

**THE SBMATE PATENT:
AMERICAN INGENUITY
OR
LOOTING OF A
TANZANIAN RESOURCE?**

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THE ALLEGATIONS

- A gene isolated from an important Tanzanian crop, sorghum, was patented by the United States in violation of the International Seed Treaty
 - The sorghum used was taken from a seed bank that is subject to the Treaty
 - No rights were conferred to Tanzania

“The genius of African farmers that is locked up in the vaults of the CGIAR and other seed banks cannot be allowed to be used to undermine diverse farming systems and earn profit for multinational corporations...”

THE ANALYSIS

- Tanzanian Sorghum Controversy-The SbMATE Patent
- “The International Seed Treaty”
- Did the Patenting of SbMATE Violate “The International Seed Treaty”?
- General Problem of Developed Countries & Businesses Patenting “Inventions” Indigenous to Developing Countries
- Outlook and Lessons Learned

TANZANIAN SORGHUM CONTROVERSY

The SbMATE Patent

SORGHUM

- Type of domesticated grass important in agriculture
- Particularly important to the developing world in Asia and Africa
 - Vital source of the energy, protein, vitamins and minerals
- Referred to as a “course grain” or a “poor people’s crop” because it is consumed mostly by disadvantaged groups



Sorghum from the ARS National Sorghum Germplasm Collection. Photo By Peggy Greb, Agricultural Research Center, USDA.

THE SbMATE GENE

- *Sorghum bicolor* major aluminum tolerance (SbMATE) gene
- Isolated from sorghum
- Enables plants to grow normally in aluminum-rich soil, which is normally toxic to crops
 - aluminum toxicity is one of the primary limitations for crop production in developing countries
 - crops such as wheat, rice, and maize are unable to grow in aluminum-rich soil because aluminum in such soil takes a chemical form that is toxic to them

THE SbMATE PATENT

Claims include isolated and recombinant DNA sequences, a transgenic seed and plant, and a method of producing the genetically transformed plant

US SbMATE PATENT

- Issued September 2009; 29 claims
- Assigned to the United States of America (represented by the Secretary of Agriculture) and the Brazilian Agricultural Research Corporation
- Inventors were listed as government researchers from the USDA, the Brazilian Agricultural Research Foundation (Embrapa), and Texas A&M University

THE PCT APPLICATION

- Filed May 9, 2008; 49 claims
- Applicants are similar to the US patent, although it also includes The Texas A & M University System for all countries except the US
- National phase processing was requested for Australia and the European Patent Office

EXPECTATIONS FOR THE SbMATE PATENT

- There has been commercial interest in licensing the SbMATE patent.
 - for example, both Dow Chemical and Oji Paper have sought to license the SbMATE patent.
- Inventors of the patent note aluminum toxicity is “the primary limitation for crop production in developing countries, including 38% of the farmland in Southeast Asia, 31% in Latin America, and 20% of the arable lands in East Asia and Sub-Saharan Africa.”
- While the patent has enormous commercial potential, widespread commercial use is years away.

THE CONTROVERSY

Tanzania is not mentioned in the US patent or the PCT application

This matters to critics because

- The cultivars used to isolate SbMATE are listed as SC283 & SC566-14, a recombinant inbred population created from SC283
 - Patent inventors described the research done with these cultivars by citing to findings in a 2004 research paper
 - That research paper stated that the SC283 line was collected in Tanzania, while the SC566 line was collected in Nigeria
- SC283 Tanzanian sorghum line is a relatively common Tanzanian farmers' variety of sorghum
 - There are other aluminum tolerant varieties of sorghum in other areas of Africa, such as the Nigerian SC566-14 line mentioned in the research paper

CONCERNS ABOUT THE SbMATE PATENT

- Critics are upset that, while the Tanzanian line of sorghum was used to isolate the SbMATE gene, no rights to the gene or related patents were conferred to Tanzania.
- Critics also argue that genes from sorghum varieties originating from Ethiopia, Sudan, and Uganda are “encompassed” by the US patent
 - Still, the possible “theft” of Tanzania’s rights to the SbMATE is written about the most.

BIOPIRACY?

“The SbMATE gene does not rightfully belong to the USDA, Embrapa, or Texas A&M, and those institutions must abandon their unjust claims to the Tanzanian gene. The institutions that are charged with protecting this resource, CGIAR and IRPGRFA, must act to protect [the Tanzanian sorghum line] and other[s] in trust plants and genes from such claims.”

-Edward Hammond, African Centre for Biosafety, Briefing Paper, Africa's Granary Plundered: Privatization of Tanzanian Sorghum Protected by the Seed Treaty (2009)

CONCERNS ABOUT PATENTS SUCH AS THE SbmATE PATENT

- Concern that developing countries must pay a high price for patented products that are reintroduced into their countries while simultaneously being unable to use the IP framework “to protect against the piracy of their own indigenous and local resources and knowledge.” *Lara Ewins as quoted in IKECHI MGBEOJI, GLOBAL BIOPIRACY 150 (2006)*
- Concern that such biological patents will “threaten[] the ability of developing countries to build their own industries, and feed and treat their people.” *Sue Mayer, Are Gene Patents in the Public Interest?, BioITWorld.com (Nov. 12, 2002)*

“THE INTERNATIONAL SEED TREATY”

*The International Treaty on Plant
Genetic Resources for Food and
Agriculture (ITPGRFA)*

THE INTERNATIONAL SEED TREATY

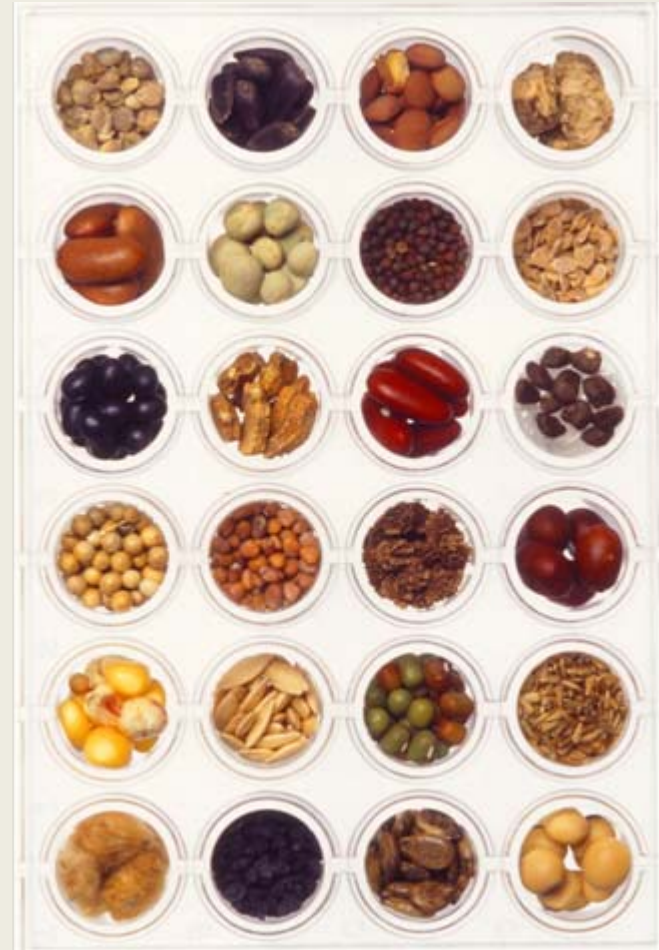
- Went into Force June 2004; 127 parties to the treaty
 - Includes Brazil, the United States, & Tanzania
- Fostered by the Food and Agricultural Organization (FAO) of the United Nations, and the Treaty remains under its control
- Aims include:
 - [R]ecognizing the enormous contributions of farmers to the diversity of crops that feed the world; establishing a global system to provide farmers, plant breeders and scientists with access to plant genetic materials; [and] ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.”

STRENGTHENING FARMERS' RIGHTS

- The International Seed Treaty sets up a Multilateral System from which resources can be obtained for use and conservation in research, breeding, and training.
- If a commercial product is developed using resources from the multilateral system and may not be used without restriction by others for further research and breeding, the Treaty provides for payment of an equitable share of the resulting monetary benefits.
 - If a product is developed that others may use without restriction, payment is considered voluntary.

ITPGRFA GERMOPLASM COLLECTIONS

- Much of Treaty is about the germoplasm collection of Consultative Group on International Agricultural Research (CGIAR)'s Future Harvest Centers.
 - this germoplasm collection is thought to contain about 560,000 accessions of crop diversity, and contains diverse farmers' landraces and local varieties
 - a large amount of this material is placed into the International Network



Samples of seeds maintained at ARS' National Seed Storage Laboratory in Fort Collins, Colorado. Photo By Scott Bauer, Agricultural Research Center, USDA.

THE INTERNATIONAL SEED TREATY & THE SbMATE PATENT

- Sorghum is included under the list of Food Crops covered by the Treaty.
- Defenders of Tanzania's right to the SbMATE patent contend that the patent and attempts to license the patent contradict the goals of the Treaty.
 - One of the aims of the Treaty is stated to be "ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated."

THE INTERNATIONAL SEED TREATY AND SbMATE

- The SC283 sorghum strain is available at a center (ICRISAT) and is subject to the Treaty's rules.
 - If the researchers who invented the SbMATE patent innovation used SC283 sorghum from the center, they would have broken the Treaty's requirement that “recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.”
 - The SbMATE patent would also have violated Article 12.3.d that “recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components”

WHY SbMATE DID NOT VIOLATE THE INTERNATIONAL SEED TREATY

HOWEVER

- The ICRISAT center is unlikely to have been the source of the material used to obtain the SbMATE patent.
 - Instead, Texas A & M is thought to have held samples of SC283 long before the Treaty was ratified, and there is no evidence that the Texas A & M sorghum line came from any Center subject to the Treaty.
- While the Treaty predates both the US patent and the PCT application, neither falls under the authority of the Treaty, for neither encompasses material covered by the Treaty.

-Gavin Lingiah, *Genetically Modified Aluminum Tolerant Sorghum: A Case of Study of Alleged "Biopiracy": A Briefing Paper for NGOs* (July 2010) (unpublished Briefing Paper) 10–11, <http://www.lingiah.com/SbMATE.pdf>

THE INTERNATIONAL SEED TREATY

- While the SbMATE patent and the PCT application may not directly violate the Treaty, they do appear to create the type of problem that the Treaty was designed to address
 - The Treaty attempts to recognize and protect the interest of local farmers who nurtured the crops
- Still the Treaty is limited in scope and cannot offer a solution for all IP biopiracy allegations
 - Focus of the Treaty is to support global food security and biodiversity

OTHER SOLUTIONS- THE CBD TREATY

- 1993 Convention for Biological Diversity (CBD) Treaty included among its objectives the right of “sovereign rights of states to determine through national legislation the conditions for access to the biological resources in their territories”
 - Also dedicated to the conservation and sustainable use of biological diversity
 - US has not ratified the CBD Treaty

THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

Does not require plant patents, but it specifically requires the protection of plant varieties “either by patents or by an effective *sui generis* system or by any combination thereof”

- term “*sui generis*” is not well defined and its meaning is debated
- generally thought that it allows WTO member countries to design their own system of protection for plant varieties if they do not issue plant patents

TRIPS & CHANGING INTERNATIONAL PATENT LAWS

- Some WTO member countries changed their patent laws to conform to the TRIPS agreement
 - As member countries, they are bound to adhere to TRIPS
- For example, prior to joining TRIPS, the Indian patent system followed the 1970 Indian Patent Act, which prevented patent claims for “substances intended for use, or capable as being used as food or medicine or drug”
 - Now that India joined WTO and must comply with the TRIPS agreement, patents are granted for seeds, plants, micro-organisms, cells and even genetically modified organisms and animals
- Similarly, it is argued that prior to Australia, Canada, and Ireland joining WTO, attempts by agribusiness to introduce legislation similar to TRIPS were rebuffed in all three countries

**GENERAL PROBLEM OF DEVELOPED
COUNTRIES & BUSINESSES
PATENTING “INVENTIONS”
INDIGENOUS TO DEVELOPING
COUNTRIES**

TRADITIONAL KNOWLEDGE & IP

- Developing countries & non-governmental organizations (NGOs) observe a “taking” of genetic resources & biodiversity
 - Claim patents are developed using traditional knowledge from local communities
- Developed countries and their constituents think of such activities as the product of legitimate research and development

COMMONLY CITED EXAMPLES OF “BIOPIRACY”

- The US Enola Bean Patent
- The US Basmati Rice Patent

Also

- The Tumeric patent
 - Ayurvedic herbs in general- Neem, Ashwagandha, Tulsi, Shatavari, Amalaki and Brahmi, Triphala, Trikatu
- The Rosy Periwinkle (Madagascar)- vincristine and vinblastine (Eli Lilly cancer fighting drugs)
- Products that are derived from *Lepidium meyenii*, *Plukenetia volubilis* Linneo and *Myrciaria dubia* — 3 plants well known among indigenous Peruvian populations for their medicinal properties

THE ENOLA BEAN PATENT

- A commonly cited as an egregious example of a “taking” of TK
- American executive, Larry Proctor, traveled to Mexico & brought back bag of yellow beans
- After 2 years of breeding bean plants, Proctor filed for a patent that issued 4/13/1999
 - claimed a field bean, the plant produced by that seed, and a method of that field bean

ENOLA- THE BIGGER PICTURE

- The Patent claimed a range of yellow colored seed coats
 - In Mexico, farmers have grown yellow colored beans since the Aztecs
 - Annual sales of Mexican beans in the US were reported at about \$50 million
- After the Enola patent issued, Proctor monitored imports and US sales of Mexican yellow beans.
 - He stated that Mexican farmers were likely raising Enola beans and selling them as Mayacoba.
 - Subsequently, Mexican export sales of yellow beans dropped over 90%, which had a severe economic impact on farmers in northern Mexico.

CHALLENGING THE ENOLA PATENT

- CIAT with support from the Food and Agriculture Association, filed a request for reexamination of the Enola patent.
 - 35 U.S.C. § 102 - *A person shall be entitled to a patent unless — (a) the invention was known or used by others in **this country**, or patented or described in a printed publication in this or a **foreign country**, before the invention thereof by the applicant for patent*
- In 2009, the Federal Circuit *In re POD-NERS*, rejects patent for obviousness (35 U.S.C. § 103 (a))
 - Anyone interested in reproducing or improving Mexican yellow beans would have done exactly what the “inventor” Larry Proctor did: “plant the beans, harvest the resulting plants for their seeds, planting the latter seeds, and repeat the process two more times.”

THE ENOLA BEAN PATENT CONTROVERSY RESOLVED?

- Despite the invalidation of the Enola bean patent, opponents of the patent state that the invalidation took too long to occur, and allowed “the owner of a flagrantly unjust patent to legally monopolize markets and destroy competition for close to half the 20-year patent term.”
 - This inability of the US patent system to quickly invalidate an improvidently granted patent is often cited as a failure of the U.S. patent system, and a concern for future “biopiracy patents.”

BASMATI PATENT

- An example of a less obvious “taking” of TK
- Claimed novel Basmati rice lines, plants and grains of those lines, and a method for breeding those lines.
- Issued Sept. 2, 1997 with 20 claims (most related to rice) by RiceTec Corporation



Photo: Ranveig, *Closeup of brown basmati rice*,
Wikimedia (2005)

THE BASMATI RICE PATENT

- RiceTec claimed to have spent an estimated 10 years and approximately \$4 million USD to create a rice plant with similar qualities to Indian basmati rice that could grow in North America
 - Crossed seeds of South Asian basmati rice with seeds of an American dwarf variety of rice
 - South Asian basmati rice came from rice donated from India & Pakistan to a US based international agricultural research center in Idaho
- RiceTec did not prevent South Asian growers from exporting their products

THE BASMATI CONTROVERSY

- Coalition of NGOs and Government of India brought challenges in USPTO & FTC
 - Basmati rice one of most prized varieties of agricultural TK native to South Asia, India's primary rice export (about \$500 million a year)
 - Exact origin of basmati rice unclear
 - Sparked fear in India that other "Indian products" would be patented

CHALLENGES TO THE BASMATI PATENT

Indian Gov. files petition for reexamination in April 2000

- Argues 3 claims were worded so that the characteristics of rice grain mentioned could apply to 90% of all basmati grown anywhere in world

USPTO began full examination of all of the claims

- Preliminary decision in March 2001 to reject most of the claims
- April 2001 RiceTec withdraw 14 claims and amended another
- USPTO upholds 3 claims, Indian Gov. and NGOs consider victory
- Patent expires for non-payment Oct. 5, 2005



 **AYURVEDA**

 **UNANI**

 **SIDDHA**

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Traditional Knowledge Digital Library

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As to 2.23 Lakh (0.22 million) Medicinal Formulations is available to Patent Offices only under TKDL Access Agreement

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We

OUTLOOK & LESSONS LEARNED

LESSONS LEARNED- THE SbMATE PATENT

- Under current IP law, the SbMATE patent represents American ingenuity and not “looting.”
- Use of the Tanzanian sorghum line must appear to some Tanzanians much like the theft of the Elgin marbles from Greece
 - HOWEVER there is no complete system in place to compensate developing countries for any use of their indigenous plants in the creation of new patentable inventions.
- The International Seed Treaty attempts to remedy these problems in the future and reward those farmer cultures that developed useful plants, like SC283 sorghum. It does not seek to correct all past “takings.”
 - Therefore, the Treaty does not address potential problems caused by the SbMATE patent.

OUTLOOK

- Ethical concerns about patents are likely to continue in spite of the International Seed Treaty.
 - It is likely that there are other germoplasms among the 560,000 accessions available in CGIAR that were also acquired outside of the Treaty's regime and may be patented despite the Treaty.
- The Treaty has been credited with “providing access to, as well as the conservation and sustainable use of, plant genetic resources on the one hand and the fair and equitable sharing of benefits derived from their use on the other.” Adejoke Oyewunmi, *The Rights of Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, in PATENTING LIVES 53, 67 (Johanna Gibson ed., 2008)
 - Presumably the Treaty will become more important over time, as plants subject to the Treaty are used to develop further innovations in agriculture and medicine.

LESSONS LEARNED

- Determinations of biopiracy are not easy, and IP systems are generally not well suited for making such determinations.
 - patent systems in particular are not usually designed to address problems of “theft” of indigenous resources
 - Can be difficult to determine when in time “theft” occurs.
 - Solutions such as the International Seed Treaty, the CBD Treaty, and the Traditional Knowledge Digital Library are still developing
 - Such solutions that are designed to address such concerns are often distinct from IP systems

LESSONS

The problem is not usually that an IP system granted a patent *per se*.

- Most biopiracy analysis should be determined without implicating IP systems and should instead focus primarily on the original “taking” and use of indigenous material
 - In the SbMATE “biopiracy” case the immediate concern is the “taking” Tanzanian sorghum not that the US allowed a patent
- When alleged “biopiracy patents” occur, generally the problem is a failure to create protections against the taking of indigenous material, the failure to adequately publicize traditional knowledge, or the failure to properly reward cultures for the use of their indigenous material

THE FUTURE OF ALLEGED “BIOPIRACY” PATENTS

- Increasing Awareness of TK concerns
- “Biopiracy” problems will probably decline over time
 - Increasing number of methods to prevent such problems- Convention on Biologic Diversity, International Seed Treaty, Consultative Group on International Agricultural Research (CGIAR)
- The SbMATE patent itself is likely to remain