1 2 3 4 5 6 7	BESHADA FARNESE LLP Peter J. Farnese (SBN 251204) pjf@beshadafarneselaw.com 1999 Avenue of the Stars, Suite 1100 Los Angeles, California 90067 Telephone: 310-356-4668 Facsimile: 310-356-4601 Attorneys for Plaintiff	SUPERIOR COURT OF CALIFORNIA COUNTY OF SAN BERNARDINO SAN BERNARDINO DISTRICT JUN 0 5 2012 BY MARTINA CARRILLO, DEPUTY	
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9	SUPERIOR COURT OF THE STATE OF CALIFORNIA		
10	FOR THE COUNTY O	F SAN BERNARDINO	
11		CIVDS 1205740	
12	SILVIA MORALES, individually and on behalf of all others similarly situated,	CLASS ACTION	
13	Plaintiffs,	CLASS ACTION	
14	V.	CLASS ACTION COMPLAINT FOR	
15		INJUNCTIVE AND RELATED EQUITABLE RELIEF	
16	COTY, INC., a Delaware Corporation, and DOES 1-250, Inclusive,	1. VIOLATION OF CAL. BUS. & PROF. §	
17	Defendants.	17200, ET SEQ. (Unlawful, Unfair, and Fraudulent Prongs)	
18		2. VIOLATION OF CAL. BUS. & PROF. § 17500, ET SEQ. (False and Misleading	
19		Advertising)	
20		3. VIOLATION OF CAL. CIV. CODE § 1750, ET SEQ. (Consumer Legal	
21		Remedies Act)	
22		4. FRAUD	
23		HIRV TRIAL DEMANDED	
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BESHADA FARNESE LLP			

CLASS ACTION COMPLAINT

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Plaintiff Silvia Morales ("Plaintiff"), individually and on behalf of all other similarly situated purchasers (hereinafter "Plaintiffs" or "the Class") of "Sally Hansen Nailgrowth Miracle Serum", "Sally Hansen Nailgrowth Miracle Salon Strength Treatment", and "Sally Hansen Nailgrowth Miracle Color Treatment" (collectively hereinafter the "Sally Hansen Nailgrowth Miracle Products or "Nailgrowth Miracle Products") brings this consumer class action against Coty, Inc., and Does 1 through 250, inclusive (hereinafter "Coty" or "Defendants") for unlawful. unfair, and deceptive business practices in violation of California Business & Professions Code Section 17200 et seq., California Business & Professions Code Section 17500 et seq., and California Civil Code Section 1750 et seq., and allege as follows:

JURISDICTION AND VENUE

- 1. This Court has subject matter jurisdiction over this class action pursuant to California Constitution, Article VI, § 10, because this case is a cause not given by statute to other trial courts. Plaintiff resides in the State of California and has standing to bring this action pursuant to California Business & Professions Code Section 17200 et seg., and California Civil Code Section 1750 et seq.
- 2. Defendant Coty is an international corporation with its principal place of business located in New York. Coty is authorized to do business in California, has sufficient minimum contacts with California, and/or otherwise has intentionally availed itself of the markets in California through the promotion, marketing and sale of their products in California, such that the exercise of jurisdiction by this Court is permissible under traditional notions of fair play and substantial justice.
- 3. Venue is proper in this Court because the transaction which led to this action occurred in San Bernardino County and Defendants have conducted substantial business in San Bernardino County. In addition, Coty has a manufacturing facility located in California and a Research & Development facility located in California. Defendants received substantial compensation from sales in San Bernardino County and Defendants made numerous misrepresentations which had a substantial effect in San Bernardino County, including, but not limited to point of purchase, print, television, and internet advertisements.

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provisions of Code of Civil Procedure Section 395.5.

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THE PARTIES

Other out of state participants can be brought before this Court pursuant to the

5. Plaintiff Silvia Morales is, and at all times relevant hereto was, an individual residing in the State of California. Plaintiff purchased Coty's "Sally Hansen Nailgrowth Miracle Serum", "Sally Hansen Nailgrowth Miracle Salon Strength Treatment" and "Sally Hansen Nailgrowth Miracle Color Treatment" in the State of California during the Class Period. In doing so, Plaintiff relied upon advertising and other promotional materials, including information on the product packaging, containing the misrepresentations alleged herein. Specifically, Plaintiff relied upon Coty's allegations that the Nailgrowth Miracle Products, when used as directed, individually and/or in conjunction with additional Nailgrowth Miracle Products, would enhance the growth of Plaintiff's fingernails. Plaintiff used the Nailgrowth Miracle Products as directed and did not receive any of the advertised benefits associated with the products and would not have purchased any of the Nailgrowth Miracle Products if she had known that Defendants' representations were false.

- 6. Defendant Coty owns the Sally Hansen brand and is the distributor of Sally Hansen Nailgrowth Miracle Products. Coty is the company that created and/or authorized the false. misleading and deceptive advertisements and packaging of the Nailgrowth Miracle Products. Coty, directly and through its agents, has substantial contacts with and receives substantial benefits and income from and through the State of California.
- 7. The true names and capacities, whether individual, corporate, associate or otherwise of certain manufacturers, distributors and/or their alter egos sued herein as DOES 1 through 250 inclusive are presently unknown to Plaintiff who therefore sues these Defendants by fictitious names. Plaintiff will seek leave of this Court to amend the Complaint to show the true names and capacities of said Doe Defendants when the same have been ascertained. Plaintiff is informed and believes and based thereon alleges that DOES 1 through 250 were authorized to do and did business in the State of California, including, but not limited to, Los Angeles County. Plaintiffs are further informed and believe and based thereon allege that DOES 1 through 250

were and/or are, in some manner or way, responsible for and liable to Plaintiff for the events, happenings and damages hereinafter set forth below.

8. Plaintiff is informed and believes and based thereon alleges that at all times relevant herein each of the Defendants was the agent, servant, employee, subsidiary, affiliate, partner, assignee, successor-in-interest, alter ego or other representative of each of the remaining Defendants and was acting in such capacity in doing the things herein complained of and alleged.

FACTUAL ALLEGATIONS

Coty, Inc. Background

- 9. Defendant Coty, Inc. ("Coty") was founded in Paris in 1904 by François Coty.
- 10. Today, Coty is an international company with over 12,000 employees and three corporate headquarter locations—New York, Paris, and Geneva. Coty is a "global player" with offices in over 30 countries and a presence in over 135 international markets including the Americas, Europe, the Middle East, Africa and Asia Pacific.
- (See http://www.coty.com/company/coty-snapshotCoty).
- 11. Coty is primarily a marketing company but also has a "global manufacturing presence" which includes "Research and Development Centers of Excellence" across the Americas, Europe, and Asia. Coty has manufacturing facilities located in the United States in: Los Angeles, CA; Sanford, NC; and Phoenix, AZ; and international manufacturing facilities located in: Ashford, UK; Granollers, Spain; Chartres, France; Monaco; Jiangsu Province, China. Coty also has Research & Development facilities located in Los Angeles, CA; Morris Plains, NJ; Phoenix, AZ and international Research & Development facilities in Monaco; Granollers, Spain; Geneva, Switzerland; and Jiangsu Province, China. (See http://www.coty.com/company/coty-snapshot)
- 12. Coty owns and/or manages numerous well-known brands in what is often referred to as the "health and beauty aids industry." Some of these brands include Adidas, Calvin Klein Fragrances, Davidoff, Guess, Espirit, Vera Wang, Stetson, Nautica, and Marc Jacobs just to name a few. Coty also enters into licensing agreements with celebrities and other brands whereby Coty uses its "creative innovation" to "strengthen" these brands in an effort to increase

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profitability and product prestige. (See http://www.coty.com/company/coty-snapshot). According to Coty's website, its "unique portfolio of widely known brands in fragrance, color cosmetics (including nail), plus skin and body care supports net sales of \$4.1 billion for the fiscal year ended June 30, 2011." Id.

Coty's "FASTER. FURTHER. FREER" Culture

- In 2001, Bernd Beetz ("Beetz") took over as the Chief Executive Officer of Coty 13. help "transform Coty into a leading global beauty company." (See http://www.coty.com/company/meet-team). At the heart of Beetz's "creative, entrepreneurial and visionary leadership" is his "management philosophy of 'innovate or die." This aggressive corporate culture is epitomized by the corporate mantra established by Beetz himself: "FASTER. FURTHER. FREER." Coty boasts that this culture enables the company "to make fast decisions, push boundaries and support creativity." Coty describes the culture established by Beetz as "a key element to our success." (See id.)
- Coty cites the fact that it was able to make four major acquisitions (Dr. Sheller 14. Cosmetics, OPI Products, Philosophy and t-joy of China) within a few short months between 2010-2011 as an example of the company's embodiment of the "FASTER. FURTHER. FREER." mantra established by Beetz. (See http://www.coty.com/company/coty-snapshot)
- Under the leadership of Beetz, Coty aggressively pursues and acquires companies 15. and then initiates "precise, coordinated launches that have led to double-digit sales growth and a doubling of profitability. [Beetz] has helped the company gain an unyielding leading position in the fragrance and nail categories." (See http://www.coty.com/company/meet-team)

Coty's Advertising and Marketing of Sally Hansen Brand Products

16. The cosmetics marketplace is an ultra-competitive, multi-billion dollar per year business. Coty has expert knowledge of this market and advertises products with claims that they know are material to consumers and intend for consumers to rely upon in purchasing Coty's products over competing brands. As Coty puts it: "We capture trends sooner than anyone else.

In doing so, we create enduring brands that speak to the aspirations and lifestyle's of today's			
consumers. We catch opportunities as soon as they appear in the market, and our fast decision			
naking process allows us to leapfrog over competitors and keep us at the front of the pack." (See			
http://www.coty.com/company/corporate-culture#jump-1) (click on "Faster")			

- 17. Recognizing the opportunities in the nail care category, in 2007, Coty acquired Sally Hansen and added the Sally Hansen brand to Coty's expanding portfolio. While Sally Hansen is best known for its nail care products, the company also markets a variety of cosmetics products, including skin and body products, and other "beauty" tools. (See http://sallyhansen.com/) (See also http://sallyhansen.com/products/nails).
- 18. The Sally Hansen products are primarily distributed in "mass retail" stores such as Walgreens, CVS, and Walmart. Coty markets several "lines" of Sally Hansen nail care products which purport to address several very specific and distinct nail care issues or concerns expressed by consumers. Aside and apart from the Sally Hansen "growth" products which will be set forth in more detail below, Coty markets numerous Sally Hansen nail "strengthening" products such as: "Vita Surge Strength Gel"; "Triple Strong"; "Double Duty Strengthening Base & Top Coat"; and "Continuous Treatment Strength" among others.
- 19. Coty also markets a separate line of nail "hardening" products such as: "Advanced Hard as Nails"; "Advanced Hard as Nails Strengthening Top Coat"; "Diamond Strength Instant Nail Hardener"; and "Continuous Treatment Hardener". Coty also markets several Sally Hansen nail "thickening" products such as: "Thicken Up" and "Miracle Nail Thickener".
- 20. In addition Coty sells several Sally Hansen nail "moisturizing/nourishment" products like "Vitamin E Nail & Cuticle Oil"; "Nail & Cuticle Hand Cream"; "Nail Nutrition Green Tea plus Olive Growth Treatment". Coty also markets a line of Sally Hansen "cuticle" products: "Maximum Growth Cuticle Pen"; "Cuticle Massage Cream"; "Quick Care Cuticle Treatment"; "Healthy Cuticles Now".
- 21. Finally, Coty also sells a line of Sally Hansen "all-in-one" nail care products which purport to address some combination of all of the above-categories such as "Complete Care 4 in 1 Treatment" and "Complete Care Extra Moisturizing".

22. Like the rest of the Sally Hansen nail care products, Coty markets the Sally Hansen Nailgrowth Miracle Products to consumers through coordinated, targeted marketing campaigns consisting of national television commercials, print advertisements in popular magazines, internet advertising, product packaging and in-store point-of-purchase displays at Coty's national retailer partners such as CVS and Walgreens. (See e.g. Exhibit A, print advertisement for Nailgrowth Miracle Serum).

- 23. Throughout the Class Period, the advertising and marketing of the Nailgrowth Miracle Products epitomized Beetz's "FASTER. FREER. FURTHER." mantra. Indeed, Defendants have spent millions of dollars on uniform nationwide advertising and marketing campaigns Nailgrowth Miracle Products. Coty has increased company profits by "pushing the boundaries" with advertising campaigns for the Nailgrowth Miracle Products. Unfortunately for consumers, as set forth herein, Coty's "push the boundaries" strategy has resulted in a multitude of false and deceptive advertising campaigns for the Nailgrowth Miracle Products.
- 24. The primary marketing vehicle for Sally Hansen products, and the cosmetics industry as a whole, is product packaging and point-of-purchase displays. Coty aggressively markets the Nailgrowth Miracle Products in an attempt to distinguish the Sally Hansen brand from its competitors. While several other companies that market and sell products which purport to enhance fingernail growth¹, Coty differentiates the Nailgrowth Miracle Products from other products on crowded store shelves with precise and express guarantees of growth.
- 25. With regards to "Sally Hansen Nailgrowth Miracle Serum", Coty falsely claims that this product is "a breakthrough nail treatment designed to support fast natural nail growth, as it perfects cuticles." Coty claims on the front and center of the packaging: "59% Longer nails! Instantly smooth cuticles. Guaranteed!" On the back of the product packaging the "results" of the product are listed as "measurably longer nails and flawless looking cuticles. The word

¹ Plaintiff asserts that these products are also false and misleading to consumers however these products are not the subject of this Complaint.

name of the product itself.

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nailgrowth
Miracle*Serum
Nail & Cuticle Treatment
59% Longer nails!*
Instantly smooth cuticles
Guaranteed!

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"Growth" is also prominently displayed on the top of the front of the packaging as well as in the

(See a true and accurate depiction of the product packaging attached hereto as Exhibit B).

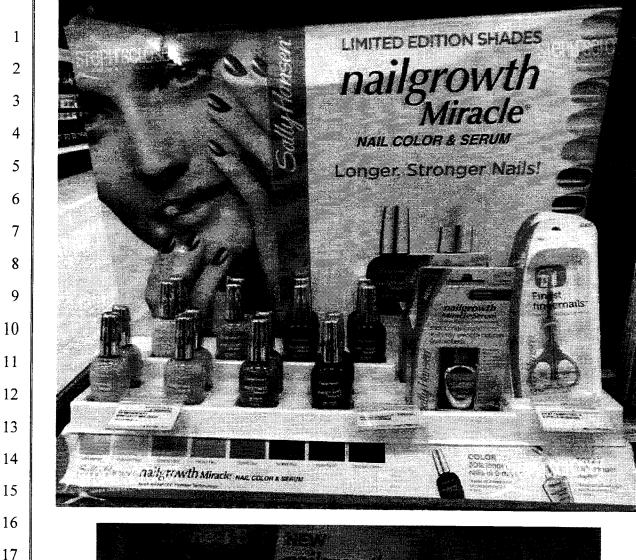
26. With regards to "Sally Hansen Nailgrowth Miracle Salon Strength Treatment" Coty falsely claims that this product is a "professional-strength treatment that promotes speedy nail growth, eliminates brittleness & protects nails against splitting, cracking & tearing." On the front and center of the packaging Coty claims "30% Longer Nails in 5 Days! Guaranteed!" The word "Growth" is also prominently displayed on the top of the packaging as well as in the name of the product itself. The Sally Hansen website also indicates that for "greater results use with Nailgrowth Miracle Serum."





(See a true and accurate depiction of the product packaging attached hereto as Exhibit C).

- 27. With regards to "Sally Hansen Nailgrowth Miracle Color Treatment" Coty tells consumers to "Expect a Miracle". Coty falsely claims that "Sally knows that miracles do happen thanks to a scientific breakthrough utilizing advanced peptide technology" and that this product will cause "nails to grow 30% longer in just 5 days." The Sally Hansen website also indicates "For greater results use with Nailgrowth Miracle Serum." This product is available in 24 different color shades. (See http://sallyhansen.com/products/nails/nail-color/nailgrowth-miracle).
- 28. In addition to the product packaging, Coty has deployed point-of-purchase displays to hawk the Nailgrowth Growth Miracle Products:







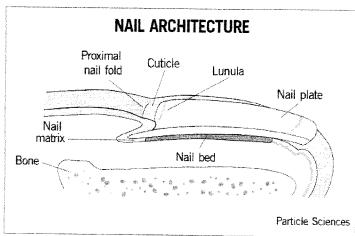
29. In sum, it is clear that the net impression of Coty's advertising of the Nail Growth Miracle Products is that the products will cause a consumer's fingernails to grow longer than they otherwise would; and this purported growth will occur at a "guaranteed" rate of "30% in 5 days" with regards to "Sally Hansen Nailgrowth Miracle Serum" and "Sally Hansen Nailgrowth Miracle Color Treatment" and "59% in 14 days" with regards to "Sally Hansen Nailgrowth Miracle Salon Strength Treatment."

The Undisputed Science Demonstrates that Coty's Growth Claims are False and Deceptive

- 30. It is scientifically accepted that fingernail growth is controlled by numerous factors including age, gender, season, exercise level, diet, and hereditary factors. Defendants claim that: (i) Sally Hansen Nailgrowth Miracle Products will cause or enhance fingernail growth when applied as directed; and (ii) that this purported growth will occur at a "guaranteed" rate of "30% in 5 days" with regards to "Sally Hansen Nailgrowth Miracle Serum" and "Sally Hansen Nailgrowth Miracle Color Treatment" and "59% in 14 days" with regards to "Sally Hansen Nailgrowth Miracle Salon Strength Treatment."
- 31. In other words, Defendants claim that the Nailgrowth Miracle Products will overcome the age, gender, season, exercise level, diet, and hereditary factors which are scientifically accepted to control fingernail growth. Instead, by applying the Nailgrowth Miracle Products topically to one's fingernails, Defendants claim that the Nailgrowth Miracle Products are "guaranteed" to cause increased fingernail growth. Defendants claim that the Nailgrowth

Miracle Products cause fingernail growth through the "Advanced Peptide Technology" and "Exclusive Protein Complex" contained in the Nailgrowth Miracle Products formula.

- 32. The relevant, generally accepted science, however, makes it clear that it is anatomically impossible for any product—drug or cosmetic—to permeate the nail plate and deliver any alleged "growth" benefit to the nail when applied topically without the use of aggressive permeation enhancement techniques such as nail abrasion, acid etching or the use of chemical agents. Not only is this true of cosmetic products containing the ingredients purportedly in the Sally Hansen Nailgrowth Miracle Products, it is also true of pharmaceutical grade drug products that allege to confer similar "benefits" to consumers. See *Skin and Nail: Barrier Function, Structure and Anatomy Considerations*, Particle Sciences, Drug Development Services, Technical Brief, Volume 3 (2009) (attached hereto as Exhibit E).
- 33. Anatomically, the growing part of the nail, the germinal matrix, is located under the epidermis at the nail's proximal end. This is the only living part of the finger nail. As new nail cells are formed, they emerge from the matrix to push the older nail plate cells forward and in this way cause the nail to lengthen or "grow". The portion of the nail plate which is pushed forward (the visible part of the nail) is comprised completely of dead cells. In order for any drug or cosmetic product to deliver any purported "growth" benefit, this product must somehow permeate the nail plate to reach the only part of the nail which consists of living cells—the germinal matrix. (See Exhibit E).



See Exhibit E, Figure 3.

34. According to the undisputed science, in order to have any chance to achieve effective transungual *drug* therapy:

permeation must be enhanced....by disrupting the nail plate using physical techniques or chemical agents... which have been shown to enhance transungual delivery. They include nail abrasion (manual and electrical), acid etching, ablation by lasers, microporation, application of low-frequency ultrasound and electric currents, and chemicals (thiols, sulphides, hydrogen peroxide, urea, water, enzymes). "

See Exhibit E, (internal citations omitted).

- 35. Accordingly, it is of no consequence whether the Sally Hansen Nailgrowth Miracle Products are applied to the cuticle or under the nail tip of the nail rather than just directly to the nail plate. The Nailgrowth Miracle Serum is referred to as a "nail and cuticle treatment" on the packaging and this seems to imply a distinction between these two parts of the nail regarding product application. Coty also instructs consumers on the product packaging to massage the product into each "nail and cuticle".
- 36. However, like the nail plate, neither the cuticle nor the tip of the nail is in contact with the germinative or "growing" cells and therefore cannot impact growth. Applying these products to any of these areas still simply results in applying product to "dead" cells which have no biological activity and therefore cannot impact growth. Thus, these claims are also false and deceptive.
- 37. There is absolutely no scientific basis whatsoever for Coty's outlandish claims that a *cosmetic* product with the ingredients contained in the Nailgrowth Miracle Products, applied topically with a feather-soft artist brush, like the brush provided with the Nailgrowth Miracle Products, could possibly permeate the nail plate to reach the growing part of the nail and deliver any purported "growth benefit". In other words, Coty's claims for the Nailgrowth Miracle Products are simply not scientifically possible and the Nailgrowth Miracle Products amount to nothing more than a very expensive placebo.

39. Furthermore, because fingernail growth is affected by numerous factors including age, gender, season, exercise level, diet, and hereditary factors, even if the "Advanced Peptide Technology" of the Nailgrowth Miracle Products was able to permeate the nail plate to deliver any sort of growth enhancement (which they scientifically cannot), large scale, double blinded, placebo controlled studies are needed to generate the statistical certainty that would be required to support such extremely precise claims (30% longer nails in 5 days and 59% longer nails in 14 days). Thus, these claims are false and deceptive.

40. Moreover, the aggressive "growth" claims set forth on the Sally Hansen website and in its other advertising of the Nailgrowth Miracle Products claim to affect the structure or function of the body, and, as such, are actually "drug products" claims under the California Health and Safety Code and the federal Food, Drug & Cosmetic Act. Thus, even if the Nailgrowth Miracle Products were able to deliver the alleged fingernail growth results – which, based on the ingredients and manner of application, they scientifically cannot – the products

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 $^{^2}$ For the purpose of evaluating these claims Plaintiff assumes the conservative figure, an average growth rate of 3 mm per month.

³ The same logic applies to Coty's claims of "59%" increased growth in 14 days for Nailgrowth Miracle Serum.

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would be misbranded "drug products" under applicable federal and California guidelines and illegal to sell over the counter to consumers.

- By making these false and deceptive claims, Coty's marketing and sale of 41. Nailgrowth Miracle Products violates California's Consumer Legal Remedies Act ("CLRA") Civil Code §§ 1750-1784); California's Unfair Competition Act ("UCL") Business & Professions Code § 17200 et seq.); California's False Advertising Law ("FAL") Business & Professions Code § 17500-17536); and the common law.
- 42. In committing the wrongful acts alleged herein, Defendants planned and participated in the furthered a common scheme by means of false, misleading, deceptive and fraudulent representations to induce members of the public to purchase the Nailgrowth Miracle Defendants participated in the making of such representations in that each did Products. disseminate or cause to be disseminated said misrepresentations.
- Defendants, upon becoming involved with the manufacture, advertising, and sale of 43. the Nailgrowth Miracle Products, and, in particular, the claims suggesting and/or outright stating that the Nailgrowth Miracle Products could, in any way, provide increased or enhanced nail growth to consumers, were false, deceptive and misleading. Indeed, since the first time that the Nailgrowth Miracle Products were advertised, Defendants have been aware that they, individually and/or collectively, possess no competent and reliable scientific evidence to substantiate their claims about the purported benefits and efficacy of the Nailgrowth Miracle Products, and that those claims are false and deceptive under the relevant, generally-accepted anatomical science.
- Defendants affirmatively misrepresented the "benefits" of the Nailgrowth Miracle 44. Products in order to convince the public to purchase and use the Nailgrowth Miracle Products, resulting in profits to Defendants, all to the damage and detriment of the consuming public. Thus, in addition to the wrongful conduct herein alleged as giving rise to primary liability, Defendants further aided and abetted and knowingly assisted each other in breach of their respective duties and obligations and herein alleged.

45. Plaintiff purchased Coty's "Sally Hansen Nailgrowth Miracle Serum", "Sally Hansen Nailgrowth Miracle Salon Strengthening Treatment" and "Sally Hansen Nailgrowth Miracle Color Treatment" in the State of California in 2011. Plaintiff purchased the Nailgrowth Miracle Products relying on Coty's advertising and label claims, including, without limitation, the label claim that the Nailgrowth Miracle Products would help her finger nails grow longer. Plaintiff purchased and used these products in conjunction with one another as directed by Coty. Plaintiff did not experience the advertised benefits of the Nailgrowth Miracle Products. Plaintiff suffered injury in fact in the amount of the purchase price of the Nailgrowth Miracle Products. Plaintiff would not have purchased any of the Nailgrowth Miracle Products had she known that Defendants' advertising claims about the product were false.

46. On April 4, 2012 Plaintiff sent a detailed, nine-page notice letter pursuant to California Civil Code 1782(a) to Coty. Plaintiff identified Coty's false and deceptive advertising claims for the Nailgrowth Miracle Products and demanded that Coty discontinue those claims. (A true and accurate copy of the correspondence and the U.S.P.S. return receipt is attached hereto as Exhibit F).

- 47. Referencing the attached objective, credible science indicating that it is anatomically impossible for cosmetic products like the Nailgrowth Miracle Products to provide any benefits of increased fingernail growth (including Coty's specific claims of 30% and 59% increases in growth), Plaintiff requested that Coty provide the scientific information that Coty believes supports its claims that the Nailgrowth Miracle Products can cause increased fingernail growth.
- 48. Two months have passed since Coty's receipt of Plaintiff's letter. To date, Plaintiff has received no response from Coty. Tellingly, Coty's silence confirms that: 1) it possesses zero credible information, scientific or otherwise, to support their fingernail growth claims and 2) that the false advertising claims for the Nailgrowth Miracle Products are simply too important to Coty's "bottom line" and Coty will not discontinue these claims absent judicial intervention.

49. Unfortunately for consumers, it is clear that the Nailgrowth Miracle Products are nothing more than bottles of broken promises. Plaintiff thus brings this action to halt Coty's false and deceptive advertising of the Nailgrowth Miracle Products and prevent further injury to California consumers.

CLASS ACTION ALLEGATIONS

50. Plaintiff brings this class action for injunctive and related equitable relief on behalf of herself, and as a class action on behalf of the following putative class (hereafter the "Class"):

All persons who purchased any of the Sally Hansen Nailgrowth Miracle Products for personal use and not for resale, in the State of California from June 2008 through the present.

- 51. Excluded from the Class are Defendants' officers, directors, employees, and any individual who received remuneration from Defendants to act as an endorser of the Sally Hansen Nailgrowth Products. Plaintiff reserves the right to amend the Class definition if further investigation and discovery indicates that the Class definitions should be narrowed, expanded, or otherwise modified.
- Numerosity: Plaintiff does not know the exact number of members of the putative classes. Due to the nature of the trade and commerce involved, however, Plaintiff is informed and believes that the total number of Class members is at least in the tens of thousands, and that members of the Class are numerous and geographically dispersed throughout California. While the exact number and identities of the Class members are unknown at this time, such information can be ascertained through appropriate investigation and discovery. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court.
- 53. <u>Well-defined Community of Interest</u>: There is a well-defined community of interest in the questions of law and fact involved affecting the plaintiff Class and these common questions predominate over any questions that may affect individual Class members. Common questions of fact and law include, but are not limited to, the following:

1	a.	Whether Defendants falsely advertise and misrepresent the benefits of the Sally
2		Hansen Nailgrowth Miracle Products;
3	b.	Whether Defendants' mass media advertising and/or the packaging for the Sally
4		Hansen Nailgrowth Miracle Products is misleading and deceptive;
5	c.	Whether Defendants' labeling and/or packaging for the Sally Hansen Nailgrowth
6		Miracle Products is misleading, false and/or illegal;
7	d.	Whether Defendants represent to consumers that the Sally Hansen Nailgrowth
8		Miracle Products have characteristics, uses, benefits or qualities that the product
9		does not have;
10	e.	Whether Defendants knew or should have known that the Sally Hansen Nailgrowth
11		Miracle Products do not have the characteristics, uses, benefits or qualities for
12		which Defendants advertised the product;
13	f.	Whether Defendants represented that the Sally Hansen Nailgrowth Miracle
14		Products are of a particular standard, quality, or grade, when they are of another;
15	g.	Whether Defendants advertised the Sally Hansen Nailgrowth Miracle Products with
16		intent to sell them not as advertised;
17	h.	Whether Defendants engaged in unfair, unlawful and/or fraudulent business
18		practices in marketing and distributing the Sally Hansen Nailgrowth Miracle
19		Products;
20	i.	Whether Defendants engaged in false advertising with respect to the Sally Hansen
21		Nailgrowth Miracle Products;
22	j.	Whether Defendants' representations, concealments and non-disclosures
23		concerning the Sally Hansen Nailgrowth Miracle Products are likely to deceive the
24		reasonable consumer;
25	k.	The nature and extent of damages and other remedies to which the wrongful
26		conduct of Defendants entitles the Class members;
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- Whether Defendants' representations, concealments and non-disclosures concerning the Sally Hansen Nailgrowth Miracle Products violate the CLRA, FAL and/or the UCL;
- m. Whether the Class is entitled to injunctive relief prohibiting the challenged wrongful practices and enjoining such practices in the future;
- n. Whether the Class is entitled to restitution; and,
- o. Whether Plaintiffs and the Class are entitled to attorneys' fees and expenses, and in what amount.
- 54. <u>Typicality</u>: Plaintiff's claims are typical of the claims of the members of the Class in that Plaintiff and the putative class members each purchased the Sally Hansen Nailgrowth Miracle Products during the Class Period, and the products purchased by Plaintiff and the putative class members contained unfairly deceptive and misleading representations.
- 55. Adequacy of Representation: Plaintiff will fairly and adequately represent and protect the interests of the Class in that Plaintiff is a typical purchaser of the Sally Hansen Nailgrowth Miracle Products and has no conflicts of interest with any member of the proposed Class. Additionally, Plaintiff has retained counsel with experience in handling complex class action litigation who will fairly and adequately protect the interests of the putative class. Plaintiff and her counsel are committed to vigorously prosecuting this action on behalf of the Class and Plaintiff's Counsel has the financial resources to do so.
- 56. Superiority: Plaintiff and the members of the Class suffered, and will continue to suffer, harm as a result of Defendants' unlawful and wrongful conduct. This class action is superior to the alternatives, if any, for the fair and efficient adjudication of this controversy. The relief sought per individual member of the putative class is small given the burden and expense of individual prosecution of the potentially extensive litigation necessitated by the conduct of Defendants. Furthermore, it would be virtually impossible for the putative class members to seek redress on an individual basis. Even if the putative class members themselves could afford such individual litigation, the court system could not. Individual litigation magnifies the delay and expense to all parties in the court system of resolving the controversies engendered by Defendants'

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BESHADA FARNESE LLP 1

common course of conduct. The class action device allows a single court to provide the benefits of unitary adjudication, judicial economy, and the fair and efficient handling of all class members' claims in a single forum. The conduct of this action as a class action conserves the resources of the parties and of the judicial system and protects the rights of the class members. Furthermore, for many, if not most, a class action is the only feasible mechanism that allows an opportunity for legal redress and justice.

- 57. Adjudication of individual class members' claims with respect to Defendants would, as a practical matter, be dispositive of the interests of other members not parties to the adjudication, and could substantially impair or impede the ability of other class members to protect their interests.
- 58. If necessary, notice of this action may be affected to the proposed class through publication.
- 59. Unless a classwide injunction is issued, Defendants will continue to commit the violations alleged, and the members of the Class will continue to be misled.

FIRST CAUSE OF ACTION

VIOLATION OF UNFAIR COMPETITION LAW (CAL. BUS. & PROF. CODE § 17200, et seq.) (Unlawful, Unfair, and Fraudulent Prongs of the Act)

- 60. Plaintiff incorporates by this reference the allegations contained in the preceding paragraphs as if fully set forth herein.
- 61. Plaintiff brings this claim individually and on behalf of the proposed Class against Defendants.
- 62. California *Business and Professions Code* § 17200 prohibits any "unfair, deceptive, untrue or misleading advertising." For the reasons discussed above, Defendants have engaged in unfair, deceptive, untrue and misleading advertising in violation of California *Business & Professions Code* §17200.
- 63. As alleged herein, Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and has lost money or property as a result of Defendants' actions.

Specifically, Plaintiff purchased the Sally Hansen Nailgrowth Miracle Products for her own personal use. In so doing, Plaintiff relied upon the false representations regarding enhanced nail growth referenced above. Plaintiff applied the Growth Products as directed and did not recieve any of the advertised benefits of the Sally Hansen Nailgrowth Miracle Products. Plaintiff would not have purchased the Sally Hansen Nailgrowth Miracle Products had she known that Defendants' claims about the products were false.

- 64. <u>Unlawful Business Practices:</u> The actions of Defendants, as alleged herein, constitute illegal and unlawful practices committed in violation of the *Business & Professions Code* §17200.
- 65. Defendants' have committed unlawful business practices by, *inter alia*, making the representations and omissions of material facts, as set forth more fully herein, and violating California *Civil Code* §§ 1572, 1573, 1709, 1710, 1711, 1770, *Business & Professions Code* § 17200 *et seq.*, *Business & Professions Code* § 17500, *et seq.*, and the common law.
- 66. In addition, Defendants have unlawfully manufactured, packaged, labeled, advertised, and/or distributed the Sally Hansen Nailgrowth Miracle Products in violation of California Health & Safety Code, which governs Defendants' conduct, in that Defendants have disseminated false advertisements of the Sally Hansen Nailgrowth Miracle Products, and that the product advertising and packaging contain false or misleading statements as to the purported benefits of the Sally Hansen Nailgrowth Miracle Products in violation of Bus. & Prof. Code § 17500, Civil Code §1750, which govern Defendant's conduct. Defendants also violated the unlawful prong of the UCL because their false advertising of the Sally Hansen Nailgrowth Miracle Products, as set forth above, violates the FTC Act (15 U.S.C. §45, et seq.).
- 67. Plaintiff and the Class reserve the right to allege other violations of law which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.
- 68. <u>Unfair Business Practices</u>: California *Business & Professions Code* § 17200 also prohibits any "unfair ... business act or practice."
 - 69. Defendants' acts, omissions, misrepresentations, practices and non-disclosures as

alleged herein also constitute "unfair" business acts and practices within the meaning of *Business & Professions Code* § 17200 et seq. in that its conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such conduct.

- 70. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein.
- 71. **Fraudulent Business Practices**: California *Business & Professions* Code § 17200 also prohibits any "fraudulent business act or practice."
- 72. Defendants' claims, nondisclosures and misleading statements with respect to the Sally Hansen Nailgrowth Miracle Products, as more fully set forth above, were false, misleading and/or likely to deceive the consuming public within the meaning of *Business & Professions* Code § 17200.
- 73. Defendants' conduct caused and continues to cause substantial injury to Plaintiff and the other Class members. Plaintiff has suffered injury in fact and has lost money as a result of Defendants' unfair conduct.
- 74. Pursuant to section 17203 of the California Business and Professions Code, Plaintiff and the Class seek an order of this court enjoining Defendants from continuing to engage in unlawful, unfair, or deceptive business practices and any other act prohibited by law, including but not limited to: (a) selling, marketing, or advertising the Sally Hansen Nailgrowth Miracle Products with false representations set forth above; (b) engaging in any of the illegal, fraudulent, misleading, unlawful, unfair and/or deceptive conduct described herein; and (c) engaging in any other conduct found by the Court to be illegal, fraudulent, misleading, unlawful, unfair and/or deceptive conduct.
- 75. In addition, Plaintiff requests that this Court enter such orders or judgments as may be necessary to restore to any person in interest any money which may have been acquired by means of such illegal practices as provided in *Bus. & Prof.* Code § 17203, and for such other relief as set forth below.
 - 76. Plaintiff engaged counsel to prosecute this action and are entitled to recover costs

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and reasonable attorney's fees according to proof at trial.

SECOND CAUSE OF ACTION

FALSE AND MISLEADING ADVERTISING (CAL. BUS. & PROF. CODE § 17500, et seq.)

- Plaintiff incorporates by this reference the allegations contained in the preceding 77. paragraphs as if fully set forth herein.
- Plaintiff brings this claim individually and on behalf of the proposed Class against 78. Defendants.
- As alleged herein, Plaintiff has standing to pursue this claim as Plaintiff has 79. suffered injury in fact and has lost money or property as a result of Defendants' actions. Specifically, Plaintiff purchased the Sally Hansen Nailgrowth Miracle Products for her own personal use. In so doing, Plaintiff relied upon the false representations regarding enhanced nail growth referenced above. Plaintiff applied the Growth Products as directed and did not recieve any of the advertised benefits of the Sally Hansen Nailgrowth Miracle Products. Plaintiff would not have purchased the Sally Hansen Nailgrowth Miracle Products had she known that Defendants' claims about the products were false.
- 80. Defendants violated Business & Professions Code § 17500 by publicly disseminating false, misleading, and unsubstantiated advertisements regarding the Sally Hansen Nailgrowth Miracle Products.
- 81. Defendants' false, misleading and unsubstantiated advertisements were disseminated to increase the sales of the Sally Hansen Nailgrowth Miracle Products.
- 82. Defendants knew or should have known that their advertisements for the Sally Hansen Nailgrowth Miracle Products were false, misleading and unsubstantiated and that those advertisements would induce consumers to purchase the Sally Hansen Nailgrowth Miracle Products. Such advertisements have deceived and are likely to deceive the consuming public, in violation of Business & Professions Code § 17500.
- Furthermore, Defendants publicly disseminated the false, misleading and 83. unsubstantiated advertisements as part of a plan or scheme and with the intent to sell the products which are not scientifically "as advertised".

- 84. Plaintiff and the members of the Class have suffered harm as a result of these violations of the FAL because they have incurred charges and/or paid monies for the Sally Hansen Nailgrowth Miracle Products that they otherwise would not have incurred or paid.
- 85. Defendants are aware, or by the exercise of reasonable care should have been aware, that the representations were untrue or misleading and that such conduct is in violation of the current injunction.
- 86. Plaintiff and the members of the Classes have suffered injury in fact and have lost money as a result of Defendant's false representations and false advertising.
- 87. Pursuant to *Business & Professions Code* § 17535, Plaintiffs and the members of the putative Class seek an order of this Court enjoining Defendant from continuing to engage, use, or employ their practice of advertising the sale and use of the Sally Hansen Nailgrowth Miracle Products.
- B8. Likewise, Plaintiff and the members of the putative Class seek an order requiring Defendant to disclose such misrepresentations, and additionally request an order awarding Plaintiffs and other members of the putative class restitution of the money wrongfully acquired by Defendants by means of responsibility attached to Defendants' failure to disclose the existence and significance of said misrepresentations.
- 89. Plaintiff engaged counsel to prosecute this action and is entitled to recover costs and reasonable attorney's fees according to proof at trial.

THIRD CAUSE OF ACTION

VIOLATION OF CALIFORNIA LEGAL REMEDIES ACT (CAL. CIV. CODE § 1750 et seq.)

- 90. Plaintiff incorporates by this reference the allegations contained in the preceding paragraphs as if fully set forth herein.
- 91. Plaintiff brings this claim individually and on behalf of the proposed Class against Defendants.
- 92. As alleged herein, Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and has lost money or property as a result of Defendants' actions. Specifically, Plaintiff purchased the Sally Hansen Nailgrowth Miracle Products for her own

personal use. In so doing, Plaintiff relied upon the false representations regarding enhanced nail growth referenced above. Plaintiff applied the Growth Products as directed and did not recieve any of the advertised benefits of the Sally Hansen Nailgrowth Miracle Products. Plaintiff would not have purchased the Sally Hansen Nailgrowth Miracle Products had she known that Defendants' claims about the products were false.

- 93. Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and have lost money or property as a result of Defendants' actions as set forth herein.
- 94. Plaintiff has concurrently filed the declaration of venue required by Civil Code §1780(d) with this complaint.
- 95. Defendants have violated and continue to violate the CLRA by engaging in the following practices proscribed by California Civil Code §1770(a) in transactions with Plaintiff and the Class which were intended to result in, and did result in, the sale of the Sally Hansen Nailgrowth Miracle Products:
 - §1770(a) (5) Representing that [the Sally Hansen Nailgrowth Miracle Products have] ... characteristics, ... uses [or] benefits ... which [it does] not have
 §1770(a) (7) Representing that [the Sally Hansen Nailgrowth Miracle Products are]
 - of a particular standard, quality or grade ... if [it is] of another.
- 96. Defendants violated the CLRA by representing through the advertisements of the Sally Hansen Nailgrowth Miracle Products as described above, when they knew, or should have known, that the representations and advertisements were unsubstantiated, false and misleading.
- 97. Plaintiffs and the members of the putative Class have each been directly and proximately injured by the conduct of Defendants, and such injury includes payment for units of the Sally Hansen Nailgrowth Miracle Products they purchased.
- 98. Pursuant to Civil Code Section 1782(a) Plaintiff's counsel sent to Defendants a written notice letter via certified mail as required by Civil Code Section 1782(a) on April 14, 2012. (A true and correct copy of the letter and certified mail receipt is attached hereto as Exhibit F).
 - 99. In that detailed notice letter, Plaintiffs set forth the basis for this action as well as

1	6.	6. For pre-judgment interest from the date of filing this suit;		
2	7.	For reasonable attorneys' fees;		
3	8.	Costs of this suit; and,		
4	9.	Such other and further r	relief as the Court may deem necessary and appropriate.	
5				
6	DATED: Jui	ne 5, 2012	BESHADA FARNESE LLP	
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8			By: Peter J. Farnese	
9			Attorneys for Plaintiffs	
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12		DEM	IAND FOR JURY TRIAL	
13	Plaintiff demands a trial by jury as to all claims for which the right to jury trial is provided			
14			• The second of the provided	
15	DATED: Jur	ne 5, 2012	BESHADA FARNESE LLP	
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17			By: Peter J. Farnese	
18			Attorneys for Plaintiffs	
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BESHADA FARNESE LLP

EXHIBIT A

EXHIBIT A



EXHIBIT B

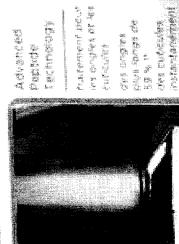
EXHIBIT B

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S A

nailgrowth Miracle Serum

59% Longer nails!* Instantly smooth cuticles Guaranteed Guaranteed



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NEW

EXHIBIT C

EXHIBIT C

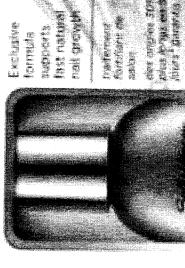
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SALON STRENGTH TREATMENT
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nailgrowth Miracle* Salon Strength Treatment

30% Longer Nails in 5 Days!* Guaranteed!



WASUDIY

EXHIBIT D

EXHIBIT D

EXHIBIT E

EXHIBIT E

PARTICLE SCIENCES

DRUG DEVELOPMENT SERVICES

Skin and Nail: Barrier Function, Structure, and Anatomy Considerations for Drug Delivery

Drug delivery to and through both skin and nails is an area receiving ever-increasing attention. In order to effectively deliver active pharmaceutical ingredients (APIs) across the skin (transdermal delivery) or nail (transungual delivery) it is necessary to consider the anatomy and physiology of these barriers. With this information in hand, one can more effectively utilize drug delivery approaches to maximize the effectiveness of the API – getting the right amount to the right place at the right time. The advantages of local delivery include, among others, minimized systemic toxicity, high local drug concentrations, avoidance of first pass issues and cost.

Topical delivery of systemic therapeutics also offers benefits but presents a greater technical challenge. Among the benefits, first pass avoidance, convenience and sustained release are most often sited.

Skin: The skin is the largest organ in the body, making up 12 - 15% of body weight and with a surface area of $1 - 2m^2$. Not surprisingly, the skin has a complex architecture that can vary depending on body location (Figure 1).

There are 3 distinct regions in the skin. From outermost inward, they are the epidermis, dermis and subcutis (hypodermis). The epidermis itself has five regions and can range in total thickness from 0.5mm (eyelid) to 1.5mm on the palms and soles (Figure 2).

The most important function of the skin is to provide a selectively permeable barrier. The outermost region of this barrier is called the stratum corneum (SC), a dynamic structure with cells migrating in a deep to superficial direction as they mature. The SC, also called the horny layer, consists of cells called corneocytes that are em-

SKIN ARCHITECTURE

Hair shaft

Sweat pore

Arrector pili
muscle
Sebaceous gland
Hair follicle
Nerve fiber
Sweat gland
Vein
Artery

Particle Sciences

bedded in a multilamellar, lipidenriched extracellular matrix. The SC comprises, depending on location, approximately 15 layers of horny cells. The transit time of the horny cells across the epidermis is approximately 1 – 2 weeks. It takes approximately 24 hours

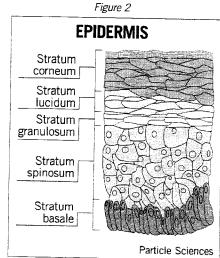
to form one layer and the SC is completely renewed about every 15 days. In addition to the skin, there is a relatively large area of accessible mucosal tissue. This includes the conjunctiva, nasal and oral cavities, respiratory tract, digestive tract, vagina, urethra

and rectum. Each of these areas has a unique histology that, for the most part, make them more permeable to many drugs compared to skin or nails. For instance, these surfaces may have a substantially reduced keratinized layer, or lack one altogether, greatly reducing barrier function. Being at the interface of the body and internal spaces, mucosal areas have highly developed transport mechanisms for dealing with foreign bodies such as

the ciliated epithelium found in the respiratory tract. Many mucosal surfaces have a single-cell-thick epidermis and most are highly vascularized. Of course, mucosal surfaces are "wet" which has obvious implications for drug transport. Mucosal surfaces have unique immunologic properties, specific to the anatomical site. Several mucosal surfaces are already regularly exploited for local and systemic drug delivery.

There are three routes for transit of substances through the epidermis: Appendagael, Transcellular, and Intercellular. Appendagael transport refers to the use of hair follicles and sweat glands. As areas of discontinuity in the SC, they can serve as a pathway for API penetration. The significance of their contribution to percutaneous absorption has been extensively investigated. Although it is estimated that these appendages account for no more than 0.1% of the total skin surface, they cannot be neglected in considering possible routes of percutaneous absorption. For instance, iontophoresis, which is a non-invasive method for transdermal delivery of charged APIs using electromotive force, appears to dramatically increase the flux of compounds via hair follicles.

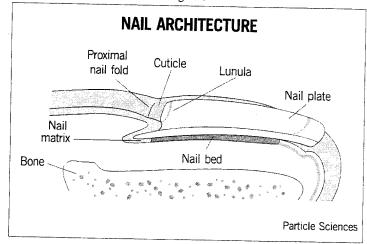
The transcellular pathway involves the movement of the API across the epithelial cell. The outer membrane of an epithelial cell may be regarded as a layer of lipid, surrounded on both sides by water. Low molecular weight and lipophilic APIs can gain systemic access transcellularly, by passive diffusion across the epithelial cells. In the process of passive diffusion, lipid-soluble substances move into the lipid membrane according to their lipid/water partition coefficient. The structural



features of compounds that determine permeability are related to hydrophobicity and molecular volume. In transcellular passive diffusion, the epithelium is assumed to act as a simple lipophilic barrier through which APIs diffuse and the rate of diffusion correlates with the lipid solubility of the API.

Lastly, drugs can travel between cells via intercellular channels. It is generally accepted that the extracellular SC lipids play a key role in limiting the diffusion of compounds through the SC. Lipids exist in bilamellar structures in the SC extracellular space, each layer separated from the other by a thin water sheet associated with the polar head group of the lipids. The intercellular lipids are organized into lamellae, which run parallel to the skin surface. Intercellular lipid is required for a competent skin barrier and forms the only continuous domain in the SC - a structural feature that may account, in part. for the barrier properties of the skin. The molar ratio of the barrier lipids were found to be cholesterol ester (15%), saturated long chain free fatty acids (16%), cholesterol (32%) and ceramides (37%). Chemical penetration enhancers generally act through disruption of the extracellular structure.

The three pathways described above are not mutually exclusive and permeation will be determined by the area/volume of the pathway, partitioning, and diffusivity of the API in each pathway. Transport across the SC, for most compounds, involves intercel-Iular lipids. However, it does not exclude the possibility that APIs also penetrate the corneocytes. The molecular basis for the penetration pathway across the SC should be considered in terms of its morphological structure and material properties. Both the composition and structure of the SC influences its material properties, which in turn determines the pathway for diffusion as well as the solubility and diffusivity of



API within the barrier.

It is essential to understand the inherent ability of an API to penetrate the SC before studying to what extent the penetration can be enhanced or reduced by appropriate choice of formulation. The relationship between the structure of a API and its permeability across the skin provides insight into the nature of the permeability barrier and is directly applicable to the prediction of percutaneous absorption.

Nails: Nails and claws of mammals are specialized epidermal derivatives which protect the delicate tip of fingers and toes against trauma and act as tools or weapons. Human fingernail gross anatomy consists of three structures. Starting from the outer structure, they are the nail plate, the nail bed, and the nail matrix (Figure 3 [1]).

The nail plate is a thin (0.25 -0.6mm for fingernails and up to 1.3mm for toenails), hard, yet slightly elastic, translucent, convex structure and is made up of approximately 25 layers of dead keratinized, flattened cells. They are tightly bound to one another via numerous intercellular links, membrane-coating granules and desmosomes, which are cell structures specialized for cell-to-cell adhesion and randomly arranged on the lateral sides of plasma membranes. The fingernail has a three-layer structure (outer to inner) - the dorsal, intermediate,

and ventral layers, with a thickness ratio of approximately 3:5:2, respectively. The dorsal outer layer is dense and hard, consisting of cornified keratin only a few cells thick (approximately 200µ). The cells at the dorsal surface of the plate overlap and produce a smooth surface. The intermediate layer, in contrast to the dorsal layer, shows highly fibrous structure oriented in a direction perpendicular to the direction of nail growth and constitutes roughly 75% of the plate's thickness. The keratin fibers are thought to be held together by globular, cysteine-rich proteins, whose disulfide bonds act as glue. The intermediate laver is believed to be both the softest and thickest. The ventral layer is very thin and consists of a few layers of cells which connect the nail plate to the nail bed below.

The growth rate of nails is highly variable among individuals, with average values of 3mm per month for fingernails and 1mm per month for toenails. A normal fingernail grows out completely in about 6 months, whereas it takes a toenail about 10 – 12 months [1].

The physicochemical properties of the human nail plate exhibit a marked difference to that of epidermis, resulting in very different permeability characteristics. Whereas the SC behaves as a lipid barrier to the permeation of low MW chemicals, the nail plate exhibits behaviors similar to that of

a hydrogel with high ionic strength and, indeed, the structure of human nail has been likened to a hydrophilic gel membrane [2]. The lipid content of the nail is reported to be low, at between 0.1 - 1%, and the nail is much more susceptible to water loss than the lipid-rich skin. Despite the reported hydrophilic properties of the nail, hydrophobic compounds also have been shown to diffuse into and through this barrier. For example, Walters and coworkers [3] reported that long chain alcohols also permeate through the nail via a lipidic pathway.

For effective transungual drug therapy, permeation must be enhanced. This can be achieved by disrupting the nail plate using physical techniques or chemical agents. Alternatively, drug permeation into the intact nail plate may be encouraged, for example, by iontophoresis or by formulating the drug within a vehicle which enables high drug partition out of the vehicle and into the nail plate.

There are several physical techniques that have been shown to enhance transungual delivery [4]. They include nail abrasion (manual and electrical), acid etching, ablation by lasers, microporation, application of low-frequency ultrasound and electric currents, and chemicals (thiols, sulphides, hydrogen peroxide, urea, water, enzymes).

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- 2. S. Murdan: International Journal of Pharmaceutics, 236, 1-26 (2002).
- 3. K.A. Walters, G.L. Flynn , J.R. Marvel: J. Pharm. Pharmacol., 37, 771-775 (1985).
- 4. M.R. Prausnitz, R. Langer; Nature Biotechnology, 26:11, 1261-1268 (2008).

PARTICLE SCIENCES

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Please Reply To: Peter J. Farnese, Esq. pjf@beshadafarneselaw.com Tel: 310-356-4668

April 4, 2012

VIA Certified U.S. Mail, RRR, #70090820000155789276

Bernd Beetz C.E.O. Coty Inc. Two Park Avenue New York, NY 10016

Re: Violation of the California Consumer Legal Remedies Act (California *Civil Code* section 1750 *et seq.*) Related to the Advertising and Marketing of Coty's Sally Hansen "Nailgrowth Miracle" Product Line

Dear Mr. Beetz:

This letter is sent on behalf of California consumer Silvia Morales pursuant to California *Civil Code* section 1782(a).). You, Coty Inc., and Sally Hansen (collectively hereinafter "Coty") are hereby notified that during the statutory time period of 2008 through the present (the "Class Period"), Coty has violated and continues to violate the provisions of the California Consumer Legal Remedies Act (California *Civil Code* section 1750, *et seq.*) (hereinafter the "CLRA") with respect to the advertising and marketing of Sally Hansen "Nailgrowth Miracle Serum", Sally Hansen "Nailgrowth Miracle Salon Strengthening Treatment" and Sally Hansen "Nailgrowth Miracle Color Treatment" (hereinafter "Nailgrowth Miracle Products"). ¹

Coty's false and deceptive advertising of Sally Hansen Nailgrowth Miracle Products has affected Silvia Morales and thousands of other California consumers (the "Plaintiff Class"), as they have entered into transactions and expended money based upon the false and misleading claims contained in Coty's marketing and advertising of these products. Specifically, by claiming

¹ To our knowledge there are also seven (7) other Sally Hansen cosmetic products, which contain very similar fingernail "growth" claims. These products include: Sally Hansen "Grow Nails Now", Sally Hansen "Maximum Growth Treatment", Sally Hansen "Quick Care Growth Treatment", Sally Hansen "Vita Surge Growth Gel Growth Treatment", Sally Hansen "Triple Strong Advanced Gel Nail Fortifier", Sally Hansen "Nail Nutrition Green Tea plus Olive Growth Treatment", and Sally Hansen "Continuous Growth Time Released Growth Formula".

that Sally Hansen's Nailgrowth Miracle Products can cause or enhance fingernail growth, Coty has violated CLRA Section 1770(a)(5) by:

Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has it sponsorship, approval, status, affiliation, or connection which he or she does not have.

In addition, Coty has also violated CLRA Section 1770(a)(7) by:

Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.

A. Coty's Sally Hansen Nailgrowth Miracle Products

The central theme of the marketing of Sally Hansen Nailgrowth Miracle Products is that "Sally knows miracles do happen" and frankly it would take nothing short of a miracle for these products to deliver on the purported benefits guaranteed by Coty. The specific claims of each product are set forth more fully below, but Coty represents, generally, that Sally Hansen Nailgrowth Miracle Products help fingernails grow longer in several days when applied topically as directed. Simply stated, these claims are not supported by the undisputed science and are, as such, are false and deceptive.

As an initial matter, it is impossible for any product—drug or cosmetic—to permeate the nail plate and deliver any alleged "growth" benefit to the nail when applied topically without the use of aggressive permeation enhancement techniques such as nail abrasion, acid etching or the use of chemical agents. That is certainly the case with cosmetic products containing the ingredients purportedly in the Nailgrowth Miracle Products, and is even true of pharmaceutical grade products that allege to confer similar "benefits" to consumers. See, e.g., Skin and Nail: Barrier Function, Structure and Anatomy Considerations, Particle Sciences, Drug Development Services, Technical Brief, Volume 3 (2009) (attached hereto as Exhibit A).

Moreover, the aggressive "growth" claims set forth on the Sally Hansen website, as well as in Coty's other advertising of the Nailgrowth Miracle Products, claim to affect the structure or function of the body, and, as such, are actually "drug products" claims under Section 201(g) of the Federal Food, Drug, and Cosmetic Act. As we understand it, Coty does not have the requisite FDA approval to market and sell Sally Hansen Nailgrowth Miracle Products as drugs. Accordingly, even if the Nailgrowth Miracle Products were able to deliver this fingernail growth "miracle", which based on the ingredients and manner of application they scientifically cannot, these products would be misbranded under applicable California and federal guidelines and subject to recall.

The Coty advertisements for Sally Hansen Nailgrowth Miracle Products convey a series of express and implied claims which Coty knows are material to the reasonable consumer and which Coty intends for consumers to rely upon when choosing to purchase its Sally Hansen Nailgrowth Miracle Products. Specifically, the claims for the individual products are as follows:

1. Sally Hansen "Nailgrowth Miracle Serum"



On its website, Coty asserts that "Sally Knows miracles do happen . . . with a little help from science. The revolutionary Advanced Peptide Technology is the secret. Infused with Biotin and Vitamins A, C and E, this concentrated serum works to enhance natural nail growth and instantly smooth cuticles." The purported benefits of the product are listed as: "59% LONGER NAILS with Advanced Peptide Technology"; "Natural Nail Growth in only 14 days"; and that "Nails grow longer, without brittleness". The instructions on the website indicate to "Use over nail color or bare nails" and that "For greater results use with Nailgrowth Miracle Color." The claim "59% Longer nails!" is also prominently displayed on the product packaging as can clearly be seen in the image of the product packaging set forth above which was taken directly from the Sally Hansen website. On the back of the packaging Coty also asserts that "the results" of this product are "measurably longer nails and flawless cuticles." The use instructions on the product packaging indicate: "Apply daily. Massage one drop on each nail & cuticle."

2. Sally Hansen "Nailgrowth Miracle Salon Strengthening Treatment"



Coty directly asserts prominently in the center of the packaging for this product, as well as on the advertisement on its website, that Nailgrowth Miracle Salon Strengthening Treatment will grow "30% Longer Nails in 5 days! Guaranteed!". Coty also asserts on the back of product packaging that "the results" of using this product will be "visibly longer, beautiful nails in 5 days." On its website, Coty claims that "Sally Knows miracles do happen thanks to a scientific breakthrough utilizing Advanced Peptide Technology. Nails grow 30% longer in just 5 days*. This exclusive nail color formula with Peptides, Keratin, Biotin and Multi-Vitamins, reinforces nails to resist splitting, cracking and breaking. *Based on consumer study of gloss and color intensity." The Application Tips indicate: "Apply 2 coats of polish. Seal with top coat." The website also indicates that "For greater results use with Nailgrowth Miracle Serum".

3. Sally Hansen Nailgrowth Miracle Color Treatment



On its website, directly underneath the name of the product, Coty asserts "Expect a miracle". Coty then claims that "Sally Knows miracles do happen thanks to a scientific breakthrough utilizing Advanced Peptide Technology. Nails grow 30% longer in just 5 days.* This exclusive nail color formula with Peptides, Keratin, Biotin and Multi-Vitamins reinforces nails to resist splitting, cracking and breaking. *Based on a fixed point nail measurement in 5 days." The website also indicates that "For greater results use with Nailgrowth Miracle Serum".

B. Coty's Marketing and Advertisements of Sally Hansen Nailgrowth Miracle Products Are False and Deceptive

Advertising claims under the CLRA and California consumer protection statues are governed by the "reasonable consumer" test, under which a plaintiff must show that "members of the public are likely to be deceived" by a particular advertisement. Williams v. Gerber Products Co., 552 F.3d 934, 938 (9th Cir. 2008) (internal quotation marks omitted). As such, any analysis of an advertisement must begin by determining the "net impression" conveyed by the particular advertisement. See Williams, 552 F.3d at 939 n.3; FTC v. Gill, 71 F. Supp. 2d 1030, 1043 (C.D. Cal. 1999); FTC v. Sterling Drug, 317 F.2d 669, 674 (2d Cir. 1963). Once the "net impression" is determined, the court must then evaluate the underlying scientific basis for the claim to ensure that the claim is adequately supported, matches the science, and is not misleading to consumers. See, e.g., Park v. Cytodyne Technologies, Inc. 2003 WL 21283814, *14 (Cal Superior (2003)) ("hereinafter Park"); see also FTC Policy Statement Regarding Advertising Substantiation, appended to Thompson Medical Co., 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987).

Under California and federal law, health efficacy and establishment claims must be supported by competent and reliable clinical or other scientific evidence. See, e.g., Cal. Business

& Professions Code §17508²; and FTC v. Nat'l Urological Group, Inc. 2008 U.S. Dist. LEXIS 44145 (N.D. Ga. 2008))³. Claims which do not match the science violate the CLRA by, among other things, representing that the product has "sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which [it does] not have," and/or (ii) is of "a particular standard, quality, or grade," when it is of another. See Cal. Civ. Code §§1770(a)(5) and (a)(7).

Coty claims that "Sally knows miracles do happen thanks to a scientific breakthrough utilizing Advanced Peptide Technology". In addition, each of the Nailgrowth Miracle Products prominently contains the word "grow" or "growth" on the product packaging, within the name of the product, and/or within the specific claims on the Sally Hansen website. Clearly, Coty is implying that this "miracle" is the ability to make dead fingernails grow. Thus, the "net impression" of the advertising conveys a message, among others, that Sally Hansen Nailgrowth Miracle Products: (1) cause or enhance fingernail growth; (2) cause or enhance fingernail growth in "5 days" or "14 days"; and (3) will cause even more significant results when used in conjunction with other Nailgrowth Miracle Products. For all of the reasons set forth below, these claims do not match the relevant science, are not substantiated, and are false and misleading to consumers.

1. The "30%" and "59%" Increased Growth Claims

Coty's most outlandish claims are its guarantees of "30%" increased growth in "5 days" and "59%" increased growth in "14 days" for Nailgrowth Miracle Salon Strengthening/Color Treatments and Nailgrowth Miracle Serum respectively. Fingernail growth is affected by numerous factors including age, gender, season, exercise level, diet, and hereditary factors. Anatomically, the growing part of the nail, the germinal matrix, is located under the epidermis at the nail's proximal end. (See Exhibit A). This is the only living part of the fingernail. As new nail cells are formed, they emerge from the matrix to push the older nail plate cells forward and in this way cause the nail to lengthen or "grow". The portion of the nail plate which is pushed forward (the visible part of the nail) is comprised completely of dead cells. Therefore, in order for a drug or cosmetic product to deliver any purported "growth" benefit, this product would somehow need to permeate the nail plate to reach the only part of the nail which consists of living cells—the germinal matrix.

According to the relevant science, in order to achieve effective transungual drug therapy:

permeation must be enhanced....by disrupting the nail plate using physical techniques or chemical agents. . . . which have been shown to enhance transungual delivery. They include nail abrasion (manual and electrical), acid etching, ablation by lasers,

Cal. Business & Professions Code §17508 provides: "It shall be unlawful for any person doing business in California and advertising to consumers in California to make any false or misleading advertising claim, including claims that (1) purport to be based on factual, objective, or clinical evidence, (2) compare the product's effectiveness or safety to that of other brands or products, or (3) purport to be based on any fact."

In order to serve as adequate substantiation, scientific testing must be (1) "internally valid," (2) consistent with the totality of available evidence, and (3) relevant to the product and claims at issue. See FTC, Dietary Supplements: An Advertising Guide for Industry (1998) at pp. 8-18.

microporation, application of low-frequency ultrasound and electric currents, and chemicals (thiols, sulphides, hydrogen peroxide, urea, water, enzymes). "

See Exhibit A, (internal citations omitted). See also Transungal Drug Delivery: Current Status, International Journal of Pharmaceutics, Volume 384, Issues 1-2 (January 2010).

There are no scientific studies that exist to support the bold claim that a *cosmetic* product, applied topically to a fingernail, with or without enhanced permeation, can provide growth or strengthening benefits to the nail. That is precisely what Coty is representing to unwary consumers through its aggressive marketing of the Sally Hansen Nailgrowth Miracle product line.

The level of precision in its guarantees of growth only makes Coty's claims more preposterous. It is well accepted in the scientific community that for the average person, fingernails grow approximately 3 mm every thirty days. In fact, recent studies have indicated that this figure may actually be closer to 3.5 mm every thirty days, particularly in younger individuals. See, e.g., Yaemsiri, S., et al., Growth Rate of Human Fingernails and Toenails in Healthy American Young Adults, Journal of the European Academy of Dermatology and VENEREOLOGY, at 420-423 (2010).⁴ Assuming this rate, the average person's fingernail will grow .5 mm every 5 days without the use of any product whatsoever. Coty's guarantee of a 30 percent increase in growth in 5 days would be the equivalent to an increase in growth of approximately .17 mm, less than two-tenths of a millimeter. Coty would have needed to have conducted large scale double blinded placebo controlled studies to support such aggressive and precise claims, and even if Coty did conduct these studies and measured using precision measuring devices or a "fixed point nail measurement" as indicated on its website and product packaging, it is not possible to generate the statistical certainty that would be required to support these claims.⁵ Moreover, an increase in growth this miniscule is nearly imperceptible to the human eye. This directly contradicts Coty's claim of "visibly" longer nails. Thus, if Coty were able to deliver on its promise of a "miracle" to its customers, it should also include a microscope so that this "miracle" could be perceived by consumers.

It is also important to note that it is of no consequence whether the Sally Hansen Nailgrowth Miracle Products are applied to the cuticle or under the nail tip of the nail rather than just directly to the nail plate. The Nailgrowth Miracle Serum is referred to as a "nail and cuticle treatment" on the packaging and this seems to imply a distinction between these two parts of the nail regarding product application. Coty also instructs consumers on the product packaging to massage the product into each "nail and cuticle". However, like the nail plate, neither the cuticle nor the tip of the nail is in contact with the germinative or "growing" cells and therefore cannot impact growth. Applying these products to any of these areas still simply results in applying product to "dead" cells which have no biological activity and therefore cannot impact growth.

⁴ For the purpose of evaluating these claims we will assume the conservative figure, an average growth rate of 3 mm per month.

⁵ The same logic applies to Coty's claims of "59%" increased growth in 14 days for Nailgrowth Miracle Serum.

In short, Coty does not possess the requisite scientific basis to claim that the Sally Hansen Nailgrowth Miracle Products can cause or enhance fingernail growth when applied as directed. As such, any reference to nail "growth" should be discontinued, as that claim is false and misleading.

2. The "5 day" and "14 day" Claims

As noted above, it is physiologically impossible for the Sally Hansen Nailgrowth Miracle Products to permeate the nail plate and affect finger nail growth. As such, there simply is no scientific support for that general claim. It follows, then, that it is also not possible for the purported "growth" to occur in "5 days" or "14 days" as is prominently asserted in Coty's advertising and marketing. To put it as simply as possible, those claims have no valid basis in the science, and are, too, false and misleading.

3. The "Use Together" Claims

It also logically follows then that if these products have no ability to provide any "growth" benefit individually, there is nothing to support the outlandish claim that they would provide an even more significant benefit when used together. This is clearly just a ploy designed to induce consumers to purchase additional Sally Hansen products.

Based upon the above, it is clear that Coty has engaged in false and deceptive advertising related to Sally Hansen Nailgrowth Miracle Products, as these products are incapable of delivering the primary benefits claimed. Furthermore, if Coty does believe that Sally Hansen Nailgrowth Miracle Products do deliver on these claims, and affect bodily function or structure, Coty would be knowingly and willfully selling a misbranded drug product that falls under the authority of the FDA. In either event, Coty is violating the CLRA through its unsubstantiated claims.

C. Demand for Relief

Pursuant to Civil Code section 1782(a)(2), Plaintiff demands that Coty agree to cure its violations of the CLRA as follows:

1. Changes to the Advertising of Sally Hansen Nailgrowth Miracle Products

On behalf of Plaintiff and the Plaintiff Class, we demand that Coty agree to stop the wrongful practices identified herein. Specifically, Plaintiff demands that Coty make the following changes to the Sally Hansen Nailgrowth Miracle Product advertising:

- a. Discontinue the "growth" claims and any reference to "growth" or "30%" or "59%" increased growth on the product packaging or advertising;
- b. Discontinue the "5 day" and "14 day" claims; and

c. Discontinue the claims that these products provide additional benefits when used together.

2. <u>Identify Purchasers</u>

In addition, pursuant to *Civil Code* section 1782(c) Plaintiff requests that Coty identifies or makes a reasonable attempt to identify the current and former California purchasers of its Sally Hansen Nailgrowth Miracle Products.

3. Recall of Misbranded Product

In addition, we demand that Coty institute a recall program, to be approved and supervised by us, as counsel to Plaintiff and the Plaintiff Class, of all Sally Hansen Nailgrowth Miracle Products in California that presently has packaging or labeling that contains any of the claims identified above.

4. Restitution to Plaintiff and Plaintiff Class

Finally, we demand that you provide Plaintiff and the Plaintiff Class restitution. Specifically, Plaintiff demands that Coty establish a consumer fund in an amount sufficient to provide each and every class member with a refund for each and every Sally Hansen Nailgrowth Miracle Product purchased during the Class Period.

Of course, the amount of restitution would be subject to our review, as class counsel, of appropriate financial information detailing all sales made to California consumers during the Class Period. We also demand that Coty provide for all costs, reasonable attorneys' fees and claims administration costs.

If you have an interest in discussing these issues, please contact me at 310-356-4668 or pif@beshadafarneselaw.com. If we do not hear from you by May 7, 2012, we will assume that Coty has no interest in attempting to amicably resolve this matter short of litigation and we will proceed accordingly.

Thank you.

Sincerely,

Peter J. Farnese

Encl.

cc:

Donald A. Beshada, Esq. (via email only)

EXHIBIT A

EXHIBIT A

PARTICLE SCIENCES

DRUG DEVELOPMENT SERVICES

Skin and Nail: Barrier Function, Structure, and Anatomy Considerations for Drug Delivery

Drug delivery to and through both skin and nails is an area receiving ever-increasing attention. In order to effectively deliver active pharmaceutical ingredients (APIs) across the skin (transdermal delivery) or nail (transungual delivery) it is necessary to consider the anatomy and physiology of these barriers. With this information in hand, one can more effectively utilize drug delivery approaches to maximize the effectiveness of the API - getting the right amount to the right place at the right time. The advantages of local delivery include, among others, minimized systemic toxicity, high local drug concentrations, avoidance of first pass issues and cost.

Topical delivery of systemic therapeutics also offers benefits but presents a greater technical challenge. Among the benefits, first pass avoidance, convenience and sustained release are most often sited.

Skin: The skin is the largest organ in the body, making up 12 - 15% of body weight and with a surface area of 1 - 2m2. Not surprisingly, the skin has a complex architecture that can vary depending on body location (Figure 1).

There are 3 distinct regions in the skin. From outermost inward. they are the epidermis, dermis and subcutis (hypodermis). The epidermis itself has five regions and can range in total thickness from 0.5mm (eyelid) to 1.5mm on the palms and soles (Figure 2).

The most important function of the skin is to provide a selectively permeable barrier. The outermost region of this barrier is called the stratum corneum (SC), a dynamic structure with cells migrating in a deep to superficial direction as they mature. The SC, also called the horny layer, consists of cells called corneocytes that are em-

Figure 1 SKIN ARCHITECTURE Hair shaft Sweat pore **Epidermis** Arrector pili muscle Dermis Sebaceous gland Hair follicle Nerve fiber Subcutis (hypodermis) Sweat gland Vein Artery Particle Sciences

bedded in a multilamellar, lipidenriched extracellular matrix. It takes approximately 24 hours

The SC comprises, depending on location, approximately 15 layers of horny cells. The transit time of the horny cells across the epidermis is approximately 1-2 weeks.

to form one layer and the SC is completely renewed about every 15 days. In addition to the skin, there is a relatively large area of accessible mucosal tissue. This includes the conjunctiva, nasal and oral cavities, respiratory tract. digestive tract, vagina, urethra

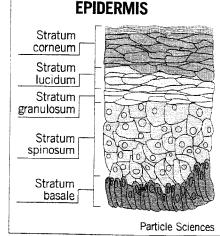
> and rectum. Each of these areas has a unique histology that, for the most part, make them more permeable to many drugs compared to skin or nails. For instance, these surfaces may have a substantially reduced keratinized layer, or lack one altogether, greatly reducing barrier function. Being at the interface of the body and internal spaces, mucosal areas have highly developed transport mechanisms for dealing with foreign bodies such as

the ciliated epithelium found in the respiratory tract. Many mucosal surfaces have a single-cellthick epidermis and most are highly vascularized. Of course, mucosal surfaces are "wet" which has obvious implications for drug transport. Mucosal surfaces have unique immunologic properties, specific to the anatomical site. Several mucosal surfaces are already regularly exploited for local and systemic drug delivery.

There are three routes for transit of substances through the epidermis: Appendagael, Transcellular, and Intercellular. Appendagael transport refers to the use of hair follicles and sweat glands. As areas of discontinuity in the SC, they can serve as a pathway for API penetration. The significance of their contribution to percutaneous absorption has been extensively investigated. Although it is estimated that these appendages account for no more than 0.1% of the total skin surface, they cannot be neglected in considering possible routes of percutaneous absorption. For instance, iontophoresis, which is a non-invasive method for transdermal delivery of charged APIs using electromotive force, appears to dramatically increase the flux of compounds via hair follicles.

The transcellular pathway involves the movement of the API across the epithelial cell. The outer membrane of an epithelial cell may be regarded as a layer of lipid, surrounded on both sides by water. Low molecular weight and lipophilic APIs can gain systemic access transcellularly, by passive diffusion across the epithelial cells. In the process of passive diffusion, lipid-soluble substances move into the lipid membrane according to their lipid/water partition coefficient. The structural

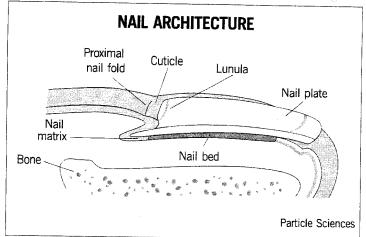




features of compounds that determine permeability are related to hydrophobicity and molecular volume. In transcellular passive diffusion, the epithelium is assumed to act as a simple lipophilic barrier through which APIs diffuse and the rate of diffusion correlates with the lipid solubility of the API.

Lastly, drugs can travel between cells via intercellular channels. It is generally accepted that the extracellular SC lipids play a key role in limiting the diffusion of compounds through the SC. Lipids exist in bilamellar structures in the SC extracellular space, each layer separated from the other by a thin water sheet associated with the polar head group of the lipids. The intercellular lipids are organized into lamellae, which run parallel to the skin surface. Intercellular lipid is required for a competent skin barrier and forms the only continuous domain in the SC - a structural feature that may account, in part, for the barrier properties of the skin. The molar ratio of the barrier lipids were found to be cholesterol ester (15%), saturated long chain free fatty acids (16%), cholesterol (32%) and ceramides (37%). Chemical penetration enhancers generally act through disruption of the extracellular structure.

The three pathways described above are not mutually exclusive and permeation will be determined by the area/volume of the pathway, partitioning, and diffusivity of the API in each pathway. Transport across the SC, for most compounds, involves intercellular lipids. However, it does not exclude the possibility that APIs also penetrate the cornecytes. The molecular basis for the penetration pathway across the SC should be considered in terms of its morphological structure and material properties. Both the composition and structure of the SC influences its material properties, which in turn determines the pathway for diffusion as well as the solubility and diffusivity of



API within the barrier.

It is essential to understand the inherent ability of an API to penetrate the SC before studying to what extent the penetration can be enhanced or reduced by appropriate choice of formulation. The relationship between the structure of a API and its permeability across the skin provides insight into the nature of the permeability barrier and is directly applicable to the prediction of percutaneous absorption.

Nails: Nails and claws of mammals are specialized epidermal derivatives which protect the delicate tip of fingers and toes against trauma and act as tools or weapons. Human fingernail gross anatomy consists of three structures. Starting from the outer structure, they are the nail plate, the nail bed, and the nail matrix (Figure 3 [1]).

The nail plate is a thin (0.25 -0.6mm for fingernails and up to 1.3mm for toenails), hard, yet slightly elastic, translucent, convex structure and is made up of approximately 25 layers of dead keratinized, flattened cells. They are tightly bound to one another via numerous intercellular links, membrane-coating granules and desmosomes, which are cell structures specialized for cell-to-cell adhesion and randomly arranged on the lateral sides of plasma membranes. The fingernail has a three-layer structure (outer to inner) - the dorsal, intermediate.

and ventral layers, with a thickness ratio of approximately 3:5:2, respectively. The dorsal outer layer is dense and hard, consisting of cornified keratin only a few cells thick (approximately 200µ). The cells at the dorsal surface of the plate overlap and produce a smooth surface. The intermediate layer, in contrast to the dorsal layer, shows highly fibrous structure oriented in a direction perpendicular to the direction of nail growth and constitutes roughly 75% of the plate's thickness. The keratin fibers are thought to be held together by globular, cysteine-rich proteins, whose disulfide bonds act as glue. The intermediate layer is believed to be both the softest and thickest. The ventral layer is very thin and consists of a few layers of cells which connect the nail plate to the nail bed below.

The growth rate of nails is highly variable among individuals, with average values of 3mm per month for fingernails and 1mm per month for toenails. A normal fingernail grows out completely in about 6 months, whereas it takes a toenail about 10 – 12 months [1].

The physicochemical properties of the human nail plate exhibit a marked difference to that of epidermis, resulting in very different permeability characteristics. Whereas the SC behaves as a lipid barrier to the permeation of low MW chemicals, the nail plate exhibits behaviors similar to that of

a hydrogel with high ionic strength and, indeed, the structure of human nail has been likened to a hydrophilic gel membrane [2]. The lipid content of the nail is reported to be low, at between 0.1 - 1%, and the nail is much more susceptible to water loss than the lipid-rich skin. Despite the reported hydrophilic properties of the nail, hydrophobic compounds also have been shown to diffuse into and through this barrier. For example, Walters and coworkers [3] reported that long chain alcohols also permeate through the nail via a lipidic pathway.

For effective transungual drug therapy, permeation must be enhanced. This can be achieved by disrupting the nail plate using physical techniques or chemical agents. Alternatively, drug permeation into the intact nail plate may be encouraged, for example, by iontophoresis or by formulating the drug within a vehicle which enables high drug partition out of the vehicle and into the nail plate.

There are several physical techniques that have been shown to enhance transungual delivery [4]. They include nail abrasion (manual and electrical), acid etching, ablation by lasers, microporation, application of low-frequency ultrasound and electric currents, and chemicals (thiols, sulphides, hydrogen peroxide, urea, water, enzymes).

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