MEMORANDUM

DATE: June 13, 2013

TO: Patent Examining Corps

FROM: Andrew H. Hirshfeld
Deputy Commissioner
For Patent Examination Policy

SUBJECT: Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc.

Today in Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad), the Supreme Court held that claims to isolated DNA are not patent-eligible under 35 U.S.C. § 101. Myriad significantly changes the Office’s examination policy regarding nucleic acid-related technology. The purpose of this memorandum is to provide preliminary guidance to the Patent Examining Corps.

As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally-occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 2106, Patent Subject Matter Eligibility.

In Myriad, the Supreme Court considered the patent eligibility of several claims directed to isolated DNA related to the human BRCA1 and BRCA2 cancer susceptibility genes. The Supreme Court held that certain of Myriad Genetics’ claims to isolated DNA are not patent-eligible, because they read on isolated naturally-occurring DNA that is a “product of nature.” The Court held that isolating a “gene from its surrounding genetic material is not an act of invention.” The Supreme Court held that other claims are patent-eligible, because they are limited to cDNA, which is a type of man-made DNA composition that is not naturally-occurring. The Court held that “cDNA is not a ‘product of nature’ and is patent eligible under §101.”

The USPTO is closely reviewing the decision in Myriad and will issue more comprehensive guidance on patent subject matter eligibility determinations, including the role isolation plays in those determinations.
Dr. William Simmons is a senior associate and his practice involves worldwide procurement, defense and enforcement or invalidation of patents in the biotechnology and related arts. He has extensive experience with monoclonal antibodies, fusion proteins, cytokines and genetic technologies, including experience working with multiple blockbuster drugs. Dr. Simmons frequently speaks on developments in biosimilar (follow-on biologic) law.

Dr. Simmons works in all areas of patent law, and has in depth experience in interferences (e.g., Centocor, Inc. v. Abbott GmbH & Co., KG; Interference No. 105,592 and Institut National de la Recherche Agronomique v. BASF Plant Science GMBH, McGill University, and DNA Landmarks, Inc., Interference No. 105,682), reexaminations (e.g., Control. No. 90/010,039), oppositions (e.g., Amgen, Inc. v. ImmunoGen, Inc., Australia Appl. No. 2003241580), and the management of worldwide patent dossiers. He frequently prepares opinions regarding patentability and infringement and has performed and managed complex, extensive freedom-to-operate analyses. Dr. Simmons also conducts pre-suit investigations and provides litigation support.

Dr. Simmons draws on over ten years of rich, preclinical scientific research, stemming from his laboratory work in genetic engineering and protein engineering in the fields of molecular immunology and molecular oncology, bringing Sughrue Mion's clients insightful, creative solutions to meet their diverse patent needs. He completed a post-doctoral fellowship, funded by the National Institutes of Health at New York University, where his work involved modulating cell signaling while working in collaboration with Cephalon, Inc. and Isis Pharmaceuticals. His predoctoral work included collaborations with Biogen, Millennium Pharmaceuticals, Pfizer, and Genetics Institute and involved work on LTβR-Ig, CTLA4-Ig, IL-2, CD30, CD30L, and IL-12, etc. Dr. Simmons began his work at New York University in the laboratory originally founded by Nobel Laureate Dr. Baruj Benacerraf, directly mentored by Dr. Benacerraf's protégée Dr. Jeanette Thorbecke, an internationally recognized immunologist and past president of the American Association of Immunologists.

Dr. Simmons works on subject matter spanning the life sciences, such as biologics engineering, diagnostics and therapeutic methods in molecular and cellular biology, immunology, microbiology, biochemistry, genomics, computational biology, small molecule pharmaceuticals, biopharmaceuticals and nanobiologics.
Dr. Simmons is a frequent commentator, speaker and author on patent law and is involved in pilot programs at the USPTO, which aim to improve the process of patenting in the U.S. He has lectured on numerous topics including strategies for biopharmaceutical patent procurement and litigation and Patent Law Reform. He lectures at the State University of New Jersey and has published in and or has been quoted by Science, Nature, Nature Biotechnology, BNA Bloomberg, Nature Medicine and others.

**News**

- **6/13/2013**  
  Patent Claims To Products Found In Nature or Such Products Chemically Modified Via Their Isolation Struck Down

- **5/13/2013**  
  US Supreme Court Agrobiotech Decision Released; The Court Upholds Biotech Patent Rights, For Now

- **4/5/2013**  
  Controversial, Upcoming Agrobiotech Monsanto Decision

- **2/1/2013**  
  Biosimilar State Laws Emerge

- **8/16/2012**  
  Federal Circuit Upholds Patent Eligibility of Isolated Genes

- **3/21/2012**  
  The Fate of Medical Methods Drawn Into Question By The Supreme Court

- **2/9/2012**  
  FDA Forges Ahead In U.S. Biosimilar Product Regulation

- **3/6/2011**  
  Sughrue Discusses Rapid Advances in U.S. and European Biosimilar Pathways

- **10/4/2010**  
  Sughrue Discusses Biopharma Law at AIPPI 2010

- **7/16/2010**  
  Sughrue Attorneys to Lead International Conference on Biosimilars

- **7/1/2010**  
  Sughrue Attorney Weighs in with Nature News Regarding Bilski v. Kappos

- **6/27/2010**  
  Sughrue Attorneys Lead ABA Program on Biosimilars

- **5/11/2010**  
  Sughrue Mion Sponsors the American Association of Immunologists (AAI) Annual Meeting

- **3/22/2010**  
  Biosimilar Approval Pathway Created by Patient Protection and Affordable Care Act

- **8/7/2009**  
  Sughrue Continues Winning Streak in Interference Proceedings

- **1/21/2009**  
  Sughrue to Host 11th Annual Sughrue Symposium

- **7/20/2007**  
  Sughrue To Co-Sponsor Nanotechnology Symposium on “Exploring The Future: Nanotechnology Innovation And Opportunities”

**Events**

- **6/25-26/2013**  
  3rd Biosimilars Summit 2013  
  Speaker

**Publications**

- Summary of Alcon Research, Ltd. v. Apotex Inc., No. 2011-1455

- Summary of Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.

- According to BNA/Bloomberg, Caution Ahead - Justices Scalia, Kennedy, Thomas and Alito Say PPACA Biosimilar Pathway Defective, available here.
<table>
<thead>
<tr>
<th>Title</th>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Person: A Career in Biotech Patent Law</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;Tips for Drafting Biotechnology and Pharmaceutical Patent Applications in the U.S. and Beyond,&quot;</td>
<td>Pune, India 2011</td>
<td>speech</td>
</tr>
<tr>
<td>Thioredoxin 1-Mediated Post-Translational Modifications: Reduction, Transnitrosylation, Denitrosylation, and Related Proteomics Methodologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>US Supreme Court avoids clarifying patent stance</td>
<td></td>
<td>publication</td>
</tr>
<tr>
<td>&quot;IP Strategies for Launching Biosimilar Ventures in the US&quot;, Bangalore India, 2010</td>
<td>speech</td>
<td></td>
</tr>
<tr>
<td>&quot;Navigating the US Biosimilar Pathway&quot;, Hyderabad India, 2010</td>
<td>speech</td>
<td></td>
</tr>
<tr>
<td>&quot;The Impact of Bilski on Pharmaceutical and Biotechnology&quot;, Akron School of Law, 2009</td>
<td>speech</td>
<td></td>
</tr>
<tr>
<td>Bilski Blundering Biotechnology, Nature Biotechnology, March 2009</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nanopharmaceuticals: Patenting Issues and FDA Regulatory Challenges</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;Determining Inventorship in Complex Multifaceted Pharmaceutical and Biotechnology Patent Applications&quot; Greater Noida, India, 2008</td>
<td>speech</td>
<td></td>
</tr>
<tr>
<td>&quot;Patenting Biotechnology Inventions in the U.S. - Focus on Recent Developments in Utility Patent Law&quot; Greater Noida, India, 2008</td>
<td>speech</td>
<td></td>
</tr>
<tr>
<td>&quot;Written Descriptions of Biotechnology and Pharmaceutical Inventions&quot; Greater Noida, India, 2008</td>
<td>speech</td>
<td></td>
</tr>
</tbody>
</table>

Interleukin-12-induced cytotoxicity against syngeneic B cell lymphomas of SJL/J mice. Leuk Res. 2002 Jun;26(6):577-90. (publication)


META-controlled env-initiated transcripts encoding superantigens of murine Mtv29 and Mtv7 and their possible role in B cell lymphomagenesis. J Immunol. 2001 May 1;166(9):5422-9. (publication)


Memberships & Affiliations

American Intellectual Property Law Association (AIPLA)

American Bar Association (ABA)

American Society for Biochemistry and Molecular Biology

American Chemical Society

American Association of Immunologists

Member, Sigma Xi- 1997-Present