Gene and genome patents: How to navigate their complexity?

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Based on invited talks at the International Association for Plant Biotechnology- New Zealand and QUT library, 2013.
Legal Contention- USA

• Tension has existed since 1980
• On April 15, 2013, the US Supreme Court began hearing the Myriad case and addressing the question: ”Can human genes be patented?”

• Whether isolated gene fragments are products of Nature or man-made.
Legal contention-Australia

• On February 15, 2013, Federal Court Justice John Nicholas held that “an isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide…” is a patentable subject matter under Australian law.

• On April 2, 2013, a draft report on pharmaceutical patents that advocates weaker rights on gene patents was published.

• On 5 April, 2013, the government released an independent government review of health and medical research arguing for stronger gene patents.

• On 15 April, 2013, amendments on the nation’s patent law system came into effect, raising the bar but not confronting the gene patenting issue.

• [http://sciblogs.co.nz/stick/2013/02/21/australian-gene-patent-held-valid-patent-is-for-isolated-nucleic-acid-not-for-information-per-se/](http://sciblogs.co.nz/stick/2013/02/21/australian-gene-patent-held-valid-patent-is-for-isolated-nucleic-acid-not-for-information-per-se/)
• [http://news.sciencemag.org/scienceinsider/2013/04/in-australia-gene-patents-also-s.html](http://news.sciencemag.org/scienceinsider/2013/04/in-australia-gene-patents-also-s.html)
Scientifically

- Chromosomes break into DNA fragments by natural biologic processes
- These DNA fragments are ubiquitous in the human body
- These fragments cover genes claimed by Myriad’s patents

http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v2/12-398_neither_amcu_lander.authcheckdam.pdf
Social and economic issues

- Gene patents are key for investors & pharmaceutical industry.
- Gene patents improve health care services one gene at a time.
- Gene patents stimulate research and follow on innovations by full disclosure.
- Gene patents claim only isolated DNA.
- Gene patents are well regulated by various rules and laws.

- Gene patents prevent new entrants in the market.
- Gene patents are not inventions and should not be issued.
- Gene patents stifle research and follow on innovations.
- Gene patents drive the high cost of health care services.
- Gene patents are benefiting only the few.
- Gene patents are unethical.
- Gene patents invade patients’ privacy.
Where is the empirical data?

- Can we navigate the complexity of gene and genome patents?
- What are the implemented practices for the public availability and use of patent sequence information?
- What resources can we develop to transform that information into public knowledge?
“Locatable region of genomic sequence, corresponding to a unit of inheritance, which is associated with regulatory regions, transcribed regions and/or other functional sequence regions.”

Pearson, NATURE|Vol 441|25 May 2006
Gerstein et al, 2007, Genome Res. 2007. 17: 669-681
Biological complexity revealed by ENCODE. (A) Representation of a typical genomic region portraying the complexity of transcripts in the genome.

Gerstein M B et al. Genome Res. 2007;17:669-681
Variation in standards and formats of submitted sequences in patents

Disclosure requirements; US7777022 discloses 4,204,095 sequences

Diversity of sequence claiming and redundancy issues

Narrow vs broad claims

Genetic sequence and patents

1982 First patent on a genetic sequence, US 4,322,499_A

323,721 patents containing sequence listings (processed so far)
147,565,859 enriched sequence listings

2012

Variation in standards and formats of submitted sequences in patents

Cambia

QUT
Narrow claim

• US 7,074,915_B2, claim 2, is for "A synthetic nuclease resistant antisense oligo deoxynucleotide, the nucleotide sequence of which is:

5’ CTGCCACGTTTCTCCTGACCC 3’ (SEQ ID NO:1)."
Broad claim

• US 6,475,797_B1, claim 13:
• “A compound up to 50 nucleobases in length comprising at least an 8-nucleobase portion of SEQ ID NO: 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 29, 31, 32, 33, 34, 36, 37, 38, 40, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 64, 65, 66, 67, 69, 70, 71, 72, 73, 74, 75, 77, 78, 80, 81, 82, 83, 85, 86 or 87 which inhibits the expression of SR-cyp.”
Broad patent(2)

• It claims a compound, not a specific type of molecule. This means that it includes DNA, RNA, and all artificial modifications thereof.

• It only necessitates an 8 nucleobase portion of the sequence. This means that any 8-nucleobase portion of the listed sequences would potentially infringe. So each of the 20-mers listed for the sequences potentially includes about 12 infringing sequences. To get a sense of how much of the genome is claimed, you’d need to BLAST each of those 12 possibilities against the genome.
Survey of patent offices

• Most patent offices offer the sequence listings information as part of the patent document and
• They are in pdf or image format NOT machine searchable!
• Compliance with the standards or rules is not consistent among jurisdictions.
• Most patent offices do not keep track of the number of sequence listings.
Sequence listings in PatSeq 2012 dataset

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<th>Patent document</th>
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(June2012)
# Sequence listings coverage in granted patents
(2012 dataset)

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<th>Jurisdiction</th>
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The biological Lens at http://www.lens.org/lens/biological_search
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