"all subject matter in claims must be given full weight"

However, the reference to lengthwise ribs "10" at page 7, line 25 was incorrect. This has now been corrected above. The lengthwise ribs bear the reference numeral "9". See Pg. 6

Withdrawal of the objection is in order and is respectfully requested.

While no rejection has been made based on the second paragraph of 35 U.S.C. 112, a review of the claims as originally filed reveals that they do not fully comply with U.S. practice. Consequently, claims 1-4 have been amended above to better particularly point out and distinctly claim the invention. No limitations have been added and none are intended.

In view of the deletion of examples from claims 2 and 3, such subject matter has now been added as new dependent claims 11 and 12. New dependent claim 13 adds subject matter deleted from claim 8. New claims 11 and 12 are based on the structure of the carrier, such as illustrated in Fig. 3 and described at the bottom of page 7 of the specification, without being limited to the precise embodiment illustrated. These claims are all patentable for the same reasons as claim 1, to be pointed out below.

Claims 1, 4 and 7-10 have been rejected as anticipated under Section 102 by Amon et al USP 5,718,726 ("Amon"). This rejection is respectfully traversed.

First, it is noted that the rejection is based on Section 102, and thus obviousness (or non-obviousness) is not an issue in this case, i.e. the sole issue is whether or not Amon

discloses the claimed subject matter. Applicant assumes that the PTO acknowledges the presence of non-obvious subject matter for reasons pointed out below solely to complete the record.

The rejection states that Amon discloses "implants", but the rejection does not state (and, respectively, cannot accurately state) that Amon discloses a "urological implant" as claimed, because Amon does not disclose a "urological implant". It is first to be emphasized that a urological implant is not the same as a cardiovascular implant, in particular a "wall support for a urinary tract" as claimed is not the same as blood vessel stent.

Stated another way, a urological implant is a defined object, which is a urinary tract versus (and independent from) a cardiovascular implant, although there might be certain parallels in the design of a urological implant and a cardiovascular stent. In fact, a urological implant shows a quite different place of application, a different purpose and different basic properties compared to the subject matter of the referenced prior art. It is very important for the skilled person whether or not the invention refers to a urological implant or to a cardiovascular stent.

Applicant respectfully notes that the introductory language of claim 1, namely a "urological implant, in particular a vascular wall support for a urinary tract" defines what the article is, and is not an intended use. In this regard, the examiner's attention is respectfully invited to *In re Steppan*

et al, 156 USPQ 143, 147. Here, the preamble of claim 25 read as follows:

> 25. An acid phosphate of a condensation product of ... .

The appellants argued that the expression "condensation product" defined "what the acid phosphate is", and the court reversed the rejection. Also see the somewhat analogous case of *In re Gernero*, 162 USPQ 221, 223, where in effect the Court held that the claim language "interbonded one to another by interfusion" defined the structure of the product. See also *In re Bulloch et al*, 203 USPQ 171, 174 (CCPA 1979).

In short, the recitation of a "urological implant, in particular a vascular wall support for a urinary tract" defines a particular structure which is a different structure than a blood vessel stent. Accordingly, Amon does not anticipate any of applicant's claims.

While the rejection does not so state, applicant assumes that the rejection may (at least in part) be based on the supposition that the language of a "urological implant, in particular a vascular wall support for a urinary tract" recites an intended use rather than structure; and, as such, may be properly ignored. However, for the reasons pointed out above, this is not so. Instead, again for the reasons pointed out above, the introductory portion of claim 1 recites what the claimed device is. In this regard, should be no doubt that, as a general rule, all subject matter recited in a claim must be given full weight; and, consequently, any rejection based on

anticipation requires that the reference relied upon show each and every feature claimed. A sometimes exception is when the claim preamble only calls for an intended use. The leading case in this area is *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

In Kropa v. Robie, the court reviewed thirty seven of its own prior decisions in cases where it had determined whether or not the claim preamble must be given effect. The court stated:

> ..., in those *ex parte* and interference cases where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims or counts. Usually, in those cases, there inhered in the article specified in the preamble a problem which transcended that before prior artisans and the solution of which was not conceived by or known to them. The nature of the problem characterized the elements comprising the article, and recited in the body of the claim or count following the introductory clause, so as to distinguish the claim or count over prior art.

The same situation exists in the present case. Particular problems exists in the environment of the urinary tract which are made clear in applicant's specification, namely the problem of recrystallization of components of the urine at the surface of the implant (which plays a major role in connection with urological implants coming into contact with urine), which

recrystallization problem has nothing to do with the anti-thrombotic or anti-coagulative properties sought and taught in Amon.

In other words, using the language of *Kropa v. Robie*, inherent in a urological implant wall support for a urinary tract as recited in claim 1 is the solution of "a problem which transcended that before prior artisans and the solution of which was not conceived by or known to them", namely the problem of preventing crystallization of components of the urine on the implant. The introductory clause is therefore "essential to point out the invention defined" by the remainder of applicant's claims.

To further emphasize the structural distinction in applicant's claims set forth in the introductory clause, claim 1 has been further amended to specify that the carrier is of such a character that it is "adapted for insertion into a urinary tract to provide a wall support for the urinary tract". Of course, a cardiovascular stent is not of such a character.

Returning to the introductory clause of claim 1, which defines what the claimed device is, the examiner may wish to consider some cases which are more recent than *Kropa v. Robie*. Attention is therefore first invited to *Perkin-Elmer v. Computervision*, 221 USPQ 669, 675 (Fed. Cir. 1984), where the introductory clause of claim 1 called for a "unity magnification catoptric image-forming system... ." In giving weight to such recitation, the court stated:

> The system of claim 1 is one of unity magnification and is image forming. Those

> limitations appear in the preamble, but are necessary to give meaning to the claim and properly define the invention. [citations omitted]

In *Loctite v. Ultraseal*, 228 USPQ 90, 91-93, the introductory portion of claim 1 of the '012 patent read as follows:

> 1. An anaerobic curing sealant composition adapted to remain in a liquid, non-polymerizing state... .

The court stated:

> Although it appears in the preambles of the '012 patent claims, the term "anaerobic" breathes life and meaning into the claims and hence is a necessary limitation to them. [citation omitted]

The holdings of the lower court were vacated, and the case was remanded.

Attention is next invited to *In re Stencel*, 4 USPQ2d 1071 (Fed. Cir. 1987) where the introductory clause of claim 1 called in part for a "driver for setting a joint of a threaded collar, ... the collar having plastically deformable lobes on its longitudinal exterior ..., the driver comprising: ... .". In reversing the rejection, the Court stated:

> We conclude that it would not have been obvious to [provide the applicant's invention] unless one had in mind the purpose taught by appellant. This purpose, set forth in the claims themselves, "is more than a mere statement of purpose; and that language is essential to particularly point out the invention defined by the claims." [citations omitted; bracketed material added]

Similarly, in the present case, the purpose of the present applicant is not to be found in the prior art; this purpose, set forth in applicant's claims, "is essential to particularly point out the invention defined by the claims".

Lastly, attention is respectfully invited to *Corning Glassworks v. Sumitomo Electric*, 9 USPQ2d 1962, 1965-66 (Fed. Cir. 1989). Here, claim 1 of the '915 patent recited an "optical wave guide comprising... ." The Court stated:

> In this case, the question of anticipation turns on claim interpretation, ... [citation omitted] If the claims are given Sumitomo's suggested interpretation, the [prior art] patent anticipates [claims 1 and 2 of the '915 patent]; otherwise, it does not. In particular, the dispute focuses on the interpretation and effect of the words "An optical wave guide" in claim 1. ... . [bracketed words added]

Sumitomo argued that the fiber of the prior art patent could "inherently" function as a "waveguide", and therefore the words "An optical waveguide" should be ignored because "the preamble is not a limitation when it merely states a purpose or *intended use* and the remainder of the claim completely defines the invention". (Italics in the court decision)

In affirming the lower court's decision of validity (no anticipation), the court stated in part as follows:

> The effect preamble language should be given can be resolved only on review of the entirety of the [disclosure] to gain an understanding of what the inventors actually invented and intended to encompass by the claim. Here, the 915 specification makes

> clear that the inventors were working on the particular problem of an effective optical communication system not on general improvements in conventional optical fibers. To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality. The invention is restricted to those fibers that work as waiveguides as defined in the specification, which is not true with respect to fibers constructed with the limitations of paragraphs (a) and (b) only. Thus, we conclude that the claim preamble in this instance does not merely state a purpose or intended use of the claimed structure [citation omitted]. Rather, those words do give "life and meaning" and provide further positive limitations to the invention claimed [citations omitted]. Thus, contrary to Sumitomo's argument, the core and cladding limitations set out in paragraphs (a) and (b) are not the only limitations of the claim [citation omitted]. The claim requires, in addition, the particular structural relationship defined in the specification for the core and cladding to function as an optical waveguide.

Similarly, the introductory clause of applicant's claim 1 is also a requirement of applicant's invention. The Court continued:

> Viewed in this manner, the fact that the [prior art] luminescent fiber could inherently transmit information for a few meters becomes irrelevant. The [prior art] patent does not disclose all the limitations of the claimed "optical waveguide" as that term is structurally defined by the '915 inventors.

The examiner should be guided by the above quoted words of the Federal Circuit from *Corning Glass Works v. Sumitomo Electric*.

Amon does not anticipate claim 1, and therefore Amon does not anticipate any of applicant's claims. The rejection should be withdrawn, and such is respectfully requested.

It has been briefly noted above that while there is no rejection based on obviousness, applicant will point out the non-obviousness of the present invention for sake of a complete record.

Amon is certainly the nearest prior art and was already discussed in the introductory part of the present application. Amon, as cannot be denied, discloses a cardio-vascular implant, e.g. cardiac valves or alloplastic vessel wall supports for the human heart, which implants are provided with a surface coating, which is formed by a spacer layer attached to the substrate surface and immobilized heparin on the spacer layer. The surface coating serves to suppress the risk of acute thrombus formation with the blood contacting the implant (see Amon, column 1, lines 14 through 18). Now, studying Amon, it becomes very clear that this prior art only deals with the problem of anticoagulative properties of the implant. In this connection, applicant particularly invites attention to the fact that the invention disclosed in Amon is based on the problem of the need to administer anti-coagulative drugs such as heparin preparations in high doses. Such medical preparations basically are problematic due to their undesirable secondary effects (see

Amon, column 1, line 18 through 24).

Now, the object of the invention disclosed in Amon is to solve the problem in finding a corresponding method

> to bond heparin preparations to the mentioned inorganic material for cardio-vascular implants to be able to exhibit anticoagulant properties. (See Among, column 1, lines 57 through 61.)

As a further result, applicant emphasizes that Amon only discloses a cardiovascular implant, which is heparin-coated and which is to show anti-coagulative properties by this heparin coating. These anti-coagulative properties are due to an interruption of the so-called "coagulative cascade".

As to the non-obviousness of the present invention, applicant again emphasizes that the subject matter of the invention is urological implant, i.e. a different kind of medical product, the character of which is clearly defined in spite of the general character of the designation itself. It is an implant which comes into contact with urine, which is clearly cited and discussed in the specification of the present application. In this regard, it should be evident that the recrystallization of components of the urine at the surface of the implant plays a major role in connection with urological implants coming into contact with urine. This recrystallization problem was unobviously solved by the present invention.

The whole problematic nature of the recrystallization of urine components, the basic functional-chemical mechanisms and the solution of these problems by using a coating which is