to respond. See In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976).

4. Obviousness based on Chu, Sabatini, and Kausch

The examiner also rejected claim 24 under 35 U.S.C. § 103 as obvious in view of Chu, Sabatini, and Kausch. We will affirm this rejection as well, although our reasoning differs from that of the examiner.

Claim 24 depends on claim 23 and adds the limitation that the transfer agent layer comprises either sucrose or glucose. Thus, claim 24 is directed to a device comprising an object that includes a region having a layer of a substance (comprising either sucrose or glucose) that can transport genetic material when the substance is moved, and that has deposited on it or in it at least two chromosomes.

Kausch discloses such a device in Example 1C (Chromosome Preparation):

[T]he microcentrifugation chambers were set up. The transparent cap of a 15 ml Falcon tube was filled with 1M sucrose at a pH of about 8.5 to a depth of about 1 cm. The coverslip was dipped in the sucrose with the prefixed side up and should rest on the raised central portion of the chamber. There should be a few mm of sucrose above the coverslip. . . .

Cells were lysed in about 1% Nonidet P-40 (a detergent). . . . The lysate was layered over the sucrose cushion in the chamber, and centrifuged.

Column 26, line 62, to column 27, line 9.

The device described by Kausch meets all the limitations of claim 24. The 1M sucrose solution forms a pool that meets the specification's definition of a "transfer agent layer," since it is a layer of "a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved." For example, if the 1M sucrose with chromosomal DNA layered on it were poured into a

different container or taken up in a pipette, it would transport the chromosomal DNA along with it.

The upturned Falcon tube cap meets the specification's definition of a substrate ("an object onto which genetic material may be deposited") that comprises a matrix ("a material that includes transfer agent spaces"; specifically, the plastic that the cap is made of) and a transfer agent space ("a region capable of containing at least one transfer agent"; specifically, the concave area inside the upturned cap, which is capable of containing the sucrose solution). Thus, claim 24 reads on the microcentrifugation chamber disclosed by Kausch.

Appellants argue that "the sucrose in Kausch that the Examiner alleges is a transfer agent layer does not meet the definition of a transfer agent layer presented in Appellants' specification. Kausch uses sucrose as a physical cushion for a coverslip, to prevent the coverslip from breaking during centrifugation. The sucrose itself never moves independent of the coverslip, and does not transport genetic material anywhere." Appeal Brief, page 28.

We disagree with Appellants' interpretation of the claim. The specification defines a transfer agent layer as a layer comprising "a substance onto or into which genetic material may be deposited, which can transport the genetic material when the [substance] is moved." Specification, page 13. A solution of 1M sucrose (or any other liquid, for that matter) is capable of having genetic material deposited into it, and of transporting the genetic material when the solution is moved. Thus, a one centimeter deep layer of 1M sucrose meets the specification's definition of a transfer agent layer. The fact that the solution was not actually used to transport chromosomes from one

place to another is immaterial – the specification's definition merely requires that the transfer agent be capable of transporting genetic material, not that it actually be used to do so.

We affirm the rejection of claim 24 as obvious in view of Chu, Sabatini, and Kausch. Since our reasoning again differs from that of the examiner, however, we designate our affirmance a new ground of rejection in order to give Appellants a fair opportunity to respond.

Summary

We affirm the rejection of claim 40 as anticipated by Chu. We also affirm the rejections based on obviousness but we designate those affirmances as new grounds of rejection because our reasoning differs from that of the examiner.

Time Period for Response

Regarding the affirmed rejection, 37 CFR § 41.52(a)(1) provides "[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options

with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

AFFIRMED, 37 CFR § 41.50(b)

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)
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