

# ***Discovering Hidden IP Assets:***

*Cost-Effective Ways to Identify and Develop Untapped Intellectual Property in Your Company*

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# *Intellectual Property*

- Patents
- Trademarks
- Copyrights
- Trade Secrets
- Licensing

## ***“Top 10” FAQs***

- Can I patent this formulation?
- Do I have to perform a patent search?
- How long does patent protection last?
- What in the world is considered patentable?
- How much does it cost?
- How much is it worth?
- Can I sell my product (i.e. practice my invention)?
- Can I file a patent if I've been selling more than 1 year?
- Can I file a patent if I've been selling for less than 1 year?
- Which countries are available for patent protection?

## ***A little about Patents...***

- *Form of exclusivity*
- *Patent confers a right to exclude*
- *Only Govt-approved monopoly*
- *Worth the investment?*

# **THE BASICS**

## ***Patent Requirements***

- *New*
- *Useful*
- *Non-Obvious (not done w/ hindsight)*

# **SUBJECT MATTER**

## ***What can be Patented?***

- *Plant, never-before extracted/ extracted components*
- *Purified or enriched extracts*
- *Seeds, GMO's*
- *New combinations of ingredients*
- *Therapeutic treatments*
- *Therapeutic method of using an old compound*
- *Indirect effect – synergy, potentiation*
- *Manufacturing method*
- *Improvement of existing product, apparatus, or method*
- *Business methods (New standard per S.C. decision In re Bilski – not merely Machine or Transformation test)*

# *For Example*

## Mars “vs.” Hershey's

- Many historical patents directed to novel hard candy shell (both product and process)
- Patent protection dates back to 1940
- Developed new product categories
- No “candy shell”



***via candyblog.net (5/27/2010):***

- Some may wonder if the light coating is like that on M&Ms Premiums. There is a light waxy coating on there, but it's thinner than the latexy and colorful stuff on the M&Ms Premiums. It's more like what you'd find on Junior Mints or Whoppers. Just a simple glaze that melts away quickly.

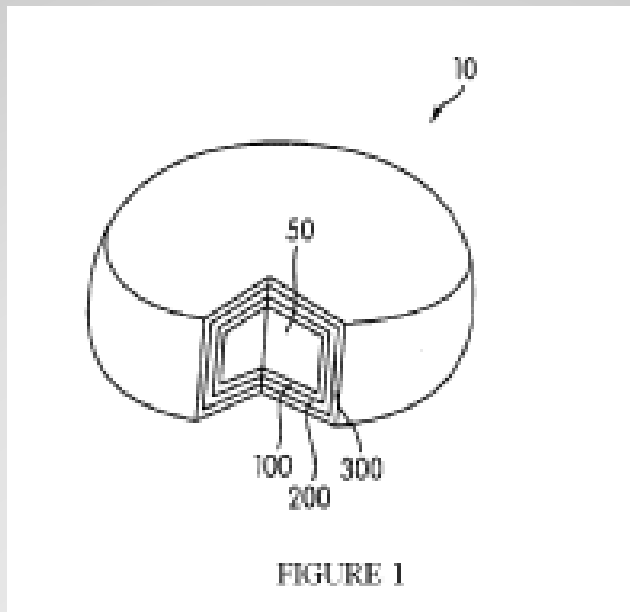


# Visual comparison:



# Hershey develops pill-like film coating for confectionery

## WO2012/146921



## *Sweeteners Category* Established Products

- Saccharin
- Sucralose
- Ace K (Acesulfame)
- Aspartame

## ***Sweeteners Category*** **Up & Comers**

- Xylitol
- Maltitol
- Stevia (*case study*)
- Rebaudioside
- Luo Han fruit (*case study*)
- Mogroside V

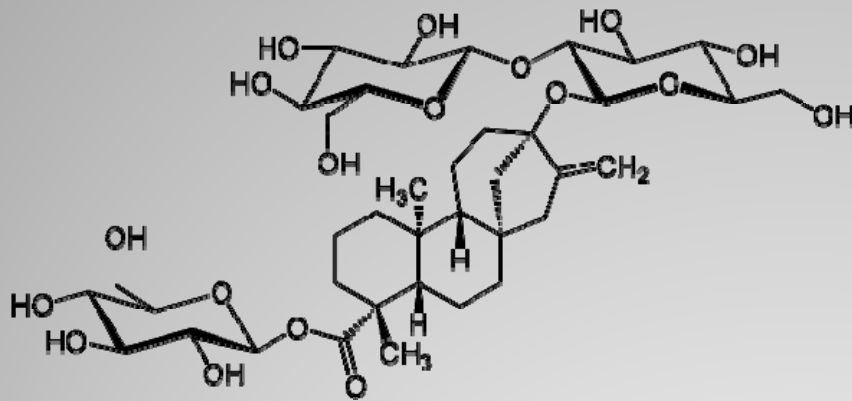
## Case Study: Stevia

- IP rights owned by, among others: COCA COLA, CARGILL, PURECIRCLE USA INC.
- Rebaudioside A, a component of Stevia leaves, granted GRAS (Generally Regarded as Safe) notification status by the FDA for use as a sweetener in 2008/2009

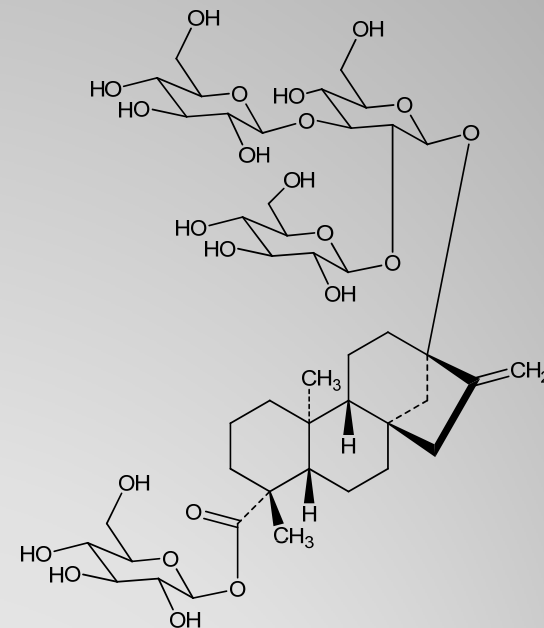
## What is Stevia?

- A purified extract derived from the leaves of the South American herb *Stevia rebaudiana*
- Chemically: Stevioside 5-10% (leaf dry wt.)
- Rebaudioside A 2-4%
- Other glycosides

# What is Stevia?



Stevioside sweetness:  
300X sucrose



Reb A sweetness:  
350-450X sucrose

# Cooking Stevia

- Stevia is a suitable sweet additive for cooked or baked foods. The Stevia leaves, as well as extract, are thermostable at temperature up to 200°C.
  - Serio, L. (2010). La Stevia rebaudiana, une alternative au sucre. *Phytothérapie*, 8, 26–32.
- Stevia sweeteners are stable at high heats after one hour of heating at 100°C.
  - Chang, S. S., & Cook, J. M. (1983). Stability studies of stevioside and rebaudioside A in carbonated beverages. *Journal of Agricultural Food Chemistry*, 31, 409–412.



# Stevia leaf: Amino Acids

- Numerous studies show Stevia leaves contain 17 amino acids, with the exception of tryptophan.
  - Abou-Arab, A., Abou-Arab, A., & Abu-Salem, M. F. (2010). Physico-chemical assessment of natural sweeteners steviosides produced from *Stevia rebaudiana* Bertoni plant. *African Journal of Food Science*, 4, 269–281.
  - Mohammad, M., Mohammad, U., Sher, M., Habib, A., & Iqbal, A. (2007). In vitro clonal propagation and biochemical analysis of field established *Stevia rebaudiana* Bertoni. *Pakistan Journal of Botany*, 39, 2467–2474.
- The amino acids are capable of matching the protein requirements recommended by the World Health Organization (WHO).
  - WHO (2007). Report of a Joint WHO/FAO/UNU Expert Consultation on Protein and Amino Acid Requirements in Human Nutrition (2002: Geneva, Switzerland). WHO Technical Report Series; No. 935.

## **Stevia leaf: Nutritional Benefits**

- Stevia leaf's nutritional benefits are due to its composition, which provides an excellent source of carbohydrates, protein and crude fibre.
- These components promotes wellness and reduces the risk of certain diseases.

# Stevia leaf: Nutritional Benefits

Case study analysis of dried Stevia leaves (g 100g<sup>-1</sup>dry weigh basis).

	Mishra et al. (2010)	Goyal et al. (2010)	Serio (2010)	Savita et al. (2004)	Abou-Arab et al. (2010)	Tadhani and Subhash (2006)	Kaushik et al. (2010)
Carbohy drate	52	ND	53	52	61.9	35.2	-
Protein	10	11.2	11.2	9.8	11.4	20.4	12
Crude Fibre	18	15.2	15	185	15.5	-	-
Moisture	7	4.65	-	7	5.37	-	7.7
Fat	3	1.9	5.6	2.5	3.73	4.34	2.7
Ash	11	6.3	-	10.5	7.41	13.1	8.4

## **Stevia leaf: Vitamins**

- The contents of folic acid, vitamin C and vitamin B2 in the Stevia leaf extracts differ than those of the Stevia callus extracts. In the leaf extract, folic acid was found to be the major compound, followed by vitamin C. In the callus extract, vitamin C was the major compound, followed by vitamin
  - Kim, I., Yang, M., Lee, O., & Kang, S. (2011). The antioxidant activity and the bioactive compound content of Stevia rebaudiana water extracts. LWT – Food Science and Technology, 44, 1328–1332.

# Stevia leaf: Vitamins

Water soluble vitamins of *S. rebaudiana* leaf and callus extracts  
(mg 100g<sup>-1</sup> dry base extract)

Vitamin	Leaf	Callus
Vitamin C	14.98 ± 0.07	1.64 ± 0.02
Vitamin B2	0.43 ± 0.02	0.23 ± 0.02
Vitamin B6	0.00 ± 0.00	0.00 ± 0.00
Folic Acid	52.18 ± 0.21	0.09 ± 0.01
Niacin	0.00 ± 0.00	0.00 ± 0.00
Thiamin	0.00 ± 0.00	0.00 ± 0.00

## **Stevia leaf: Minerals**

- Stevia is a mineral loaded ingredient needed to protect the body, regulate and maintain the various metabolic processes. The high concentration of potassium, calcium, magnesium, and sodium present in Stevia leaves can be very beneficial to health.

# Stevia leaf: Minerals

Studies of mineral content (mg 100 g<sup>-1</sup> ) of dried stevia leaves.

	Mishra et al. (2010)	Goyal et al. (2010)	Serio (2010)	Tadhani and Subhash (2006)	Kaushik et al. (2010)
Calcium	464.4	544	600	1550	722
Phosphorous	11.4	318	318	350	-
Sodium	190	89.2	-	160	32.7
Potassium	1800	1780	1800	2510	839
Iron	55.3	3.9	3.9	36.3	31.1
Magnesium	349	349	500	-	-
Zinc	1.5	1.5	-	6.39	-

## **Stevia leaf powder: food technology**

- Possibly due to high protein content, Stevia leaf powder has an increased water holding capacity. Proteins increase water holding capacity, thus enhancing the swelling ability, an important function of protein in preparation of viscous foods such as soups, gravies, dough and baked products.
  - Mishra, P., Singh, R., Kumar, U., & Prakash, V. (2010). Stevia rebaudiana – A magical sweetener. Global Journal of Biotechnology & Biochemistry, 5, 62–74.



# Stevia Clinical Outlook

Potential uses and indications:

- Anti-oxidant potential
- Toxicological studies have shown that stevioside does not have mutagenic, teratogenic or carcinogenic effects
- Non-allergenic when used as sweetener
- anti-hyperglycemic
- anti-hypertensive
- anti-inflammatory
- anti-tumor
- dental caries

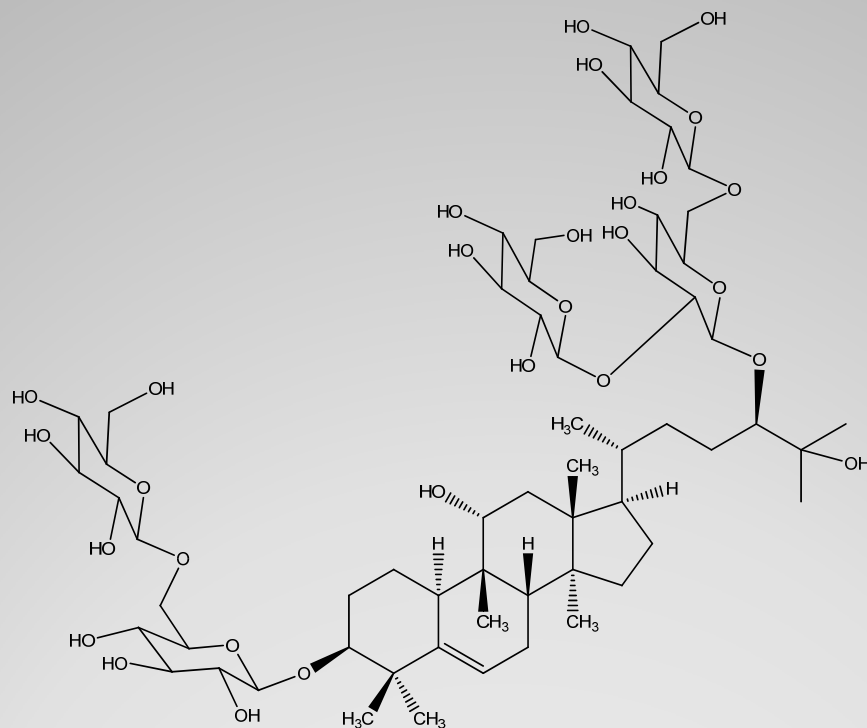
## Case Study: Luo Han

- IP rights in development – patenting activity
- Mogroside V, luo han fruit component, has been granted GRAS (Generally Regarded as Safe) notification status from the FDA

# What is Luo Han?

- monk fruit
- produced by a plant (*Siraitia grosvenorii*), which only grows in the northern parts of Guangxi province, in southern China
- Chemically: contains Mogrosides II-VI (0.5-1% wt. in dried fruit)

# What is Luo Han?



Mogroside V: 300X sucrose

## **Record of Invention**

- *Details and describes your idea*
- *E-mail us at [info@amintalati.com](mailto:info@amintalati.com)*
- *We'll send you one*

# *Record of Invention*

RECORD OF INVENTION  
REFERENCE No.: CLIENT CODE-###

*PRIVILEGED AND CONFIDENTIAL*  
*ATTORNEY-CLIENT COMMUNICATION*

Submitted by:

(Name and address)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Submitted to:

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Suite 3400  
Chicago, Illinois 60603

- Inventors need to keep good records and memorialize technical content
- May be witnessed and/or notarized

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# Patent Strategy

**What Issue Are You Addressing?**

**What Problem Are You Solving?**

**Are You Doing it Better?**

- *Yes? Then explore your IP options*
- *Efficiency, Economy*
- *You can license technology*
- *Defensive strategy*
- *Blocking strategy*

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# New Law

## America Invents Act of 2011 (AIA)

- *Signed into law by Pres. Obama on Sept. 16, 2011 (new provisions 9-16-12)*
- *1<sup>st</sup> Inventor to file **(in effect 3-16-2013)***
- *Invokes First User/Prior User rights*
- *Inventors no longer can antedate ("swear behind") a disclosure by another*
- *Blocking purpose: may want to prevent someone else (publishing websites, ROI form)*
- *If you document, you can practice*



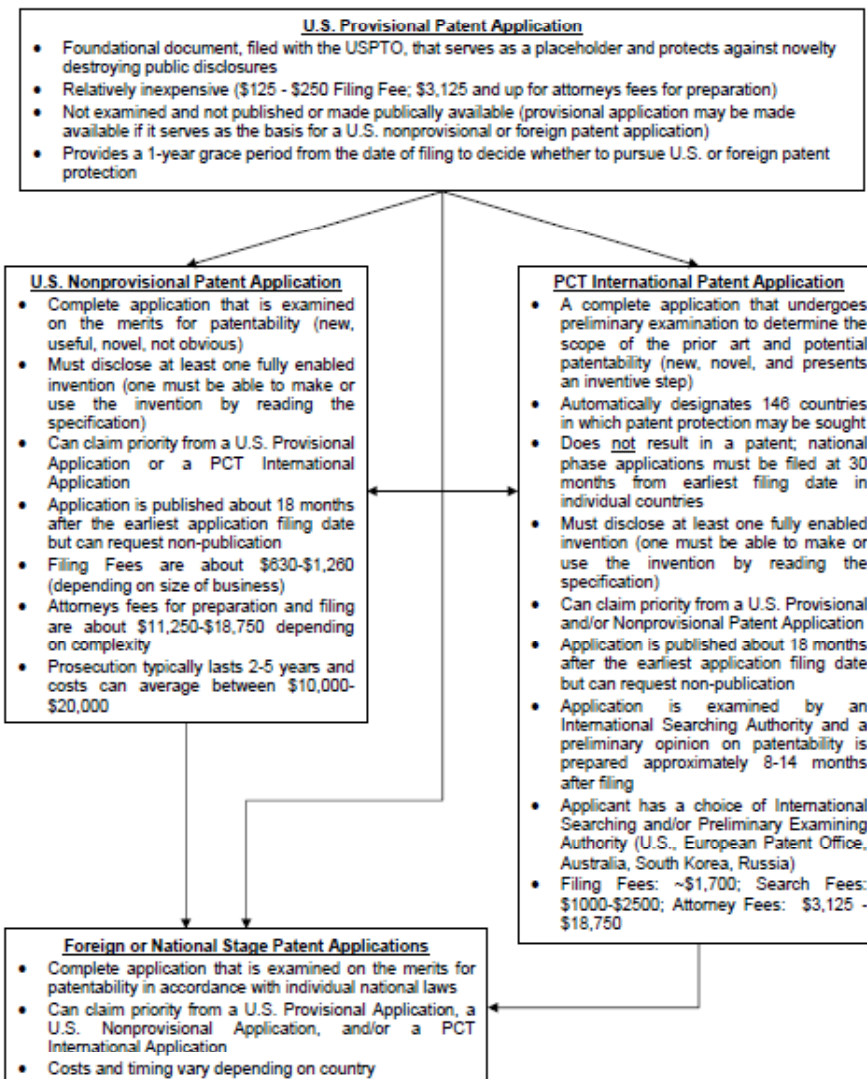
## New Law

# America Invents Act of 2011 (AIA) TIMELINES

- 1-Year Grace Period exists in U.S. (for publication, sales, or other disclosures)
- “Absolute Novelty” applies in many countries (so file first)
- 1<sup>st</sup> Inventor-to-File Regime dawning in U.S. for the first time (March 16, 2013)
- Can file a full application within 1 year of “domestic” priority (U.S. Provisional) or foreign priority filing
- ‘Accelerated’ options carry over (guaranteed 1 year to “final disposition”)

# T I M E L I N E S

## U.S. AND FOREIGN PATENT APPLICATIONS



# Other Patent Types

## Design Patents

- Ornamental aspects only
- Can be valuable if not a driver of function
- Overlooked often, since not given much scope
- Damages can be forceful: go straight to profits (contrast util.: reasonable royalty)
- Examples: packages/containers; shapes of food
- Shining example is iPhone:  
Apple v. Samsung, (N.D.Cal 2012)

# Other Patent Types

## Plant Patents

- Varietals
- Hybrids
- Asexually reproduced

# Timing Considerations & Patent Filing Strategies

- Can prepare botanical extracts or isolate bioactives
- Clinical trial (not necessary at outset)
- Correlation: in vitro to in vivo (animal or human)
- Have window of time before publication

# Costs

- If have a great product or idea – can go all out with patent investment - Int'l filings (PCT up to 146 countries)
- If on a budget – buy time:
  - don't need a prior art search (no obligation)
  - file a quick Provisional application (fees lowered)
  - don't need clinical data right away (but put in as much as possible)
- If don't want patent investment – keep as a trade secret (talk w/ an attorney)
  - Need good employee agreements/ confidentiality or NDAs
  - Marking issues

## You've Scoured Your Potential IP Ideas, But You Don't Have Anything?

- License patents and published/pending apps
- Partner/JV with industry start-ups
- Patent auction sites
- Bankruptcy sales
- Solve a problem:
  - Adverse effect resolution
  - Bad taste/ Taste-masking
  - Organoleptic properties
  - Improved flavoring & sweetening
  - Soluble protein
  - Soluble fiber

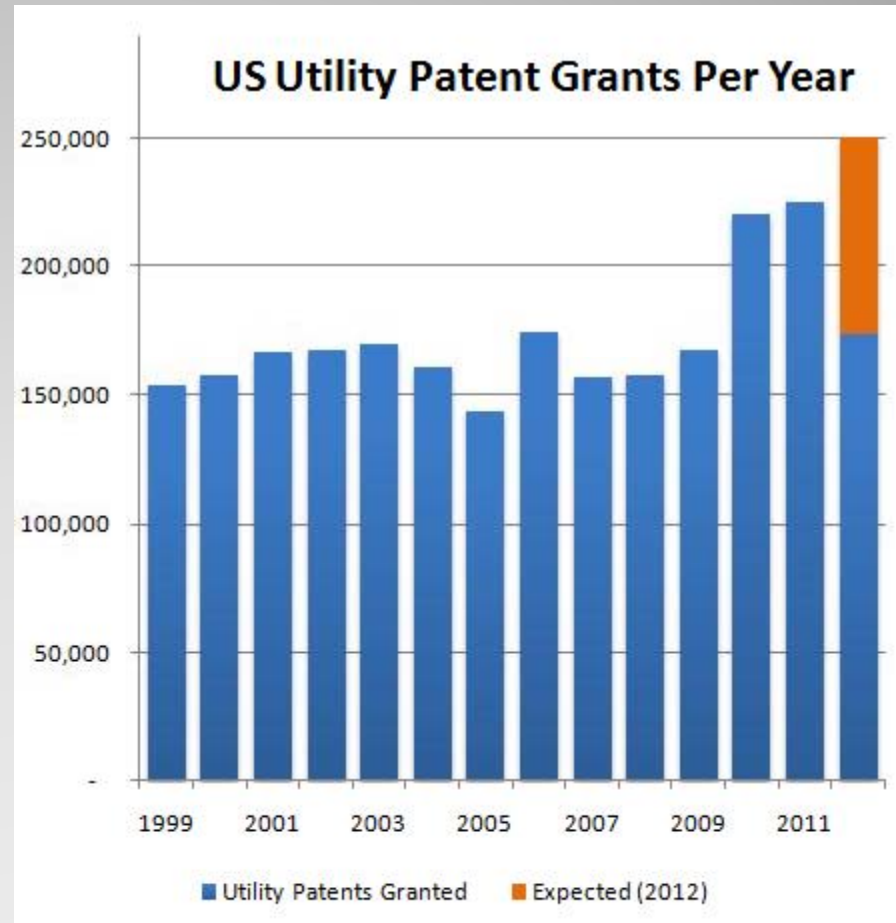
## Other Ways to Protect Your Product or Brand

- Trademark/ Trade Dress
- ITC/ Customs enforcement
- Regulatory approvals/notifications - GRAS notifications, New Dietary Ingredient (NDI)notifications, New Drug Applications (NDA) etc.
- Clinical Studies
- Establish a strong and distinguishable branding presence (i.e. – product/ingredient branding)



# *A Surprising Development*

- The USPTO's backlog of unexamined applications dropped by over 100,000 cases in the past year from a starting point of over 700,000 unexamined cases
- <http://www.patentlyo.com> (*Dennis Crouch, 9/5/12*)
- 2012 grants: 253,000 (a record)
- 2013 forecast: >290K



## RECAP

- Patent confers a right to exclude (may license some rights back to yourself)
- Patent is an asset on your balance sheet
- Real assets may be monetized
- Freedom-to-Operate/ Clearance (\$10K-90K)
- Patent infringement litigation is very expensive (\$1 MM for a small case, and up)
- Enforcement
  - You don't have to enforce (foreign jurisdiction questions)
  - Can obligate another party to enforce (if you license)

# Questions?

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