

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

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### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte ARTHUR SCHLEIFER and  
MAGDALENA OSTROWSKI

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Appeal No. 2006-0103  
Application No. 10/172,892

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ON BRIEF

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Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.  
GRIMES, Administrative Patent Judge.

#### DECISION ON APPEAL

This appeal involves claims to a method of performing an array hybridization experiment, which the examiner has rejected as anticipated. We have jurisdiction under 35 U.S.C. § 134. Because we find that the claimed method is not distinguished from the prior art by the “form-in-place gasket” limitation, we affirm.

#### Background

“Biomolecular arrays (such as DNA or RNA arrays) are known and are used, for example, as diagnostic or screening tools.” Specification, page 1, lines 13-14. “In use, the surface of the array is contacted with a solution containing the sample. . . . Samples tend

to be expensive, precious, or limited to very small quantities. Therefore, current methods seek to reduce the amount of sample required by reducing the amount of sample solution needed to contact the array.” Page 1, line 30 to page 2, line 2.

One such technique is “to place a gasket between the array surface and a mating opposite surface and clamp with an external force. The distance between the two surfaces is typically between 0.5mm and 1.0 mm. . . . The problem with these types of chambers is the large volume of liquid sample required to fill the volume between the two surfaces while covering the array area.” Page 2, lines 24-34.

The specification discloses “a method of performing a hybridization assay using an assay chamber that includes a form-in-place gasket.” Page 5, lines 22-23. “A form-in-place gasket . . . refers to a gasket which is formed on a gasket surface in a process that involves depositing a gasket material onto the gasket surface.” Page 8, lines 1-3. “Gasket material references a fluid material having properties that render the fluid material suitable for formation of a gasket.” Page 8, lines 9-10. “Suitable gasket materials include, e.g. silicone sealants, urethanes, and polysulfides. Still other suitable gasket materials are, e.g. latex, and acrylic sealants.” Page 16, lines 15-16. “After the gasket material is deposited in the predetermined configuration at the desired site, the gasket material is allowed to cure to form the form-in-place gasket.” Page 17, lines 25-27.

### Discussion

#### 1. Claim construction

Claims 1-17 are pending. Appellants have argued claims 1, 10, and 17 separately. See Appeal Brief, pages 5-50. We will therefore consider claims 1, 10, and

17 as representative; claims 2-9 and 11-16 will stand or fall with claim 1. Claims 1, 10, and 17 reads as follows:

1. A method of performing an array hybridization experiment comprising:

contacting a target solution with an array disposed in an assay chamber, wherein the assay chamber is substantially defined by a substrate, a cover, and a form-in-place gasket, the form-in-place gasket positioned between the substrate and the cover, wherein the contacting is done under conditions and for a period of time sufficient to allow specific binding interactions between the target solution and the array, and

Interrogating the array.

10. The method of claim 1, wherein contacting comprises depositing the target solution into a well defined at least in part by one of the substrate or the cover and placing the other one of the substrate or cover over the well with the form-in-place gasket positioned between the substrate and the cover such that a fluid tight seal is formed by the form-in-place gasket positioned between the substrate and the cover.
17. A method of performing an array hybridization experiment comprising:

contacting a target solution with an array disposed in an assay chamber, wherein the contacting is done under conditions and for a period of time sufficient to allow specific binding interactions between the target solution and the array, wherein the assay chamber is substantially defined by a substrate, a cover, and a form-in-place gasket, the form-in-place gasket positioned between the substrate and the cover, wherein the form-in-place gasket comprises a gasket formed by a process comprising depositing a fluid gasket material on a one or more of the substrate and the cover and curing the fluid gasket material,

the method of performing an array hybridization experiment further comprising:

interrogating the array.

Thus, claim 1 is directed to a method of performing an array hybridization experiment using an assay chamber comprising a substrate and a cover, separated by a

“form-in-place gasket.” As defined by the specification (page 8), a form-in-place gasket is one that is formed by depositing a fluid gasket material on a surface and allowing the gasket material to cure (pages 17-18).

Claim 10 adds the limitation that the target solution is placed into a well on either the substrate or cover, and then the other plate is placed over the well to form the assay chamber.

Claim 17 is similar to claim 1 but adds the express product-by-process limitation that “the form-in-place gasket [is] formed by a process comprising depositing a fluid gasket material on one or more of the substrate and the cover and curing the fluid gasket material.”

## 2. Anticipation by Chen

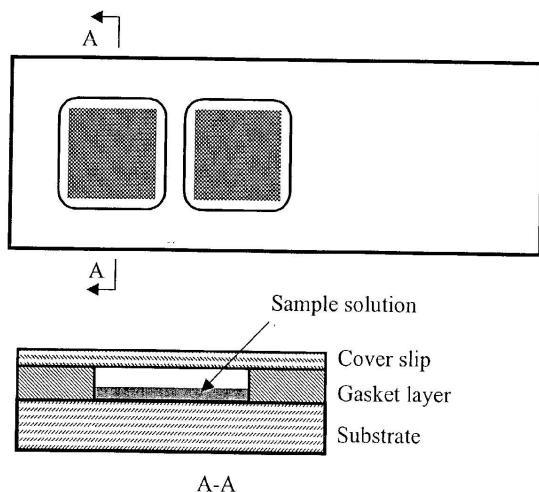
The examiner rejected claims 1-13, 16, and 17 under 35 U.S.C. § 102(e) as anticipated by Chen.<sup>1</sup> Chen discloses a “hybridization assembly compris[ing] a reaction chamber (or hybridization chamber) to confine and allow interaction or binding of a target liquid to an array of probes deposited on an inner surface of the reaction chamber. The hybridization assembly may comprise a substrate slide, a gasket layer and/or a middle slide, and a cover slip.” Page 1, paragraph [0156]. Chen teaches that the “gasket layer may be attached to the surface of the middle slide that contacts the substrate to serve as a seal. . . . This gasket layer should ideally be made of softer and hydrophobic material such as silicone rubber, polytetrafluoroethylene, Teflon<sup>®</sup>, or polydimethylsiloxane

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<sup>1</sup> Chen et al., U.S. Publication No. 2003/0087292, published May 8, 2003 (application filed Oct. 4, 2002 and claiming priority to Oct. 4, 2001). The examiner also rejected claims 1-13, 16, and 17 as anticipated by Sandstrom (U.S. Patent 6,545,758, issued April 8, 2003 on an application filed Oct. 5, 2000). Since we conclude that these claims are anticipated by Chen, we need not reach the rejection based on Sandstrom.

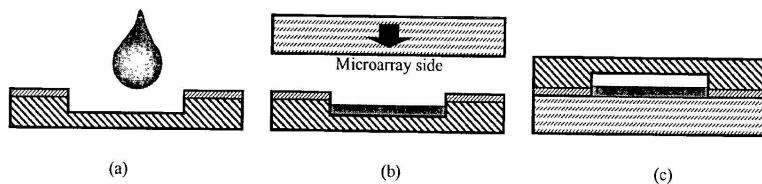
(PDMS). The method of attachment can be lamination, injection molding[,] gluing or any other means, or the gasket layer can be held in place by the clamping force.” Page 11, paragraph [0158].

Chen’s Figure 18 is reproduced below:



The figure shows an “embodiment [in which] the cover slip can be flat and have a thick gasket layer bonded to the bottom surface. The gasket layer has openings which form the wells.” Page 11, paragraph [0162].

Chen’s Figure 19 is reproduced below:



The figure is said to show how, “[i]n various embodiments, during hybridization, the cover slip is placed upside down and such that the wells face up. . . . Sample or target liquid is added to the wells (FIG. 19a). Then the microarray substrate slide is placed upside

down on the cover slip, i.e. the surface having the microarray probes deposited thereon faces the cover slip. The cover slip and the substrate slide can be pressed tightly against each other to squeeze out the air bubbles from the interface between the slide and the gasket (FIG. 19b). Before hybridization, the entire assembly is inverted to position the microarray substrate underneath the cover, thereby allowing the target fluid to contact the array of probes, as shown in FIG. 19c.” Page 11, paragraph [0163].

Chen does not describe the disclosed gasket as one that is formed from a liquid material deposited on a surface and allowed to cure, which is Appellants’ definition of a form-in-place gasket. However, “[t]he patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).

“Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.” In re Marosi, 710 F.2d 799, 803, 218 USPQ 289, 292-93 (Fed. Cir. 1983). The product-by-process limitation of the instant claims does not appear to distinguish the apparatus used in the claimed process from that used in the prior art. We therefore agree with the examiner that the method disclosed by Chen meets all the limitations of claims 1, 10, and 17.

Appellants argue that the claim language “defines the structure of the ‘form-in-place gasket’ relative to the other features of the assay chamber. It should also be noted that the inherent meaning of the words of the limitation ‘form-in-place gasket’ . . . define the dimensions of the gasket as a gasket that is formed where the gasket material is placed. In addition, the ‘form-in-place gasket’ is formed on a surface and a fluid tight seal is formed upon curing . . . of the gasket material. The ‘form-in-place gasket’ includes an additional inherent physical characteristic that the prior art does not include.”

Appeal Brief, pages 22-23.

We do not find this argument persuasive. It is true that the claims define the form-in-place gasket as located between the substrate and the cover, but that limitation is met by Chen. Chen also discloses a gasket “that is formed where the gasket material is placed” and that forms a fluid-tight seal. See, e.g., page 11, paragraph [0158] (the “gasket layer may be attached . . . [by] lamination, injection molding[,] gluing or any other means”). Thus, we do not agree with Appellants’ position that the form-in-place gasket limitation includes any physical characteristic not possessed by Chen’s gasket.

Appellants also argue that, according to the definition in the specification, a “form-in-place gasket” is defined by structural characteristics, and is therefore not a product-by-process limitation. Appeal Brief, page 23. See also page 24:

[T]he specification states that the “form-in-place gasket” has a predetermined configuration as defined by the surface on which the gasket material is disposed. The specification elaborates on the meaning of predetermined configuration . . . by stating that the “form-in-place gasket” will have a certain spatial conformation on the gasket surface and dimensions, as well as structural features such as conduits, chamber, mixing features, and the like. Thus, the inherent meaning of “form-in-place

gasket” in conjunction with the other portions of claim 1 . . . as well as the specification, define the structure of the “form-in-place gasket”.

We find this argument unpersuasive as well. Claim 1 is not limited to a process carried out using an array having a gasket of any particular spatial conformation or dimensions, nor does it require “structural features such as conduits, chamber, [or] mixing features.” Neither the claim language nor the specification’s definition of a “form-in-place gasket” require the features relied on by Appellants. Therefore, Chen anticipates claim 1 whether or not it teaches such features.

With respect to claims 10 and 17, Appellants merely reiterate the same arguments made with respect to claim 1. For the reasons discussed above, we agree with the examiner that the “form-in-place gasket” limitation does not distinguish the claimed method from the method disclosed by Chen. The rejection of claims 1, 10, and 17 is affirmed. Claims 2-9, 11-13, and 16 fall with claim 1.

3. Anticipation by Schermer

The examiner rejected claims 1-6, 9, 10, and 13-17 under 35 U.S.C. § 102(e) as anticipated by Schermer.<sup>2</sup> Schermer teaches “a method for incubating a liquid reagent with target spots on a first surface of a microarray substrate.” Column 3, lines 44-46. One embodiment is shown in Figures 2 and 3A, reproduced below (with unnecessary reference numerals redacted):

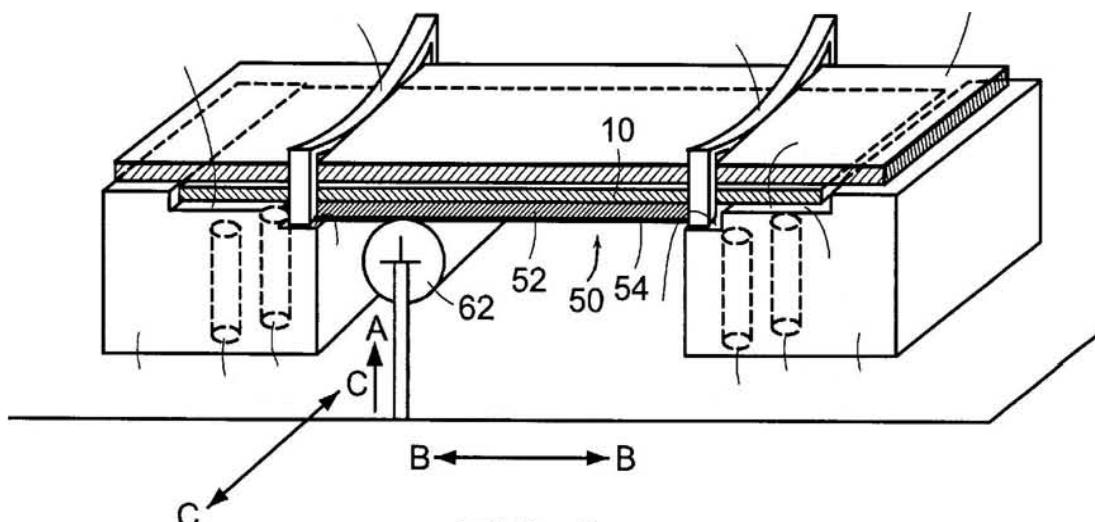


FIG. 2

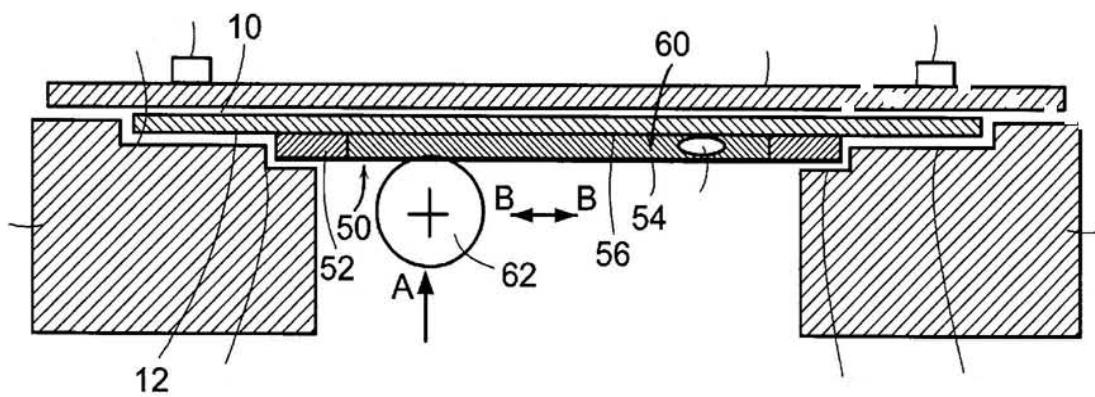


FIG. 3A

<sup>2</sup> Schermer et al., U.S. Patent No. 6,485,918, issued Nov. 26, 2002 (application filed July 2, 2001).

According to Schermer, Figure 2 is a perspective view and Figure 3A is a cross-sectional view of a microarray apparatus. Column 5, lines 19-22. The figures show

[An] embodiment of the invention includ[ing] a stick-on cap or cover **50** and a deflector **62**. The cover can have a gasket region **52** and a top region **54**. . . . Either the gasket region **52** or top region **54** of the cover **50** can be deformable. . . . The deflector **62** is a mechanical device that can be used to physically contact the cover **50** to deform the cover **50**.

Column 5, lines 22-30.

Schermer discloses that

the cover **50** can be a two-piece embodiment having a gasket region **52** and a top region **54**. . . . In still other embodiments, the function of the gasket region **52** of the cover **50** can be provided by a structure where the gasket portion of the cover **50** is permanently affixed to the microarray substrate **10**. . . .

The gasket region **52** of the cover **50** can be designed in a variety of manners to accommodate the application. As indicated above, the gasket **52** can be permanently affixed to the top region **54**, permanently affixed to the substrate **10**, or it can be a separate component.

Column 7, line 60, to column 8, line 13.

Schermer describes a method of using the apparatus shown in Figures 2 and 3A as follows:

In operation, a volume of liquid reagent **56** is placed in the cover **50**, and a microarray substrate **10** is placed on top of the liquid reagent-filled cover **50** with the top surface **12** . . . of the substrate **10** facing downward, toward the cover **50**. The cover **50** can then be sealed onto the microarray substrate **10** by adhesive or mechanical clamping, or a combination of adhesive and clamping. The gasket region **52** of the cover **50** contacts the microarray substrate **10** in this embodiment, and a sealed reaction chamber **60** results in the space between the top surface **12** of the microarray substrate **10** and the cover **50**.

Column 5, lines 30-40.

We agree that the disclosed method meets all the limitations of claims 1, 10, and 17. Schermer does not describe the gasket shown in Figures 2 and 3A as a “form-in-place gasket” but, as previously discussed, a product-by-process limitation does not distinguish a claimed product from an identical product made by a different process. See In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).

Appellants’ arguments with respect to Schermer are identical to their arguments with respect to Chen. We find them no more persuasive the second time around. We affirm the rejection of claims 1, 10, and 17 as anticipated by Schermer. Claims 2-6, 9, and 13-16 fall with claim 1.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Demetra J. Mills	)
Administrative Patent Judge	)
	)
	)
	) BOARD OF PATENT
Eric Grimes	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
Lora Green	)
Administrative Patent Judge	)

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