

# Patents, plant breeding and biotechnology

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# Outline

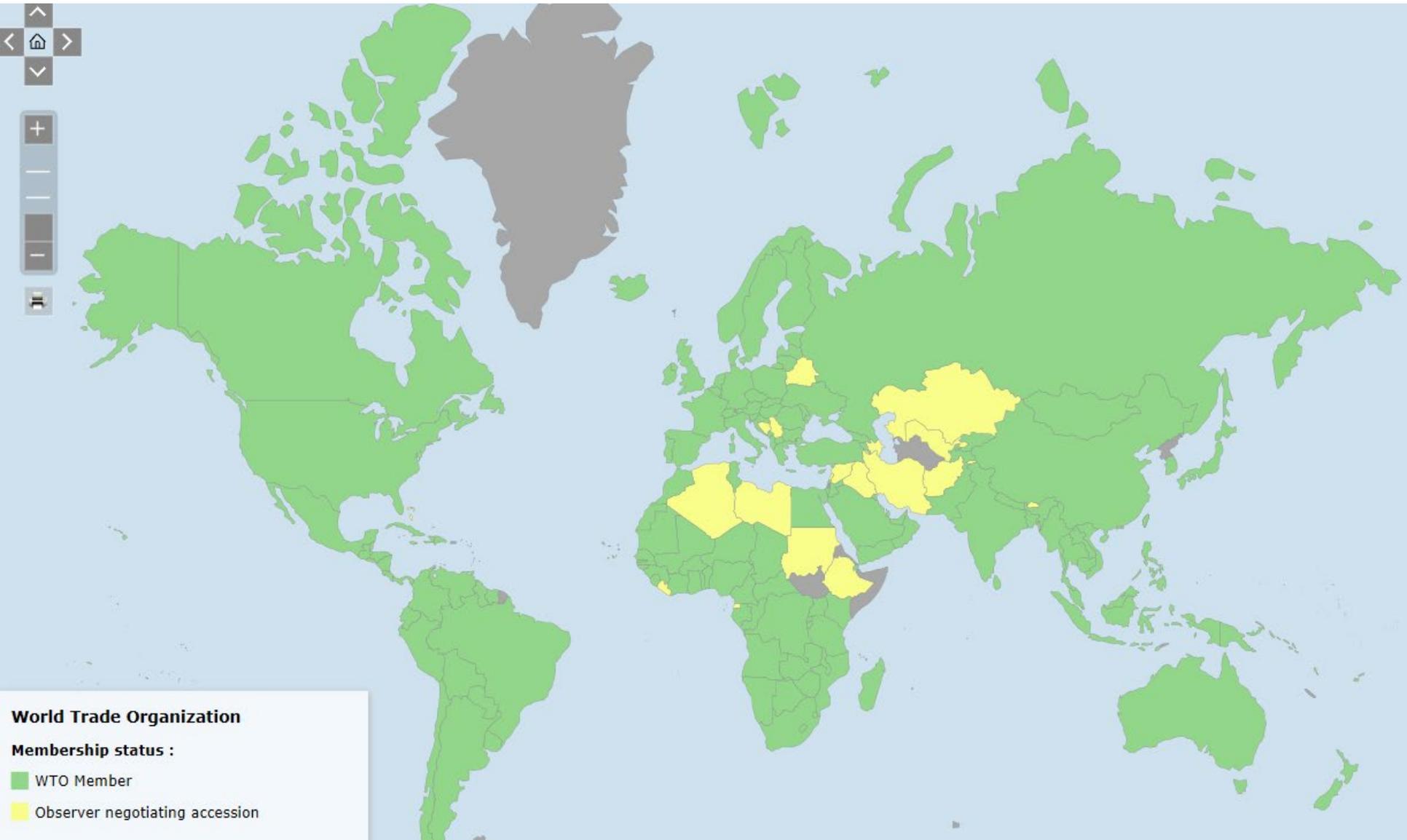
- WTO TRIPS Agreement
- Invention and genetic engineering
- Myriad Genetics litigation
- Genetic modification and patenting

# Formation of the World Trade Organization (WTO)

- Established on 1<sup>st</sup> January 1995
- As a result of the GATT Uruguay Round negotiations
- 164 members since 29 July 2016
- “A global organisation dealing with rules of trade between nations”.

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# WTO Membership



**World Trade Organization**  
**Membership status :**  
■ WTO Member  
■ Observer negotiating accession

# The Uruguay Round agreements

- The Agreement establishing the WTO
- Annexes
- 1A - GATT 1994 , related agreements (e.g. Agreements on Agriculture, Subsidies, TBT, SPS, etc.) and texts
- 1B- General Agreement on Trade in Services (GATS) and Annexes
- 1C- Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
- Annex 2 Understanding on the Rules and Procedures Governing the Settlement of Disputes (aka **Dispute Settlement Understanding /DSU**)
- Annex 3 Trade Policy Review Mechanism
- Annex 4 Plurilateral Agreements (e.g. Agreement on Trade in Civil Aircraft)

# World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), Art.27.1

- ...patents shall be available for any **inventions**, whether products or processes, in all fields of technology, provided that they are **new**, involve an **inventive step** and are capable of **industrial application**.
- ...patents shall be available and patent rights enjoyable without discrimination as to the ...field of technology

# TRIPS Agreement Art 27.2

2. Members may **exclude** from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to **protect ordre public or morality**, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

# Patents Act 1977 (UK)

## Patentable inventions

Section 1.-(1) A patent may be granted only for an **invention** in respect of which the following conditions are satisfied, that is to say -

- (a) the invention is **new**;
- (b) it involves an **inventive step**;
- (c) it is capable of **industrial application**;

UK Patents Act s.1(2) It is hereby declared that the following (among other things) **are not inventions** for the purposes of this Act, that is to say, anything which consists of—

- (a) a **discovery**, scientific theory or mathematical method;
- (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
- (d) the presentation of information;

# DNA- Invention or discovery?

- *Reynolds v Herbert Smith & Co Ltd* (1903) 20 RPC 123 at 126 per Buckley J:
- Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. **Invention necessarily involves also the suggestion of an act to be done**, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result.

Patents Act 1977 (UK) s.1(3)A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

# UK Patents Act s.2 Novelty

- (1) An invention shall be taken to be **new** if it does not form part of the state of the art.
- (2) The state of the art in the case of an **invention** shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

# UK Patents Act s.3 Inventive step

- An invention shall be taken to involve an inventive step if it is **not obvious** to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above.

# Section 4 Industrial application.

(1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, **including agriculture.**

Is DNA an invention?

# The Myriad Genetics Controversy

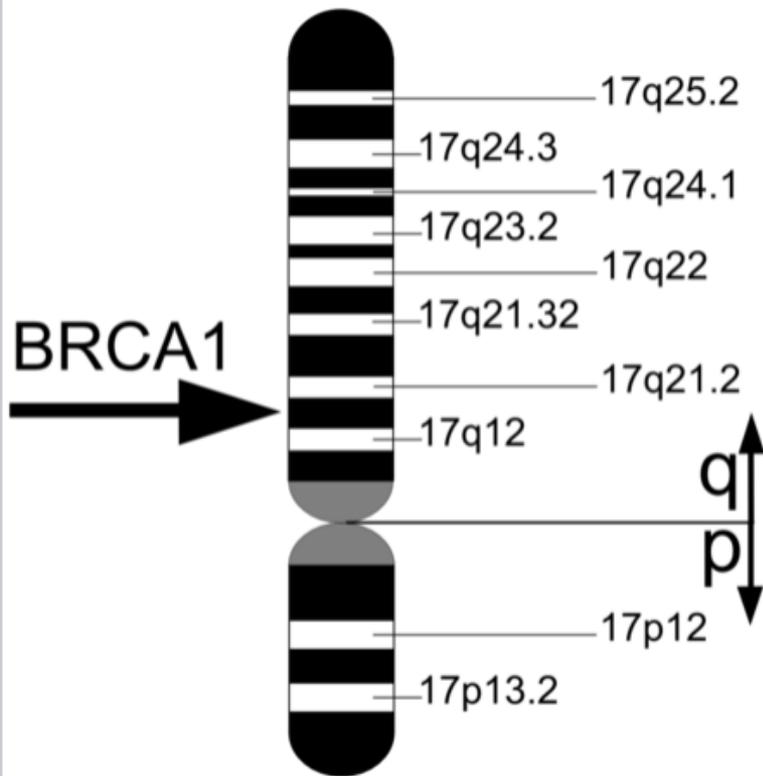
Among the genes associated with breast and ovarian cancer are:

*BRCA1* (located on chromosome 17); and

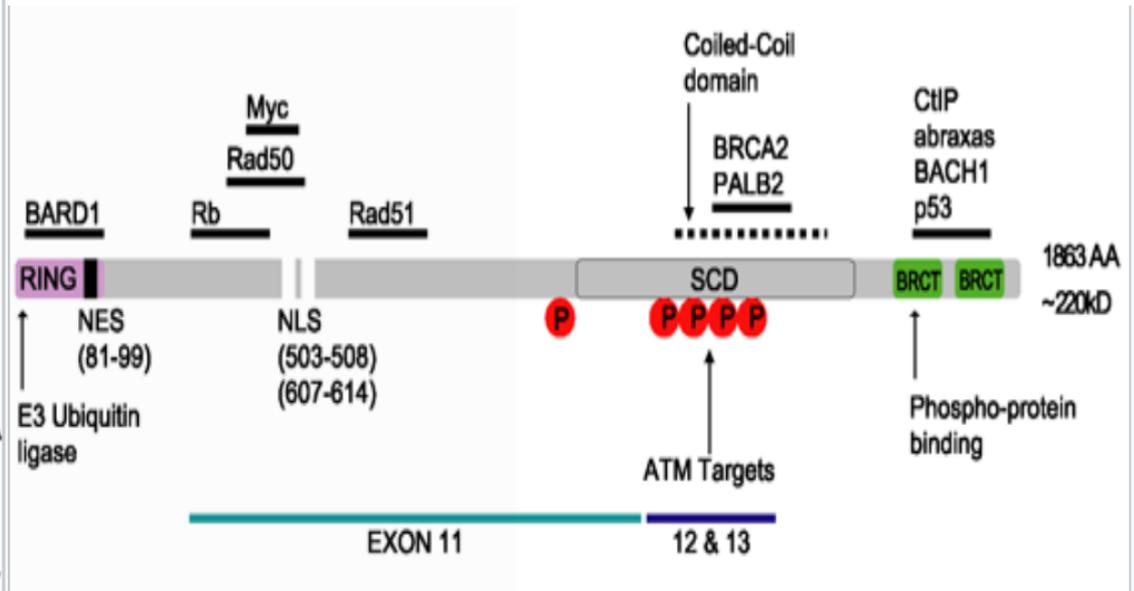
*BRCA2* (located on chromosome 13).

# BRCA1

## Chromosome 17



Location of the *BRCA1* gene on chromosome 17.



Domain map of BRCA1; RING, serine containing domain (SCD), and BRCT domains are indicated. Horizontal black lines indicate protein-binding domains for the listed partners. Red circles mark phosphorylation sites.<sup>[26]</sup>



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## Angelina Jolie, inherited breast cancer and the BRCA1 gene

Category: [Science blog](#)  **May 14, 2013** [Henry Scowcroft](#)  [7 comments](#)

# Competition between researchers

The major research teams working to locate *BRCA1* and *BRCA2* included:

- USA - Mary Claire King's group and Mark Skolnick's group
- UK- the main group were associated with Michael Stratton, Bruce Ponder, and Richard Wooster.
- France (Gilbert Lenoir and Dominique Stoppa-Lyonnet),
- Japan (Yusuke Nakamura)
- Canada (Stephen Narod)

- In 1993 Mark Skolnick's team at the University of Utah, working with a database of 200,000 Mormon family groups and most of the 1.6 million descendants of the initial 10,000 Utah settlers, sought to identify the BRCA genes.

# Formation of Myriad Genetics

- Skolnick's group formed Myriad Genetics, Inc with the aim of obtaining the funding needed to complete the research.
- Myriad secured funding from Eli Lilly and Co.
- In 1993, Myriad raised \$10 million of which Eli Lilly contributed \$2.8 million over 3 years to search for the genes associated with hereditary breast cancer in return for licensing privileges for diagnostic kits and therapeutic products on *BRCA1*.

# Myriad's Patents

- August 12 1994 Myriad filed a US patent application covering the BRCA1 and on December 2, 1997, the US Patent Office granted Myriad a patent over 47 separate mutations in the *BRCA1* gene.
- Subsequently, the USPTO granted seven additional patents to Myriad covering the *BRCA1* gene and associated diagnostic tests, methods of detecting *BRCA1* mutations and the entire sequence of the *BRCA1* gene and tools used in their work.
- These patents gave Myriad covered all uses of the *BRCA1* gene.

# International patenting by Myriad

- Canada - 2000 and 2001 patents covering *BRCA1* and mutations and diagnostic tests
- Europe – 2001
- Australia – 2001
- New Zealand 2001
- Japan 2001

# Commercialisation

- In 1996 Myriad began marketing its diagnostic tests:
  - (1) the Comprehensive BRCA Analysis, which involved full sequence testing of the *BRCA1* and *BRCA2* genes (offered at the time at US\$2400),
  - (2) the Single Site BRCA Analysis test (offered at US\$395.00)

# Infringement of Myriad's patents

- From May 1998, Myriad sought to eliminate BRCA testing at competing laboratories by sending cease-and-desist letters.

genetic technologies

Tuesday

6 7<sup>th</sup> July, 2008

Professor Ruth Salom,  
SA Pathology,   
P.O. Box 14,  
Rundle Mall,  
Adelaide SA 5000

  
Dear Professor Salom,

Microsoft **RE: Infringement of Exclusive Rights** 

Mostly Sunny 16°  
I am writing to notify you that Genetic Technologies Limited (Genetic Technologies) is seeking to enforce its intellectual property rights with regard to offering diagnostic testing of the *BRCA1* and *BRCA2* genes for suspected cases of hereditary breast and ovarian cancer syndrome in Australia and New Zealand.

Perth  
In the interests of avoiding costly and time consuming litigation, Genetic Technologies proposes a commercial solution whereby Genetic Technologies will perform all of SA Pathology's future *BRCA1* and *BRCA2* testing requirements as settlement of all SA Pathology's past and prospective infringement of our exclusive patent rights.

Play and explore



Groove Music

As an organization working in the field of medical research and diagnostic testing, I am sure you would appreciate that the effective protection of intellectual property rights is fundamental to the continued investment in, and commercialisation of, medical research and technology in Australia. As a substantial investor in Australian biomedical research and technology, Genetic Technologies is greatly concerned by the ongoing infringement of its intellectual property rights. This situation is untenable and unacceptable to Genetic Technologies and our shareholders.

Genetic Technologies is the exclusive licensee from Myriad Genetics, Inc., of Australian Patents, including Patents No. 686004, 691958, 691331, and 773601 (the Patents), making us the exclusive holder of the right to offer diagnostic testing of the *BRCA1* and *BRCA2* genes in Australia. We are aware that SA Pathology is:

- (a) using the methods and compositions claimed in the Patents; and
- (b) selling the results generated from using such methods and compositions.

We hereby request that SA Pathology, within 7 days of the date of this letter, provide confirmation in writing that it agrees to cease using the Patents and is willing to refer the performance of all *BRCA1* and *BRCA2* testing to Genetic Technologies.

However, in the event that SA Pathology is not prepared to provide the requested undertaking in writing by Monday, the 14<sup>th</sup> of July, 2008, Genetic Technologies will then immediately proceed with legal action without further notice. Our lawyers have prepared a detailed Statement of Claim and are ready to file an Application with the Federal Court if necessary.

# The Myriad Genetics controversy

Concerns centred on

- the prices charged by Myriad for its screening tests (up to three times those charged by laboratories in Australia, Europe and Canada)
- the quality of the tests
- the potential loss of research expertise and data
- the separation of clinical services from research and counselling.

# Myriad Genetics in Australia

The validity of the invention claimed in Myriad's patent was challenged by Ms Yvonne D'Arcy, on the ground that it was not a patentable invention within the meaning of the *Patents Act 1990*



# *D'Arcy v Myriad Genetics Inc* [2015] High Court of Australia

That feature of the patent claims raises a question about how they fit within the concept of a "manner of manufacture".

An **invention is something which involves "making"**. It must reside in something. It may be a product. It may be a process.

Whatever it is, it must be something brought about by **human action**.

The code in the invention as claimed refers to the sequence of nucleotides which, in a cellular environment, can ultimately be translated into the BRCA1 polypeptide. That sequence can properly be described as "information".

*D'Arcy v Myriad Genetics Inc*  
[2015] High Court of Australia 35

Isolated DNA held to be unpatentable

*Association for Molecular Pathology v. Myriad Genetics Inc.* 569 U.S. 12-398 (2013)  
United States Supreme Court

- Myriad Genetics, Inc. Obtained patents on two human genes, mutations of which can substantially increase the risks of breast and ovarian cancer.
- This case required the Supreme Court to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U. S. C. §101 [the US Patents Code] by virtue of its isolation from the rest of the human genome.

# Myriad Genetics in the US Supreme Court

- “we hold that a naturally occurring DNA segment is **a product of nature** and not patent eligible merely because it has been isolated”

# Myriad Genetics in the US Supreme Court

- “It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. **Nor did Myriad create or alter the genetic structure of DNA.** Instead, Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13.”

# Myriad Genetics

- “Scientific alteration of the genetic code presents a **different inquiry**, and we express no opinion about the application of §101 [US Patent Code] to such endeavors. We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material.”

# Art. 5.2 EU Biotechnology Directive

## Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological 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.

# Patents Act 1977 (UK) (s.76A introduced by the Patents Regulations 2000)

Section 76A(1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a **biotechnological invention**, subject to the provisions of Schedule A2.

## s.76A, Patents Act 1977

- Biological material **which is isolated** from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

# Brexit

- Will the UK continue to apply the European Biotechnology Directive or will it follow the Australian and US approaches to the patenting of DNA?

# Types of gene patents granted by UK IP

- synthetic genetic or DNA sequences;
- mutant forms and fragments of genetic sequences (including polymorphisms);
- isolated or recombinant DNA coding for a sequence of a gene;
- proteins expressed by a gene;
- vectors containing a gene;
- probes for a gene;
- methods of transformation using a gene;
- host cells, higher plants or animals carrying a gene; and
- recombinant DNA methods—such as polymerase chain reaction (PCR) and novel expression systems.

# Genetic Modification and Patenting

# Patents and GM agriculture

- Eg glyphosate resistant crops



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
2 September 2004 (02.09.2004)

PCT

(10) International Publication Number  
**WO 2004/074443 A3**

**Abstract:** The compositions and methods disclosed herein provide novel DNA molecules that encode glyphosate resistant EPSPS proteins and plants containing these new proteins.

The plants that express the new PSPS proteins are themselves tolerant to the herbicidal effects of glyphosate

**Applicant (for all designated States except US): MON-SANTO TECHNOLOGY LLC [US/US]; 800 N. Lindbergh Boulevard, St Louis, MO 63167 (US).**

**Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

**Designated States (unless otherwise indicated, for every kind of regional protection available):** ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

## TRIPS *Article 28, Rights Conferred*

1. A patent shall confer on its owner the following exclusive rights:
  - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing ... that product;

# Why Does Monsanto Patent Seeds? Part 1

<http://www.monsanto.com/newsviews/pages/why-does-monsanto-patent-seeds.aspx>

- **Can You Patent Seed?**

According to the U.S. Department of Agriculture's Economic Research Service (USDA ERS), Monsanto and its subsidiaries (including *Asgrow*<sup>®</sup> and *DeKalb*<sup>®</sup>) currently own more than 400 separate plant technology patents.

- Agricultural companies such as Monsanto are able to patent seed trait technology because it is considered intellectual property, and intellectual property rights are protected in the U.S.

# Saved Seed and Farmer Lawsuits

<http://www.monsanto.com/newsviews/pages/saved-seed-farmer-lawsuits.aspx>

- Since 1997, we have only filed suit against farmers 145 times in the United States. This may sound like a lot, but when you consider that we sell seed to more than 250,000 American farmers a year, it's really a small number.

***Monsanto Canada, Inc and Monsanto Company  
v Percy Schmeiser and Schmeiser Enterprises***

2001 FCT 256,

- In 1993, Monsanto US was issued Canadian Letters Patent No. 1,313,830 for an invention termed "Glyphosate-Resistant Plants." The patent granted Monsanto US the exclusive right, privilege and liberty of making, constructing, using and selling the invention for the full term of the patent.
- Monsanto Canada was a licensee under the patent. The invention was used by Monsanto in Canola and marketed under the trade name "Roundup Ready (RuR) Canola

# Monsanto v Schmeiser

- Schmeiser grew canola commercially in Saskatchewan. He had never purchased RuR Canola nor did he obtain a licence to plant it. Yet, in 1998, tests revealed that 95 to 98 percent of his 1,000 acres of canola crop was made up of RuR plants.
- The origin of the plants is unclear. They may have been derived from RuR seed that blew onto or near Schmeiser's land, and was then collected from plants that survived after Schmeiser sprayed Roundup herbicide around the power poles and in the ditches along the roadway bordering four of his fields.

# Monsanto v Schmeiser

- Schmeiser argued that by the unconfined release of the gene into the environment Monsanto did not control its spread, and did not intend to do so, and they had thus lost or waived their right to exercise an exclusive patent over the gene.
- The trial judge found that Schmeiser had infringed Monsanto's patent.
- An appeal was rejected by the Canadian Federal Court of Appeal, which ruled that Schmeiser had infringed s. 42 of the *Patent Act* by "using" the patented cell and gene.

# ***Monsanto Co. v. Scruggs* 342 F. Supp 2d 584 (2004).**

Monsanto's US patent 5,352,605 concerned genetically modified soybeans and cotton which were resistant to glyphosate herbicide.

Monsanto licensed the technology to seed companies, imposing two provisos: (i) it forbade seed companies from selling seed which contained Monsanto's biotechnology to growers unless the grower first signed a technology license agreements, reserving the patented technology to Monsanto and (ii) seed so sold could only be used by growers to grow a single commercial crop, i.e growers could not save seed produced from a harvested crop for replanting during the following growing season.

# Monsanto v Scruggs

- Mitchell Scruggs, who had not signed a technology licensing agreement purchased a small quantity of Roundup Ready (“RuR”) 5601 Asgrow soybeans from a seed company in Memphis. The seed was sufficient to plant approximately ten acres of soybeans. After the fall harvest, Mr. Scruggs retained the soybean seed from those ten acres; he cleaned it and saved it for planting during the 1997 crop season. Through saving seed from all subsequent crop seasons up to the year 2000, by 2000, Scruggs had enough saved RuR soybean seed to plant more than 8,000 acres.
- Patent infringement found against Scruggs for using the protected seeds.

<http://www.monsanto.com/newsviews/pages/gary-rinehart.aspx>

- Gary Rinehart was indeed approached by Monsanto investigators in response to a report of patent infringement.
- The investigators had seen unmarked, brown-bagged seed (generally indicative of saved seed) delivered to a couple of fields.
- Gary Rinehart acknowledged that he sharecropped with his brother. He was otherwise uncooperative. He became angry, attracting the attention of others in the store, prompting Monsanto's representatives to leave.
- Lawsuits are a legal, and often the only, option available when one party in a dispute is uncooperative.

# Organic Seed Growers and Trade Association (and 38 others) v. Monsanto Company and Monsanto Technology LLC (2012-13)

ORGANIC SEED GROWERS AND TRADE ASSOCIATION, ORGANIC CROP IMPROVEMENT ASSOCIATION INTERNATIONAL, INC., THE CORNUCOPIA INSTITUTE, DEMETER ASSOCIATION, INC., CENTER FOR FOOD SAFETY, BEYOND PESTICIDES, NAVDANYA INTERNATIONAL, MAINE ORGANIC FARMERS AND GARDENERS ASSOCIATION, NORTHEAST ORGANIC FARMING ASSOCIATION OF NEW YORK, NORTHEAST ORGANIC FARMING ASSOCIATION/MASSACHUSETTS CHAPTER, INC., NORTHEAST ORGANIC FARMING ASSOCIATION OF NEW HAMPSHIRE, NORTHEAST ORGANIC FARMING ASSOCIATION OF RHODE ISLAND, CT NOFA, NORTHEAST ORGANIC FARMING ASSOCIATION OF VERMONT, RURAL VERMONT, OHIO ECOLOGICAL FOOD & FARM ASSOCIATION, FLORIDA CERTIFIED ORGANIC GROWERS AND CONSUMERS INC., SOUTHEAST IOWA ORGANIC ASSOCIATION, MENDOCINO ORGANIC NETWORK, NORTHEAST ORGANIC DAIRY PRODUCERS ALLIANCE, MIDWEST ORGANIC DAIRY PRODUCERS ALLIANCE, WESTERN ORGANIC DAIRY PRODUCERS ALLIANCE, CANADIAN ORGANIC GROWERS,

AGRICULTURAL INSTITUTE, FEDCO SEEDS INC., ADAPTIVE SEEDS, LLC, SOW TRUE SEED, SOUTHERN EXPOSURE SEED EXCHANGE, MUMM'S SPROUTING SEEDS, BAKER CREEK HEIRLOOM SEED CO., LLC, COMSTOCK, FERRE & CO., LLC, SEEDKEEPERS, LLC, SISKIYOU SEEDS, COUNTRYSIDE ORGANICS, WILD GARDEN SEED, CUATRO PUERTAS, SEED WE NEED, ALBA RANCH, WILD PLUM FARM, GRATITUDE GARDENS, RICHARD EVERETT FARM, LLC, PHILADELPHIA COMMUNITY FARM, INC, GENESIS FARM, CHISPAS FARMS LLC, MIDHEAVEN FARMS, KOSKAN FARMS, CALIFORNIA CLOVERLEAF FARMS, NORTH OUTBACK FARM, TAYLOR FARMS, INC., RON GARGASZ ORGANIC FARMS, ABUNDANT ACRES, T & D WILLEY FARMS, FULL MOON FARM, INC., COMMON GOOD FARM, LLC, AMERICAN BUFFALO COMPANY, RADIANCE DAIRY, QUINELLA RANCH, NATURE'S WAY FARM LTD., LEVKE AND PETER EGGERS FARM, FREY VINEYARDS, LTD., BRYCE STEPHENS, CHUCK NOBLE, LARHEA PEPPER, PAUL ROMERO, BRIAN WICKERT, BRUCE DRINKMAN, MURRAY BAST, AND DONALD WRIGHT PATTERSON, JR.,

# *Organic Seed Growers and Trade Association et al v. Monsanto (2013)*

- Appellants, a coalition of farmers, seed sellers, and agricultural organizations, sought declaratory judgments of non-infringement and invalidity with respect to 23 patents owned by Monsanto.

They alleged that they have been forced to “forgo growing corn, cotton, canola, sugar beets, soybeans, and alfalfa, since it is widely known that those crops are currently under severe threat of transgenic seed contamination.”

*(alleging that “over 85-90% of all soybeans, corn, cotton, sugar beets, and canola grown in the U.S. contains Monsanto’s patented genes”).*

They further alleged that they must take costly precautions to avoid contamination, such as testing seeds for transgenic traits and creating “buffer” zones between their farms and those of neighbors growing modified crops.

The appellants contended that if they do not take these precautions, their crops would be contaminated, and they would be sued for infringement by Monsanto.

*Organic Seed Growers & Trade Ass'n v. Monsanto Co.,  
851 F. Supp. 2d 544 (S.D.N.Y. 2012)*

- The district court concluded that there was no justiciable case or controversy and dismissed for lack of jurisdiction. Because Monsanto has made binding assurances that it will not “take legal action against growers whose crops might inadvertently contain **traces** of Monsanto biotech genes (because, for example, some transgenic seed or pollen blew onto the grower’s land),”

**MONSANTO COMPANY AND MONSANTO  
TECHNOLOGY LLC,**  
*Defendants-Appellees.*

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2012-1298

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Appeal from the United States District Court for the  
Southern District of New York in No. 11-CV-2163, Judge  
Naomi Reice Buchwald.

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Decided: June 10, 2013

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No. 12-1298 (Fed. Cir. 2013) affirmed the SDNY  
decision that the plaintiffs did not present a sufficient  
controversy to warrant adjudication by the courts.  
*Organic Seed Growers & Trade Ass'n v. Monsanto Co.*  
cert. denied, 134 S. Ct. 901 (2014).

- The Court of Appeals affirmed the SDNY decision that the plaintiffs did not present a sufficient controversy to warrant adjudication by the courts.
- On January 13, 2013, certiorari was denied by the U.S. Supreme Court

***Monsanto Technology LLC v Cargill International S.A.*** [ 2007] UK High Court

The defendant imported to the UK 5000 tonnes of soy meal from Argentina.

Monsanto argued that the meal carried its patented gene for an enzyme called CP4R, generally referred to as 'Round Up Ready' ('RuR') seed.

# Monsanto v Cargill

The Trial Judge referred two questions to the European Court of Justice (ECJ):

1. Whether the importation of soy meal was capable of infringing any of the patent claims.
2. whether Monsanto's patent was infringed by meal containing fragments of the Round Up Ready gene.

# Monsanto v Cargill

The Trial Judge referred to 5 scientific tests which were unable to establish that any of the patented DNA survived the process of producing soy meal.

Similar cases in the Netherlands and Spain were referred to the European Court of Justice.

# Monsanto Technology LLC v Cefetra BV

## Case C-428/08, 6 July 2010

A patent to protect soy from glyphosate (a herbicide) could not perform its function, since the genetic information can be found only in a residual state in soy meal, which is a dead material obtained after the soy has undergone several treatment processes.

38 It follows from the foregoing that the protection provided for in Article 9 of the Directive is not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived.