

GETTING THE START-UP STARTED

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GCD
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EverSmart Inc./LLC



- Intellox
- “Special” Capsule
- Ingredients X and Y
- It makes you smart

THE PROGRAM

Corporate / Venture Capital

- Choice of Entity
- Raising Money
- Sources of Capital
- Legal Issues in Financings

Q&A

Intellectual Property

- Patent
- Copyright
- Trademark
- Trade Secret
- Agreements

- Q&A

CORPORATE / VENTURE CAPITAL

CHOICE OF ENTITY

- What are the choices?
 - C corporation
 - S corporation
 - Limited liability company (LLC)

- What factors are relevant to the decision?
 - Taxes
 - Limitation of liability
 - Plans for future growth/outside investors
 - Desire for flexibility
 - Equity incentive arrangement
 - Ease of conversion to another form
 - Exit

- C Corporations
 - Double taxation
 - Better for Venture Capitalists (VCs)
 - More flexibility for equity incentive plans
 - Exit: IPO – ready, but double tax on asset sales

- S Corporations and LLCs
 - “Flow through” tax treatment
 - S corp limitations: 75 shareholders and 1 class of stock
 - LLC limitation: VCs may object
 - Flexibility: LLCs can accommodate customized management and capital structure
 - Equity incentive: S corps preferable to LLCs
 - Exit: the “flow throughs” have the advantage

- Assessing the factors for the entrepreneur

	C Corp	S Corp	LLC
Taxes		√	√
Limitation of Liability	√	√	√
Plans for future growth/outside investors	√		
Desire for flexibility			√
Equity incentive arrangement	√	√	
Ease of conversion		√	√
Exit		√	√

RAISING MONEY

- Founders' Stock
 - Generic term referring to the initial shares issued to the founder or founders of a company
 - Generally low-basis shares for “sweat equity”, although founders can build basis by funding the business on their own

- Valuation: Pre-Money
 - How much ownership do I need to give away to raise a certain amount of money?
 - or
 - If I want to retain a certain percentage ownership, how much money can I raise for the percentage I'm willing to give up?
- Answer: What the market will bear! But... often the founders are setting the valuation and it's a take it or leave it proposition.

- Valuation: Pre-Money (continued)
 - Traditional valuation metrics based on financial condition, historic results and future projections
 - Comparable company analysis
 - Capital infused to date
 - Size of market and company's existing and projected market share
 - Competition
 - Barriers to entry – how easily can competitors take market share?
 - Quality and completeness of management team
 - Present value of expected future valuation

- Valuation: Pre-Money (continued)
 - Ranges based on stage
 - Seed stage - \$500k up to \$5 million
 - Angel - \$1 million up to \$20 million
 - VC - \$5 million and greater
 - Outside valuation expertise
 - Professional valuation firms, charging \$2,000-\$15,000; investment banks will charge more

- Valuation: Pre-Money (continued)
 - Other issues
 - Raise required amount all at once v. staging the investments over time
 - How much capital is required and how effectively will that capital be utilized
 - Danger of placing too high a valuation on the company too early

- Fully-diluted Equity

- Definition: number of shares of common stock issued and outstanding, plus all shares of common stock issuable upon (i) conversion of outstanding debt or preferred stock, (ii) exercise of outstanding warrants or (iii) exercise of outstanding options.
- Should “fully diluted” equity include employee options that have not yet been granted?

- Valuation: Post-Money

- Post-Money Valuation = Pre-Money Valuation
plus Amount Raised

- Per Share Valuation =
$$\frac{\text{Pre-Money Valuation}}{\text{\# of shares on a fully diluted basis}}$$

- Securities Laws
 - Securities Act of 1933, as amended
 - State “blue sky” laws
 - Must register the offered securities or qualify for an exemption
 - Regulation D “safe harbor”

- Securities Laws (continued)
 - Definition of “accredited investor”
 - Disclosure requirements
 - No advertising or general solicitation
 - Anti-fraud rules apply
 - Restricted securities
 - Form D

SOURCES OF CAPITAL

- Founders / Self-Funding
- Government

- Bridge Loans
 - Investors like the priority position of debt
 - Companies can get capital while deferring the valuation discussion to a time when the value will likely be higher
 - Investors typically get a “risk premium”
 - Convertible into equity

- Friends and Family
 - Valuation set by Founder
 - Typical raise: \$100,000 - \$1 million
 - Security: Common Stock
 - Minimal other investor protections
- Angels
 - Valuation typically set by Founder
 - Typical raise: \$500,000 - \$5 million
 - Security: Common Stock; maybe Warrants
 - Maybe a board seat

- Venture Capitalists
 - Valuation set by negotiation
 - Typical raise: \$5 million and greater
 - Security: Convertible redeemable preferred stock; warrants
 - Detailed financial and legal due diligence
 - Additional terms include board seats and “protective provisions”
- Banks

LEGAL ISSUES IN FINANCINGS

- Terms of Security – Convertible Preferred Stock
 - Liquidation preference
 - Dividend
 - Conversion
 - Anti-dilution Protection
 - Redemption
 - Voting Rights

- Purchase Agreement
 - Terms of investment
 - One or more closings
 - Representations and warranties
 - Covenants by the Company
 - Annual budget
 - Monthly, quarterly and annual financial statements
 - Key-person life insurance
 - D&O insurance
 - Legal opinion
 - Expenses

- **Stockholders' Agreement**
 - Board composition
 - Transfer restrictions
 - Permitted transfers
 - Rights of first refusal
 - Co-sale / tag-along rights
 - Drag-along rights
 - Pre-emptive rights
 - Protective provisions
 - Amendment of charter or bylaws
 - Fundamental transactions (mergers, acquisitions, dispositions)
 - Issuance of additional equity
 - Incurrence of indebtedness

- Registration Rights Agreement
 - Demand rights
 - Piggyback rights
- Employment Issues and Equity Incentive Plans

INTELLECTUAL PROPERTY

WHAT IS A PATENT?

- A patent is a document, which gives the patentee/assignee the right to exclude others from making, using, and selling what is claimed as the invention for a limited period of time
- A patent does not necessarily give the patentee/assignee the right to make, use, and sell what is claimed as the invention because there may be other patents that dominate



US006464973B1

(12) **United States Patent**
Levitsky et al.

(10) **Patent No.:** US 6,464,973 B1
(45) **Date of Patent:** Oct. 15, 2002

(54) **UNIVERSAL GM-CSF EXPRESSING
BYSTANDER HUMAN K562 CELL LINE**

(75) Inventors: **Hyam I. Levitsky**, Owings Mills; **Ivan Borrello**, Baltimore, both of MD (US)

(73) Assignee: **Johns Hopkins University, School of Medicine**, Baltimore, MD (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/241,939**

(22) Filed: **Feb. 2, 1999**

Related U.S. Application Data

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(51) **Int. Cl.**⁷ **A01N 63/00**; A61K 48/00; C12N 15/00; C12N 15/09; C12N 5/08

(52) **U.S. Cl.** **424/93.21**; 424/93.2; 435/320.1; 435/325; 435/366

(58) **Field of Search** **424/93.2**, 93.1, 424/93.21; 435/320.1, 325, 366; 514/44

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(57) **ABSTRACT**

The present invention provides a universal immunomodulatory cytokine-expressing bystander cell line, a composition comprising such a cell line cancer antigen, a method of making such a cell line, and a method of using such a composition.

21 Claims, 4 Drawing Sheets

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What is claimed is:

1. A universal bystander cell line, which:
 - (i) is the human cell line K562 or a subclone thereof, which naturally lacks major histocompatibility class I (MHC-I) antigens and major histocompatibility class II (MHC-II) antigens, and
 - (ii) is modified by introduction of a nucleic acid molecule comprising a nucleic acid sequence encoding granulocyte macrophage-colony stimulating factor (GM-CSF) operably linked to a promoter, wherein the universal bystander cell line expresses about 500 ng or greater GM-CSF/ 10^6 cells/24 hours.
2. The universal bystander cell line of claim 1, which expresses about 1,000 ng or greater GM-CSF/ 10^6 cells/24 hours.

WHAT IS PATENTABLE?

- 35 U.S.C. § 101 Inventions patentable
 - 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.

WHAT IS NEW?

- 35 U.S.C. § 102....NOVEL...
 - Not known or used by others
 - Not patented or described in a printed publication
 - Not in public use or on sale
 - Invented by you
- 35 U.S.C. § 103....UNOBVIOUS...
 - The difference between what is claimed to be the invention and what is already known is not obvious to “a person having ordinary skill in the art”

WHAT IS USEFUL?

- Something that benefits society
- Utility must be:
 - Specific
 - Substantial
 - Credible

WHAT ELSE IS REQUIRED?

- Description: have you sufficiently described what you claim as your invention?
- Enablement: have you taught how to make and use what you claim as your invention?

HOW DO I KNOW IF SOMETHING IS PATENTABLE?

- Seek advice of patent counsel
- Something can be “obvious to try,” yet still be patentable
- So can an unknown combination of known parts
- So can an improvement

PATENTABILITY OF HYPOTHETICAL PRODUCT?

- Intellox
 - “Special” capsule
 - Contains ingredients X and Y
- Patentability search
 - X is known; patented
 - Y is novel and unobvious
 - No teaching in art to combine X and Y
 - No teaching/suggestion of “special” capsule

WHAT'S PATENTABLE?

- Y (compound, composition, and method of making)
- X in combination with Y (composition)
- “Special” Capsule
 - Composition
 - Method of making
- Use of X and Y together to make you smart (method)

TYPES OF PATENT APPLICATIONS

- Provisional
- Utility
- Design
- Plant
- International
- National Phase of International
- Direct National

PROVISIONAL PATENT APPLICATION

- Secures filing date
- Does not undergo examination
- Does not get published
- Can be informal document
- No need to include claims but recommended
- Recommend ensuring descriptive and enabling
- \$150/\$300 filing fee
- If competitive area and/or invention is important to success of company and still in early stages of product development, can file multiple provisional applications and claim priority to all of them when file utility application within 1 year of first-filed provisional application

UTILITY PATENT APPLICATION

- Secures filing date
- Undergoes examination
- Gets published, unless request nonpublication at time of filing (careful: foreign filing)
- Looks like a patent application
- Need to include claims
- Needs to be descriptive and enabling
- \$395/\$790 filing fee, plus
 - \$100/\$200 per independent claim in excess of 3
 - \$25/\$50 per claim in excess of 20
- Patent term is 20 years from earliest priority date, subject to patent term extension
- Pendency of prior provisional application does not count towards patent term

DESIGN PATENT APPLICATION

- Single claim to new, original and ornamental design as shown in figure
- Patent term is 14 years from date of issuance

PLANT PATENT APPLICATION

- Invent/discover and asexually reproduce a distinct and new variety of plant
- Not a tuber-propagated plant or a plant found in an uncultivated state
- Claim to plant as shown and described

INTERNATIONAL PATENT APPLICATION

- Can be first-filed application or can claim priority to provisional/utility application filed within 1 year
- Preserves option to file in all countries signatory to Patent Cooperation Treaty (PCT)
- Delays time by which have to file “national phase” applications to 30/31 months from priority date
- Undergoes preliminary review and many patent offices give deference to preliminary review

- National Phase of International Patent Application
 - Application filed in country signatory to PCT
- Direct National
 - Application filed in foreign country as other than a national phase application of an international patent application

ABOUT WHAT ELSE DO I NEED TO BE CONCERNED?

- Avoid prior disclosure
 - Absolute novelty required in Europe
 - Grace periods elsewhere
 - 1 year in U.S., Canada and Australia
 - 6 months in Japan (limited exception)
 - This includes oral and written disclosures
 - Journals publish online in advance of paper copy
 - Journals publish manuscript, itself, upon acceptance
 - Meeting abstracts sometimes are distributed early
 - Avoid prior public use/offer for sale

- Keep good laboratory notebooks
 - Write legibly in permanent ink in bound notebook with consecutively numbered pages
 - Provide prompt, complete, and clear written record of ideas (conception), experiments (reduction to practice), and conversations
 - Keep track of who did what when, including failures (diligence)
 - Be specific enough such that another expert in the field can understand what you have written

- Keep good laboratory notebooks (cont'd)
 - Sign and date all pages
 - Do not skip pages (if you do, cross out page, sign and date)
 - Have your notebook entries read and witnessed by someone who is not involved with the project, yet understands what was done, preferably daily or at least weekly
 - Keep in a secure location

WHY IS IT IMPORTANT TO KEEP GOOD LABORATORY NOTEBOOKS?

- While patents are granted in the rest of the world on a “first to file” basis, patents are granted in the U.S. on a “first to invent” basis (for the time being)
- **CRITICAL** to determining inventorship and who was the first to invent (interference)
- Important for preventing a prior publication from being cited by the patent office
- Litigation

INFRINGEMENT/FREEDOM TO OPERATE (FTO)

- Patent gives you right to exclude – not right to use
- There may be dominating patents

FTO OF HYPOTHETICAL PRODUCT?

- Intellox
 - “Special” capsule
 - Contains ingredients X and Y
- Patent on X
 - What is scope of claims?
- 1. Compound X
- 2. Composition consisting of X. (X is only ingredient)
- 3. Composition comprising X. (can be other ingredients)
- 4. Method of making X:
 - Step (a),
 - Step (b), and
 - Step (c).
- 5. Method of administering X to treat heart disease.

ADDITIONAL INTELLECTUAL PROPERTY RIGHTS

- Copyright
- Trademark
- Trade Secret

COPYRIGHT: PURPOSE AND EXAMPLES

- Purpose – protects creative expression
- Examples include –
 - Books
 - Magazines
 - Movies
 - Records
 - Business Forms
 - Software

COPYRIGHT

- Original works of authorship
- Fixed in a tangible form of expression
- Published and unpublished
- Does not protect facts, ideas, systems or methods of operation
- Novelty not required

COPYRIGHT: RIGHTS

- Exclusive Affirmative Rights
 - Reproduce and distribute copies
 - Prepare derivative works
 - Perform or display the copyrighted work publicly

OBTAINING COPYRIGHTS

- Protection attaches as soon as the work is created
- Legend – “Copyright (year) (author)” or “© (year) (author)”
- Copyrights may be registered by the Copyright Office of the Library of Congress – not required

EVERSMART COPYRIGHT MATERIAL

- EverSmart items subject to copyright:
 - Brochures
 - Advertisements/Advertising Copy
 - White papers
 - Posters
- Legend –
 - “Copyright 2005 EverSmart” or
 - “© 2005 EverSmart”

TRADEMARKS

- Word, name, symbol, or device, sometimes a color
- Used in trade with goods
- Indicates the source of the goods or services
- Distinguishes them from the goods or services of others

TRADEMARK RIGHTS

- Trademark rights –
 - Can prevent others from using a confusingly similar mark (e.g., “Intellox” vs. “Intellax”)
 - Can not prevent others from making or selling the same goods

OBTAINING TRADEMARKS

- Common Law Trademark
 - Rights attach based on use of the mark
 - Legend – “Name™”
 - Limited enforceability
- Registered Federal Trademark
 - Registered with the USPTO
 - After registration, Legend – “Name®”

FEDERAL TRADEMARKS

- Hurdles for Federal Registration –
 - Must establish use in interstate commerce
 - Registration process
- Benefits of Federal Registration –
 - Nationwide constructive notice of use of mark
 - Ability to sue in federal court and obtain monetary damages
 - Basis for foreign registration

EVERSMART TRADEMARKS

- Company name – EverSmart
- Product name – Intellox
- Logo
- Slogan
- Shape – only if non-functional
- Color – only if secondary meaning

TRADE SECRET

- Information qualifies for protection as a trade secret, if –
 - It is secret and non-obvious
 - It has economic value because of its secrecy
 - The party claiming it has taken reasonable efforts to keep it secret

TRADE SECRET EXAMPLES

- Examples include –
 - Formulas
 - Methods
 - Processes
 - Procedures
 - List of actual or prospective customers
 - Databases
 - Software

OBTAINING TRADE SECRET RIGHTS

- Establish rights established by maintaining secrecy
 - Limited disclosure
 - Non-disclosure agreements
- No registration
- Owner has rights to control use and disclosure
- No time limit on rights

EVERSMART: PATENTS OR TRADE SECRETS

- Patent – if easy to reverse engineer
- Trade Secret – if not easy to reverse engineer
- Examples
 - Compound Y – easy to ascertain
 - Special formula for creating capsule
 - Customer lists

AGREEMENTS

TYPES OF AGREEMENTS

- Independent Contractor and Employee Confidentiality
- Third Party Confidentiality Agreement
- License Agreement
- Sponsored Research Agreement

INDEPENDENT CONTRACTOR AND EMPLOYEE CONFIDENTIALITY

- Issue - Employees and contractors will develop intellectual property
- Employee Agreements and Independent Contractor Agreements
 - Include terms to assign to the company all inventions and other work developed
 - Include terms to protect the confidentiality of all company information

THIRD PARTY CONFIDENTIALITY AGREEMENTS

- Issue – A company will need to disclose information to current and potential business partners
- Confidentiality Agreements
 - Use whenever disclosing company information
 - Limitations on use of information
 - Term of Use
 - Specify return of information

LICENSE AGREEMENT

- Issue – In order to drive revenue, a company will need to give others the right to use information
- License Agreement - Permits third parties to use any materials protected by patent, copyright, trademark or trade secret

SUBJECT OF LICENSE

- Define items to be licensed
- Limit rights to use
- Specify number of users
- Third party items

TYPES OF LICENSES

- Exclusive License
 - More than a “mere license,” yet less than “an assignment.”
- Non-Exclusive License
- Non-exclusive Royalty-Free License
- Sublicense Rights

COMPENSATION

- Fixed Fee
- Subscription
- Timing of payments/Milestones
- Royalties

OWNERSHIP

- Statement of ownership
- Address any development issues
- Assignment terms

CONFIDENTIALITY RIGHTS

- Definition of “Confidential Information”
- Limits on Use
- Return of Information
- Security

RISK MITIGATION

- Warranties
- Disclaimer of Liability
- Limitation of Liability
- Indemnification
- Dispute Resolution
- Termination Rights

MASTER AGREEMENTS

- Maintains Uniformity of Terms
 - Type of License
 - Confidentiality
 - Ownership
 - Warranties
 - Risk Mitigation
- Reduces Negotiation Time

SPONSORED RESEARCH AGREEMENTS

- Issue – A company may not have the resources (e.g., equipment and people) necessary to engage in certain research and development activities
- Sponsored Research Agreement

SPONSORED RESEARCH AGREEMENTS

- Third Party
 - An agreement with a third party such as a university or government laboratory to engage in research in a specific area of technology
- Private Corporation
 - A private corporation sponsors an employee of the university or government lab to conduct research in the university's or government's lab in conjunction with employees of the corporation

IP OWNERSHIP AND LICENSE RIGHTS

- Who owns the intellectual property?
 - Inventor(s) are the owners of a patented invention unless there is a duty to assign their rights in the invention to another entity such as a university or corporation.
 - Must name ALL inventors
 - Risks of Improper Inventorship Designation:
 - Patent Invalidity
 - Patent Unenforceability

IP Ownership and License Rights (Cont'd)

- Ownership of Unpatented Intellectual Property
 - Know-how
 - Access to trade secrets

IP Ownership and License Rights (Cont'd)

- Transfer of Ownership of Intellectual Property
 - Owner of intellectual property may assign or license the invention to others
 - Assignment – a transfer or making over to another of the *whole* of any property, real or personal, in possession or in action, or of any estate or right therein

IP Ownership and License Rights (Cont'd)

- Transfer of Ownership of Intellectual Property (Continued)
 - License –a waiver by the patent owner of its right to exclude the licensee from making, using, selling, offering for sale, or importing the claimed invention

OPTIONS AND OPTION PERIODS

- Options with Respect to University/Lab and Joint IP:
 - To obtain patent protection
 - To exclusively evaluate the technology
 - To license the technology
- Option Periods:
 - Six to eighteen months depending on the option involved

CONFIDENTIALITY RIGHTS

- Confidentiality
 - Need to ensure certain information is kept confidential
 - Mark Documents as “Confidential”
 - Follow-Up Meetings where oral disclosures were confidential with written memo.
 - Verbal Communications must be identified as “confidential”

BACKGROUND INTELLECTUAL PROPERTY

- What is Background Intellectual Property (BIP)?
 - Timing of BIP Identification
 - Potential BIP
 - Sponsor BIP
 - University/Lab BIP
 - Third Party BIP

BIP (Cont'd)

- Using BIP of Third Parties
 - Make Determination of BIP
 - Identify Third Party BIP Assignees
 - Potential License

MADEY V. DUKE

- No Experimental Use Exception
 - Universities may not freely use BIP
 - Prior to 2002, universities relied on the “experimental use exception”
 - *Madey v. Duke* case in 2002
 - Actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry

PUBLICATION RIGHTS

- Publication Rights
 - Need to protect rights to seek patent protection
 - Publication commences one-year period to file for patent protection
 - Eliminates ability to obtain patent protection in countries with “absolute novelty” requirement

SCOPE OF WORK

(Yes, You Do Need One)

- Deliverables
 - All necessary results, samples, data, software know-how (source/object code), and all materials and information needed to use the deliverables
 - Reports
 - Specific, to capture the necessary detail of all desired deliverables

Scope of Work (Cont'd)

- Deliverables
 - But not too specific, to make sure nothing is left out
 - Samples
 - Export Laws
 - Software

FEDERAL FUNDING AND THE BAYH-DOLE ACT

- Receipt of Federal Funding Triggers the Provisions of the Bayh-Dole Act
 - Must disclose the invention to the federal government within a reasonable period of time
 - If sponsor granted exclusive license, then product must be substantially manufactured within the United States

- Provisions of the Bayh-Dole Act (continued)
 - If title to invention retained by University or Lab, federal government get a non-exclusive, non-transferable, irrevocable, paid-up right to practice or have practiced the invention on behalf of the United States throughout the world
 - Even \$1 of federal funds “contaminates” the entire project

CONTROL OVER PATENT PROSECUTION

- Who controls and pays for patent prosecution?
- Who has right to amend claims?

CREATE ACT AND COLLABORATIONS

- Summary of CREATE Act
 - Subject matter developed by another person, which qualifies as prior art, shall not preclude patentability where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person

CREATE ACT AND COLLABORATIONS

- Requirements to comply with CREATE Act:
 - Must have a joint research agreement
 - Agreement must be recorded with the Patent Office
 - Agreement must be in effect on or before the date that the parties made the invention
 - The invention must fall within the scope of the joint research agreement

KEYS TO SUCCESSFUL COLLABORATIONS

- Employee Taking Personal Responsibility for Research Matter
 - Likely to be Joint Inventor
- Statement of Work is Helpful to Ensuring Successful Collaboration

KEYS TO SUCCESSFUL COLLABORATIONS

- Clear Understanding of Expectations
 - Budget
 - Deliverables
 - Renewal
 - Payment Terms

CONFLICTS OF INTEREST

- How Do They Arise?
 - University/Lab Does Similar Research for Competitor
 - Corporation's Need for Confidentiality Runs Counter to University's Policy of Academic Freedom

CONFLICTS OF INTEREST

- How Are They Harmful?
 - Competitor's May Gain Access to Confidential Information
 - May Lead to an Overall Loss of Confidentiality
 - Lead to Conflicts With Respect to Ownership of Technology

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