

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

Paper No. 89

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AND INTERFERENCES**

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

HENRY B. SCHUR and NICHOLAS G. LEVANDOSKI  
Junior Party<sup>1</sup>

v.

JOSEPH P. D'ANGELO  
Senior Party<sup>2</sup>

Interference No. 104,178

**FINAL DECISION**

Before URYNOWICZ, PATE and MARTIN, Administrative Patent Judges.  
URYNOWICZ, Administrative Patent Judge.

The invention at issue in this interference relates to a method and apparatus for collecting saliva. The particular subject matter in issue is illustrated by counts 1

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<sup>1</sup> Application 08/501,417, filed August 8, 1995. Assigned to Analyte Diagnostics, Inc.

<sup>2</sup> Application 08/500,535, filed July 11, 1995, which is a continuation-in-part of Serial No. 08/432,778 filed May 2, 1995, which is a continuation-in-part of Serial No. 08/239,726 filed May 9, 1994, both abandoned.

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and 2 as follows:

Count 1

A method of collecting saliva samples for body fluid analysis, which comprises:

placing absorptive means into a patient's oral cavity; absorbing saliva into the absorptive means;

removing the absorptive means from the patient's oral cavity and placing the absorptive means into a collection container having elastically resilient walls; and

driving the saliva from the absorptive means and collecting the saliva in the collection container by squeezing the collection container to drive the saliva out of the absorptive means and into the collection container.

Count 2

An assembly for collecting saliva for body fluid analysis, comprising:

absorptive means for placing into a patient's oral cavity and for absorbing saliva therein;

a collection container defining a cavity adapted to receive said absorptive means, said collection container having elastically resilient walls adapted to collapse toward one another upon being squeezed to drive the saliva from said absorptive means when said absorptive means is disposed in said collection container.

The claims of the parties which correspond to the counts are:

Count 1:

Schur et al. (Schur) : Claims 1 and 5  
D'Angelo : Claims 1 and 2

Count 2:

Schur et al. (Schur) : Claims 6-10, 17 and 20  
D'Angelo : Claims 3-12

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This proceeding was declared on April 13, 1998 and party D'Angelo was accorded senior party status based on its earlier filing date of July 11, 1995.

On September 8, 1999, D'Angelo was accorded benefit of the May 9, 1995 filing date of PCT/US95/05889 for counts 1 and 2 (Paper No. 39).

Both parties took testimony, filed briefs and appeared for oral argument at final hearing.

**The Issues Set Forth by Schur**

At page 1 of its brief, Schur presents the following issues for decision by the Board,

- (a) Whether Schur, not D'Angelo, is entitled to benefit of the filing date of PCT/US95/05889 filed May 9, 1995,
- (b) Whether D'Angelo is entitled to amend his preliminary statement, and if not, whether D'Angelo is entitled to any date earlier than his July 11, 1995 filing date,
- (c) Whether D'Angelo is held to his filing date based on his failure to file and serve his record in this interference,
- (d) Whether D'Angelo derived the invention of his application S.N. 08/500,535 from Schur and Levandoski,
- (e) Whether Levandoski's testing was a reduction to practice of count 1,

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(f) Whether the work of William Sullivan was a reduction to practice of count 2 and attributable to Schur and Levandoski, and

(g) Whether evidence presented by D'Angelo is admissible. D'Angelo has not provided a separate listing of the issues for decision by the Board.

Benefit of the May 9, 1995 Filing Date

of PCT/US95/05889

The party Schur argues to the effect that it is entitled to benefit of the filing date of the PCT application because the junior party co-inventors, Henry Schur and Nicholas Levandoski, are listed inventors in the application, and the showing made in its original preliminary motion for benefit of the application established support for counts 1 and 2 therein. According to Schur, the Administrative Patent Judge (APJ) inadvertently confused the sole applicant, Joseph D'Angelo, in the PCT application with the inventors Henry Schur and Nicholas Levandoski in said application, and should not have granted D'Angelo benefit of the filing date of the PCT application simply because it was amended to name D'Angelo as the sole applicant.

Schur further argues to the effect that D'Angelo is not entitled to benefit of the PCT application because

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D'Angelo never filed a timely motion for benefit of the application.

D'Angelo states that the PCT application was filed in the United States Patent and Trademark Office (PTO) as the receiving office of the PCT, and not in a foreign country. The senior party submits that priority cannot be claimed under 35 U.S.C. § 119 because benefit of priority under this section can only be based on a foreign application.

D'Angelo takes the position that 35 U.S.C. § 120 is also not available as a basis on which to claim benefit of the PCT application. The contention is made that benefit of priority under this section can only be based on an application filed in the United States or on an international application under 35 U.S.C. § 363. It is submitted that in the latter case, priority applies only if the international application designated the United States and that the PCT application in question did not designate the United States.

Rule 1.655(a) has been amended to make it clear that a Board panel at final hearing will resolve the merits of an interference (e.g., patentability or an attempt to obtain benefit of an earlier application) without giving deference to any interlocutory order which is substantive and not procedural. See Consideration of Interlocutory Rulings at Final Hearing in Interference Proceedings, 64 Fed. Reg.

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12,900, 12,901 (March 16, 1999). Accordingly, we consider the substantive issues dealt with by the APJ in his interlocutory capacity and raised by the parties in their briefs giving them de novo consideration in this decision.

Under 35 U.S.C. § 365(a), which specifically relates to 35 U.S.C. § 119, a national application is entitled to the right of priority based on a prior filed international application which designated at least one country other than the United States. Whereas the PCT application in question designated at least one country other than the United States, sections 119 and 365(a) are controlling here.

We are of the opinion that the junior party Schur is not entitled to benefit of the May 9, 1995 filing date of the application PCT/US95/05889. Schur and Levandosky, the inventors named in the involved Schur application, are both named along with Dr. D'Angelo, the senior party, as inventors in the PCT application. Thus, there is a disagreement as to inventorship between the national and PCT applications. In such a situation, the priority date should be refused until the inconsistency is resolved. See MPEP § 201.15, Reitz v. Inoue, 39 USPQ2d 1838, 1840 (Bd. Pat. App. & Int. 1995). Here, the party Schur never resolved the inconsistency when it filed its motion (Paper No. 11) for benefit of the PCT application.

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Whereas the senior party D'Angelo failed to resolve the inconsistency in inventorship between its involved application and the PCT application as of the time D'Angelo was accorded benefit of the PCT application, it is our finding that the senior party should not have been granted benefit of the PCT application, and benefit thereof is hereby denied to it.

In view of the above findings with respect to the PCT application, the party D'Angelo is senior party by virtue of the earlier filing date, July 11, 1995, of its involved application. Whereas this proceeding involves co-pending applications of the parties, the junior party Schur has the burden of establishing priority by a preponderance of the evidence. 37 CFR § 1.657(a).

D'Angelo's Motion to Suppress Evidence

(Paper No. 77)

The senior party moves to suppress "Schur et al.'s Affidavit" because it is not notarized, and Schur Exhibits 1, 4 and 5 because they are not authenticated<sup>3</sup>.

The motion is dismissed. The senior party was obliged to file objections to admissibility by December 12,

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<sup>3</sup>Hereinafter, Schur and D'Angelo exhibits will be referred to as SX and DX, respectively, and the Schur and D'Angelo records will be referred to as SR and DR, respectively.

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1999 and notify the APJ via a conference call with the participation of opposing party of the filing of objections but failed to do so. See page 2 of the ORDER of the APJ dated September 8, 1999 (Paper No. 40). As such, party D'Angelo waived objections to Schur's evidence.

**Schur's Motion to Strike (Paper No. 54)**

On March 6, 2000, Schur moved for an order to strike D'Angelo's affidavit testimony and DX - B through M, and O. With respect to affidavits, Schur submits that these were to be served by February 18, 2000 and that they were served belatedly on February 29, 2000. It is argued that DX - B through F are irrelevant, DX - G is not admissible to show a first conception because it was not attached to D'Angelo's preliminary statement (37 CFR § 1.629(d)), Schur has had no opportunity to cross-examine with respect to DX - H, and DX - I through M, and O are not admissible as unauthenticated hearsay.

Schur's motion is dismissed. At page 2 of the ORDER of the APJ dated February 3, 2000 (Paper No. 45), the APJ stated that,

Any objections to the admissibility of any evidence contained in or submitted with an affidavit under §1.672(b) must be filed by March 3, 2000 and the party objecting must notify the Administrative Patent Judge (APJ), via a conference call with the participation of opposing party, of the filing of objections.

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Failure to so notify the APJ will constitute a waiver of any objection raised.

Schur did not comply with this order in that it did not notify the APJ via a conference call, with the participation of the opposing party, D'Angelo, of the filing of objections. Thus, Dr. D'Angelo, who was prosecuting his case pro se, was denied an opportunity during a conference call with party Schur to come to an agreement with Schur overcoming its objections. In accord with the notice in the order, failure by Schur to notify the APJ constitutes a waiver of any objection raised in its motion to strike<sup>4</sup>.

#### The Party Schur's Record

The testimony of the co-inventor, Henry Schur, is to the following effect.

On or about January 10, 1994, he, in conjunction with co-inventor, Nicholas Levandoski, conceived a saliva sample collection apparatus and a method of collecting saliva samples for body fluid analysis. The apparatus contained a polyurethane sponge for placing in a patient's oral cavity for absorbing saliva therein and a container having elastically resilient walls adapted to collapse toward one another upon

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<sup>4</sup>Even if Schur's motion were not dismissed on the above ground, it would not have been granted on the basis the evidence was belatedly served because the service was only several days late and there was no prejudice resulting therefrom.

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being squeezed to drive the saliva out of the polyurethane sponge when the sponge is disposed in the collection container.

In mid-February 1994, he prepared a prototype of the sponge and resilient container with the assistance of a colleague, Daniel Glenn, and showed the prototype to Dr. Joseph D'Angelo, the senior party. He made a drawing of the sponge and resilient container containing the sponge on or about March 27, 1994 (SX - 1). On or about April 1994, he prepared a general description of the saliva collection sponge system (SX - 2).

Schur actively pursued the development of a saliva sponge and resilient container for collecting saliva from the sponge from conception with Nicholas Levandoski on or about January 10, 1994, up through making a prototype product in mid-February 1994, and thereafter continued to refine the sponge and resilient container up through August 1995, with the desire to manufacture a commercial saliva tester as described in involved application S.N. 08/501,417.

The co-inventor, Nicholas Levandoski, testified to the following effect.

On or about January 10, 1994, he, in conjunction with Henry Schur, conceived a saliva sample collection apparatus and a method of collecting saliva samples for body

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fluid analysis, the apparatus containing a polyurethane sponge for placing in a patient's oral cavity for absorbing saliva therein and a container having elastically resilient walls adapted to collapse toward one another upon being squeezed to drive the saliva out of the polyurethane sponge when the sponge is disposed in the collection container.

In mid-February 1994, Henry Schur arranged to have a prototype of the sponge and a resilient container therefore built by Donald (sic:Daniel) Glenn and showed the prototype to Dr. Joseph D'Angelo. On or about March 27, 1994, Levandoski reviewed a drawing prepared by Henry Schur of the sponge and resilient container containing the sponge (SX - 1), and he subsequently reviewed a general description titled "SALIVA COLLECTION SPONGE SYSTEM" prepared by Schur on or about April 1994 (SX - 2).

In paragraph 5 of his testimony, Levandoski asserts that he took several of the saliva collection sponges and container apparatus to Jackson Memorial Hospital<sup>5</sup> on or about March, 1994 and placed the polyurethane sponges from each apparatus in a control serum containing drugs of abuse and Phenobarbital, among other drugs. A sponge was placed with the control serum in the collection container having elastically resilient walls. The serum was squeezed out of

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<sup>5</sup> Jackson Memorial Hospital is in Miami, Florida.

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the sponge by squeezing the collection container. The collected serum was tested to confirm the presence of drugs of abuse, Phenobarbital and other drugs in the recovered fluid. Levandoski asserted that the test was analogous to testing for these drugs in saliva.

In paragraph 6 of his testimony, Levandoski states that he conducted another test in his home in March 1994. He drank a cup of coffee and drew a blood sample to test for the presence of caffeine in his blood. He placed a sponge in his oral cavity to absorb saliva and then squeezed the saliva out of the sponge in a resilient tube. A test of the saliva confirmed that the presence of caffeine in the saliva was approximately at the same concentration found in his blood sample.

Schur's involved application substantially discloses the same apparatus which was used to test for caffeine in Levandoski's saliva.

The co-inventors actively pursued the development of the saliva sponge and resilient container for collecting saliva from the sponge from their conception on or about January 10, 1994, through the making of a prototype in mid-February, 1994. The prototype was used successfully in testing the apparatus in Jackson Memorial Hospital. Thereafter, Levandoski continued to refine the refine the

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sponge and resilient container apparatus with Henry Schur up through August 1995.

Joel Marcus testified that in the Spring of 1994, he was Henry Schur's accountant. He averred that he remembers discussions and personal observations pertaining to a saliva collector and a squeeze tube, and that Schur and Levandoski "...were the inventors of the Saliva Collection and Dr. D'Angelo was the person in overall charge of fundraising and other administrative functions."

William Sullivan testified to the effect that he is an employee and part owner of Double B Tool and Dye Company for the last nineteen years. Double B Tool and Dye builds custom molds for the plastic industry.

Henry Schur contacted him in the summer of 1994 about preparing a mold for a saliva collector. Schur explained to him the need for plastic parts with a foam sponge at one end and a squeezable tube for retaining the foam sponge and allowing saliva to be squeezed from the sponge. There also would need to be a cap at the bottom of the flexible tube. The tube was to be made from a soft vinyl or a soft polyethylene so it could be squeezed. Sullivan indicated that his recollection of the meeting with Schur is based on records of job numbers forward and backward of the job number for the squeezable tube and noted the date of completion. He made the

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mold for the flexible tube requested by Schur and delivered it to Schur in September or October 1994 at his office in Americare Transtech Inc.<sup>6</sup>

In a supplemental declaration, Sullivan testified that the resilient flexible tube shown in the picture identified as SX - 5 is one of the resilient flexible tubes made by him for Henry Schur from the mold delivered to Schur in September or October 1994, and that the tube is one of about 100 which he prepared in the equipment of East Coast Plastics in about October 1994, at Schur's request<sup>7</sup>. These tubes were delivered to Schur in October, 1994.

The testimony of Daniel Glenn is to the following effect. He was employed by Americare Transtech, Inc. between May, 1992 and June, 1994, and that after he left he did some consulting work for the company. It was in January, 1994 when he began working on a saliva collection device. At that time, a tube was to be utilized as part of the device. Glenn worked with the inventors in an attempt to produce a sponge for the collection device. Henry Schur provided him with pacifiers and Glenn used the nipples of the pacifiers as molds to produce sponges from commercially available material, which

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<sup>6</sup>Americare Transtech, Inc. was Schur's employer and Dr. D'Angelo was president of the company.

<sup>7</sup>Sullivan was a partner in East Coast Plastics.

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Schur also provided him. It was at a staff meeting that Dr. D'Angelo assigned Schur the task of finding an inert material for making the sponges.

After leaving the company, Glenn was called back by Dr. D'Angelo to solve a problem with the sponge device. The problem was that the glue holding the sponge to a cap separated. The solution was to put a hole in the cap and to pour the material for making the sponge through the hole such that the sponge is molded into the cap. Glenn indicated that he did not know when the idea of making the tube of the collection device flexible was conceived.

#### Opinion as to Schur's Case

We are of the opinion that the junior party Schur has failed to establish conception of the subject matter of either count prior to its filing date.

There is simply no independent corroboration of the activity of Henry Schur and Nicholas Levandoski in the period January through March of 1994. The testimony of Joel Marcus, a certified public accountant, is deficient as to dates when he had discussions with Schur and when he made observations pertaining to a saliva collector and a squeezable tube. Marcus testified that to his knowledge Henry Schur and Nicholas Levandoski were the inventors "...of the Saliva Collection", but this does not establish that he is testifying

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Collection", but this does not establish that he is testifying about either the method or apparatus defined in counts 1 and 2. Furthermore, the testimony of Marcus to the effect that Schur and Levandoski are the inventors is a mere conclusion. There appears to be no reason why Marcus did not testify as to facts and dates upon which his belief is based. Daniel Glenn was unable to state with any degree of certainty when discussions occurred with Henry Schur concerning a saliva collection device with a flexible collector or tube, and the testimony of William Sullivan is not concerned with the January through March, 1994 time period. Lastly, the documents identified as SX - 1 and 2, of which page 2 of SX - 1 has a date of March 27, 1994, were made by Schur. No corroborating witness testified about those exhibits, and they are but self-serving documents.

The testimony of William Sullivan concerning later inventive acts by the junior party is unpersuasive. That testimony concerns alleged activity involving Henry Schur and Sullivan in the summer of 1994, and as late as October of that year. The co-inventor and witness, Henry Schur, did not testify about any such activity with Sullivan in the above time period and this casts doubt on whether the activity occurred as related by Sullivan. Sullivan testified in paragraph 3. of his declaration that he was certain of the

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time of year of these inventive acts because he looked at his job numbers forward and backward of the job number for constructing the mold for the making of a squeezable tube and noted the date of completion. However, no files carrying these job numbers are of record, and cross-examination testimony of Sullivan from a prior proceeding of record in the senior party D'Angelo's case, indicates that Sullivan had no file having a job number for making a mold for a squeezable tube with respect to which he could have checked job numbers forward and backward of the job number of the mold so as to identify a date of completion of the mold (DX - N, pages 2-6). Sullivan's testimony in this regard is inconsistent.

Furthermore, in his supplemental affidavit, William Sullivan testified that he prepared about 100 flexible tubes at the request of Henry Schur in about October, 1994 and delivered them to Schur that same month. However, in contrast, in the aforementioned cross-examination of Sullivan from the prior proceeding (DX - N, page 8, lines 17-22), he testified that,

I built the molds, the steel molds that make the plastic parts. East Coast Plastics runs the molds, they put them in a molding press and they squeeze the plastic into the mold, open the mold up and have the parts come out. I build the molds.

Sullivan testified at page 10 of this testimony that he went down to a lab in Miami to Henry Schur and Dr. D'Angelo to

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prove out his tool or mold. This testimony is to the effect that Sullivan did not prepare any flexible tubes himself which he delivered to Henry Schur but that he brought a mold to the laboratory where it was used to make flexible tubes.

Sullivan's accounts are difficult to harmonize, and it is not clear from them what, if anything, he actually did for the junior party in about October, 1994.

Still further, there is no document in the record of the junior party which is a bill or charge from Double B Tool and Dye Company to Americare Transtech, Inc. for work performed at the request of Henry Schur in constructing a mold to be utilized in making a squeezable tube. The existence of such a document would normally be expected if Sullivan constructed a mold in response to a request from Henry Schur at the time alleged.

In its brief at page 9, the junior party argues that Dr. D'Angelo derived the invention of counts 1 and 2 from Schur and Levandoski. The basis for this charge is that D'Angelo admits at paragraph 8 of his preliminary statement (SR-64) that "Schur communicated the concept that 'the prototype tube with the pipette tip needs to be very flexible on the sides...' on January 27, 1995" and further admits at paragraph 20A. of his preliminary statement (SR-66) that "Schur contacted the company's patent attorney, Mr. Werner

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Stemer (reg. No. 34,956) with a description of the invention of Count 1 and Count 2".

This argument is unpersuasive. A preliminary statement is not regarded as evidence but as merely setting dates earlier than which evidence is not effective. Halbert v. Schuurs, 220 USPQ 558, 565 (Bd.Pat.Int. 1983); Dewey v. Lawton, 347 Fd. 629, 630-31, 146 USPQ 187, 188 (CCPA 1965). Consequently, the particular statements in D'Angelo's preliminary statement are not regarded as effective admissions except for the setting of limiting dates.

**Actual Reduction to Practice and**

**Diligence by Schur**

Even if the junior party had established a date of conception prior to D'Angelo, the senior party would have been entitled to prevail herein because (1) the party Schur has no corroborating evidence establishing that the aforementioned testing of Levandoski constituted an actual reduction to practice of count 1 (Schur issue (e) at page 1 of its brief), (2) William Sullivan's testimony as to his activity in 1994 is not credible and cannot establish actual reduction to practice of count 2 (Schur issue (f) at page 1 of its brief), and (3) party Schur has no specific facts establishing that it was reasonably diligent from just prior to D'Angelo's entry into

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the field on July 11, 1995 to its constructive reduction to practice on August 8, 1995<sup>8</sup>.

In view of our findings above, the senior party D'Angelo is entitled to prevail herein on the basis of its earlier filing date.

Whereas party D'Angelo is entitled to prevail on the basis of its earlier filing date, D'Angelo's motion to file a corrected preliminary statement (Paper No. 60), Schur's motion for sanctions to strike the testimony of Larry Shanley (Paper No. 67) and D'Angelo's motion for extension of time to take testimony and to compel Schur to cooperate with the scheduling of the deposition of Mr. Shanley (Paper No. 66) are dismissed as moot.

#### Judgment

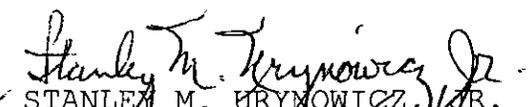
Judgment as to the subject matter of counts 1 and 2, the only counts, is hereby awarded to Dr. Joseph P. D'Angelo, the senior party. On the present record, the party D'Angelo is entitled to a patent with claims 1 and 2 corresponding to

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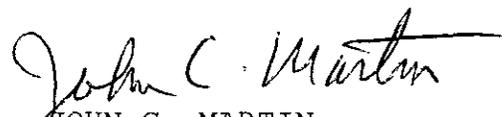
<sup>8</sup>Even if Sullivan's testimony were convincing, at best it would have established that a flexible tube intended for use in the collection of saliva was made. There was no test establishing that apparatus satisfying the subject matter of count 2 was used successfully for collecting and storing samples of saliva which could be used to provide accurate body fluid constituent analysis. This was the intended use as per Schur's specification at page 1, lines 9 and 10. The nature of the alleged testing by co-inventor Levandoski set forth at paragraphs 5 and 6 of his testimony, referred to above, reflects the extensive degree of testing he considered necessary to establish successful testing in this field of endeavor.

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count 1, and claims 3-12 corresponding to count 2; the party Schur is not entitled to a patent with its claims 1 and 5 corresponding to count 1, and claims 6-10, 17 and 20 corresponding to count 2.

  
STANLEY M. BRYNOWICZ, JR. )  
Administrative Patent Judge )

  
WILLIAM F. PATE, III. ) BOARD OF PATENT )  
Administrative Patent Judge ) APPEALS AND )  
INTERFERENCES )

  
JOHN C. MARTIN )  
Administrative Patent Judge )

SMU/gjh

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Attorney(s) for Schur et al.:

Herbert W. Larson  
Larson and Larson  
7381 114th Avenue N. #406  
Largo, Florida 33773

Attorney(s) for D'Angelo:

Dr. Joseph P. D'Angelo  
Americare Building, Third Floor  
20 N.W. 181st Street  
Miami, Florida 33169