Patent Highlights 2012
US Biotech Patents: Recent Developments and Practical Considerations

Madrid, 15 October 2012
Barcelona, 16 October 2012
Introduction

Under the term "Patent Highlights" the organizers want to offer advanced patent training of major significance or special interest, in the form of one-day sessions. This training is held in duplicate: in Madrid and in Barcelona, in two consecutive days. This is the third Patent Highlights of 2012. Two others are being offered in 27-28 February and in 11-12 June.

The bases for patenting in the US are experiencing many changes every day. "US Biotech Patents: Recent Developments and Practical Considerations" intends to be an essential round up of the key questions and case law any patent practitioner need to know about patenting biotech inventions in US. Overlapping with our Curso Avanzado sobre Patentes, particularly its Módulo de biotecnología y biomedicina, has been reduced to a minimum. Given the substantial differences between US and Europe in terms of patentability in this field, and the recent developments that have occurred, this Patent Highlights session is particularly interesting to supplement the background of European practitioners.

The speaker is a experienced US patent attorney in a firm where many proceedings before the patent offices and courts have been handled. He will report about the recent trends in the courts on what is considered patentable subject matter for biotech inventions, an essential question in this field. Patentability of DNA/RNA sequences and related subject matter such as SNP, biomarkers and diagnostic methods will occupy a large part of the program. The key decisions on this matter will be dealt with: Myriad Genetics, Classen and Prometheus. The patentability of stem cells will be included. The course will also address infringement and practical claim-drafting considerations. We look forward to benefiting from the understanding and insights of the speaker and to discussing these important topics with course participants.

Objective

This one-day course will provide updated analysis and practical considerations related to recent developments of US biotech patents, to which European practitioners should pay special attention for the benefit of their employers or clients.

Who should attend

Spanish or European patent attorneys, patent lawyers, patent examiners, intellectual property consultants, experts from patent departments in industry and from technology transfer offices of research institutions or universities.
1. Background on written description and enablement requirements for biotechnology inventions
   a. Written description standard
   b. Enablement standard
      i. Utility prong of the enablement requirement
   c. Important factors particular to biotechnology inventions

2. Background on patentable subject matter for biotechnology inventions (§ 101)
   a. Supreme Court *Bilski* decision and its implications
   b. "Machine or Transformation" test and other approaches
   c. Software and business methods cases having an impact on biotech inventions
      i. *Cybersource Corp. v. Retail Decisions, Inc.* (Oct. 2011)
   d. Are claims having mental steps patentable?
   e. Justice Breyer (Supreme Court) dicta on *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*

3. Patentability of DNA/RNA sequences and related subject matter
   a. Gene sequences
      i. Isolated genes are patentable subject matter. *Ass’n for Molecular Pathology v. USPTO* (*Myriad Genetics*) (Federal Circuit, Jul 2011)
      ii. Cases where a claim to an isolated gene might not be patentable
         1. Complying with § 101, written description, and enablement simultaneously
      iii. Appeal of *Myriad* Federal Circuit decision filed with Supreme Court: current status
   b. ESTs, SNPs, antisense, and biomarkers
      i. How much utility does applicant need to show?
      ii. Are known sequences patentable if applicant is the first to demonstrate utility?
         1. Does the prior art need to enable its disclosure?
         2. Does the prior art need to provide utility for its disclosure?
      iii. Potential effects of written description and enablement issues on scope of allowed claim
   c. Diagnostic/screening methods
      i. Method claims comparing information not patentable (abstract mental processes) (*Myriad, Classen*)
      ii. Method claims having a transformative step are patentable (*Myriad, Classen*)
         1. How much transformation is required for patentability?
         2. Is the "transformation" test the most applicable test for diagnostic methods?
      iii. Are method claims containing transformative steps AND abstract mental processes patentable?
iv. *Mayo v. Prometheus*
   1. Federal Circuit decision in 2011. Case appealed to Supreme Court, oral argument on December 7, 2011
   2. Definitive Supreme Court decision
   3. Issues:
      a. Are method claims that cover observed correlations between blood test results and patient health patentable?
      b. Is "transformation" due to body chemistry acceptable?
   d. Kits
      i. Is the preamble disclosing an intended use limiting?
      ii. Can functional limitations impart patentability when the kit is known in the art?
      iii. Factors to consider for second-medical-use kits

4. **Patentability of stem cells**
   a. Stem cells qualify as patentable subject matter
   b. History and post-issuance challenges to WARF stem cell patents
   c. Lessons to be learned from WARF cases

5. **Infringement and practical claim-drafting considerations**
   a. Infringement under 35 U.S.C. 271
      i. Direct, induced and contributory infringement
      ii. Infringement by foreign manufacture and subsequent importation of a patented product into U.S.A.
      iii. Safe harbor against infringement for research activity under 35 U.S.C. 271(e)
   b. How much disclosure is necessary to support a claim?
   c. At what point during development should the application be filed?
      i. Effect of U.S. patent law reform on timing of filing
   d. Factors to consider when determining the desired scope of protection
   e. Drafting claims based on identity of potential infringers
      i. How many parties will be needed to infringe a method claim?
      ii. Is the primary care physician a party to the infringement?
      iii. For method claims, is manufacturing taking place outside the U.S.?
   f. Consider evidence necessary to prove infringement
Carlos M. Téllez

Carlos Téllez is J.D. from Georgetown University Law Center, Ph.D. in Chemical Engineering from University of Arizona, M.S. in Mathematics from Southern Oregon University and B.S. in Chemical Engineering from University of Guanajuato, Mexico.

Dr. Téllez works as an associate at Finnegan in Washington DC. He focuses on client counseling, and domestic and foreign patent prosecution in the biotechnology and chemical areas. His work includes development of patent strategies and opinion counseling such as validity/invalidity, freedom to operate, and due diligence.
Venue in Madrid
Oficina Española de Patentes y Marcas
Sala de Usos Múltiples (planta 16)
Paseo de la Castellana 75
28046 Madrid

Time
10:00 to 18:00 h
With lunch break

Venue in Barcelona
Auditori Antoni Caparrós
Parc Científic de Barcelona
Baldiri Reixac 4 - Torre D
08028 Barcelona

Attendance Fee
250,00 EUR + 18% VAT
Includes course documentation and lunch

Registration
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Payment
By bank transfer to the account
no. 2013-0088-63-0200326711
By cheque payable to Fundació Bosch i Gimpera (projecte 3584)
Payment must be received by 1 October 2012
Provide invoice details
Invoice and confirmation will be forwarded to you

Notes
A certificate of attendance will be provided under request
The organizers reserve the right to cancel this course or to modify any aspect thereof. Besides, they are not responsible for the opinions expressed by the speakers

Cancellation
Fee will be refunded
(less 4% administration expenses)
if cancellation occurs on
1 October 2012 at the latest

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