SOCIO ECONOMIA E BREVETTISTICA FARMACEUTICHE

insegnamento a scelta per

CTF e Farmacia 2018/2019

4 CFU

BREVETTO
FARMACEUTICO

www.brevettofarmaceutico.it

Il **brevetto** è un documento a contenuto tecnico-scientifico
con validità legale nel Paese in cui è stato rilasciato

Consente di proteggere l' invenzione **in regime di monopolio per 20 anni**

(+ proroghe per il brevetto farmaceutico)

Questo monopolio ventennale consente il **recupero degli investimenti**

- **R&D**
- **AIC**

e la programmazione di successivi investimenti in R&D

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Cosa si può brevettare in ambito farmaceutico ?

- formule
  - composizioni di sostanze
    - proteine
      - forme farmaceutiche
        - anticorpi
          - metodi di preparazione
            - sintesi
              - eccetera….

se presenti i tradizionali requisiti di brevettabilità:

novità, step inventivo, applicabilità industriale, liceità

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Nozioni di brevettistica farmaceutica/biotecnologica sono utili a:

chi fa ricerca

Università

chi gestisce l'attività di ricerca

Aziende farmaceutiche

Nuova figura professionale :

solide competenze scientifiche

+

essenziali competenze giuridiche

(facilmente acquisibili)

Successi economici e professionali

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INFO

PROGRAMMA INSEGNAMENTO	**Parte generale** comune a tutti i settori della tecnica **Parte speciale** brevetti medicinali: Chim Farm + Biotech (aggiornabile nel corso delle lezioni)
LEZIONI	Frontali con partecipazione di docenti esterni di chiara fama e/o cultori della materia
ESERCITAZIONI	In aula informatica: ricerca brevetti
ESAME	a) orale classico b) possibilità di iniziare l'esame orale presentazione PPT di un argomento originale scelto dallo studente inerente il programma

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TESI

PRATICO
PROFESSIONALE

3 mesi presso Società Italiana Brevetti – Dott. Germinario – Roma

6 CFU

COMPILATIVA
CLASSICA

3 CFU

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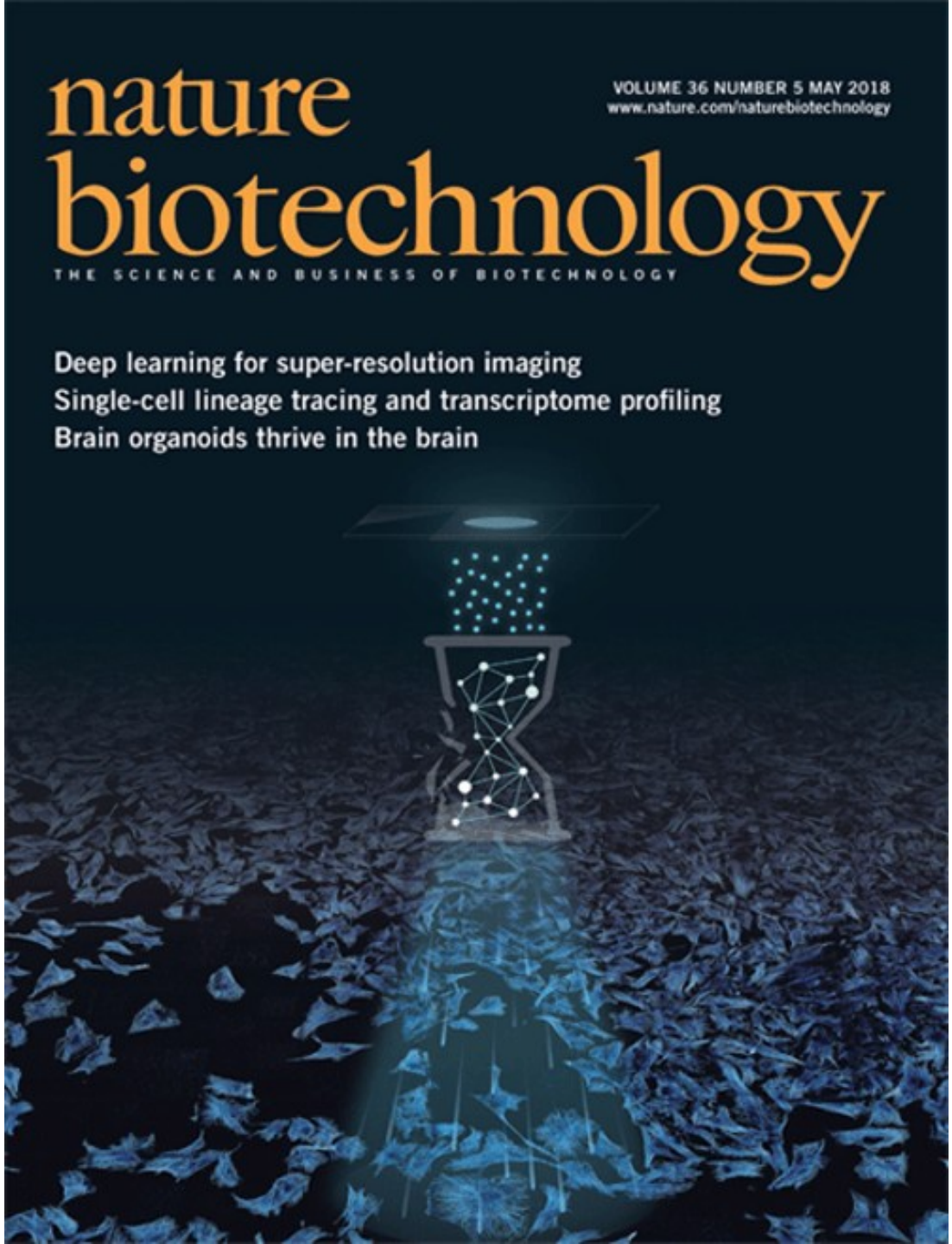
5 Maggio 2018



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1	CA-A CANCER JOURNAL FOR CLINICIANS	24,539	187.040	0.06452
2	NEW ENGLAND JOURNAL OF MEDICINE	315,143	72.406	0.69989
3	NATURE REVIEWS DRUG DISCOVERY	28,750	57.000	0.06077
4	CHEMICAL REVIEWS	159,155	47.928	0.24655
5	LANCET	214,732	47.831	0.40423
6	NATURE REVIEWS MOLECULAR CELL BIOLOGY	40,565	46.602	0.09573
7	JAMA-JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION	141,015	44.405	0.28035
8	NATURE BIOTECHNOLOGY	53,992	41.667	0.16973
9	NATURE REVIEWS GENETICS	32,654	40.282	0.10240
10	NATURE	671,254	40.137	1.43257
11	NATURE REVIEWS IMMUNOLOGY	34,948	39.932	0.09292
12	NATURE MATERIALS	81,831	39.737	0.20397
13	Nature Nanotechnology	48,814	38.986	0.17241
14	CHEMICAL SOCIETY REVIEWS	113,731	38.618	0.28411
15	Nature Photonics	35,595	37.852	0.12598
16	SCIENCE	606,635	37.205	1.15823
17	NATURE REVIEWS CANCER	46,017	37.147	0.08488
18	REVIEWS OF MODERN PHYSICS	45,510	36.917	0.06964
19	LANCET ONCOLOGY	38,110	33.900	0.12184
20	PROGRESS IN MATERIALS SCIENCE	10,521	31.140	0.01671

IF 41.667

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Patentability of antibodies for therapeutic use in Europe

Claudio Germinario, Sara Bertoli, Patrizia Rampinelli & Maurizio Cini

General guidelines are presented on the types of patent protection available for inventions arising from research in the field of monoclonal antibodies, using concepts drawn from European case law and expert practice.

Although antibodies and the substances derived from them have been patented for decades, new antibody-based inventions are of great interest owing to their potential applications in the fields of immunotherapy and diagnostics. Obtaining patent protection for these inventions is therefore an inevitable—but by no means routine—step for all researchers in the sector, and a considerable challenge for the patent experts involved. Here we provide some general guidelines on the types of patent protection available in the immunology field. We discuss the legal provisions and relevant case law, along with examples of their concrete application by sector experts in everyday practice, with particular focus on the specific circumstances surrounding the patenting of antibodies, especially monoclonal antibodies (mAbs) destined for therapeutic use.

Antibodies have long been used in a wide range of technologies, particularly in diagnostics (immunoenzymatic assays) and other biochemical analyses, including for the detection of specific markers for cancer and other diseases to diagnose tumors, bacterial infections or hormonal disorders; pregnancy tests; assessments of cancer immunohistopathology; and other uses.

Antibodies have proved useful for protein purification (e.g., of hormones or cytokines) by approaches such as immunoaffinity chromatography, and are also used in forensic medicine to assess autoantibodies in cases that require the identification of specific individuals. Individual-specific autoantibodies are autoantibodies that a person develops from birth and produces until the age of 2. Every individual possesses a specific complex of these antibodies.

More recently, antibodies have garnered interest for practical use as therapeutic agents in themselves owing to their cytotoxicity, such as antibody-dependent cell-mediated cytotoxicity (ADCC), or apoptosis-inducing potential. They are used to treat autoimmune diseases, cancer and immune deficiencies; to destroy pathogens; in anti-rejection therapy; and to enhance the immune defense system. They are also used as a means of interfering with the complicated mechanisms of stimulation or repression of the body's immune response, and as carriers in drug delivery and drug-targeting strategies. They can be used in radio-immunotherapy or as carriers to transport drugs to specific target tissues or organs; conjugated with toxins to form immunotoxins for cancer and viral therapy, or with enzymes to convert a pro-drug into a drug, as in the conjugation of tissue plasminogen activator with an antibody to fibrin, which helps dissolve thrombi; and attached to the surface of liposomes.

Equally recent applications involve the genetic manipulation of hybrid antibodies, which combine different proteins and functions to form 'abzymes' that have enzymatic and catalytic activity. Both enzymes and antibodies are proteins, and abzymes have the advantage of combining the specificity of a mAb with the catalytic capacity of an enzyme.

All antibody applications, especially those that use mAbs, depend on antibodies' ability to form specific and selective bonds with a given epitope on the surface of an antigen. This selective specificity is also key in determining the patentability of an invention involving antibodies.

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Patentability of antibodies for therapeutic use in Europe

The protection by patent of an antibody, especially of a mAb designed for therapeutic use, involves four general patent aspects: (i) the patentability of proteins, (ii) the structural or functional characterization of the object to be patented, (iii) selection inventions and (iv) inventions of therapeutic applications.

(i). An antibody is a protein complex and, like any other protein, falls within the definition of patentable biotechnological inventions as set forth in the articles of the European Patent Convention (EPC), along with the provisions of EPC Rules 26–30, which establish patentability rules and limits in the field of biotechnology[1]. An antibody may be identified as such by means of its structural or functional characterization.

(ii). As with all proteins, the structural characterization of an antibody is ascertained on the basis of its particular amino acid sequence (or partial sequence) through, for example, identification of the amino acid sequence of the variable region or, even better, the oligopeptide sequence of the complementarity-determining regions (CDRs) that enable the antibody to recognize an antigen.

Functional characterization of an antibody is the most common approach and entails a demonstration of the antibody's ability (function) to recognize and bind selectively to a specific antigen or, in the case of mAbs, to a specific antigenic site of a protein. For example, anti-PD-1 antibody is an antibody whose main characteristic is its capacity to recognize and bind to the PD-1 receptor.

These types of functional characterization are considered normal and admissible by the European Patent Office[2] and other national patent offices, provided certain conditions are met. The European Court of Justice has also

Abstract

Sono presentate linee guida generali sui possibili tipi di protezione brevettuale per invenzioni derivanti dalla ricerca nel campo degli anticorpi monoclonali, utilizzando concetti tratti dalla giurisprudenza europea e dalla pratica degli esperti.

UN MONDO DI SCIENZA

RICERCA I docenti autori dello studio e, dietro, gli studenti

ALMA MATER PUBBLICATO LO STUDIO DEL DIPARTIMENTO DI FARMACIA

«Brevetto per gli anticorpi monoclonali»

GLI ANTICORPI monoclonali, glicoproteine create in laboratorio con tecniche di Dna utilizzate nelle terapie innovative contro cancro, malattie autoimmuni e per trattamenti anti-rigetto, si possono brevettare. Un gruppo di ricerca del Dipartimento di Farmacia e Biotecnologie dell'Alma Mater ha messo a punto uno studio, pubblicato su Nature Biotechnology, per indicare i casi in cui gli anticorpi monoclonali possono essere considerati invenzioni e quindi essere brevettati per uso terapeutico. «Senza brevetti queste molecole non arriverebbero mai al paziente – spiega Patrizia Rampinelli, docente Unibo che ha guidato lo studio – perché le aziende farmaceutiche non investirebbero il denaro per arrivare alla messa in commercio di questi medicinali innovativi senza la necessaria protezione brevettuale. Il nostro lavoro aiuta i ricercatori e le Aziende a risolvere i dubbi sulla brevettabilità elencando una serie di casistiche, per ognuna delle quali abbiamo cercato di chiarire quando è possibile ottenere il brevetto. Inoltre, a livello nazionale è la prima volta che uno studio di questo genere viene pubblicato come articolo scientifico». Gli autori, oltre a Rampinelli, sono Claudio Germinario, Sara Bertoli e Maurizio Cini.

d. b.

Lo studente FEDERICO COSTANTINI, con cui stiamo collaborando per una pubblicazione, si è generosamente offerto come riferimento nel caso siate interessati al parere di chi ha già ha frequentato il corso

- mail o chiacchierata nelle pause delle lezioni -

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GRAZIE PER L'ATTENZIONE!

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