H. INDUSTRY FAILURE TO REMOVE NICOTINE FROM TOBACCO DESPITE AVAILABLE TECHNOLOGY

The tobacco industry has developed, over several decades, technologies to selectively remove nicotine from tobacco. This capability is evidenced by the various patents for methodologies to extract nicotine from tobacco,[597] attempts to market denicotinized cigarettes,[598]

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[597] *See, e.g.:*

U.S. Patent No. 3,139,435. Staley J, Clarke AB. *Process for Selective Extraction of Alkaloid.* Philip Morris Inc. June 30, 1964.

U.S. Patent No. 4,557,280. Gravely LE, Geiss VL, Knobs F, Gregory CF. *Process for Reduction of Nitrate and Nicotine Content of Tobacco by Microbial Treatment.* Brown and Williamson Tobacco Corporation. December 10, 1985.

U.S. Patent No. 3,046,997. Hind JD. *Selective Alkaloid Extraction.* Philip Morris Inc. July 31, 1962.

U.S. Patent No. 4,068,671. Casey WJ. *Nicotine Removal Process.* AMF Inc. January 17, 1978.

U.S. Patent No. 4,821,749. Toft HC, Smith KW, Carpenter CR. *Extruded Tobacco Materials.* R.J. Reynolds Tobacco Company. April 18, 1989.

U.S. Patent No. 5,018,540. Grubbs HJ, Prasad R, Howell TM. *Process for Removal of Basic Materials.* Philip Morris Inc. May 28, 1991.

U.S. Patent No. 5,119,835. Heeman V, Schmekel G, Ebling U, Hauser B, Koene CH, Rabitz H. *Method for Extracting Tobacco Alkaloids.* B.A.T. Cigarettenfabriken GmbH. June 9, 1992.

U.S. Patent No. 4,898,188. Niven Jr BF, Mays CD. *Tobacco Processing.* R.J. Reynolds Tobacco Company. February 6, 1990.

U.S. Patent No. 4,967,771. Fagg BS, Frederickson JD. *Process for Extracting Tobacco.* R.J. Reynolds Tobacco Company. November 6, 1990.

U.S. Patent No. 4,150,677. Osbourne Jr JS, Hartung HA, Bebbs Jr JF. *Treatment of Tobacco.* Philip Morris Inc. April 24, 1979.

U.S. Patent No. 5,065,775. Fagg BS. *Tobacco Processing.* R.J. Reynolds Tobacco Company. November 19, 1991.

European Patent No. 280,817. Grubbs HJ, Prasad H, Howell TM. *Process for Removal of Basic Materials.* Philip Morris Inc. Filed on December 24, 1987.

[598] Citizen Petition submitted by the American Heart Association, the American Lung Association and the American Cancer Society, acting as the Coalition on Smoking OR Health, to the U.S. Food and Drug

and industry practices.[599] Despite these denicotinization methods, the tobacco industry uniformly leaves nicotine, an addictive substance, in cigarettes and smokeless tobacco products at levels that are high enough to maintain a pharmacological response in consumers. See FINDINGS § I.C. The fact that tobacco manufacturers could remove an addictive substance from their products, yet choose to leave nicotine in their products at specified levels, demonstrates the tobacco industry's intent to market products that affect the structure and function of the body.

FDA recognizes that the mere existence of a patent is not confirmation that the patent holder is using the invention claimed in the patent. Evaluation of the type and scope of patent assignments to an individual company does, however, provide evidence of the capabilities and interests of the individual company. Taken as a whole, evaluation of these particular patents demonstrates the tobacco industry's capabilities and technologies available for removing nicotine from tobacco.

Patents assigned to several of the major cigarette manufacturers demonstrate that the industry has been investigating, and has at its disposal, various ways to remove nicotine from tobacco. Many of these patents are for technologies that selectively remove nicotine while maintaining the integrity and utility of the rest of the tobacco.[600]

Administration, requesting Classification of "NEXT" and other DeNicotinized Cigarettes as Drugs under the Food, Drug, and Cosmetic Act. FDA Docket No. 91P-0144, submitted April 8, 1991.

[599] Browne C. *The Design of Cigarettes*. Hoechst Celanese. 1990. Page 43. (The process of manufacturing reconstituted tobacco removes nicotine from the tobacco and most cigarettes contain about 20% reconstituted tobacco.)

[600] *See:*
U.S. Patent No. 3,139,435, note 597, *supra.*

More than 30 years ago Philip Morris was assigned a patent that "relates to an efficient process for selective extraction of nicotine and other alkaloids from tobacco while not materially affecting the content or properties of waxes, aromatics, flavoring, and other constituents of the tobacco."[601] Philip Morris subsequently patented an invention that the company claimed improved prior processes in the ability to extract nicotine from tobacco.[602] The claimed improved invention provided a "simpler and less expensive means for removing nicotine."[603]

R.J. Reynolds also has patented several solvent extraction processes which first produce a tobacco extract and then denicotinize the extract.[604] One particular patent is for a process that removes and then redistributes certain components of a tobacco material.[605] The patent describes the ability to provide a denicotinized tobacco material in which 95% of the nicotine is removed.

A different type of patented extraction process that significantly reduces the nicotine content of tobacco uses ammonia as an exudant. RJR was assigned a patent for this type of denicotinization process.[606]

U.S. Patent No. 3,046,997, note 597, *supra.*
U.S. Patent No. 5,018,540, note 597, *supra.*
U.S. Patent No. 4,967,771, note 597, *supra.*
U.S. Patent No. 4,068,671, note 597, *supra.*

[601] *See* U.S. Patent No. 3,046,997, note 597, *supra.*

[602] *See* U.S. Patent No. 3,139,435, note 597, *supra.*

[603] *Id.* at C:51-52.

[604] *See* U.S. Patent No. 4,967,771, note 597, *supra,* at C2:31-33. (Provides for the removal of greater than 95% weight percent of the nicotine.)

See also U.S. Patent No. 5,065,775, note 597, *supra.*

[605] *Id.* U.S. Patent No. 5,065,775, C1:39-43.

[606] *See* U.S. Patent No. 4,821,749, note 597, *supra.*

Several cigarette manufacturers, including Philip Morris, BATCO, and RJR, have been awarded patents over the last 5 years for supercritical extraction[607] procedures that can selectively remove nicotine from tobacco.[608] In a Philip Morris patent for a supercritical extraction process, the patent states that one of the objects of the invention is transferring "nicotine from one tobacco substrate (leaf material or reconstituted leaf) to a second tobacco substrate (leaf material, reconstituted leaf material, or tobacco stems) or to a non-tobacco substrate."[609] An RJR patent describes the company's patented process for extracting tobacco components from tobacco material for transfer to a "smokable material" that is "suitable for use and/or processing for the manufacture of . . . cigarettes."[610] The component to be extracted, as claimed in the patent, is nicotine.[611]

Brown and Williamson and its parent company, BATCO, have patented several processes

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[607] Supercritical extraction processes use solvents that are in their supercritical state. This means that the solvent is above its critical point with respect to temperature and pressure. (U.S. Food and Drug Administration. Center for Food Safety and Nutrition. Office of Plant & Dairy Foods and Beverages. Division of Natural Products. What is Supercritical Fluid? Standard Guide for Supercritical Fluid Chromatography Terms and Relationships.) Most of the patents use carbon dioxide (CO_2) as the solvent. As described in one of the patents, critical CO_2 occurs when the CO_2 temperature is above its critical temperature of 31.3° C in its gaseous phase under high pressure, e.g., 70 to 1500 atmospheres pressure. U.S. Patent No. 4,153,063. Roselius W, Vitzthum O, Hubert P. *Process for the Extraction of Nicotine from Tobacco.* Studiengesellschaft Kohle mbH. May 8, 1979. C-1.

[608] *See:*
U.S. Patent No. 5,018,540, note 597, *supra.*
U.S. Patent No. 5,119,835, note 597, *supra.*
U.S. Patent No. 4,153,063, note 607, *supra.*
U.S. Patent No. 4,898,188, note 597, *supra.*
European Patent No. 280,817, note 597, *supra.*

[609] *See* U.S. Patent No. 5,018,540, note 597, *supra,* at C2:39-43.

[610] *See* U.S. Patent No. 4,898,188, note 597, *supra,* at C5:12-14.

[611] *Id.* at C9:10-11.

for denicotinizing tobacco by exposing the tobacco to microbes.[612] The processes in these patents are based on the recognition that when tobacco is inoculated with certain types of microorganisms for a specified period of time the nicotine is degraded. The longer the tobacco is exposed to the microorganism, the more nicotine is degraded.

Further evidence of the ability of the tobacco industry to remove nicotine is seen in the marketing of a cigarette that was advertised as "de-nicotined." In 1989, Philip Morris test-marketed a cigarette, NEXT, that contained less than 0.1 milligrams of nicotine. The company's own advertisements for NEXT announced that a process called the "FreePLUS" system "naturally extract[s] nicotine from fine tobaccos, . . . with rich tobacco flavor and less than 0.1 mg nicotine."[613] This product was withdrawn from the market shortly after it was introduced for test-marketing.

Despite this arsenal of nicotine-removing technologies, all brands of currently marketed cigarettes contain levels of nicotine that are sufficient to maintain a pharmacological response in smokers. Although cigarette manufacturers have the ability to market denicotinized tobacco products, to date there has not been any serious attempt, except for NEXT cigarettes, to market these types of products. All cigarettes on the market today have, and deliver, levels of nicotine

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[612] *See:*
U.S. Patent No. 4,557,280, note 597, *supra.*

U.S. Patent No. 4,037,609. Newton RP, Geiss VL, Knobs F, Jewell JN, Gravely LE. *Process for Reduction of Nicotine Content of Tobacco by Microbial Treatment.* Brown and Williamson Tobacco Corporation. July 26, 1977.

U.S. Patent No. 4,038,993. Geiss VL, Knobs F, Gregory CF, Newton RP, Gravely LE. *Process for Reduction of Nicotine Content of Tobacco by Microbial Treatment.* Brown and Williamson Tobacco Corporation. August 2, 1977.

[613] Package label for NEXT brand cigarettes.

that maintain an addiction to the product. These levels are deliberately maintained by the manufacturers. Because tobacco manufacturers can control the amount of nicotine, and even remove nicotine altogether if they choose, it is evident that manufacturers intend to market cigarettes and smokeless tobacco products that affect the structure and function of the body.