Update on what is patentable in the Biotech Sector

December 8, 2014

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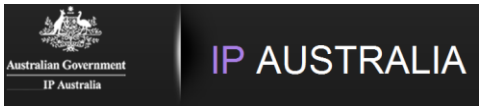
Lawyers • Patent and Trade-mark Agents

Update - what is patentable in Biotech:

- Utility & the promise of the patent (Canada)
- Gene patenting & Natural products



- Conclusions

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Promise of the Patent - unique to Canada:

i) "Applicants have now discovered"

ii) "[the product] possessed a unique combination… making it outstanding"

iii) "[the product] displays surprising and unexpected properties", "surprising and excellent results", "the invention shows marked superiority"

i) Eli Lilly Canada Inc. v. Novopharm Ltd et.al. (2009), 76 CPR (4th) 407.

*ii) Ratiopharm Inc. v. Pfizer Limited, (*2009) FC 711.

iii) Eli Lilly Canada Inc. et. al. v. Novopharm Ltd, (2009) FC T-1048-07

Promised Results: Canada

- In each case:
  - no advantage or promise of the invention being unique or outstanding over the prior art was established;
  - evaluation of specification and external data considered;
  - patents lacked utility and were found invalid

- Use of language that makes a promise in a specification needs to be carefully considered
- A promise requires comparative data demonstrating the improvement to be included in the specification

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Promise of the Patent

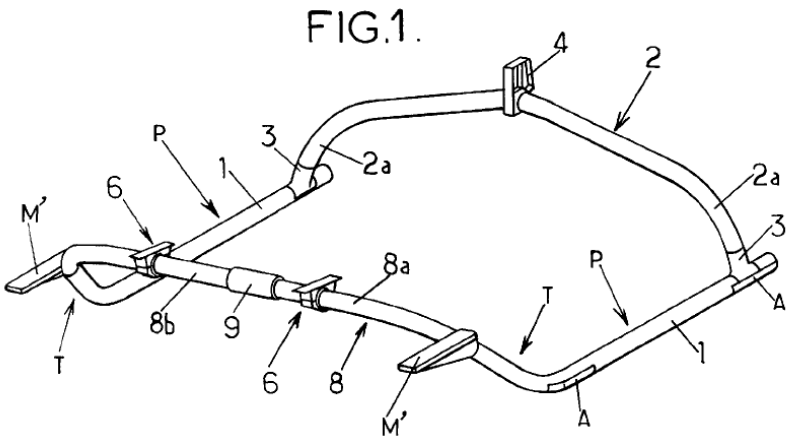
Utility - Yes

- Quiapril 2005 (ACE inhibitor): FC & FCA
- Nefazodone 2005 (depression): FC & FCA
- Omeprazole 2007 (gastric ulcer): FC
- Atorvastin 2008 (cholesterol): FCA rev'g
- Perindopril 2008 (blood pressure): FC & FCA
- Metamine 2009 (Alzheimer's): FC
- Escitalopram I 2009 (antidepressant): FC, FCA
- Latanoprost I 2009 (glaucoma): FC & FCA
- Atomoxetine I 2010 (ADHD): FC
- Escitalopram II 2010 (antidepressant): FC
- Olanzapine 2010 (schizophrenia): FCA, rev'g
- Lovastatin 2010 (cholesterol): FC & FCA
- Replinigade 2010 (diabetes): FC
- *Bauer 2010 (skate quarter): FC & FCA*
- Latanoprost II 2011 (glaucoma): FC
- Rosiglitazone 2011 (diabetes): FC
- Anastrozole 2011 (cancer): FC & FCA
- Donepezil 2011 (Alzheimer's): FC & FCA
- Fenofibrate 2012 (cholesterol): FC
- Efavirenz 2012 (HIV): FC
- Imatinib 2013 (leukemia): FC
- ★ Clopidrogel 2013 (platelet aggregation): FCA rev'g
- Zelendroic acid 2013 (bone resorption): FC (for '937)
- Lumigan 2014 (glaucoma): FC [sound prediction]
- Celecoxib 2014 (NSIADs); FC & FCA

Utility - No

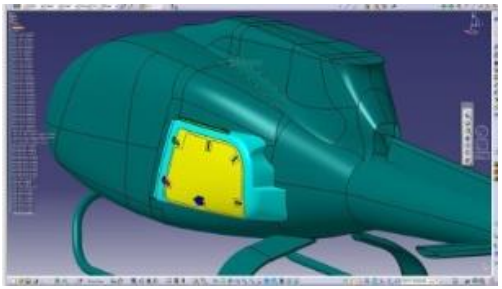
- Ramipril I 2005 (blood pressure) FC & FCA [sound prediction]
- Atorvastin 2007 (cholesterol): FC
- Modafinil 2008 (narcolepsy): FC
- Rampril II 2009 (blood pressure): FC & FCA
- Amlodipine 2009 (blood pressure): FC & FCA
- Atomoxetine II 2010 (ADHD): FC &FCA
- Esomeprazole 2010 (acid reflux): FC
- Olanzapine 2009, 2011 (schizophrenia): FC 2x's
- Irbesartan 2010 (blood pressure) FC
- Latanoprost II 2011 (glaucoma): FCA rev'g
- Clopidrogel 2011 (platelet aggregation): FC
- Zelendroic acid 2013 (bone resorption): FC (for '895)
- *Eurocopter 2012, 2013 (landing gear): FC & FCA (partial)*
- Olopatadine 2014 (eye drops): FC [sound prediction]
- Esomeprazole 2014 (gastric acid) (FC) [sound prediction]

- Disclosed a landing gear with a forward or backward offset cross-piece:



- Specification stated that the landing gear reduced the problem of ground resonance
  - potentially dangerous vibrations that can occur on landing
- This statement considered by the Court to be a promised utility for both forward and backward offset

- Backward offset never made or tested
  - backward offset modeled;
  - "calculations and mathematical modeling are, by their very essence, a prediction of a given utility" – and not a demonstration of utility
  - no explanation of the promised effect of reduced ground resonance for the backward offset provided.



- "Eurocopter did not provide evidence that it had either demonstrated or soundly predicted the utility of the backward inclination embodiment prior to [the filing date]."
  - all claims to generic offset or backward offset landing gear lacked utility
  - claim 15 (forward offset) held valid and infringed

"[64] the inventor need not expressly set out the utility of the invention in the patent…utility can be shown to be demonstrated or soundly predicted as of the patent's filing date….the threshold that must be proven to establish utility is generally quite low, described as being no more than a "scintilla of utility"...

"[65] The promise doctrine represents an exception to the above minimum statutory requirements. Though an inventor need not describe any particular utility for the invention, an inventor who explicitly promises a specific result will be held to that promise when called upon to prove utility." (emphasis added)

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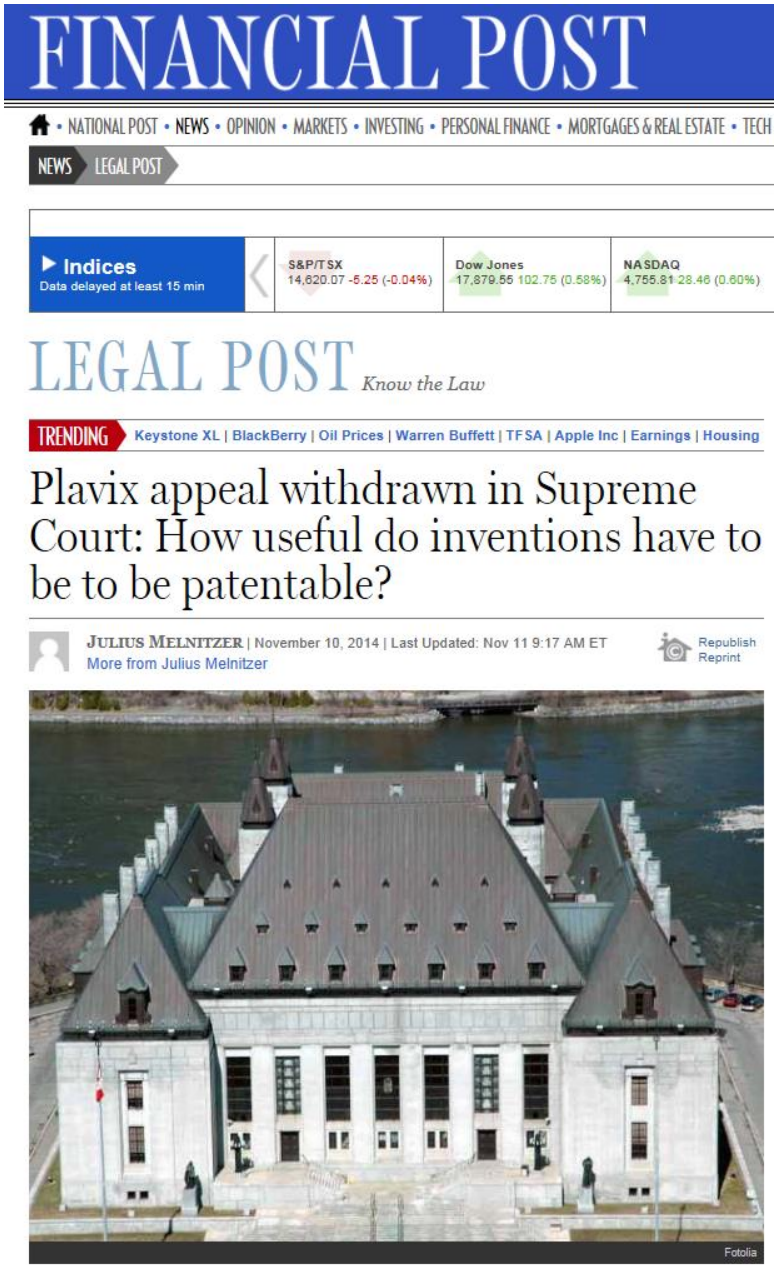
Plavix ® /Clopidrogrel appeal to Canadian Supreme Court withdrawn



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S&P/TSX 14,620.07 -6.25 (-0.04%)
Dow Jones 17,879.55 102.75 (0.58%)
NASDAQ 4,755.81 28.46 (0.60%)

LEGAL POST *Know the Law*

TRENDING Keystone XL | BlackBerry | Oil Prices | Warren Buffett | TFSA | Apple Inc | Earnings | Housing

Plavix appeal withdrawn in Supreme Court: How useful do inventions have to be to be patentable?

JULIUS MELNITZER | November 10, 2014 | Last Updated: Nov 11 9:17 AM ET
More from Julius Melnitzer

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Federal Court of Appeal:

- not every patent contains an explicit promise of a specific result;
- there is no obligation on the part of the inventor to disclose the utility of the invention in the patent;
- advantages were clearly disclosed in the patent specification and demonstrated at the time of the patent application.

-Day before Supreme Court hearing, Apotex withdrew appeal

SANOFI APOTEX ADVANCING GENERICS

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Will the patentability of genes survive?

Howard Leslie Hoffenberg

Recent court decisions in the United States and Europe have brought the patentability of genes under attack.

NATURE BIOTECHNOLOGY VOLUME 28 NUMBER 9 SEPTEMBER 2010

MYRIAD

Not quite a myriad of gene patents

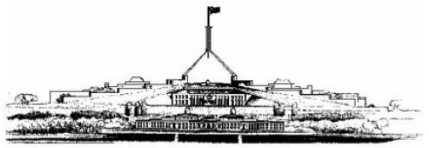
Gregory D Graff, Devon Phillips, Zhen Lei, Sooyoung Oh, Carol Nottenburg & Philip G Pardey

A new study assesses the impact of recent US Supreme Court rulings on the changing landscape of US patents claiming nucleic acids.

VOLUME 31 NUMBER 5 MAY 2013 NATURE BIOTECHNOLOGY

COMMONWEALTH OF AUSTRALIA

PARLIAMENTARY DEBATES



THE SENATE

PROOF

PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

First Reading

PROCEDURAL TEXT

Wednesday, 24 November 2010

BY AUTHORITY OF THE SENATE

European Parliament
Texts Adopted by Parliament
Provisional Edition : 04/10/2001

Patenting of human genes
B5-0633, 0641, 0651 and 0663/2001

European Parliament resolution on the patenting of BRCA1 and BRCA2 ('breast cancer') genes

MYRIAD
GENE PATENT LITIGATION

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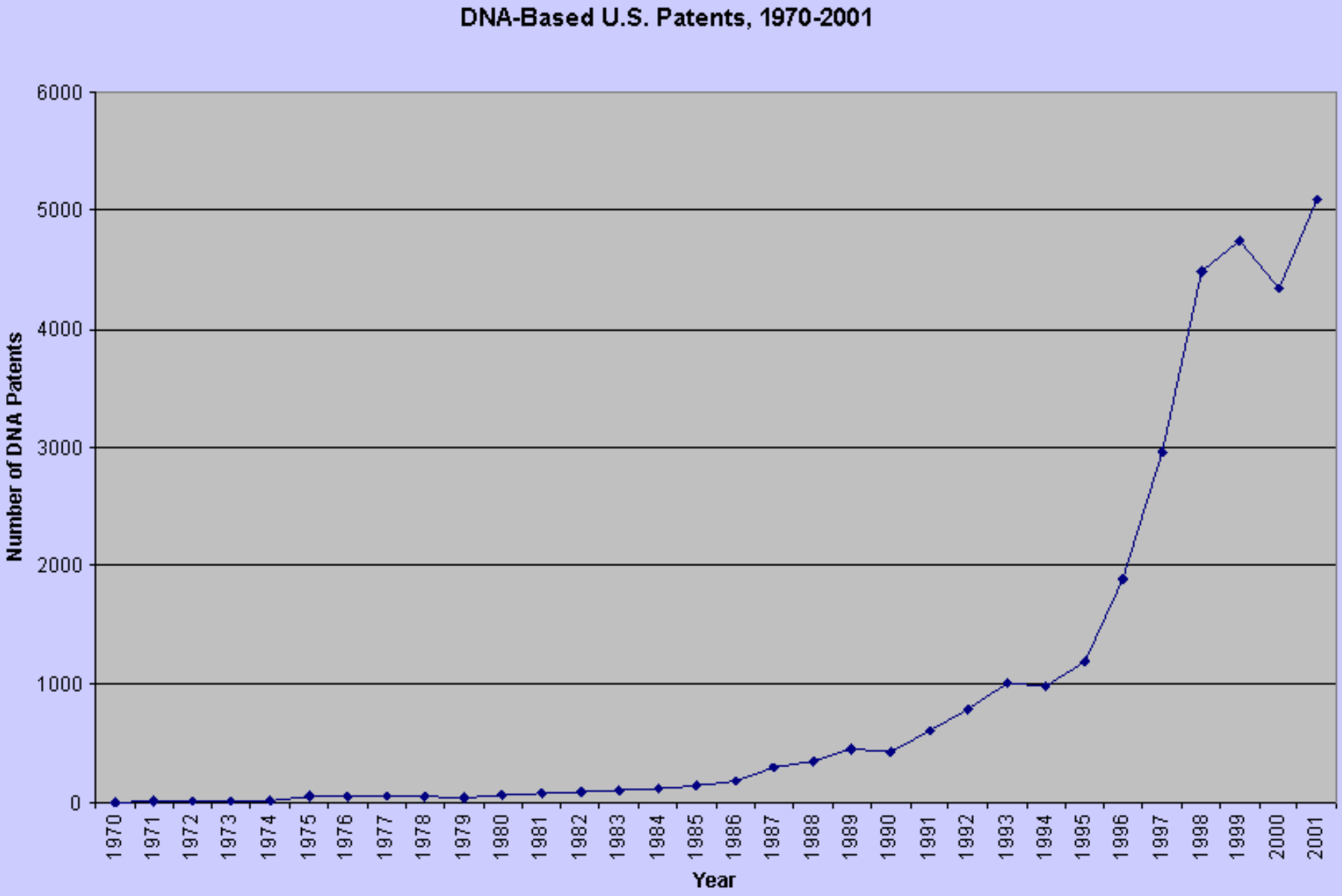

Source: LeRoy Walters, DNA Patent Database, January 2002

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 July 1998

on the legal protection of biotechnological inventions

Article 5

1. 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.

2. 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.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

European Patent Convention Rule 23(e) (2000)

1) 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.

2) 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.

3) industrial application must be disclosed

Europäisches Patentamt
European Patent Office
Office européen des brevets

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USPTO Guidelines: January 2001

Utility Examination Guidelines

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the "utility" requirement of 35 U.S.C. 101. This revision supersedes the Revised Interim Utility Examination Guidelines that were published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136 (2000); and correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67 (2000).

DATES: The Guidelines are effective as of January 5, 2001.

Responses to Specific Comments

(1) *Comment:* Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions. *Response:* The suggestion is not adopted. An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S.

uspto.gov
The United States Patent and Trademark Office
an agency of the Department of Commerce

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USPTO Guidelines: January 2001

When Congress enacted the patent statutes, it specifically authorized issuing a patent to a person who "invents or discovers" a new and useful composition of matter, among other things. The pertinent statute is 35 U.S.C. 101, which reads: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

uspto.gov
The United States Patent and Trademark Office
an agency of the Department of Commerce

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Trilateral Studies re: patentability of DNA (~1999)

Trilateral Project B3b

Comparative study on biotechnology patent practices

Theme: Patentability of DNA fragments

4. Conclusion

Following points are revealed through this comparative study.

1. A mere DNA fragment without indication of a function or specific asserted utility is not a patentable invention.
2. A DNA fragment, of which specific utility, e.g. use as a probe to diagnose a specific disease, is disclosed, is a patentable invention as long as there is no other reasons for rejection.
3. A DNA fragment showing no unexpected effect, obtained by conventional method, which is assumed to be part of a certain structural gene based on its high homology with a known DNA encoding protein with a known function, is not a patentable invention. (EPO, JPO)
   The above-mentioned DNA fragment is unpatentable if the specification fails to indicate an asserted utility. (USPTO)
4. The mere fact that DNA fragments are derived from the same source is not sufficient to meet the requirement for unity of invention.

Trilateral Project 24.1
Biotechnology Comparative Study
on Biotehnology Patent Practices Comparative Study
Report

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trilateral
European Patent Office
Japan Patent Office
United States Patent and Trademark Office

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French researchers take a stand against cancer gene patent

Declan Butler and Sally Goodman, Paris

The Curie Institute in Paris is to challenge a European patent held by the US biotechnology company Myriad Genetics. The patent covers the *BRCA1* gene, used in tests to assess a patient's predisposition to hereditary breast and ovarian cancers.

The French government is officially supporting the institute's action and intends to introduce legislation that would extend compulsory licensing to cover genetic tests.

Utah-based Myriad Genetics, which won a US monopoly on the *BRCA1* gene in 1999, obtained a European patent on it in January. As a result, Europeans will be obliged to pay $2,400 for Myriad's screening test — alternative French tests cost less than a third of this.

Worldwide, Myriad has aggressively exercised its exclusive rights to carry out diagnostic testing on *BRCA1* and a related gene, *BRCA2*. It requires that all samples for testing be sent to the company's labs in Salt Lake City.

Health worries: Dominique Stoppa-Lyonnet says Myriad's test did not identify some expected mutations.

Estimates vary as to the proportion of breast cancer cases that are hereditary, but the US National Cancer Institute suggests that *BRCA1* is responsible for about half of those cases that are genetically inherited.

Myriad's patent, EP 699754, covers all methods for diagnosing the risk of breast cancer based on comparing a sample sequence with the sequence it describes for

Nature 403:95, September 2001

Australian Law Reform Commission

Australian Government
Australian Law Reform Commission

Final report June 30, 2004 (austlii.edu.au/au/other/alrc/publications/reports/99/

ALRC 99

Genes and Ingenuity: Gene Patenting and Human Health

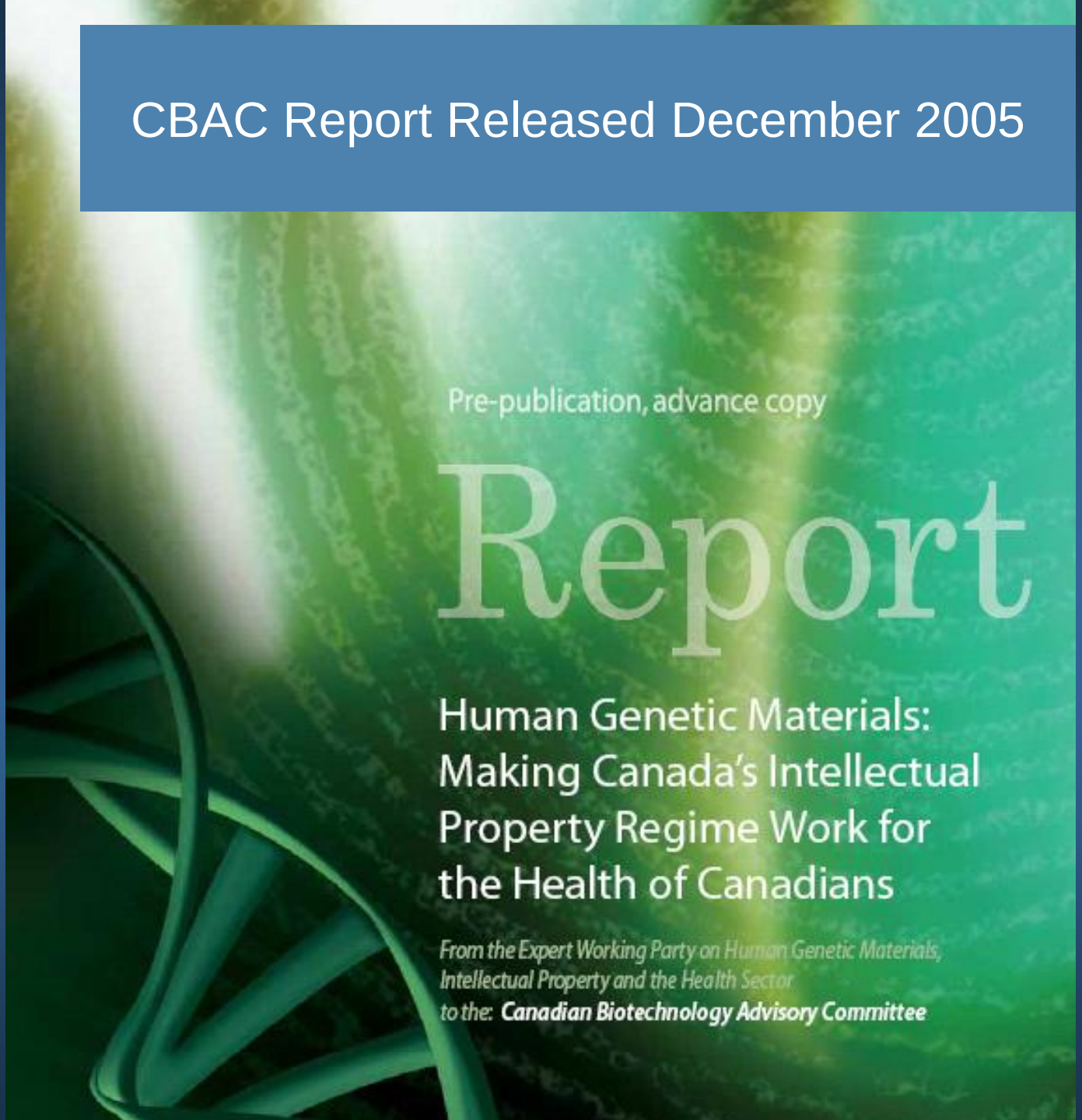
Table of Contents

Purpose:

To review impact of gene patenting, licensing and access to healthcare.

> *"Of special concern was the behaviour of … Myriad Genetics Inc… related to the breadth of their patents and to the manner of their exploitation."*

CBAC Report Released December 2005



Public Patent Foundation
Representing the Public's Interests in the Patent System

PUBPAT

Protecting the Public Domain » Breast Cancer Gene Patents

Breast Cancer Gene Patents

On May 12, 2009, PUBPAT and the American Civil Liberties Union (ACLU) filed a lawsuit charging that patents on two human genes associated with breast and ovarian cancer are unconstitutional and invalid. The lawsuit was filed on behalf of four scientific organizations representing more than 150,000 geneticists, pathologists, and laboratory professionals, as well as individual researchers, breast cancer and women's health groups, and individual women. Individuals with certain mutations along these two genes, known as BRCA1 and BRCA2, are at a significantly higher risk for developing hereditary breast and ovarian cancers.

The U.S. Patent and Trademark Office (PTO) has granted thousands of patents on human genes – in fact, about 20 percent of our genes are patented. A gene patent holder has the right to prevent anyone from studying, testing or even looking at a gene. As a result, scientific research and genetic testing has been delayed, limited or even shut down due to concerns about gene patents.

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ACLU challenged several product and method claims:

An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises gene comparing a first sequence ... from said tumor sample with a second sequence . . . from a nontumor sample, wherein a difference in the . . . indicates a somatic alteration in the BRCA1 gene in said tumor sample.

- "For the reasons that follow, we hold that a **naturally occurring DNA segment is a product of nature and not patent eligible** merely because it has been isolated, but that **cDNA is patent eligible because it is not naturally occurring**."

…cDNA with a proviso:

- "cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under §101, except insofar as **very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA**."

SUPREME COURT OF THE UNITED STATES

DO NOT PATENT MY GENES ACLU

MYRIAD

AMP Association for Molecular Pathology

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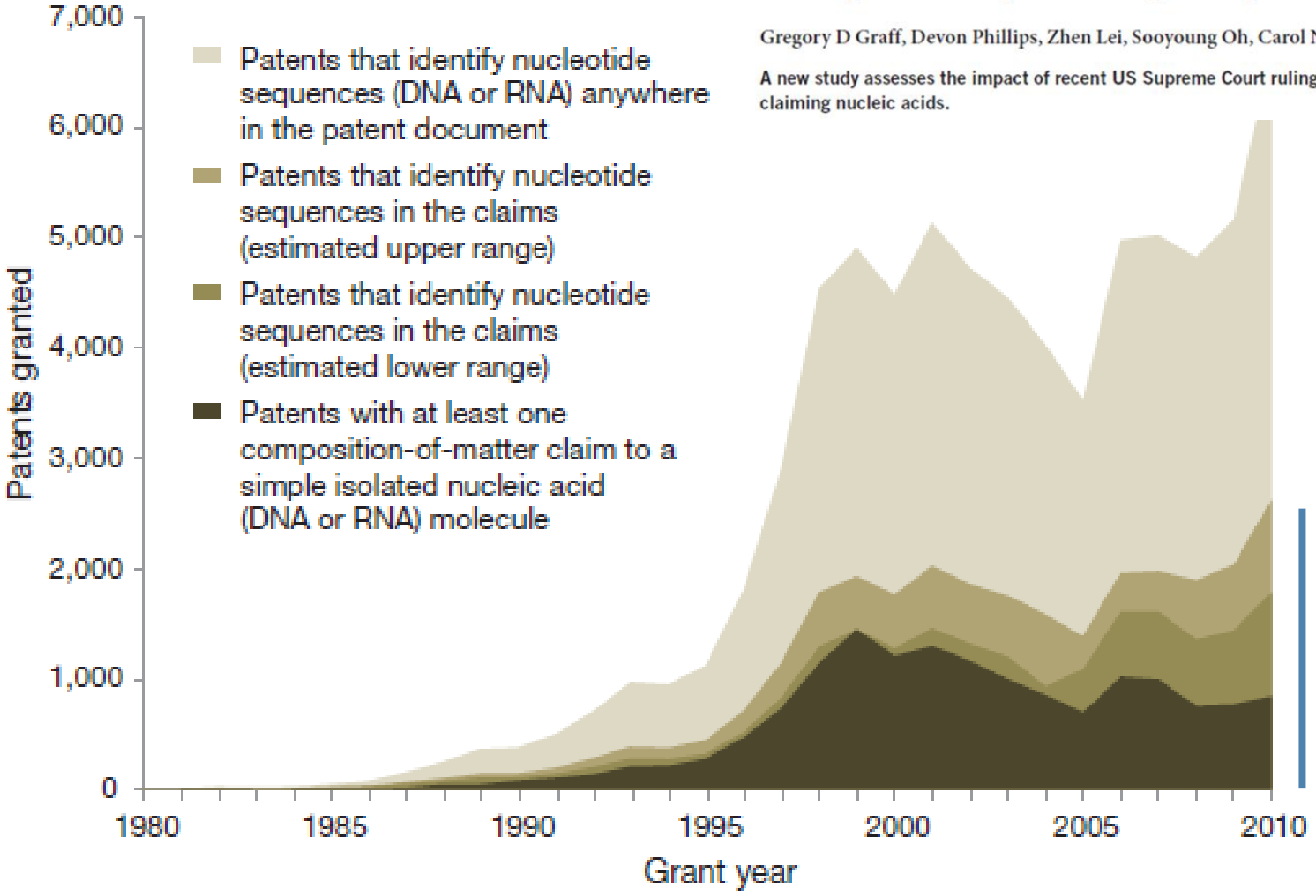
Issued US patents: Nature Biotech May 2013, 31: 404-410

Not quite a myriad of gene patents

Gregory D Graff, Devon Phillips, Zhen Lei, Sooyoung Oh, Carol Nottenburg & Philip G Pardey

A new study assesses the impact of recent US Supreme Court rulings on the changing landscape of US patents claiming nucleic acids.



Patents potentially at risk

Figure 1 The shifting structure of US patents referring to and claiming nucleotide sequences. The darker categories are those more likely at risk if the "product of nature" exception to patent eligibility is extended to isolated nucleic acid molecules with naturally occurring sequences.

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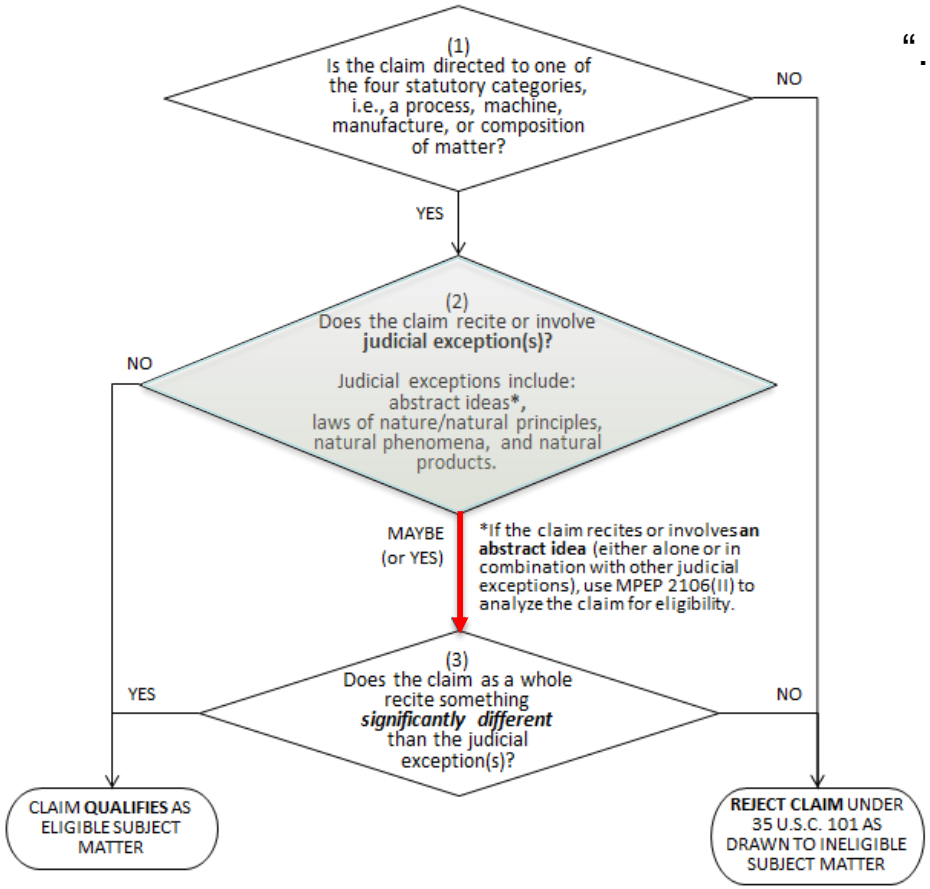
Impact of decision on products of nature?

- "…Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes."
- "Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes ... The question is whether this renders the genes patentable."
- "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."



"… **chemicals derived from natural sources** (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); **foods** (e.g., fruits, grains, meats and vegetables); **metals and metallic compounds** that exist in nature; minerals; **natural materials** (e.g., rocks, sands, soils); **nucleic acids; organisms** (e.g., bacteria, plants and multicellular animals); **proteins and peptides**; and **other substances** found in or derived from nature."

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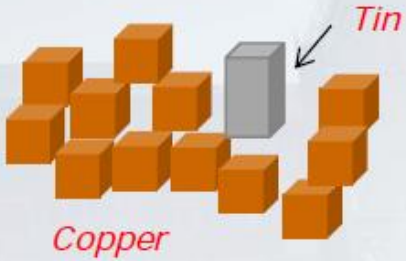
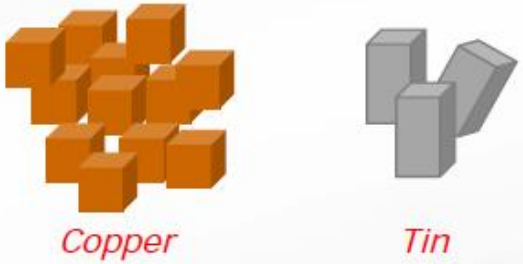
Example: No Marked Difference Factor g) is Satisfied

Claimed "composition comprising 90% copper and 10% tin"



Naturally occurring copper and tin



Claimed composition is not markedly different

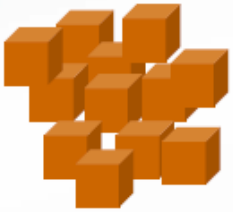
1. **Fails to satisfy non-naturally occurring requirement**, because copper and tin exist in nature.
2. **No structural difference** because the mere mixture or aggregation of naturally occurring metals together as a "composition" does not change the metals from what exists in nature.

Example: Marked Difference Factor a) is Satisfied

Claimed
"alloy comprising
90% copper and 10% tin"

Alloy (bronze)

Naturally occurring
copper and tin



Copper

Tin

Claimed alloy is markedly different

1. Non-naturally occurring because the alloy of copper and tin does not occur in nature, but instead was created by human manipulation. This particular alloy is a type of bronze.

2. Markedly different in structure

- structural difference (the alloy is a solid solution of tin in copper, which has a different crystalline arrangement of atoms than in the natural metals);
- structural difference results in change to properties of alloy (the alloy has a different color, tensile strength, hardness, and melting point than either natural metal).

Not eligible

1. A beverage composition comprising:
a) pomelo juice; and
b) a preservative.

Claim scope includes:

- naturally occurring preservatives (vitamin E; naturally occurring) and

- non-naturally occurring preservatives such as preservative X (a known preservative that is non-naturally occurring and markedly different from naturally occurring chemicals).

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JPO's Examination Guidelines:

- Discoveries of natural things like an ore or natural phenomena, for which an inventor does not consciously create any technical idea
  - Not statutory
- Chemical substances or microorganisms have been isolated artificially from their surroundings are creations
  - Statutory

- Human genes are patentable if have utility
  - JPO's Examination Guidelines on Biological Inventions (1993) provide that a gene is patentable:
    - No distinction between human and non-human genes
    - An invention for a gene whose utility is not described in the specification or cannot be inferred, does not meet the industrial applicability requirement.

JPO JAPAN PATENT OFFICE

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Brazil bans products of nature: April 2013

New Draft Guidelines For Patent Applications In The Biotechnology Field

Apr 1, 2013

Joao Luis D'Orey Facco Vianna and Edson Paula de Souza

Brazilian Patent Office has maintained the position that any product of nature, even in an isolated form, is not patentable

Product of nature in isolate form not patentable

The Brazilian Patent & Trademark Office (PTO) has recently opened a new Public Consultation, this time on the draft guidelines for the examination of patent applications in the biotechnology field. The Public Consultation was published in the Federal Official Gazette on December 5, 2012 and any interested party may make their submissions within a 60-day-term counted as from that publication date.

In this connection, the Patent Office has maintained the position that any product of nature, even in an isolated form, is not patentable. Claims to isolated, truncated or artificial nucleic acids, isolated proteins, enzymes and antibodies will be rejected, as will be claims to recombinant products if there are equivalent molecules in nature. Extracts, even if enriched, are also said to fall within the product of nature bar unless they show features not normally attained and are product of direct human intervention.

Claims to artificial nucleic acids, proteins, antibodies to be rejected

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BrazilPatents.com

Nucleic acids found patentable:

- human intervention that creates an artificial state of affairs that has some discernible effect is essential;
- patentability boundaries must encompass the development of science and technology and human ingenuity;
- expressions such as “the work of nature” or “the laws of nature” are not found in the statute; nor are they useful tools of analysis
- the chemical and physical makeup of an isolated nucleic acid renders it not only artificial but also different from its natural counterpart.

Court also noted that the Australian Parliament had considered and specifically declined to exclude purified and isolated gene sequences from the scope of patentable subject matter

Canada: Long QT patents: U of Utah

THE GLOBE AND MAIL

‘Bad patents’ on human genes hinder health care, hospital says

André Picard - PUBLIC HEALTH REPORTER
The Globe and Mail
PublishedMonday, Nov. 03 2014, 10:15 AM EST
Last updatedMonday, Nov. 03 2014, 7:18 PM EST

One of the country’s premiere pediatric hospitals is challenging the notion that human genes can be patented by filing a lawsuit that, if successful, could lead to a rewriting of patent law and sharply advance the advent of personalized medicine.

The Children’s Hospital of Eastern Ontario argues in court filings that restricting access to genetic information by researchers and clinicians undermines patient care and is morally and legally untenable.

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Conclusions

- Utility & Promise of the Patent (Canada)
  - Still a significant issue; case law still evolving
  - Need to be careful re: statements that promise an advantage/utility and that claim the utility
- Gene patenting & natural products
  - DNA that directly corresponds to naturally occurring sequences not patentable (US; BR)
  - Interpretation of USSC decision & impact on natural products currently problematic; still evolving
  - EP, JP, AU, CA more lenient re: protecting nucleic acids and natural products

Thank You

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Lawyers • Patent and Trade-mark Agents