Patent Applications Overlapping the Biotechnology and Mechanical Arts

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Overview

- The overlap of patent applications within the biotechnology and mechanical arts
- How patent applications are classified
- 101 and claims directed towards a combination that includes parts of the human body

Intersection of Biotechnology and Mechanical Arts

- An example of a biotechnology class associated with the mechanical arts is Class 435-Chemistry: Molecular Biology and Microbiology
- An example of a mechanical class associated with biotechnology arts is Class 623- Prosthesis (i.e., Artificial Body Members), Parts Thereof, or Aids and Accessories Therefor

Class 435

Over 172,000 patents & published applications

Within these 172,000 references, over 8,000 disclose at least one of the following delivery devices:

Stent, prosthetic or prosthesis.

Class 623

Nearly 30,000 patents & published applications, including stents, prosthetics and prostheses.

Areas of Overlapping Art

- Stents and prosthetics are just some of the possible devices found in the mechanical art that can be used for delivery of body treating compositions.
- Other delivery devices, such as syringes, are less often claimed in combination with the treating compositions.

Example

Coatings for eluting therapeutic compositions on stents. These therapeutic compositions may act as anti-thrombotics, antibiotics, and anti-inflammatories etc.

Obviousness

If a body treating therapeutic composition is disclosed within the prior art as acting as anti-thrombotics, antibiotics, and anti-inflammatories etc., and the stent is not novel, the combination of the composition and the stent may be obvious.

Example Claim

A vascular stent graft comprising:
a biologically active surface which exhibits cell attachment activity and growth activity,
said surface having linked thereto the expressed protein of a vector containing a DNA sequence of cDNA coding for the A chain of laminin.

Some Rationales for Obviousness

- Simple substitution of one known element for another to obtain predictable results
- Combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

Possible Rebuttal Evidence

- One of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);
- The elements in combination do not merely perform the function that each element performs separately; or
- The results of the claimed combination were unexpected.

Where is the Application Classified?

If the claims are directed to both a body treating composition and a mechanical device, what class is it placed in?

Purposes of Classification

For administrative and examination purposes (e.g., ensuring the examination of patent applications by the best qualified examiner on the subject matter, restricting patent applications to properly related inventions, interference or infringement searches, etc.), there is a need to designate for U.S. patents a primary, or Original, classification.

Purposes of Classification (cont)

Applications placed in the correct class, subclass and technology center from the start can also help reduce pendency.

Classification

In this section we will look at:

- How an application is classified.
- How an applicant can help to ensure proper classification.

Classifying Patent Applications and PGPubs: Controlling Claim

If a document has claims directed towards inventions classified separately, the controlling claim:

a) Determines the class for the original classification and,

b) Determines the class where a patent application is to be assigned for examination

Classifying Patents and PGPubs: Controlling Claims

Principles used to determine the controlling claim (in order of precedence):

I. **Most Comprehensive Claim**

II. **Hierarchy of Categories of Subject Matter**

III. **Superiority of types of subject matter**

IV. **Class Superiority**

Most Comprehensive Claim

The claim setting forth the most comprehensive organization (for example, a claim to a combination as compared to a claim to a subcombination or element of that combination) will control placement of a patent or application among classes.

Example

1. A coating for a vascular graft having a polymeric external surface comprising:
a biologically active surface which exhibits cell attachment activity and growth activity, said surface having linked thereto the expressed protein of a vector.

2. The coating of claim 1, wherein said vector contains a DNA sequence of cDNA coding for the A chain of laminin.

3. The coating of claim 1, in combination with a vascular graft.

Exception - Most “Examinable”

In cases where there is a claim drawn to hybrid or mixed subject matter and the Supervisor in one discipline determines that the application requires consideration by, or may be best examined by, a TC in one of the other technical disciplines, he or she may request a transfer of the application on a "best examinable" basis.

Reasons Supporting a Transfer of an Application

- An application contains a hybrid claim wherein, for instance, a product is defined merely in terms of the process for producing it.
- Where an application properly assigned to a mechanical class contains at least one claim to mixed subject matter, a part of which is biotechnical, the application *may* be assigned to the appropriate biotechnology art unit for examination.

Application Data Sheet

Application information in the Application Data Sheet- This information includes a suggested classification, by class and subclass and the Technology Center to which the subject matter of the invention is assigned.

PCTs

If a U.S. national application has been acted upon by an examiner to whom the national application was assigned on the basis of the controlling (not necessarily the first) claim, a subsequent PCT application claiming priority of the national application will normally be assigned to the same examiner, or to the examiner's art unit in his/her absence.

PCTs

In all other situations where a U.S. national application and a corresponding PCT application are copending, irrespective of which application was filed first, every effort should be made to ensure that both applications are assigned for search and examination to the examiner to whom the PCT application would normally be assigned on the basis of the first claimed invention, or to the examiner's art unit in his/her absence.

Information Resources for Classification

- MPEP 902-903.09(a)
- Examiner Handbook to the U.S. Patent Classification System –

  Available online at:
  www.uspto.gov/web/offices/pac/dapp/sir/co/examhbk/index.htm

Combinations Including Parts of the Human Body

Within the overlap of biotechnology and mechanical arts, an issue sometimes occurs wherein a claim recites an apparatus (as opposed to a method) with certain elements "attached to" the human body or specific body parts.

Functional Recitations

Limitations to parts of the human body presents no problem as long as the language is recited in the format “adapted to be attached” or “for attachment to” or in some similar way which does not positively set forth the human body or portions thereof as part of the claimed subject matter.

Claimed Combination

But what about those situations where the portion of the human body is actually set forth as part of the claimed combination?

MPEP 2105- Patentable Subject Matter

If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 USC 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.

Animals-Patentability

On April 7, 1987, then Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, set forth PTO policy on this issue in the form of a notice entitled “Animals – Patentability”.

Animals-Patentability

The notice stated that the "Patent and Trademark Office would now consider nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101"

Animals-Patentability

The Commissioner stated that a "claim directed to or including *within its scope a human being* will not be considered to be patentable subject matter under 35 U.S.C. 101" since the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.

Claimed Combination

Accordingly, where a claim is directed to apparatus "attached to" the human body or any part thereof an examiner is to reject such claim under 35 U.S.C. 101.

112 1st Paragraph

However, claims which contain language "attached to" a part of the human body raise an issue under 35 U.S.C. 101 but do not inherently raise questions of enablement or indefiniteness.

Example

An intravascular stent which is permanently implanted in the vessel lumen of a patient and which is used for locally delivering genes in a vessel comprising: (a) a substrate, (b) a coating adhering to the substrate, and (c) a genetic material which is adsorbed to the surface of the coating, wherein the coating comprises a matrix of randomly interconnected protein molecules comprising one or more species of protein.

Example

An intravascular stent FOR permanent implantation in the vessel lumen of a patient and which is used for locally delivering genes in a vessel comprising: (a) a substrate, (b) a coating adhering to the substrate, and (c) a genetic material which is adsorbed to the surface of the coating, wherein the coating comprises a matrix of randomly interconnected protein molecules comprising one or more species of protein.

Questions?

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