Development of Permanent but Removable Tattoos



Duke Surgery

SITY MEDICAL CENTER

Bruce Klitzman, PhD Kenan Plastic Surgery Research Labs, and Departments of Biomedical Engineering and Cell Biology Duke University Medical Center Durham, NC 27710 USA

June 6-7, 2013





Robert Lefkowitz of Duke University wins Nobel Prize



USA Basketball wins second gold medal in a row under the leadership of Coach Mike Krzyzewski of Duke University

False Title

ALL tattoos can be removed; the question is how aggressive/invasive to be, how long it will take, and how much it will cost. -If need be, surgical excision can physically remove all tattooed tissue



The medical need to change tattoo initiated my interest





Less Aesthetic

After Shifting

<u>This is a real need, but</u> <u>is a very small market.</u>

Is tattoo alteration needed?

50% of all tattoo clients eventually have regret about their tattoos. However, only 4% pursue medical or surgical removal due to very high cost and potential for scarring with current techniques. Lasers are not effective at removal.

*R. R. Anderson, M.D., Dermatologist, Harvard School of Medicine



Norman Rockwell "The Tattooist"



Some want change because of a bad decision in tattoo design



What was he thinking?



Others want change because of a bad decision in tattoo artist



Others want change because of a bad decision in tattoo artist



Technology and Tattooing



Patent, 1877: Motorized Reciprocating Ink Needle for Paper Marking

Patent, 1877: Motorized Reciprocating Ink Needle for Paper Marking





Thomas Alva Edison Why paper marking? Edison wanted a practical electric stock price printer to rival the telegraph: "ticker-tape"



Samuel O'Reilly Patented a Tattooing Machine, 1891

(No Model.) S. F. O'REILLY. TATTOOING MACHINE. Patented Dec. 8, 1891. No. 464,801. Fid.2 INVENTOR. WITNESSES. SamuelF.O'Reilly

UNITED STATES PATENT OFFICE.

SAMUEL F. O'REILLY, OF NEW YORK, N. Y.

TATTOOING-MACHINE.

SPECIFICATION forming part of Letters Patent No. 464,801, dated December 8, 1891.

Application filed July 16, 1891. Serial No. 399, 731. (No model.)

To all whom it may concern:

citizen of the United States, residing at New York, in the county and State of New York, < have invented new and useful Improvements in Tattooing-Machines, of which the following is a specification.

My invention relates to a tattooing - machine, the peculiar and novel construction of 10 which is pointed out in the following specification and claims, and illustrated in the accompanying drawings, in which-

Figure 1 represents a front elevation. Fig. 2 is a longitudinal section in the plane x x. 15 Fig. 1. Fig. 3 is a transverse section in the plane y y, Fig. 2. Fig. 4 is a similar section in the plane z z, Fig. 2.

In the drawings, the letter A designates the handle of my tattooing-machine, said handle 20 being made hollow, so that it is adapted to

form the guide for the perforating - instrument B.

In the example shown in the drawings this instrument is composed of five needles; but 25 it may consist only of a single needle, or the lower end of the handle and provided with a number of needles which constitute the perforating-instrument may be changed to suit circumstances. The perforating-instrument rating-instrument reciprocating through the

perforating-instrument pass into the skin. 50 Be it known that I, SAMUEL F. O'REILLY, a For the purpose of adjusting the gage a, I use a tube b, which is provided with an internal screw-thread and which swivels freely round on the handle A, being held in place by screws c, which engage a circular groove d in the 55 handle. The tube b engages an external screw-thread on the ink-reservoir E, and this ink-reservoir is prevented from turning round on the handle by a feather-key f, which engages a groove or slot q in the ink-reservoir. 60 By turning the tube b the ink-reservoir E is moved in or out and the gage a can be adjusted in the required position. A thumbnut h serves to lock the tube b in the required position. The rod C is geared with 65 the electromotor by means of a lever F, which has its fulcrum on a stud i, so as to produce a comparatively large stroke of the perforating-instrument.

What I claim as new, and desire to secure 70 by Letters Patent, is-

1. The combination, with a tubular handle, of a tubular ink-reservoir movable along the gage, means for moving the ink-reservoir on 75 the handle to adjust the gage, and a perfo-

Our Innovation

removability of the markings could be easier if *ink* was made to be erasable from the beginning ("pencil vs pen"), instead of better lasers

- Key Idea: using a pigment that is rapidly cleared "reverses" the challenge: how do we stabilize a shortterm ink?

- use of microencapsulation

Microencapsulation Applied to Removability



Microencapsulation: How it Works

Intact Microcapsules



<u>Microcapsules</u> <u>After Rupture</u>



x3.0H 7453 25kV 10+m

United States Patent 6,013,122 *Klitzman*, et al. January 11, 2000 **TATTOO INKS**

Abstract

Tattoo inks are composed of pigments or dyes combined with a tattoo pigment vehicle which entraps, encases, incorporates, complexes, encapsulates, or is otherwise associated with the pigment to form pigment/vehicle complexes that retain the pigment in the tissue. The vehicle can be chosen so that pigments which alone are unsuitable for tattooing can be used for tattooing and optionally can be retained in the tissue permanently. Alternatively, the vehicle renders the tattoo erasable, wherein the tattoo disappears after imposition of an exogenous energy. Alternatively, the tattoo pigment vehicle renders the tattoo semipermanent, so that the tattoo spontaneously disappears at a predetermined time.

Inventors: Klitzman; Bruce (Durham, NC); Koger; Kim Edward (Tequesta, FL)

Assignee: **Option Technologies, Inc.** (Durham, NC)

Appl. No.: **135814**

Filed: August 18, 1998

Technical Development

First attempt; water soluble dye encapsulated in wax in my kitchen
Then, prototypes made of pigment microencapsulated in poly-olefin; cost (\$25K)



In Vivo Clearance Studies in Hairless Rats Self clearance (no laser) of FD&C water soluble colorants 20% (w:v) in 20% PEG 8,000; abdominal tattoos



Business Problem

- HALT!!! STOP

- phone call from investor/manager from Freedom-2, LLC that we would be involved in an "Interference Action"
- even though our patent had issued, a group at Harvard led by Dr. Rox Anderson had filed a similar patent application > 3 months after we filed

Intellectual Property Issue

- met with Harvard group and began discussions regarding possible merger; without merger, lawyers get rich and no investor will invest until resolved
- they thought "Option Technologies" was a very weak opponent and hired the best Interference attorney;
 - But, he happened to be one of my father's students

American Intellectual Property Law Association

AIPLA annual meeting 2012

washington, dc october 25-27 marriott wardman park

Thursday Luncheon 12:30 – 2:00 pm

(Tickets required)

Hon. David J. Kappos Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Visit www.aipla.org/events/2011annual often for updates.

Afternoon Tracks 2:00 - 3:30 pm

Patent Eligibility (101) andInvolIndefiniteness (112)InvolModerator: Raymond Van Dyke, Van DykeSettiLaw, Washington, DCModerator

Madness in Methods: Claiming Inventions Relating to Personalized Medicine

James Kelley, *Eli Lilly and Company*, Indianapolis, IN The Implications of Government Involvement in Technical Standard Setting for Standards and IP Moderator: Monica M. Barone, Qualcomm Incorporated, San Diego, CA

Gridlock or Greased Lightning? The Future of Patents and Standards for the National Smart Grid Jorge L. Contreras, American University, Washington, DC Understanding the Real Value of Your Patent Portfolio Moderator: Richard D. Kirk, *Bayard*, Wilmington, DE

You Think Your IP is Worth Something? Prove It! Michele Riley, Invotex Group, Baltimore. MD

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AIPLA is proud to announce establishment of

The Maurice Klitzman Award

Through the generosity of the Klitzman Family, and Mrs. Mary Ann Klitzman as the initial benefactor, AIPLA is proud to introduce The Maurice Klitzman Award. The Award is intended to provide a junior corporate attorney or corporate patent agent the opportunity to attend the AIPLA's Annual Meeting in Washington, D.C. and to be connected with an experienced AIPLA mentor.



The award was established as a lasting and appropriate memorial to Mr. Klitzman, who passed away in January 2010, for his active service to AIPLA, including serving as a member of the Board of Directors and a member of the Amicus Committee, as well as the active role he took in educating many new patent attorneys, both as a senior corporate patent counsel and as an adjunct law professor. His heart and soul were dedicated to training young patent attorneys and helping them to develop a broad approach to IP Law with a conviction to moral principles and ethics. Mr. Klitzman also promoted and recognized innovation by helping found the National Inventors Hall of Fame. His career was a unique blend of corporate IP law, heart-felt support for the inventor and shaping the mindset of future IP leaders.

orts training for young patent attorneys, and providing them access apportunities and top quality educational programming. The award serson's reasonable travel and accommodation expenses for the dueeting; namely, coach air or train fare, hotel accommodation at the el, complimentary registration and function tickets and incidental rtation. The recipient of the award will be assigned a mentor to profuring the meeting and facilitate the opportunity to meet members adership. We look forward to welcoming the first recipient of the in Award at the 2011 Annual Meeting. October 20-22, 2011.



ww.aipla.org/events/2011Annual to apply online today!

Award application deadline:

Winnerselected:



September 15, 2011

October 3, 2011

Award includes: Coach airfare or train fare, hotel accommodations at the conference hotel, registration and functions tickets, and incidental ground transportation.

ashington, DC

Merger with Anderson group

- 12-month delay in beginning next steps of building company, including financing
- But now, we had the best team and money
- Also, Bob Langer agreed to help

Product Development

- 2004 hire PhD chemical engineer from MIT/Tufts (Bob Langer's group)
- discuss prototypes
- initiate biodistribution studies:
 - What size particles?
 - Where do tattoo pigments go?
 - Where do we want them to go?

Three likely products

 Permanent but new colors, fluorescent, less blurring

-Disappearing (time-limited)

-Permanent but erasable

Business Decision to Publicize

Finances were low so CEO decided to issue press releases in 2006

Press Reports April, 2006 to July, 2008

Laser Focus World (April 17, 2006) ABC 7 News - Washington DC (June 10, 2006) WMSLUK.com (online radio station based in the UK) Ananova – UK Website NPR (September 25, 2006) Self Magazine (September 2006) Pittsburgh Post-Gazette (October 11, 2006) NBC10.com (WCAU Philadelphia) Video (October 16, 2006) Harvard University Gazette (October 19, 2006) Beauty Flash (2006), page 72

The Hartford Courant (December 2, 2006) Fortune Small Business (December 2006) Skin and Allergy News (November 2006) Plasmetic.com (October 26, 2006) World Net Daily (October 20, 2006) Pick-Up of Press Release: Freedom-2, LLC press release: Offering the First Permanent but Removable Tattoo Ink (October 18, 2006) Canadian Web site (Canadian Body Mod Community) Yahoo News: Entertainment Yahoo Finance The Hollywood Reporter Online Lycos (very popular search engine at the time) The Dallas Morning News Entertainment Zone MomMD (Connecting Women in Medicine) Hollywood MVP WHAS-11 (Louisville, KY TV Station Portal)

Smithsonian (December 30, 2006) CareFair.com – Switzerland (December 30, 2006) TCPalm - FL Daily - Treasure Coast and Palm Beach - (Dec, 2006) ABC News (December 28, 2006) Popgadget - Personal Technology + Innovative Lifestyle for Women (December 27, 2006) Gizmodo (December 27, 2006) Medgadget (December 26, 2006) Engadget (December 26, 2006) The Repository, Canton, OH (December 26, 2006) Birmingham News (December 25, 2006) Seattle Times (December 24, 2006) Kitasup Sun (December 23, 2006) St. Paul Pioneer Press (December 22, 2006) LA Times (December 11, 2006) (Original) Max World News (December 6, 2006)

2007

Smithsonian Magazine (January 2007) Medical Device Online (January 22, 2007) The Metro West (January 19, 2007) Photonics.com (January 19, 2007) Worcester Business Journal (January 19, 2007) DrugLinx (January 19, 2007) The Denver Business Journal (January 18, 2007) The Red Herring (January 18, 2007 The Boston Globe (January 18, 2007) The Boston Stock Group (January 18, 2007) The Knowledge Express (January 18, 2007) Health Care Sales and Marketing Network (January 18, 2007) Genetic Engineering & Biotechnology News (January 18, 2007) Wall Street Journal - Online Quote section (January 18, 2007) The Denver Post (January 18, 2007) Fibre to Fashion (January 4, 2007) The Fayetteville Observer (January 3, 2007)

Scripps News Service (January 2, 2007) Yahoo News (July 19, 2007) The Providence Journal (July 18, 2007) Daily Breeze – LAX to LA Harbor (July 15, 2007) Riverside Press-Enterprise (July 14, 2007) Tech Review (July 13, 2007) Medical News Today (July 12, 2007) Polish Website (July 12, 2007) The Press Syndicate – San Bernadino, CA area (June 26, 2007) The International Herald Tribune (June 17, 2007) The New York Times (Sunday, June 17, 2007) Front Page The Seattle Times (June 17, 2007) Fox News Online (May 14, 2007) Boston Globe (February 26, 2007) Mass High Tech (January 12, 2007) The Rod Ryan Radio Show (January 5, 2007) KG-TV San Diego (January 5, 2007)

NBC – San Diego (July 31, 2007) Newsday (July 23, 2007) The Boston Globe (July 27, 2007) IT Wire - Australia (July 27, 2007) CBS 11 News Providence, RI (July 20, 2007) Science Daily (July 20, 2007) AP Story ran in the following publications: Washington Post (July 19, 2007) (Original) Sydney Morning Herald (July 21, 2007) Paris Herald Tribune (July 20, 2007) Brisbane Times, Australia (July 20, 2007) Herald News Daily - The Voice of the Dakotas (July 19, 2007) Business Week (July 19, 2007) Newsday (July 19, 2007) Daily Times, Pakistan (July 19, 2007) South Florida Sun-Sentinel.com, FL – (July 19, 2007) Jordan Falls News, IA (July 19, 2007)

CNN.com (July 19, 2007) ABC News – Wash., DC - World News Tonight Story (Aug 28, 2007) Chicago Tribune (August 19, 2007) Ran LA Times Story Buddy TV (August 16, 2007) Miami Ink (August, 2007) "Removable-ink-not-allowed-in" CTV.ca Canada (August 13, 2007) Pain Magazine (August, 2007) Print issue only ABC World News Tonight (August 12, 2007) Impact News (August 9, 2007) Daily India.com (August 8, 2007) News 8 Austin, TX - Ivanhoe Broadcast News (August, 7, 2007) Discovery News (August 7, 2007) The Daily Mail - UK (August 3, 2007) The Guardian - UK (August 2, 2007) The Kentucky Post - Riverside Press Syndicate story (July 31, 2007)

Georgia College and State Universities Campus News (Nov., 2007) Chemical and Engineering News (November 12, 2007) Time Magazine (Nov. 12, 2007) Courier Post (Sunday, November 4, 2007) The Galveston County News (Sunday, November, 4, 2007) Georgia Straight, Vancouver, Canada (November 1, 2007) Science News (Oct. 13, 2007) Cover Story BET - The 5ive (October 10, 2007) Segment on culture show – link no longer up. Courier Post - Camden, NJ (October 4, 2007) Courier Press (October 1, 2007) New York Magazine (October 1, 2007 issue) CNN Health Minute (September 17, 2007) Wall Street Journal (September 17, 2007) ***CNN** *Technology Pioneers* (sched September 16, 2007)* Fox Chicago (September 5, 2007) Bloomberg News (August 30, 2007) -(Toronto Star, Boston Globe, The Virginian Pilot, Vancouver Sun)

AOL Top Products of the Year

Philadelphia Business Journal (December 14, 2007)
Fortune Small Business (December 2007/January 2008)
Medill News-News Service for Greater Chicago Area – (Nov., 2007)
Now Magazine, Toronto, Canada (November 29, 2007)
CBS - KKTV- Denver, CO (November 19, 2007)
ABC - WHAM - Rochester, NY (November 16, 2007)
The Philadelphia Business Journal (Nov. 15, 2007) Online

2008

USA Today Weekend (January 20, 2008) The Age Australian Newspaper (February 7, 2008) The Daily Journal (March 17, 2008) Allure Magazine (May 2008) Telemedicine Law Weekly (June 28, 2008) Biotech Law Weekly (June 27, 2008) Drug Week (June 27, 2008) Lab Law Weekly (June 27, 2008) Biotech Week (June 25, 2008) Healthcare Finance, Tax & Law Weekly (June 25, 2008) Health & Medicine Week (June 23, 2008) Pharma Business Week (June 23, 2008) Cosmetics Design.com (June 12, 2008) Special Chem–Innovations and Solutions in Cosmetics (June, 2008) The Philadelphia Business Journal (July 11, 2008) Tattoo MD (July 2, 2008) Health Business Week (June 23, 2008) Medical Patent Week (June 29, 2008) Pharma Investments, Ventures & Law Weekly (June 29, 2008) Healthcare Mergers, Acquisitions & Ventures Week (June 28, 2008) Law & Health Weekly (June 28, 2008) Medical Imaging Week (June 28, 2008) Obesity, Fitness & Wellness Week (June 28, 2008)

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the most invasive species snake beats frog toxins drug-resistant bug spreads nobel for gene engineering

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not permanent

Pabina Birgit Doudia

Colbert Report; 7/25/07



http://www.colbertnation.com/the-colbert-report-videos/183173/july-25-2007/the-word---no-regrets

CNN shot hours of video about our company and they were going to feature us on their "Pioneers in Technology" show at 5pm on Sunday Sept 16, 2007

This will transform our company!



Police: No bail for O.J. Simpson in Las Vegas robbery arrest

SUNDAY SEPTEMBER 16, 2007 03:30 PM EDT LAS VEGAS, Nevada (CNN) --

Former football star O.J. Simpson will be held without bail after his arrest on robbery and assault charges, police announced late Sunday.

Simpson is accused of having directed several other men in an alleged armed robbery of sports memorabilia in a room at a Las Vegas hotel room.

Las Vegas authorities said they have no information leading them to believe Simpson was carrying a firearm during the alleged incident at the Palace Station Hotel and Casino



2007

The Best Inventions Of The Year

INVENTION OF THE YEAR	CARS & BUSES	AIRCRAFT	SPACE	ROBOTS	ENTERTAINMENT
LAW & ORDER	LIVING	ENVIRONMENT	ARCHITECTURE	FASHION	COMPUTERS
HEALTH	TECH BUYER'S GUIDE	GADGET OF THE YEAR	BEST INVENTORS	VIEWPOINT	GADGET POLL RESULTS

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LATEST HEADLINES

BRANDON BOND

Fashion





Now that tattoos are more popular than ever, it's about time there's a reliable way to get rid of them. After all, one in five people say they regret getting a tattoo in the first place. Freedom-2 ink is made of biodegradable dyes coated in plastic, instead of the heavy metals most dyes use, so tattoos can be removed with a single treatment. When a laser zaps the capsules, they break open, and your body safely reabsorbs the dye.

Overall Invention of the year: iPhone

Histopathology of conventional tattoos

Pigment



Histopathology of Freedom2 tattoos





Microencapsulation **Production Methods:** -Solvent Evaporation -Anhydrous Precipitation

Laser Treatment of Encapsulated Iron Oxide and India Ink and Tattoos



Freedom-2 Human Biopsy (between left lateral triceps and deltoid muscles)



Some pigment intracellular, some in collagen matrix

Pigment can migrate from papillary dermis to reticular dermis over time

- July, 2008; bought a building near Philadelphia for product development, production, tattooing, removal, and administration and investment
- In late Aug, 2008, Board approves major product launch for Jan, 2009. We rapidly get verbal commitments for <u>\$15M</u> for launch; <u>financing to close Sept 30, 2008</u>



Greenspan to Congress "I WAS WRONG"



The Washington Post

Brooksley Born, the Cassandra of the Derivatives Crisis

Post)

By Manuel Roig-Franzia Washington Post Staff Writer Tuesday, May 26, 2009

Friends nudge the woman who saw the catastrophe coming.

THIS STORY

» Credit Crisis Cassandra

Regulation Debate Hinged on Arcane Point of Law

They want Brooksley Born to say four words, four simple words: "I told you so."

Ah, but she won't -- not at legal conferences or dinner parties. Not even in a quiet moment in her living room, giving her first interview with a major news

organization since last fall's economic collapse.

She just smiles, perched ever so properly in an upholstered armchair at her Kalorama home.

"More coffee?" she asks daintily, changing the subject.

A little more than a decade ago, Born foresaw a



Ms. Born foresaw the problem, but Greenspan convinced Congress to strip \$\$\$ and regulatory authority from her **CFTC office**

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"We didn't truly know the dangers of the market, because it was a dark market," says Breaksley Born, the head of an obsoure federal regulatory agency - the Commedity Futures Trading Commission [CFTC] - who not only warned of the potential for economic meltdown in the late 1990s, but also tried to convince the country's key economic powerbrokers to take actions that could have helped avert the crisis. "They were totally opposed to it," Born says. "That puzzled me, What was it that was in this



Recommend 952 497

The Go-Go '90s

Alan Greenspan rules the economy and "the less regulation, the better" is the administration's attitude toward Wall Street.

Business Survival

Cash almost gone Payroll expenses Development bills to pay Mortgage Real Estate prices collapsing **BANKRUPTCY?**

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SCOTTSDALE, Ariz(BUSINESS research and development of nutra into a definitive share exchange ag known for its pioneering developme	preement with Freedom2 Holdings, Inc., a w ent of a permanent and safer, more easily r	a January 12, 2009 it entered vorldwide skin care company emovable tattoo ink.

Y? Search

Conclusions

- Concept of microencapsulation to facilitate removal was demonstrated in rodents
- There is wide variability and poor predictability in the response of individual humans

Acknowledgments

- A. Peter Morello, PhD
- Ljiliana Kundakovic, PhD
- Edith Mathiowitz, PhD
- Rebecca Showgo, PhD
- R. Rox Anderson, MD

Development of Permanent but Removable Tattoos Bruce Klitzman, PhD

Associate Professor of Surgery, Biomedical Engineering, and Cell Biology Duke University, Durham, NC USA

Studies have shown that 50% of tattoo recipients have regret. All tattoos are removable, although the removal process may have serious side effects. Surgical excision, sometimes after tissue expanders generate extra adjacent skin for local flaps, is the most aggressive technique and has the ability to completely remove tattooed tissue. Noninvasive laser irradiation of skin can effectively cause removal of a fraction of tattoo pigment. Numerous alternative techniques can encourage removal of some pigment, often through inducing a cutaneous inflammatory response. However, rigorous well controlled studies of removal efficacy are severely lacking. Our interest tattoo ink removal had its beginnings in breast reconstruction. Some patients need to return a tattooed nipple-areola on a reconstructed breast to an aesthetically pleasing position following shifting of the breast mound. We designed a more removable tattoo ink by starting with colorant that would be easily cleared by the body, but stabilized it through microencapsulation. Removal could then be accomplished by disrupting the encapsulating shell instead of requiring more extensive disruption of an entire pigment particle. Our first failed attempt relied on microencapsulating water soluble dyes in polyolefin. Then, a team at Harvard University, led by Dr. Rox Anderson, challenged our patent. After many months of legal maneuvers, it was determined that we were indeed the inventors of microencapsulated tattoo ink. The two groups then merged. With leading experts in microencapsulation, we attempted microencapsulation of water soluble dye in polymethyl-methacrylate. A fundamental challenge in the use of water soluble dye is the generation of very high osmotic pressure. Low dye volume percentages (about 10% or less) could successfully retain the dye. Higher payload volumes led to generation of osmotic pressure that disrupted the capsule and released the dye. Next, we investigated using insoluble pigment particles. Preclinical studies in hairless rats and guinea pigs showed significantly increased removability. One laser treatment effectively removed 80% of tattoo intensity, while only 20% of conventional ink was removed in a single identical laser treatment. While these results proved our concept, effective removal in humans with any technique continues to be highly variable and difficult to predict because of variability in the inflammatory response.

Disclosure: Dr. Klitzman has less than 0.1% ownership in Nuvilex, Inc., producer of InfinitInk.





eFoodSafety.com

Biotechnology and Natural Products

Revolutionizing Body Art Through Technology



Shell (solid)



SG Austria Receives Milestone Payment Click Here For Article

Good for You Good for the Environment

