PATENT ASSESSMENT AND EVALUATION
UNDERSTANDING THE CLOSEST PRIOR ART

Lorenzo ROSSI
Fondazione Istituto Italiano di Tecnologia

Crash Course on Research Funding, Intellectual Property and Startup Creation
Trento, May 22, 2019
DIFFERENT FORMS OF INTELLECTUAL PROPERTY
An **intangible asset** is an asset that lacks **physical substance**.

- Patent
- Design
- Trademark
- Copyright
Article 1, Section 8, Clause 8 (Copyright Clause)

[Empowers the United States Congress] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries
**Ius Excludendi Alios**

**Ius Facendi**

The patent does not guarantee to the Applicant the right of realize, dispose of and commercialize the invention.

**Ius Excludendi Alios**

The patent is a title of industrial property which confers to the Applicant a temporary monopoly on the exploitation of the invention, which consists in the exclusive right to prevent third parties to produce, use, put on the market, sell or import the invention.
Eligibility

Eligible for Patents

- Machine
  - Ex: cotton gin, bicycle, typewriter
- Manufacture
  - Ex: Monopoly® board game, safety pin, Velcro® fastener
- Method
  - Ex: Morse code, telephone call, magnetic tape recording, public key cryptography

Ineligible for Patents

- Natural Phenomenon
  - Ex: mineral, wild plant
- Abstract Idea
  - Ex: mental process, mathematical algorithm
- Law of Nature
  - Ex: gravity, fire, requiring oxygen

Patent Requirements

Subject Matter
- From an eligible category and not from an ineligible category

Novelty
- This exact invention was not known before

Non-Obviousness
- If parts of the invention were known separately before, no one would have thought to combine them

Written Description
- Through, clear description of how to make and use the invention

Timing
- File as soon as possible

Questions?
lorenzo.rossi@iit.it
Article 52 Patentable Inventions

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
   (a) discoveries, scientific theories and mathematical methods;
   (b) aesthetic creations;
   (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
   (d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.
Treatment of the human or animal body by surgery or therapy and diagnostic methods.
**Article 53 Exceptions to patentability**

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.
Novelty is a patentability requirement. An invention is not new and therefore not patentable if it was known to the public before the date of filing of the patent application, or before its date of priority if the priority of an earlier patent application is claimed. The purpose of the novelty requirement is to prevent the prior art from being patented again.
**Patentability requirements**

The inventive step and non-obviousness reflect a general patentability requirement present in most patent laws, according to which an invention should be sufficiently inventive — i.e., non-obvious — in order to be patented. In other words, "[the] non-obviousness principle asks whether the invention is an adequate distance beyond or above the state of the art." The expression "inventive step" is predominantly used in Europe, while the expression "non-obviousness" is predominantly used in United States patent law. The expression "inventiveness" is sometimes used as well. Although the basic principle is roughly the same, the assessment of the inventive step and non-obviousness varies from one country to another.
In certain jurisdictions' patent law, industrial applicability or industrial application is a patentability requirement according to which a patent can only be granted for an invention which is susceptible of industrial application, i.e. for an invention which can be made or used in some kind of industry.
Disclosure of the Invention

Disclosure requirement

- Novelty
- Inventive Step
- Industrial Application
- Disclosure of the Invention
PATENTABILITY REQUIREMENTS

RECAP

Novelty
Inventive Step
Industrial Application
Disclosure of the Invention
EUROPEAN PATENT CONVENTION

**Article 54 Novelty**

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.
**Article 56 Inventive Step**

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.
**Inventive Step**

**Problem – Solution Approach**

In order to assess whether an invention involves an inventive step the problem-solution approach is applied.

- Identifying the closest prior art, the most relevant prior art.

- Determining the objective technical problem, that is, determining, in the view of the closest prior art, the technical problem which the claimed invention addresses and successfully solves; and

- Examining whether or not the claimed solution to the objective technical problem is obvious for the skilled person in view of the state of the art in general.

This last step is conducted according to the could-would approach.
**Inventive Step**

**Could – Would Approach**

Is there any teaching in the prior art, as a whole, that would, not simply could, have prompted the skilled person, faced with the objective technical problem formulated when considering the technical features not disclosed by the closest prior art, to modify or adapt said closest prior art while taking account of that teaching [the teaching of the prior art, not just the teaching of the closest prior art], thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves?

If the skilled person would have been prompted to modify the closest prior art in such a way as to arrive at something falling within the terms of the claims, then the invention does not involve an inventive step.
OBJECTIVE TECHNICAL PROBLEM

To establish in an objective way the technical problem to be solved by the claimed invention, the closest prior art and the difference (also called "the distinguishing feature(s)" of the claimed invention) in terms of features (either structural or functional) between the claimed invention and the closest prior art, must be carefully analyzed.

The technical effect resulting from the distinguishing features is the solution to the objective technical problem.

In the context of the problem-solution approach, the technical problem means the aim and task of modifying or adapting the closest prior art to provide the technical effects that the invention provides over the closest prior art. The technical problem thus defined is often referred to as the "objective technical problem".

The objective technical problem derived in this way may not be what the applicant presented as "the problem" in his application. Reformulation might lead to the objective technical problem being less ambitious than originally envisaged by the application.
Article 57 Industrial Application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.
CASE STUDY
**Record of Invention**

**Description of the Invention**

Provide a technical detailed description of how the invention is made and operates, specify novel technical characteristics and advantages respect to known solutions.

**Scheme 1:** Sketch of the proposed device

**Scheme 2:** Schematic of the proposed approach

We propose the realization of an optogenetic tool able to selectively and dynamically target different regions of neuronal tissues or any optical sensitive environment. It is based on the modal selectivity of a micro-structured and tapered optical fiber, which radiate in the surrounding tissue only defined subsets of propagating modes by means of properly designed optical windows. A three-dimensional and a schematic representation of the proposed approach are reported in Schemes 1 and 2, respectively.

**Scheme 3:** Example of multi-point emitting fiber with integrated recording pads
**INTERNAL PRELIMINARY OPINION**

<table>
<thead>
<tr>
<th>Prior art</th>
<th></th>
</tr>
</thead>
</table>

**D1** PCT/US2010/055720 “Waveguide Neural Interface Device”

| Inventors | SEYMOUR, John, P. et al. |
| Assignee | Neuronexus Technologies |

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US 2011/112591</td>
<td></td>
</tr>
<tr>
<td>EP 2498673</td>
<td></td>
</tr>
<tr>
<td>CN 102686147</td>
<td></td>
</tr>
</tbody>
</table>

| Filed | Nov. 5, 2010 |
| Priority | 61/258,494 Nov. 5, 2009 |
| | 61/321,089 Apr. 5, 2010 |
| | 12/940,748 Nov. 5, 2010 |

| Int. CI. | A61B 5/00 (2006.01) |
CLOSEST PRIOR ART

**D1 PCT/US2010/055720 “Waveguide Neural Interface Device”**

Inventors: SEYMOUR, John, P. et al.
Assignee: Neuronexus Technologies

Abstract
A waveguide neural interface device including: a neural device implantable in tissue and including an array of electrode sites that electrically communicate with their surroundings, in which the array of electrode sites that electrically communicate with their surroundings, in which the array of electrode sites includes at least one recording electrode site; and a wave guide, coupled to the neural device, that carries light along a longitudinal axis and includes a light directing element that redirects the carried light from the waveguide to illuminate selectively targeted tissue, in which at least a portion of the redirected light is directed laterally away from the longitudinal axis and the recording electrode site is configured to sample illuminated tissue. A method for assembling a waveguide neural interface device is also described.

Description

[0020] ... The waveguide neural interface device may provide a one-dimensional optical stimulation pattern (e.g., FIGURES 1 and 3-6), or at least a two-dimensional optical stimulation pattern (e.g., FIGURES 10 and 11). The waveguide neural interface device preferably provides such optical stimulation patterns with neural recording capabilities for applications of optogenetic techniques. For example, the device may enable the
As shown in FIGURES 1-9, the neural device 110 includes an electrode substrate and an array of electrode sites 112 coupled to the electrode substrate. The array of electrode sites 112 preferably includes one or more recording electrode sites that sample illuminated tissue, and may further include one or more stimulation electrode sites that provide electrical stimulation. At least a portion of the array of electrode sites 112, particularly the recording electrode sites, are preferably located adjacent to the light directing element 122 of the waveguide 120, in a manner to avoid direct illumination on the electrode site, thereby reducing or eliminating impact of the Becquerel effect on signals obtained through the neural interface device and improving the accuracy of data collection in the neural interface device. The neural device 110 is preferably substantially planar and includes a front face and a back face behind or opposite the front face. Although the front and back faces are preferably flat, the neural device 110 may alternatively have a curved shape, such as one in which the front and/or back faces are concave, convex, or wavy. In an alternative version, the neural device 110 is approximately cylindrical and the electrode sites 112 are arranged axially along and/or circumferentially around the neural device. The neural device 110 may alternatively have any suitable shape or cross-section, such as elliptical or rectangular. The neural device may be flexible (e.g., may include a flexible interconnect coupled to an electrode substrate) or rigid (e.g., electrode substrate coupled to a rigid backing, rigid carrier, or other rigid structure).

The waveguide 120 functions to redirect light away from the waveguide neural interface device to optically stimulate targeted tissue. In some embodiments, as shown in FIGURE 6, the waveguide 120 may further function as a carrier or other structure for providing structural support of the waveguide neural interface device for insertion into tissue. In these embodiments, the waveguide 120 is preferably rigid or rigid enough to provide support for insertion into tissue. For example, the neural device 110 may be a flexible neural probe substrate, with the waveguide 120 relatively thick and rigid and the neural probe substrate relatively thin and/or flexible. The waveguide 120 may be tapered, narrowing towards a distal end of the waveguide, to reduce tissue damage during insertion into the tissue. The waveguide 120 preferably receives light along its...
OBJECTIVE TECHNICAL PROBLEM

We regard D1 as the closest prior art document.

The **objective technical problem**, which the claimed invention addresses and successfully solves, is to deliver light in biological tissues (optical stimulation) via **multiple and independently addressable optical windows** using a non-intrusive probe equipped with **multiple co-localized recording sites**.
**Prior Art**

**D2** “Optetrode: a multichannel readout for optogenetic control in freely moving mice”

Polina Anikeeva, Aaron S Andalman, Ilana Witten, Melissa Warden, Inbal Goshen, Logan Grosenick, Lisa A Gunaydin, Loren M Frank and Karl Deisseroth

Nature Neuroscience, Volume 15, Number 1, January 2012
Received 4 August; accepted 24 October; published online 4 December 2011; corrected online 11 December 2011; doi:10.1038/nn.2992

**D3** Integrated device for optical stimulation and spatiotemporal electrical recording of neural activity in light-sensitized brain tissue

Jiayi Zhang, Farah Laiwalla, Jennifer A Kim, Hayato Urabe, Rick Van Wagenen, Yoon-Kyu Song, Barry W Connors, Feng Zhang, Karl Deisseroth and Arto V Nurmikko
**Teachings in the Prior Art**

**D1** foresees a neural device implantable in tissue and including an array of electrode sites that electrically communicate with their surroundings, and a wave guide, coupled to the neural device, that carries light along a longitudinal axis and includes a light directing element that redirects the carried light from the waveguide to illuminate selectively targeted tissue. There is no explicit reference to the possibility of using a multimode fiber to selectively stimulate different areas, on the contrary, D1 explicitly mentions “...a light directing element 122 that directs light laterally away from the longitudinal axis of the waveguide (i.e., the directed light is aimed or travels in a direction having a nonzero component perpendicular to the longitudinal axis of the waveguide). The light directing element 122 may be one or more of several variations, including one or more features that refract, reflect, focus, and/or scatter light, and/or perform any suitable manipulation of light.”

**D2** describes an optetrode, a device that allows for colocalized multi-tetrode electrophysiological recording and optical stimulation. In figure 1, the document mentions “...a protective tube containing the four tetrodes and the multimode fiber is glued.”, there is no other reference to the multimode fiber across the whole document. Complexity of the device and limitation about the co-localization of the electrodes (or tetrodes) are clear form figure 1.

**D3** describes “...a novel dual-modality hybrid device, which consists of a tapered coaxial optical waveguide (‘optrode’) integrated into a 100 element intra-cortical multi-electrode recording array... The single optrode is a tapered glass optical fiber with a sub-micron-sized aperture at its tip formed by gold metallization cladding... It was fabricated from a multimode optical fiber”. The device described is able to locally deliver light through the aperture at the tip of the tapered optical fiber to nearby neurons; the neuronal activities are recorded through the thermally metalized gold tip of the optrode. No co-localized multiple recording sites, no multimode fiber, no selective stimulation are mentioned.
PROBLEM-SOLUTION APPROACH

In order to decide whether an invention involves an inventive step the “problem-solution” approach consists in:

1. identifying the closest prior art, the most relevant prior art;

2. determining the objective technical problem, that is, determining, in the view of the closest prior art, the technical problem which the claimed invention addresses and successfully solves; and

3. examining whether or not the claimed solution to the objective technical problem is obvious for the skilled person in view of the state of the art in general.
**COULD-WOULD APPROACH**

Is there any teaching in the prior art, as a whole, that would, not simply could, have prompted the skilled person, faced with the objective technical problem formulated when considering the technical features not disclosed by the closest prior art, to modify or adapt said closest prior art while taking account of that teaching [the teaching of the prior art, not just the teaching of the closest prior art], thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves?

If the skilled person would have been prompted to modify the closest prior art in such a way as to arrive at something falling within the terms of the claims, then the invention does not involve an inventive step.

The point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he would have done so because the prior art incited him to do so in the hope of solving the objective technical problem or in expectation of some improvement or advantage. This must have been the case for the skilled person before the filing or priority date valid for the claim under examination.
INVENTIVE STEP ASSESSMENT

We regard D1 as the closest prior art document. This document describes a neural device implantable in tissue and including an array of electrode sites that electrically communicate with their surroundings, and a wave guide, coupled to the neural device, that carries light along a longitudinal axis and includes a light directing element that redirects the carried light from the waveguide to illuminate selectively targeted tissue.

However there is no teaching, in the examined prior art documents, that would and not simply could have prompted the skilled person to modify or adapt said closest prior art solving the objective technical problem, achieving what the invention achieves.
1. A multi-point light-delivering device, comprising a waveguide (1) carrying light along a longitudinal axis and including multiple optical windows (10), through which the carried light is out-coupled from the waveguide;

characterized in that said waveguide comprises a tapered region (5) along which said optical windows are distributed, wherein each optical window out-couples a specific subset of propagating modes of the carried light, to which said optical window is matched.

2. A device according to claim 1, wherein said multiple optical windows include at least one optical window formed on a side surface of the tapered region of the waveguide.
Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document(s):


D1 is regarded as being the prior art closest to the subject-matter of claim 1 and discloses a waveguide for stimulating neural tissue, the waveguide comprising a two-dimensional optical stimulation pattern.

The subject-matter of claim 1 therefore differs from this known device by optical windows arranged on a tapered region of the waveguide in an arrangement suitable for decoupling a subset of propagating modes.

The problem to be solved by the present invention may be regarded as to provide signal multiplexing.

The solution to this problem is considered as involving an inventive step because the prior art does not suggest to include the above-mentioned differentiating features.
**OPINIONE SCRITTA**

<table>
<thead>
<tr>
<th>Riquadro N.  V</th>
<th>Dichiarazione motivata a riguardo di novità, attività inventiva o applicazione industriale; citazioni e spiegazioni giustificative della dichiarazione</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 1. Dichiarazione</td>
<td></td>
</tr>
<tr>
<td>Novità (N)</td>
<td>Si: Rivendicazioni 1-11</td>
</tr>
<tr>
<td></td>
<td>No: Rivendicazioni</td>
</tr>
<tr>
<td>Attività inventiva (IS)</td>
<td>Si: Rivendicazioni 1-11</td>
</tr>
<tr>
<td></td>
<td>No: Rivendicazioni</td>
</tr>
<tr>
<td>Applicazione industriale (IA)</td>
<td>Si: Rivendicazioni 1-11</td>
</tr>
<tr>
<td></td>
<td>No: Rivendicazioni</td>
</tr>
</tbody>
</table>
# Patent Family

<table>
<thead>
<tr>
<th>Docket</th>
<th>Application</th>
<th>Filing Date</th>
<th>Publication</th>
<th>Publication Date</th>
<th>Patent</th>
<th>Issue Date</th>
<th>Patentno</th>
<th>Title</th>
<th>Inventors</th>
</tr>
</thead>
<tbody>
<tr>
<td>IT 300159K02175482 (TO2013/000000)</td>
<td>IT TO201300081</td>
<td>July 17, 2013</td>
<td>IT 0001418932</td>
<td>October 26, 2015</td>
<td>IT TO201300081</td>
<td>Strumento Optogenetico Per L’Energizzazione Multipla Ed Indipendente Di Fisiche Ottiche Patternate</td>
<td>Femuccio Pisanello, Luigi Martriradonna, Leonardo Silvio, Ian Oldenburg, Marco Pisanello, Bernardo Sabatini, John Assad, Massimo De Vittorio</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US 14/0053774</td>
<td>US 15/157706</td>
<td>January 17, 2016</td>
<td>US 15/157706</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Femuccio Pisanello, Luigi Martriradonna, Leonardo Silvio, Ian Oldenburg, Marco Pisanello, Bernardo Sabatini, John Assad, Massimo De Vittorio</td>
<td></td>
</tr>
</tbody>
</table>
THANK YOU

Lorenzo ROSSI

Fondazione Istituto Italiano di Tecnologia
Technology Transfer
lorenzo.rossi@iit.it