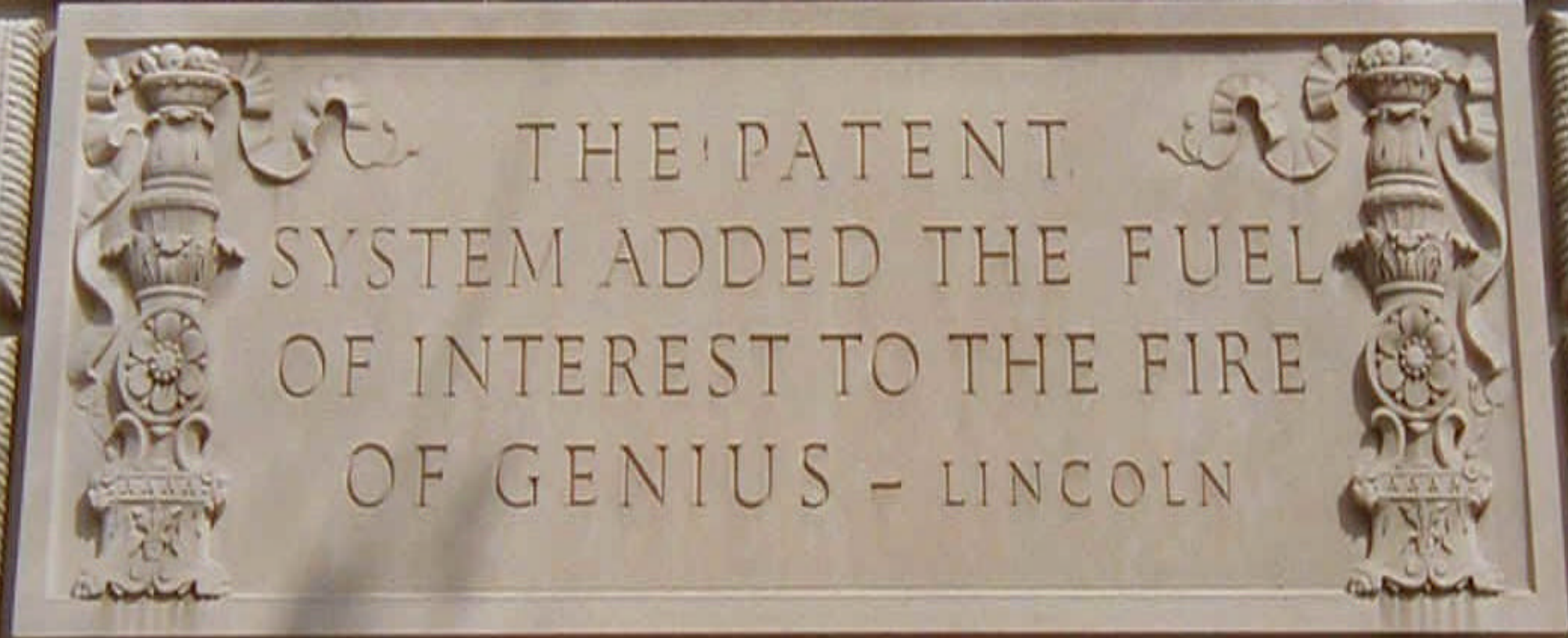


How to Use Patents to Protect Market Share

Chemical Week Magazine
Chicago (June, 2004)

A stone relief carving of a quote by Abraham Lincoln. The text is centered and reads: "THE PATENT SYSTEM ADDED THE FUEL OF INTEREST TO THE FIRE OF GENIUS - LINCOLN". The quote is flanked by two ornate, classical-style columns with decorative capitals and bases. The entire relief is set within a rectangular frame.

THE PATENT
SYSTEM ADDED THE FUEL
OF INTEREST TO THE FIRE
OF GENIUS - LINCOLN

Agenda

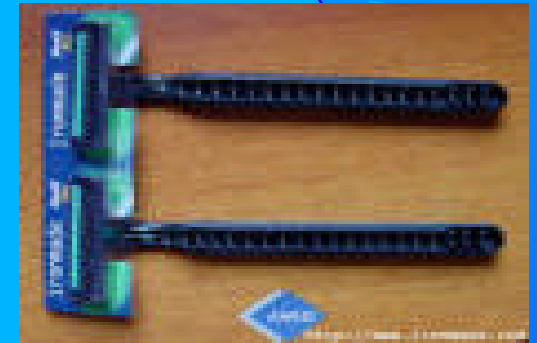
- **What's so important about patents?**
- **What is a patent?**
- **The Three Requirements for a Patent**
- **How do you get started?**

The Importance of Patents

- IBM, Hewlett Packard make more from licensing patents than from making things
- "At 8:13 am on Feb. 16, a news release from HGS crossed news wires, and instantly its shares began soaring in premarket trading. the company said it had just received a [key] US patent The news release excited a hyperbolic Wall Street ... and within two days HGS shares had leapt 41%, adding \$3.8 billion to the little company's value." Wall St. Journal

The 3 Requirements

- Constant for any industry
 - Gillette : over 206 razor patents
- 1. Formalities
- 2. Useful
- 3. New



Formalities

- **The physical appearance of the patent application**
- **A patent application looks like a scientific paper or marketing plan**
 - **Abstract**
 - **Introduction**
 - **Materials & Methods (may be speculative)**
 - **Results, Data (not required)**
 - **Conclusions (may be speculative)**
 - **cf. Crick & Watson : double helix theory**

Usefulness

- The patent application must assert a usefulness
- usefulness : "made or used in any industry"
 - *cf.* throwaway uses
- a : not "all," not even "best"
- assert
 - "I think / hope / suspect this will work."
 - Clinical data not required.
 - Exception : if assertion of usefulness appears on its face unbelievable.

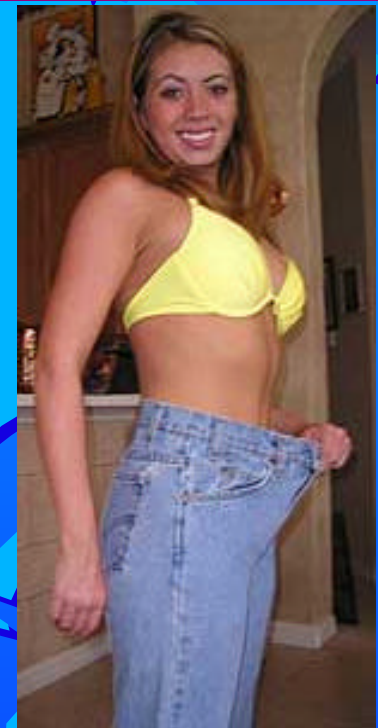
Usefulness - Example

- **Glucosamine - discovered in late 1880s.**
- **Glucosamine + fiber known since ca. 1980s for weight control.**
- **New discovery - use glucosamine to regulate blood sugar levels, and thus regulate fat-formation metabolism.**
- **Patent filed ca. 1991.**

Usefulness



- Patent Office questions if glucosamine without fiber works.
 - Is it the glucosamine, or is it really the added dietary fiber that works?



12) **United States Patent**
Fleischner

(10) **Patent No.:** **US 6,420,350 B1**
(45) **Date of Patent:** **Jul. 16, 2002**

54) **WEIGHT LOSS PRODUCT**

(56)

References Cited

75) **Inventor:** **Albert M Fleischner, Westwood, NJ**
(US)

U.S. PATENT DOCUMENTS

5,730,988 A * 3/1998 Womack 424/195.1
5,795,576 A * 8/1998 Diaz et al. 424/195.1
5,888,514 A * 3/1999 Weisman 424/195.1

73) **Assignee:** **Goen Group, Inc., Cedar Knolls, NJ**
(US)

OTHER PUBLICATIONS

*) **Notice:** Subject to any disclaimer, the term of this <http://www.nutrasentials.com/TrimSpaOriginal.html>—

- **Patent Office ultimately concludes that glucosamine works, and awards patent (July 2002).**
- **"glucosamine in an amount effective to promote weight loss, the dietary fiber ... being less than the amount of dietary fiber required to prevent the absorption of undigested dietary fat"**

Usefulness

- Patent on ephedra-free weight loss product
- Remember limit of patent: "the dietary fiber ... being less than the amount of dietary fiber required to prevent the absorption of undigested dietary fat"
- What of glucosamine + fiber product?





FEDERAL TRADE COMMISSION FOR THE CONSUMER

- **Federal Trade Commission enforcement action against glucosamine + fiber product in 2003.**
- **Glucosamine + fiber = FTC violation**
- **Glucosamine w/o fiber = patent violation**



FEDERAL TRADE COMMISSION FOR THE CONSUMER

- **Federal Trade Commission enforcement**
 - The Food & Drug Administration has express limits on its legal authority to control nutritional supplements.
 - Proof of "safety and efficacy" vs proof required for drug products.
 - The FTC is requiring proof of safety and efficacy with "deceptive advertising" enforcement actions
 - Why?



FEDERAL TRADE COMMISSION FOR THE CONSUMER

- **The danger of success**
 - **Nutritional products : recession-proof growth**
 - **Pharmaceutical industry : price controls, global competition**
 - **Nutritional Products appear strategically attractive to large pharmaceutical makers**
 - **Is this a repeat of what happened to OTC drugs in the 1970s?**

Newness

- The invention cannot be the same as what has been done before
 - Exactly the same as
 - Rare
 - Typically, your own products or prior work
 - "Substantially" the same as
 - Unrelated third parties, et cetera
 - What is "substantially" the same?

Newness (*continued*)

- **Lack of newness prevents patenting**
 - formal article published in peer-reviewed journal
 - published patent
 - on sale, non-confidential display, informal disclosures
 - e.g., Ming dynasty text, Lancet letter, custom centrifuge
 - e.g., product launch at Natural Products Expo (West)
 - USA: one-year grace period.

Newness - example

- Diet tailored to a person's blood type
- Widely-sold cookbooks
- If you're blood type x, then eat more greens, or eat less dairy, etc...

4 Blood Types, 4 Diets

EAT RIGHT

FOR

YOUR TYPE

The

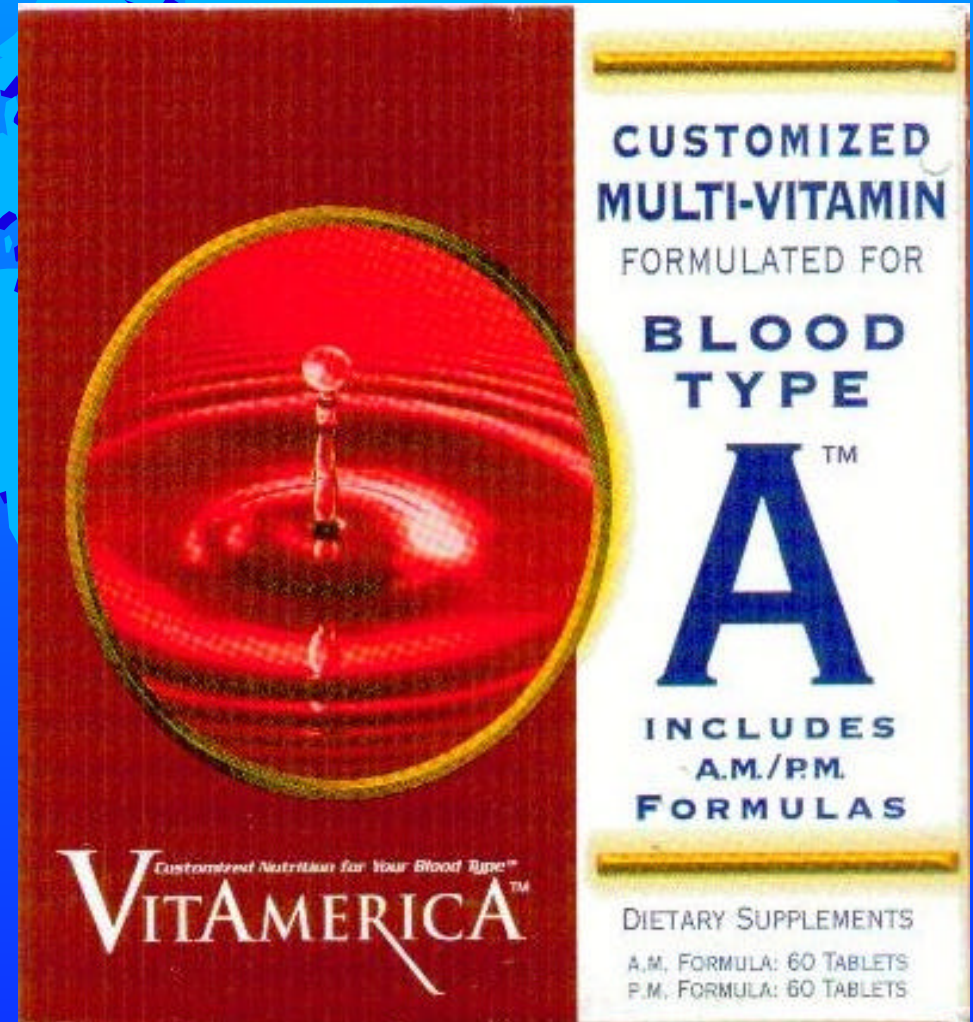
INDIVIDUALIZED

Diet Solution to Staying Healthy, Living
Longer & Achieving Your Ideal Weight

Dr. Peter J. D'Adamo
with Catherine Whitney

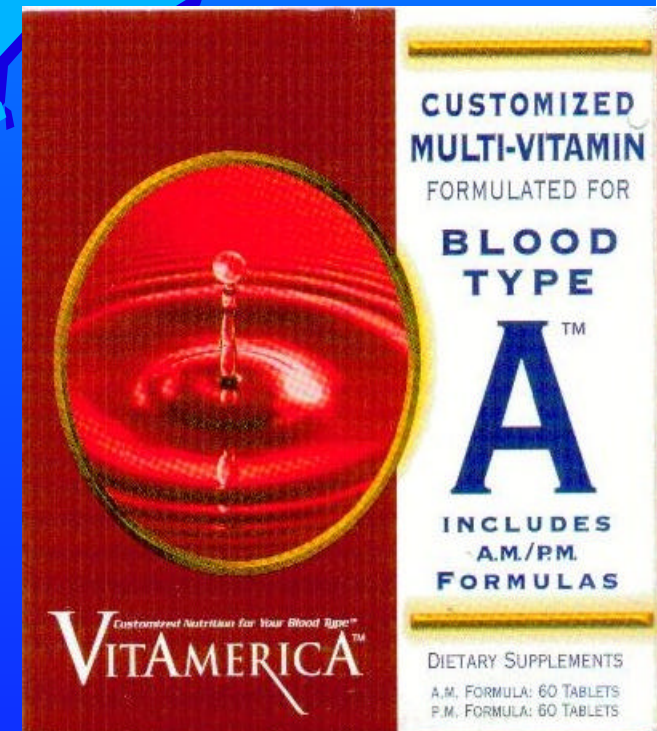
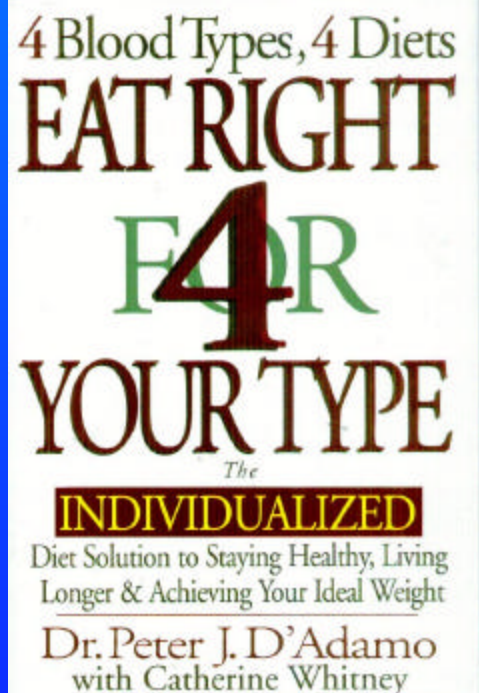
Newness - example

- **Vitamin Company :**
 - Why bother with changing your whole diet / cooking regime?
 - Develop a product line of nutritional supplements specific for each blood type



Newness - example (continued)

- Apply for patent
 - Preferably before commercial launch, to preserve OUS rights
 - Disclose "prior art" information to US Patent Office
 - Patent Office makes comparison
 - Is it new?



(12) **United States Patent**
Fleischner

(10) Patent No.: **US 6,503,529 B1**
(45) Date of Patent: **Jan. 7, 2003**

(54) **BLOOD TYPE METHODS AND DIETARY SUPPLEMENTS**

(56) **References Cited**

(75) Inventor: **Albert M. Fleischner, Westwood, NJ (US)**

U.S. PATENT DOCUMENTS

5,904,921 A * 5/1999 Gaynor et al. 424/195.1

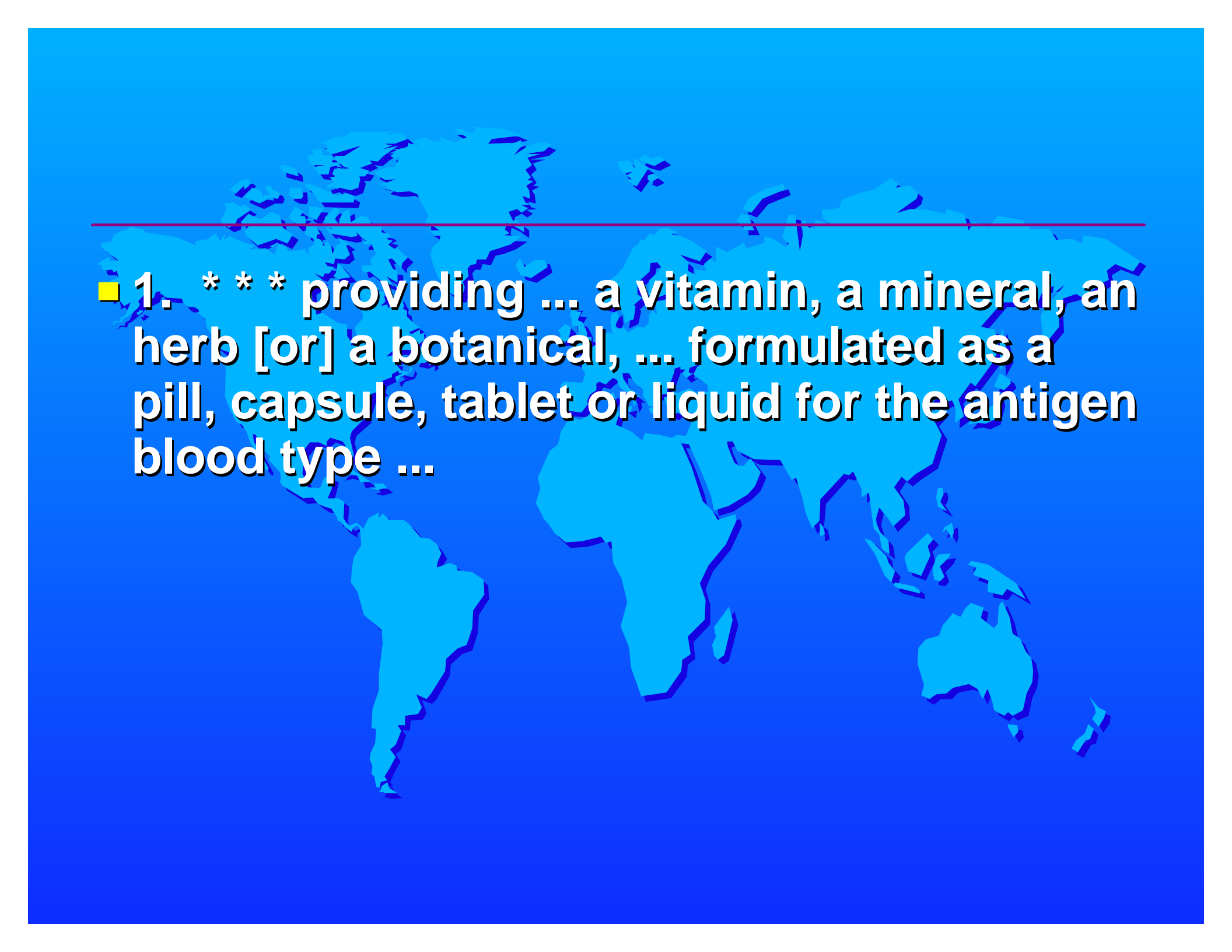
(73) Assignee: **Gen Group, Inc., Cedar Knolls, NJ (US)**

FOREIGN PATENT DOCUMENTS

FR 2704393 * 11/1994

- **Patent Office compared cookbooks to nutritional supplements, and concluded that blood-type nutritional supplement products are new.**
- **Patent issued in January, 2003**


- 1. A method to supplement the diet of a human of a specific antigen blood type with a specific dietary supplement for said specific blood type, wherein said method consists essentially of providing to said human said dietary supplement, said dietary supplement consisting essentially of a substance selected from the group consisting of a vitamin, a mineral, an herb and a botanical, and wherein said dietary supplement can be formulated as a pill, capsule, tablet or liquid for the antigen blood type of the human.

- 
-
- 1. * * * providing ... a vitamin, a mineral, an herb [or] a botanical, ... formulated as a pill, capsule, tablet or liquid for the antigen blood type ...



NATURAL FOODS
MERCHANTS

Meeting of the Minds



March 1999

Dr. Peter J. D'Adamo

4 Blood Types, 4 Diets
COOK RIGHT
F4R
4 Blood Types, 4 Diets
EAT RIGHT
F4R
YOUR TYPE
For
INDIVIDUALIZED
Diet Solution to Staying Healthy, Living
Longer & Achieving Your Ideal Weight
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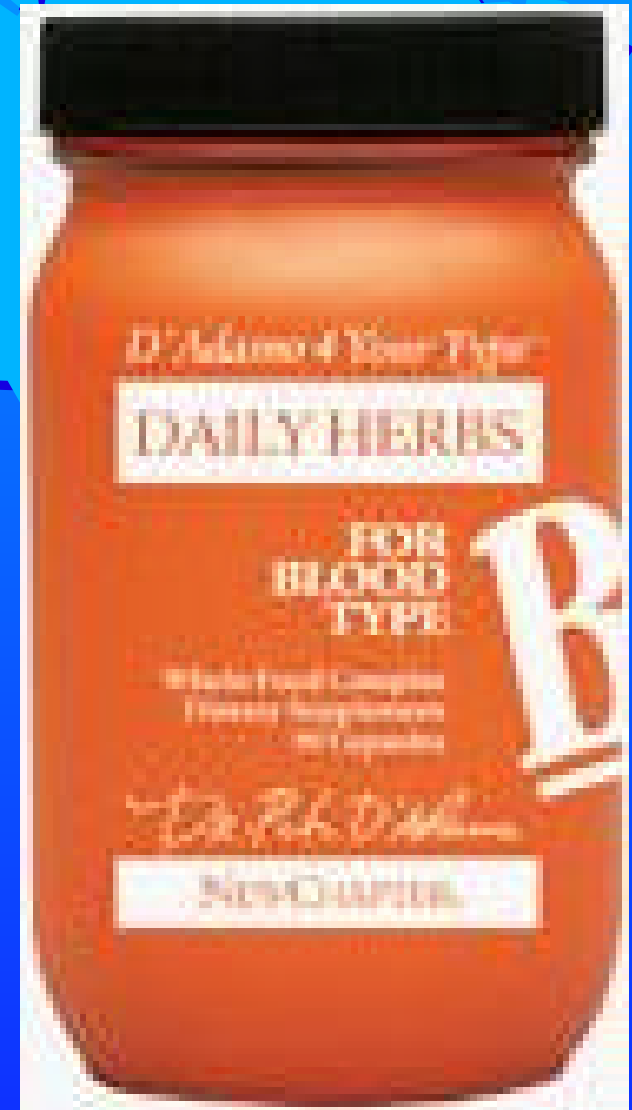
THE RIGHT
PRODUCTS
F4R
YOUR TYPE

Dr. Peter J. D'Adamo

THE RIGHT PRODUCTS 4 TYPE O <i>Dr. Peter J. D'Adamo</i>	THE RIGHT DAILY PROPS 4 TYPE A <i>Dr. Peter J. D'Adamo</i>	THE RIGHT MULTIPLE 4 TYPE B <i>Dr. Peter J. D'Adamo</i>	THE RIGHT MULTIPLE 4 TYPE AB <i>Dr. Peter J. D'Adamo</i>
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Newness - example

- 1. * * * providing ... a vitamin, a mineral, an herb [or] a botanical, ... formulated as a pill, capsule, tablet or liquid for the antigen blood type ...



How Do You Get Started?

- Look at the competition
- Look in the mirror
- Identify the difference
- Value the difference

!!! Opportunity !!!

- **Underutilization of [intellectual property] ... represents ... the greatest opportunity to be handed to CFOs in a generation. Indeed, the current run-up in intellectual asset values . . . suggests that patent rewards may be as great as the rewards the leveraged buyout kings obtained 20 years ago with undervalued real estate and pension holdings. *Harvard Business Review***

Implementation Considerations

- **Start to develop a relationship with patent counsel**
 - legal experience
 - nutritional products industry experience
 - awareness of FDA and DSHEA law is important

Implementation Considerations (*continued*)

- To be ready next year, start immediately
 - complex communications
 - large amount of legal learning required
 - large amount of R&D planning required
 - lead time to apply for patent can range to 5-6 years

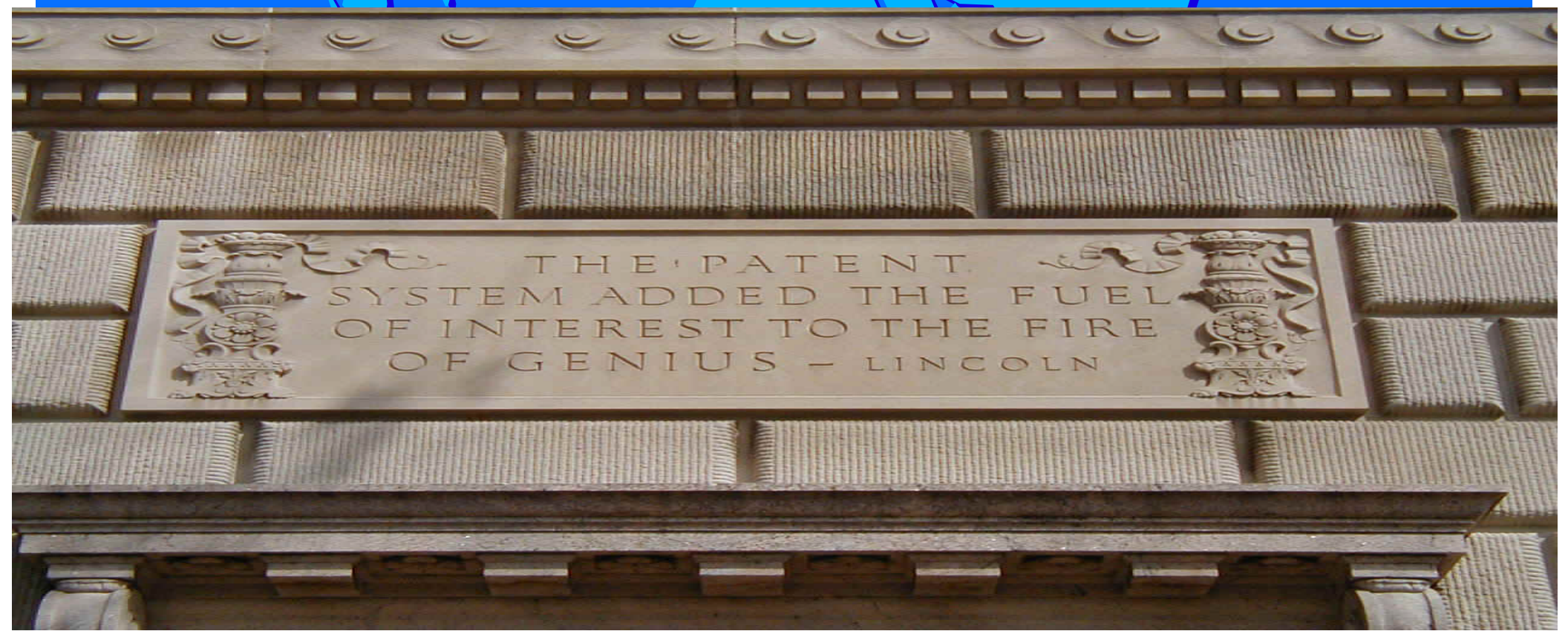
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