A CLOSER LOOK TO NEW PATENT LAW

THE CASE OF BIOTECHNOLOGY/GENETIC PATENTS

Dr. Emre Bayamlıoğlu
Law school
AN OVERVIEW OF GENETIC PATENTS US & EU
Judgments since the 1980s have confirmed that living things may be claimed in patent applications.
• Most legal jurisdictions encountered difficulties in incorporating
  – chemicals,
  – drugs, and
  – biological matter
into their patent systems.
Stretching of the patent system

• The patenting of **antibiotics** can easily be regarded as the **pivotal** development in the stretching of the patent system **into nature**. This is because the post-Second World War antibiotics revolution involved so much patenting activity.
Hormones

Once hormones were shown to be patentable, there was no reason to deny protection to other chemicals found in living things as long as they were purified or at least isolated in a way that made them available to the public for the first time.
• Today patent protection in relation to processes using living organisms is also widely accepted, provided the requirements of patentability,

✓ Novelty
✓ Inventive step
✓ Industrial app/utility are fulfilled;
Novelty

- Art. 54(2) European Patent Convention (EPC)

  (...) The state of the art shall comprise everything made available to the public (...)
Inventive step

• Art. 56 EPC

(….) it is not obvious to a skilled person in the art (…)
Industrial applicability

- Art. 57 EPC
  (...) if it can be made or used in any kind of industry (…)

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Sufficiency (enablement)

- **Art. 83 EPC**
  The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
General categories of biotechnological inventions

- human DNA sequences,
  recombinant production of human therapeutic proteins, genetic testing.
- human stem cells.
- transgenic plants and transgenic plant cells
- transgenic animals and animal cells.
THE US "MYRIAD" CASE
Gene Patents and Genetic Tests

• May 2013, actress Angelina Jolie underwent a preventive mastectomy surgery.

• BRCA1/2 gene mutations which made her susceptible to breast and ovarian cancer
Risk of Cancer (%)

- **General Population**
  - Breast Cancer By Age 50: 2%
  - Breast Cancer By Age 70: 8%
  - Second Breast Cancer By Age 70: 11%
  - Ovarian Cancer By Age 70: <1%

- **BRCA Mutation**
  - Breast Cancer By Age 50: Up to 50%
  - Breast Cancer By Age 70: Up to 87%
  - Second Breast Cancer By Age 70: Up to 64%
  - Ovarian Cancer By Age 70: Up to 44%
BRCA1 & BRAC2
deciding treatment options, such as prophylactic surgery, hormonal therapy, chemotherapy, and other measures.
• *Myriad Genetics Inc.* owns both “product” and “method” patents on BRCA1 and BRCA2 gene sequences.
• The product patents on the nucleotide strings that constitute the BRCA gene sequences confer Myriad with an exclusive right to conduct genetic tests for the detection of these BRCA mutations.
• Method patent involved ‘analyzing a sequence of a BRCA1 gene and comparing it with a reference sequence of a healthy gene to search for one of the enumerated mutations.'
Worldwide Reaction

Myriad licensed the test exclusively to a limited number of commercial genetic laboratories within specific geographical regions.
Refusal of the payment of 3,000 US Dollars by her health insurance

Patents on BRCA1 AND BRCA2 gene sequences owned by Myriad Genetics Inc. was challenged by a US citizen named Genae Girard joined by co-plaintiffs: ACLU, AMP
US SUPREME COURT
13th June 2013
• Genomic DNA ➞ gDNA
• Complementary DNA ➞ cDNA
• The isolation of a nucleotide string as it exists within the genome is not a patentable invention: \( \text{gDNA} \rightarrow \text{NO PATENTS} \)

*Myriad’s* principal contribution was nothing more than uncovering the precise location and nucleotide series of BRCA1 and BRCA2 genes.

The Court held that no matter how ground breaking; this was not an effort eligible for patent protection since it lacked the requisite inventive step.
cDNA contains only the nucleotides (exon) that are used by the ribosomes to code one of 20 amino acids. cDNA is an exons-only molecule (omitting the intervening introns), which is not naturally occurring - **cDNA ➔ PATENTABLE**
Genomic DNA ➔ gDNA

Compl. DNA ➔ cDNA
GENE PATENTS

EVIL?  INEFFICIENT?  OR USEFUL?
BRCA and GENETIC TESTING

EPO
Patent grant process before the EPO

Applicant

- Refusal of application

EPO

- Substantive examination
- Grant of European patent
- Opposition by third parties possible
- Limitation or revocation proceedings
- Opposition proceedings
- Appeal proceedings

Public domain

T" Decisions (Technical Board)
"G" Decisions (Enlarged Board)

CASE LAW
Finding of unrecognised substance occurring in nature is mere discovery and therefore unpatentable.

However, if a substance found in nature can be shown to produce a technical effect, it may be patentable.

A mere DNA sequence without indication of a function does not contain any technical information and therefore is not a patentable invention.
Relaxin

- Rule 29/2(23e) allows the patentability of biological material, and in particular of an element isolated from the human body, such as a GENE SEQUENCE.
BRCA 1/2 before the EPO

Myriad Genetics / EPO Patents, 2002

- 3 patents based on the genes BRCA1 and BRCA2
- 1 patent, relating to a method for diagnosing breast and ovarian cancer.
• Nucleic acid probes comprising a fragment of the 17q-linked breast and ovarian cancer susceptibility gene

AG GAA AGT TCT GCT GTT TTT AGC AAA AGC GTC CAG
AAA GGA GAG CTT AGC AGG AGT CCT AGC CCT TTC ACC
CAT ACA CAT TTG GCT CAG GGT TAC CGA AGA GGC GCC
AAG AAA TTA GAG TCC TCA GAA GAG AAC TTA TCT AGT
GAG GAT GAA GAG CTT CCC TGC TTC CAA CAC TTG TTA
TTT GGT AAA GTA AAC ATT ATA CCT TCT CAG TCT ACT
AGG CAT AGC ACC GTT GCT ACC GAG TGT CTG TCT AAG
AAC ACA GAG GAG AAT TTA TTA TCA TTG AAG AAT AGC
TTA AAT GAC TGC A

MAINTAINED AS AMENDED IN OPPOSITION.
• Mutations in the 17q-linked breast and ovarian cancer susceptibility gene
European Patent No. 0785216

- Chromosome 13-linked breast cancer susceptibility gene BRCA2

**MAINTAINED IN AMENDED FORM**

**FIGURE 3D**

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9781 CATTCCAGT GTCCAGCGAT CTGCGTACCT ATCCATCATT TTAGGCAGAC GGGGCCTAAT
9841 GCTAGAGTCA TTCCGCTGAT AAGGAAAGGG CTTGGATGCT TTTCTCTATA TTGGAGATGA
9901 TATATGACCA GTGATCTCCT GTGCCTGAGT CACCCCCCTG GCTGAGAGGG AAATGGACGA
9961 TACGGCAACG TACTCAATCA GTCTGAGAAC GAGGGGATGG GAATGGAGCA CAAAGGAGAC
10021 TGCACAAGAG GAAGACCTTG GATTTCTGG CTGTAACGTCC CTTTCCTCTCC ACTGTTGATT
10081 GCCATTATCA CATTGCTTTC TCCGGCTGCA CAGAGCCGAT TTACGCCACC AGGGATGTGT
10141 GGCACCAAA AAGAGCAACC CATATGCTAA AAGAGACTGA ATTCCTCTCT GACGGCTCCA
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10561 ACGAGTCATG ACTTTATCTG CACAGGGAGA AAGAATTATG GTTCTGAAAAT CTACTACGAC
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10801 AGCCAGAGGTT TCCGGACTCA GTCTGACGCA CTTAAGAGGA CCCCCTATCTT TACGGAGAA
10861 AAAAAACAGG GGAAGAGAAA ATCTCAAAATG TCTTCCGTCT TTGCCACCTAC AATATATTAT
10921 TATAGAATGA AATTAACCAA CCGATTCTCT TTGAGGGTGG TCTGTTAAATG GAATTGAGTC
10981 TCTTAAATCA GATTATTTGA TCGATATTTG ATCTGAATAT TTTAGAGGGA TGCTGCTGCT
11041 CTGAAGTTTT ATCCGAATCA GTGATCTCTA ATCCAAATAT ATGTTCTTGT
11101 CTATGTTACC AATCGAGAGT TCCATAGTGA GAGTTGTTAT TTCTCTTATGA
11161 CATTCTTTCA TCTTTACCTCA AAGGATGTA TAAGAAAAAT AGACCCTCTC GTATTAACCT
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11281 AATACCTTGA TCTATAATGA ATTATTTTT TTTTTAAACA AAATGGTTCT
11341 CCAAACATCAA ACTTGAAGAA ATATCTCTGT TCAAAATAGA CACT
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European Patent No. 0699754

- Method for diagnosing a predisposition for breast and ovarian cancer

The claimed method involved ‘analyzing a sequence and comparing it with a reference sequence of a healthy gene to determine whether one of the enumerated mutations had occurred.'

LIMITED TO DIAGNOSTIC METHOD ONLY FOR
FRAME SHIFT MUTATIONS.
CONCLUSIONS FROM THE EPO APPEAL

• Internal review
  – The internal opposition and appeal procedures of the EPC are structured so that “any” person may challenge the validity of a patent on broad terms

• External review
  – After the patent grant or the maintenance of the patent—potentially in amended form—the opportunity to challenge the patents in invalidity procedures before national courts remains open.
State Intervention: compulsory license

• compulsory licenses can be granted with respect to patents issued for
  ▪ medicines,
  ▪ medical devices,
  ▪ in vitro diagnostic medical devices, related therapeutic products, processes for obtaining such products, products necessary in obtaining these products,
  ▪ processes for manufacturing such products, and ex vivo diagnostic methods
• *statutory macro* policy tool: compulsory license
  – An indirect policy instrument with a preventive and dissuading effect towards patent holders applying (extremely) restrictive licensing policies and may compel a noncooperative patent holder to enter into fair and reasonable licensing negotiations.
• In reaction to Myriad patents, various European countries have
  – adjusted existing compulsory license regimes, or
  – designed additional compulsory license mechanisms to remedy problems resulting from restrictive licensing practices in particular in the field of genetic testing.
  • France, broadened the existing compulsory license in 2004.
  • Belgium, introduced a new compulsory license in 2005.
BIOTECHNOLOGY &
new TURKISH PATENT LAW
I) OMISSION
“Biotechnological Invention”

• Definitions / biotechnological invention:

  Rule 26 Imp. Reg. EPC

  – (2)"Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
II) SELECTIVE IMPLEMENTATION

Article 6

- Patents shall not be granted in respect of:
  
  a. inventions which are contrary to "ordre public" or morality; EPC Art. 53(a)

  b. (f) 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; EPC Art. 53(b)
Article 6

c. All methods for treatment of the human or animal body including surgery and diagnostic methods applied to human or animal body. (This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.)

EPC Art. 53(c)
Article 6

d. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

EPC - Implementing Regulations Rule 29/1

e. Processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

EPC - Implementing Regulations Rule 28, 98/44 EC – Art. 6
III) GENE SEQUENCES

Turkish Patent Law

NOT PATENTABLE

Art. 6(d) : The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Imp. Reg. R. 29/1

Imp. Reg. – R. 29/2

The human body and its elements - PATENTABLE

An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Imp. Reg. – R. 27(a)

biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
IV) SURGICAL METHODS EXCLUDED BUT, NOT SUBSTANCES USED in METHODS OF TREATMENT

Art. 6(c) ➔ EPC Art. 53(c)

- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.
- Exclusion of methods of surgery applied to all physical interventions in the human or animal body which require professional medical skills to be carried out and which involve substantial health risks.
Exception to exclusion = Article 6(c)

- **Exclusion** in Art. 6(c) shall not apply to products, in particular **substances or compositions**, for use in any of these methods.

  - substances used in treating patients remained **PATENTABLE**

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Art. 53(c) is the borderline between unallowable method claims directed to a therapeutic treatment and allowable claims to products for use in such methods.
**NOVELTY in Medical uses**

**Product:** "Substance X"

**1st medical use:** "Substance X for use in medicine"

**2nd medical use:** "Substance X for use in treating MS x 3 p/day"

**Further medical use:** "Substance X for use in treating MS once p/day prior to sleep"
**A) NEW MEDICAL USES OF KNOWN SUBSTANCES – EPC Art. 54/4**

- Any substance or composition comprised in the state of the art, cannot be excluded from patentability 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.

  - Such substances may not be regarded as lacking **NOVELTY**
    - “the novelty of the medicament is derived from the new pharmaceutical use – not the product

EPC Art.54/4  - No corresponding provision
A) SECONDARY USE – EPC Art. 54/5

• If a medicament is known to treat an illness, Article 54(5) EPC does not exclude patenting of this medicament for use in a different treatment of the same illness.

• Such patenting is also not excluded where a dosage regime is the only claimed feature not comprised in the state of the art.

EPC Art.54/5 - No corresponding provision
The treatment process

Compound

Drug Formulation

Route of Administration

Patient group

Dosage Regime

Treatment
NEW DOSAGE REGIMEN

- **Conclusions of G 2/08 EPC Art. 54/5**

  The new use within the meaning of Article 54(5) EPC need not be the treatment of another disease.

  Technical Boards of Appeal had established the patentability of second and further therapeutic uses of a known medicament in the broadest sense of the term by allowing claims not only directed to the treatment of another disease, but also claims drawing novelty from;

  - a new method of administration,
  - a new class of patients,
  - a new dosage regime.
once per day prior to sleep..

• Claim:
  – The use of nicotinic acid ... for the manufacture of a medicament....**once per day prior to sleep**...

• NOVELTY: inventive dosage regimen.

*Demonstrating inventive step will nearly always require experimental data to confirm some unexpected technical effect associated with the selected dose.*
Use of HCG for the manufacture of a medicament for treating male infertility "by subcutaneous administration"

Prior art: same by intramuscular administration

Subcutaneous novel and inventive over intramuscular administration;

Conclusion:

• difference in mode of administration basis for a new therapeutic use,

• Technical effect essential to acknowledge Inventive step
• Time to file a divisional application is shortened as 1 year.
  
  Imp. Reg. R. 36/1(a) = 24 months
  
  ➢ The divisional application is filed before the expiry of a time limit of twenty-four months

• EPC - Art. 76/1

  A divisional application may only be filed in respect of subject-matter which does not extend beyond the content of the earlier application as filed. The divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall enjoy any right of priority.
VI) NO IMPRISONMENT for PATENT VIOLATION

• TRIPs Article 61

.... Members **may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.**
VII) “Bolar exception” NOT REVISITED

• It is internationally a widely accepted principle that the submission of a request for a marketing authorisation for a pharmaceutical product by a generic company does not constitute patent infringement (the so-called Bolar exemption).

• The EU Council and the EU Commission marketing authorisation as well as the granting of an authorisation are considered as administrative acts and as such do not infringe patent protection" (Official Journal of the European Union 2003, C 297 E/66,).
Clinical trials and generic filings

  • “Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products”
Turkish Patent Law Art. 75

• The principle:
  – The Bolar exemption is that generic companies should be in a position to take the necessary preparatory measures in order to be able to enter the market without delay once patent protection expires.

• Art. 75(f): Acts done for experimental purposes relating to the subject matter of the patented invention, including authorization/market approval, testing and trials necessary thereof.
LESSONS TO BE LEARNT...
How to build a participatory regime
• patent term erosion
• (Supplementary Protection Certificates/ SPC) ”
• Data exclusivity is not like other intellectual property rights, such as patents or copyright. 6.07 The latter rights may be enforced privately against infringers in the courts. Data exclusivity is better characterized as a governmental or administrative obligation not to allow data that has been provided to support a registration dossier for an active ingredient to be used by third parties.
The industry specific nature of patent protection

• Innovation and patent patterns differ among sectors.
• Firms’ propensity to obtain patents differs across sectors and some industries rely more heavily on patents than others.
• And the construction of a patent portfolio is also industry specific.
Pharmaceutical industry

- Pharmaceutical industry is characterized by **noncumulative** innovation, where **the need for further research on a particular drug after the approval** of the public authority is not high.
- Pharma industry heavily relies on patent protection, and that it is one of the key users of the patent system. However pharmaceutical and biotechnology industries do not patent intensely, at least not in Europe.

![Barcode chart](image)
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U.S. Patents Granted in 2012

Source: IFI Claims Patent Services. (Chart by Bloomberg.)
More burdensome to obtain

- As to patent prosecution, chemical, pharmaceutical, and biotechnological patents seem to spend much longer in prosecution, cite more prior art, and are abandoned and refiled more frequently.
collaborative licensing

• the potential detrimental effect all that many DNA patents may have on further research and development, and on access to healthcare. The omnipresence of patents for DNA may produce an anti-commons effect, threatening rather than stimulating downstream innovation.

• At present, it is being examined to what extent new models of collaborative licensing may facilitate access to gene patents and render clusters of patents more readily available for use in research and healthcare.
• purely unitary system no longer fits the diverse needs of technology innovation.
  – tailoring the unitary patent rules to the needs of the different industries,
Research tools

• recombinant DNA was widely licensed on non-exclusive and inexpensive terms, which made the research tool conveniently accessible.

• Yet, the PCR and taq polymerase patents caused some problems. Cetus sold its PCR and taq polymerase patents to Roche and Roche started several litigations and license disputes with more than 200 scientists.
A PARTICIPATORY PATENT REGIME

• to address the impact of two key changes in patent law:
  ✓ a more diverse set of institutional actors;
  ✓ a more diverse set of stakeholders
Whose interests does patent law serve?

- Patent-holders?
- Competitors?
- The public?
Who is in the best position to address these respective interests?

• The legislature?
• The executive?
• The judiciary?
• The industry?
• And if so, how could the patent community optimally exercise this role?
Practical controversies ➔ philosophical inquiries.

• Is patent law still fulfilling the most basic functions of law?
• Has it reached its limits?
• Are other models more appropriate in an ever-changing technological environment?
• Is there a role for the patent community in this respect?
• patent system considers and is impacted by other policy making areas, such as
  – public health
  – privacy / human dignity
  – Competition law / antitrust.
How to establish a networked governance

• Patent system should be analyzed in its entirety by focusing on
  – the roles played by various actors, rather than the individual institutional actors themselves.
  – The interrelationships between formal institutions and informal actors
Instruments available

- persuasion,
- economic pressure,
- norm creation
- manipulation.
PRIMARY FORMAL ACTORS
The Legislator

• Sets the roles of the other actors through its grants of regulatory powers.

• Makes institutional, philosophical, economic, and policy choices.
The Examining Administrator

• Article 27 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement) requires signatory countries to carry out a substantive inquiry into novelty and inventive step.

• participatory mechanisms

• transparency mechanisms
The Examining Administrator

- PARTICIPATORY MECHANISMS
  - third-party participation at the initial stage of review of a patent.
  - present written statements during the course of proceedings.

- TRANSPARENCY MECHANISMS
  - formal “publication” requirements.
  - access to the files
  - informal” transparency mechanisms
    - Example: Blogs by experts, TPE, EPO employees
The Reviewers

• Two types of review
  – Internal administrative review - post-issuance procedures
    • re-examination
    • opposition.
  – External judicial review
    • initial review of factual and legal issues that impact an issued patent,
    • review of the internal administrative review.
REPLICATIVE ACTORS

• serves to supplement the role of a primary internal or adjudicative actor.

• Significant impact on doctrinal development.
  – Drug administration
  – Food administration
INFORMAL ACTORS
COMMUNITIES

• transnational firms with important patent portfolios,
• technically sophisticated lawyers,
• legal academics,
• legally trained scientific experts and officials
• ad hoc panels or institutionalized bodies

Epistemic communities continue to shape patent law reform, policies, and doctrine
THE PATENT CIVIL SOCIETY

• policy- influencing civil society organizations
  ✓ development and human rights NGOs,
  ✓ environmental and other pressure groups,
  ✓ trade unions,
  ✓ consumer organizations,
  ✓ faith-based and inter-faith groups,
  ✓ certain professional organizations.
PUBLIC’s ROLE
Interest groups

• Legislators often yield to intense interest group pressure, with variable outcomes that often do not take broader “public interest” values into consideration.

• The dominance of the “inventive community” ➔ the use of the legislative process to intensify certain inequities within the pre-existing patent regime.
• Full reliance on a small group of patent law experts
  ➔ serious democratic deficits in patent policymaking.