



## A CRITICAL ANALYSIS OF INTELLECTUAL PROPERTY PROTECTION FOR NUTRACEUTICALS IN INDIA

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### ABSTRACT

Food and nutrition play a major role in maintaining not only one's health but also majorly impacts the economy of a nation. The Food and Agricultural Organization (FAO) of the United Nations' key focus is on public health, which is also one of its Sustainable Development Goals of 2030, that directs the health supplements and nutraceuticals to fit in the consumer market. The Food Safety and Standards Authority of India (FSSAI) has enacted regulations on nutraceuticals in India on Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food. This research spotlights the importance of nutraceuticals in the current Indian scenario, where the whole world is trying to foster immunity and health with the aid of additional nutritional supplements. India is one of the major contributors of nutraceuticals in the global market, the research

also walks through the pros and cons of patenting nutraceuticals in India. The study highlights a few suggestions that would encourage the nutraceutical industry and improvise the growth of Indian novel nutraceuticals in the global market with Indian patent protection.

**Keywords:** Health supplements, Nutraceuticals, Novel, Patent, Public health.

### INTRODUCTION

In today's hustles and strenuous fast-moving world people's preferences for food are based on its appearance and on the advertisements of processed and refined food products. The trend of focusing on the sensory evaluation of foods has turned towards modern food innovations and food technologies superseding the traditional approach of sensory and basic nutritive value of food prioritizing health and nutrition-loaded foods.<sup>2</sup> The current lifestyle and food systems also

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<sup>2</sup> Food, Agriculture Organization Of The United Nations. Combating Iron Deficiency: Food-Based Approaches, [www.fao.org/docrep/013/am027e/am027e00.pdf](http://www.fao.org/docrep/013/am027e/am027e00.pdf). (last visited Jan.2, 2023).

demand an increase in nutraceuticals and other health supplements.<sup>3</sup>

Hippocrates' adage, "Let food be thy medicine", has been replaced by the term nutraceuticals' which was first coined by Stephen DeFelice in 1989 to describe nutraceuticals as "a food or part of a food that has medical or health benefits, including the prevention and treatment of disease."<sup>4</sup> The term nutraceutical means 'nutrition' and 'pharmaceuticals'. Though the terms pharmaceuticals and nutraceuticals exhibit similarities and overlap functional components they lack compendious definitions and legal regulations. The key differences between pharmaceuticals and nutraceuticals are that pharmaceuticals are medicinal drugs and food plays a major part in nutrition in nutraceuticals.

Nutraceuticals are isolated and concentrated forms of food as a medicine in powder, pill, or other medicinal forms that enhances overall immunity, alleviate other chronic diseases, and increase life expectancy.<sup>5</sup> Nutraceuticals are neither a mere mixture of vegetables or animal products nor any other food in their mere form, it is a formulation of substances of food scientifically proven to overcome or support the health aspects of sound medicine or nutrition<sup>6</sup>. Nutraceuticals can be either from traditional sources such as nutrients, herbals, spices, phytochemicals, nutraceutical enzymes, prebiotics, and probiotics or from non-

traditional sources such as fortified nutraceuticals and recombinant nutraceuticals.<sup>7</sup>

Nutraceuticals play a significant role in current trends in the food industry and healthcare sectors as an adjunctive aid in the treatment of illnesses bridging the mere gap between nutrition and medicine. Functional foods are fortified food with micronutrients to enhance nutrition and to meet the essential requirements for one's health with the possibility of reduced intake of conventional medications which otherwise might have adverse effects eventually.<sup>8</sup> The objective of the study is to analyze the patentability of nutraceuticals under Section 3(d) of The Patents Act, 1970 in India.

## NUTRACEUTICALS AND PUBLIC HEALTH

Nutraceuticals play a vital role in providing the right amount of nutrients to foster the health systems in combating diseases in preventing health disorders or diseases. To mention a few evidentiary studies on the administration of nutraceuticals to certain diseases for the betterment of the patients are: firstly found in Alzheimer's – a neurodegenerative disorder affecting cognitive functions due to dementia predominantly found in aged individuals.<sup>9</sup> Secondly, diabetes mellitus is another dominant disorder globally which if uncontrolled in a long run would lead to other health complications that can be prevented by nutraceutical supplements toward a balanced

3 DEBASIS BAGCHI, "NUTRACEUTICALS AND FUNCTIONAL FOOD REGULATIONS IN THE UNITED STATES AND AROUND THE WORLD", Book: 2008: <https://1lib.in/book/1088469/d7ba63>.

4 DeFelice - definition on nutraceuticals, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5338166/> Last visited on: 6 December 2021.

5 Nasri, H., Baradaran et al., "New concepts in nutraceuticals as alternative for pharmaceuticals." International Jnl. of Preventive Medicine, 5(12), 1487–1499. (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4336979/> Last Visited Jan. 3, 2023.

6 NUTRACEUTICAL/ FSSAI-2013, [https://fssai.gov.in/upload/uploadfiles/files/Nutraceuticals\\_Regulations.pdf](https://fssai.gov.in/upload/uploadfiles/files/Nutraceuticals_Regulations.pdf). Last visited Dec.8, 2021.

7 EGBUNA CHUKWUEBUKA ET AL, FUNCTIONAL FOODS AND NUTRACEUTICALS BIOACTIVE COMPONENTS, FORMULATIONS AND INNOVATIONS, 17 (2020).

<https://doi.org/10.1007/978-3-030-42319-3>

8 Gamal Osman Elhassan et al, "Nutraceuticals – An opportunity of healthcare: A review.", Article PHARMACEUTICAL JRNL., <https://www.researchgate.net/publication/311876288> Last visited on: 8 December 2021.

9 Khan et al., "Nutraceuticals – An opportunity of healthcare: A review", Article reviewed on December 2016 in WORLD JRNL. OF PHARMACEUTICAL RESEARCH, <https://www.researchgate.net/publication/311876288>. Last Visited Dec.8, 2022.

diet to maintain a healthy active life.<sup>10</sup> Even in gestational diabetes mellitus, nutraceuticals have played a vital role in balancing insulin levels to normal.<sup>11</sup> The worldwide common disorder obesity is a malnutrition deficiency where the imbalance in the weight management program, and nutraceuticals aid in increasing the metabolism rate in the body to burn more calories in the long run to prevent obesity.<sup>12</sup> Thirdly, in Osteoporosis and Osteoarthritis on a precautionary mode administration of nutritional supplements to aged people on a regular advisory basis prevents the occurrence of such disorders in the future.<sup>13</sup> These evidentiary examples show the importance and positive effects of nutraceuticals and other health supplements on public health.

### **Role of Nutraceuticals in Foods**

The change in the trend of consumers' food preferences, health consciousness, and eating habits impacts the social environment giving way to the emerging need for nutraceuticals and health supplements as a part of the dietary nutritional requirements. Food and Agricultural Organization (FAO) has recommended infant formulas and health supplements for infants and children to combat the daily nutritional requirements. FAO specifies specifications on the admixture of the infant formula as infant formula cannot be a substitute for breast milk in any way.<sup>14</sup> Any product

that poses health concerns must pass through strict regulations,<sup>15</sup> and in India, FSSAI govern nutraceuticals, functional foods, and other health supplements.<sup>16</sup>

COVID-19 (2019-nCoV) pandemic and epidemic in 2020 increased the grave need to focus on public and individual health with essential nutrients to sustain and maintain a healthy life. During the COVID-19 epidemic around four lakhs were initially confirmed COVID-19 positives where a substantial reduction to 9600+ was noted with the aid of vaccines and due to public awareness of immunity system supplements, which had increased a huge demand for nutraceuticals in India and the global market. Another recent initiative towards public health is the Food Safety and Standards (Nutra) Regulations, 2022<sup>17</sup> which combines all the other health supplements and dietary supplements into one category as 'Nutra' as health supplements.

### **IPRS AND NUTRACEUTICALS**

Emerging innovations in food, health, and nutrition are a tribute to the Intellectual Property Rights that grandeurs statutory protection such as Patents, Trademarks, Trade secrets, Geographical Indications, Copyrights, Plant Varieties and Farmers' rights. Worldwide patents play a major role in every innovation industry including

- 10 Derosa, G., Limas, C. P., et al. "Dietary and nutraceutical approach to type 2 diabetes." Archives of medical science: AMS, 10(2), 336–344. 2014. <https://doi.org/10.5114/aoms.2014.42587>. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4042055/>, Last Visited May. 8, 2022.
- 11 Khan et al., "Nutraceuticals – An opportunity of healthcare: A review", WORLD JRNL. OF PHARMACEUTICAL RESEARCH, <https://www.researchgate.net/publication/311876288>.
- 12 Chintale G Ashwini et al, "Role of nutraceuticals in various diseases", INTL JRNL OF RESEARCH IN PHARMACY AND CHEMISTRY, <http://www.ijrpc.com/files/17-382.pdf>.
- 13 David Appleton et al, "Building bones with nutraceuticals", THE PHARMACEUTICAL JRNL., 15 July 2006 <https://pharmaceutical-journal.com/article/ld/building-bones-with-nutraceuticals> , Last visited Jan.4, 2022.
- M. K. PANDEY, S. C. GUPTA, ET AL. "Dietary nutraceuticals as backbone for bone health." BIOTECHNOLOGY ADVANCES, 36(6), 1633–1648, (2018).
- 14 Helal, N. A., Eassa, H. A., Et al. "Nutraceuticals' Novel Formulations: The Good, the Bad, the Unknown and Patents Involved." RECENT PATENTS ON DRUG DELIVERY & FORMULATION 13(2), 105–156 (2019).
- 15 Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, 2016 Acts of Parliament amended by FSS(Nutra) Regulations, 2022.
- 16 Guidance note on Food for Special Medical Purpose (FSMP) 2020 Guidance note of Parliament, 2020 (India).
- 17 FSS(Nutra) Regulations, 2022. Acts of Parliament, 2022.

nutraceuticals and healthcare supplements. IPR fosters protection from commercial exploitations and attracts investors while keeping an eye on the infringers, especially on the soon-to-be-launched patentable product where disclosure of the confidentiality of the product information is protected under the “provisional patent application” for a period of twelve months. Even though there are no explicit provisions of law that restrict the patent protection for nutraceuticals in India but indirectly it had been restricted under Section 3 of the Patents Act, 1970<sup>18</sup>, but such patented nutraceuticals from other countries are imported and permitted in the Indian market under ‘*New Drugs and Clinical Trials Rules 2019*’<sup>19</sup> where human clinical trials are waived off once it has been approved and sold in other countries. This acceptance from consumers and the Indian government proves that there is a grave need for nutraceuticals from a public health perspective, but the imported nutraceuticals in the Indian market are suppressing the patent-worthy nutraceuticals that has an indirect impact from an economic perspective in India.

The gap in the protection of Indian nutraceutical innovation has a profound impact on such an industry that indirectly pressures the reverse engineering of such nutraceuticals that holds patent protection globally but are unshielded in India. The lack of motivation and encouragement for our Indian scientists and their novel nutraceutical innovations demotivates the scientists and makes them move to other countries for obtaining patents. In some instances, such novel innovations

of nutraceuticals are patented in other countries and imported to India or Indian innovators join hands through mergers and acquisitions with other countries for their patent protection. This makes one think about the law on patentable inventions in support of nutraceuticals from public health and economic perspective.

Worldwide, globalization, fast-moving lifestyle adjustments, other environmental factors, and stress demand the need for the nutraceuticals market.<sup>20</sup> The research sources state that there is a huge market demand for nutraceuticals worldwide, especially in the United States and it is noted that our Indian nutraceuticals hold a substantial demand for the nutraceutical market globally.<sup>21</sup> The market analysis of the nutraceutical market is expected to have an annual growth rate of 9.0% from 2021 to 2030 on consumer demand of USD 826 Billion.<sup>22</sup> This makes one think that when there is a demand for our Indian nutraceuticals in the global market then there is a grave need for intellectual property protection at national and international levels from public health perspectives.

## INTERNATIONAL IP PROTECTIONS FOR NUTRACEUTICALS

IPRs play a major role in the nutraceuticals on the patentability of new and novel food supplements, with their trademarks and trade secrets that have a greater impact on public health globally. Article 31(b)<sup>23</sup> of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and “*Doha Declaration on the TRIPS*

18 The Patent Act, 1970. No. 3, Acts of Parliament, 1970 (India), amended by The Patent (Amendment) Act, 2005.

19 New Drugs and Clinical Trials Rules 2019, Rules of Parliament, 2019 (India).

20 Grandview Research.com, “*Nutraceuticals Market Size, Share & Trends Analysis Report By Product (Dietary Supplements, Functional Food, Functional Beverages), By Region (North America, Europe, APAC, CSA, MEA), And Segment Forecasts, 2021 – 2030*”, MARKET ANALYSIS, <https://www.grandviewresearch.com/industry-analysis/nutraceuticals-market>, (last visited Jan.4, 2023).

21 Avijeet S chopra et al, “*The current use and evolving landscape of nutraceuticals*”, SCIENCE DIRECT JRNL., <https://www.sciencedirect.com/science/article/abs/pii/S1043661821005855>, (last visited Jan. 4, 2023).

22 Shwetha Sharma, “*Nutraceuticals- Insights on Industry & Associated IP Rights*”, Website Article, <https://sagaciousresearch.com/blog/nutraceuticals-insights-on-industry-associated-ip-rights/>. (last visited Jan.4, 2023).

23 Article 13(b) TRIPS: <http://www.cptech.org/ip/wto/trips-art31.html>



*Agreement and Public Health*”<sup>24</sup> affirms that TRIPS Agreement is to be interpreted and implemented whilst protecting public health and promoting the accessibility of such essential medicines for the benefit of the public at large.

World Intellectual Property Organization (WIPO) plays a predominant role in encouraging new and novel innovations in medical and health-related technology and patent protection and patent flexibility for medical or health needs and supplements in developing nations. WIPO encourages the protection of Traditional Medical Knowledge (TMK) in the IP sense. IP protection prevents unethical and illegitimate access to Traditional Knowledge (TK) and TMK where currently negotiations are underway in the *WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC)*.<sup>25</sup>

World Health Organization (WHO) is an international agency of the United Nations Organizations which is primarily responsible for protecting public health, providing overall nutrition, monitoring, and setting up standards worldwide. WHO plays a major role during epidemics and outbreaks of diseases around the world.<sup>26</sup> The role of WHO extends to monitor the impact of the trade aspects and intellectual property concerning public health and releases the ‘*Model List of Essential Medicines (EML)*’<sup>27</sup> once every two years. WHO has recommended modern medicine as well the traditional medicines as they

contribute to public health at large. It is noteworthy that Traditional Chinese Medicine (TCM) and our ancient ayurvedic medicines are backed by ancient kinds of literature and have gained public confidence globally,<sup>28</sup> and WHO recommends such healthcare measures and traditional medicines to foster public health globally.

The Paris Convention gives international protection on IP rights in a wider sense where the contracting parties are obliged to grant the same national treatment to the other contracting nations. Another protection for non-contracting parties who are domiciled or hold an industrial or commercial establishment in that contracting state is obliged for their IP protections as per the ‘right of priority’<sup>29</sup> on the date of filing the application.

The Patent Cooperation Treaty (PCT) where one international application is filed under the International Patent Treaty under one unified procedure in one contracting State and the protection is guaranteed in all other contracting States. Such application gets published in the International Bureau, WIPO in one of ten languages, which gets parallel patent protection.<sup>30</sup>

The regulations of Codex Alimentarius focus predominantly on the international standards and guidelines on the safety of food and food products. Codex Alimentarius, the FAO and WHO work on a science-based activity with rigorous scientific scrutiny of the experts and scientists in food safety.<sup>31</sup>

24 Doha declaration on the TRIPS Agreement and Public Health, 2002, [https://apps.who.int/iris/bitstream/handle/10665/67345/WHO\\_EDM\\_PAR\\_2002.3.pdf](https://apps.who.int/iris/bitstream/handle/10665/67345/WHO_EDM_PAR_2002.3.pdf), (last visited Jan. 4, 2023).

25 WIPO INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE, AND FOLKLORE (IGC). <https://www.wipo.int/tk/en/igc/>, (last visited Jan. 3, 2023).

26 WHO – WORLD HEALTH ORGANIZATION, <https://www.who.int/>, (last visited Jan. 4, 2023).

27 WHO model list of essential medicines, <https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>, (last visited Jan. 4, 2023).

28 WHO Director-General addresses traditional medicine forum, <https://www.who.int/director-general/speeches/detail/who-director-general-addresses-traditional-medicine-forum>, (last visited Jan. 4, 2023).

29 Paris Convention for the protection of Industrial Property, <https://wipolex.wipo.int/en/text/287556>

30 PCT- PATENT COOPERATION TREATY, <https://ipindia.gov.in/writereaddata/images/pdf/pct-filing.pdf>, (last visited Jan. 4, 2023).

31 CODEX ALIMENTARIUS, [https://www.fao.org/fao-who-codexalimentarius/about-codex/science/it/#jfmulticontent\\_c484221-4](https://www.fao.org/fao-who-codexalimentarius/about-codex/science/it/#jfmulticontent_c484221-4), (last visited Jan.4, 2023);

The Food and Drug Administration (FDA) ensures the safety, efficacy, and security of human drugs and biological products in the nation's food supply on nutraceuticals and health supplements missions to focus on public health.<sup>32</sup> FDA recommends the fortification of foods that would benefit public health at large.

International Organizations and States unitedly work for public health treating people of all nations at par with uniform regulations to be followed in their respective national laws that would support the economy and public health. Intellectual Property has been given importance towards technological transfers and benefit sharing of the TK for harmonization and benefit of the public at large. TRIPS Agreement and Convention on Biological Diversity (CBD) under Article 27.3(b)<sup>33</sup> and Article 71.1<sup>34</sup> of the TRIPS Agreement protect the TK and TMK based on the plants and animals.

Some countries and their patent offices like the United States Patent Trademark Office (USPTO)<sup>35</sup>, European Patent Office (EPO)<sup>36</sup>, Australian Patent Office<sup>37</sup>, Japan Patent Office (JPO)<sup>38</sup>, China National Intellectual Property Administration (CNIPA)<sup>39</sup> follow the TRIPS agreement and public health of World Trade Organization (WTO).<sup>40</sup>

Even though India is a party to the TRIPS Agreement, holds restrictions on the patentability

of the Indian TK. In a debate in the TRIPS Agreement, when such a question arose on the patentability of one nation's traditional knowledge, India amongst other member nations suggested that such can be amended with a clause marked as "prior informed consent" that is recommended in Article 41 of the TRIPS<sup>41</sup> and CBD for fair and equitable benefit sharing of such TK.

## INDIAN IP PROTECTION AND NUTRACEUTICALS

The positive impact of nutraceuticals in public health encourages the emerging need for new innovations all around the world, and demands the patentability of such innovations. In India, it was observed that the applications filed in the patent office for nutraceuticals are comparatively lesser in other countries.

The view of ICAR Scientist opines that one who innovates a product for public health needs to be protected for the process of making such formulations of the product and the product itself.<sup>42</sup> Any novel product has its own chemical components and admixtures, which in combination with another chemical component may have a positive or negative impact on public health needs which should have a clinical approach on both animals and humans before approaching for

32 FOOD AND DRUG ADMINISTRATION (FDA), FDA MISSION, <https://www.fda.gov/about-fda/what-we-do>, (last visited Jan. 5, 2023).

33 WTO, TRIPS: ARTICLE 27.3(b), explained (November 2008) [https://www.wto.org/english/tratop\\_e/trips\\_e/art27\\_3b\\_background\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm)

34 WTO, TRIPS: ARTICLE 71.1, explained (November 2008) [https://www.wto.org/english/res\\_e/publications\\_e/ai17\\_e/trips\\_art71\\_oth.pdf](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art71_oth.pdf)

35 United States Patent and Trademark Office, <https://www.uspto.gov/>

36 European Patent Office (EPO), <https://www.epo.org/>, (last visited Jan. 5, 2023).

37 Australian Patent Office, IP Australia, <https://www.ipaustralia.gov.au/>, (last visited Jan. 5, 2023).

38 Japan Patent Office,(JPO) <https://www.jpo.go.jp/e/>

39 China National Intellectual Property Administration, (CNIPA). <https://english.cnipa.gov.cn/>

40 WTO, "Declaration on the TRIPS Agreement and Public Health", WT/MIN (01)/DEC/W/2? [https://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm). Last visited Jan.3, 2023.

41 WTO, TRIPS: ARTICLE 41. [https://www.wto.org/english/res\\_e/publications\\_e/ai17\\_e/trips\\_art41\\_jur.pdf](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art41_jur.pdf)

42 Dr. G. Krishnan, MVSC. PH.D. ARS. ICAR – Senior Scientist- NIANP, Adugodi, Bangalore.

patentability for such nutraceuticals and other health supplement products.

### **Judicial interpretation on Section 3(d) and 3(j) of The Patents Act, 1970**

Section 3(d) of the Patents Act, 1970 states that a new patent cannot be obtained simply by discovering a new form of an existing substance or making a trivial improvement to an existing substance, or using an existing drug. These restrictions specifically affect pharmaceutical companies that attempt to obtain new patents on mixtures of existing compounds.

In the case of *The Research Foundation of State University of New York vs Assistant Controller of Patents*<sup>43</sup> observed that when a claim for product-by-process is obvious from a prior product, such are not patentable irrespective of prior art being made available in another process. Therefore, a claim must define novelty and non-obviousness in a product along with an inventive step. When Section 3(d) was challenged as being unconstitutional against the TRIPs Agreement, the Delhi High Court upon its discretion held that when there lies a dispute between international law with municipal law, the municipal law shall prevail.

The Supreme Court ruled in the case of *Novartis AG vs Union of India*<sup>44</sup> that any such amendment or addition, particularly one dealing with chemical components in the pharmaceutical industry, must be imposed to prevent the patentability of drugs that are already well-known or repetitively patented in the same or similar ways. The Supreme Court also supports the patentability of true ideas and inventions that help prevent sickness and promote public health, but it also ruled that an innovation's efficacy should be measured by how successfully it treats a disease.

Today's hustle and move towards convenient ready-to-eat foods from traditional food led to the development of health problems and micronutrient deficiencies demanding the need for nutraceuticals for optimum nutrition and public health. Bio-piracy affects the economy and unethical practices causing threats to the rights of indigenous communities for commercial exploitation<sup>45</sup> and IP violations as seen in the long battle from turmeric, neem, and arogyapacha plant cases<sup>46</sup>.

### **CHALLENGES TO THE PATENTABILITY OF NUTRACEUTICALS IN INDIA**

Obtaining patent protection in India has to undergo tedious scrutiny in proving the novelty of the product under section 3(d) of the Patents Act, 1970. The stringent laws prevent 'patent evergreening', where the chances of making a slight alteration or modification on the existing patented food product, health supplements, or drugs would indirectly extend the life of patent protection.

Other unethical tactics faced were 'patent trolls' wherein the weaker companies are dominated by the well-established companies to take over the patentable product of the weaker companies. Traditional Knowledge Digital Library (TKDL) documents the traditional knowledge of the medicinal properties of certain foods, herbs, botanicals, and animal extracts. While some are documented in TKDL, most others are left undocumented, which becomes a disadvantage to the innovators if they add such components that may become unpatentable under Section 3(j) of the Patent Act, 1970.

43 The Research Foundation of State University of New York Vs Assistant Controller of Patents, MANU/IC/0100/2012.

44 Novartis AG vs Union of India, [2013] 13 S.C.R. 148.

45 WIPO Magazine, 2011, "Protecting Indian Traditional Knowledge from biopiracy". [https://www.wipo.int/export/sites/www/meetings/en/2011/wipo\\_tkdl\\_del\\_11/pdf/tkdl\\_gupta.pdf](https://www.wipo.int/export/sites/www/meetings/en/2011/wipo_tkdl_del_11/pdf/tkdl_gupta.pdf). Last Visited Jan. 4, 2023.

46 G.Krishna Tulasi et al, "A detailed study of patent system for protection of inventions", 2008

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038276/>. Last Visited Jan.4, 2023.



## CONCLUSION AND SUGGESTIONS

India gives more importance to its biological resources under its laws. Patent protection and restrictions are proven to be focused on bringing out novel innovations in patentable products that apply to nutraceuticals and other health supplements too. When prioritizing the benefits arising out of sharing our traditional resources as well as Indian patented products can bring harmonization with TRIPS and DOHA declaration and at par with other international agreements. The increase in nutraceuticals and such patented products can benefit the Indian economy worldwide as there is a huge demand for Indian nutraceuticals in the global market. Covid19 epidemic became a wake-up call for the whole world to focus on health and immunity development systems, and the Indian nutraceuticals and health supplements are among the trusted supplements as they are proven and backed by scientific works of literature since time immemorial.

As estimated India's current nutraceutical industry has reached 3.5 percent in 2023 of the global nutraceuticals market further to extend by US \$18 by 2025. India imports US \$ 2.7 billion worth of nutraceuticals which broadens the Foreign Direct Investment (FDI) in India.<sup>47</sup> The demand for Indian nutraceuticals is a need of the hour to support public health, which can be exported as patented products helping in reaping the benefits internationally. Such a paradigm shift liberalizing the patent restrictions for novel nutraceutical innovations can ultimately purge the current IP rights issues while protecting our traditional knowledge and adding wealth to India.

The research highlights that the patent applications filed from the Traditional Knowledge category decreased from 114 in the year 2015-2016 to only 11 in the year 2019-2020.<sup>48</sup> When there is regulation such as the FSS(Nutra) Regulations of 2022 in India that protects nutraceuticals and

other health supplements proves the importance of nutraceuticals that deserve patent protection in India from public health and human rights perspective. Patent protection can shield the Indian novel innovations in nutraceuticals preventing reverse engineering of such supplements throughout the industrialized world.

The research posits a few suggestions in support of the patentability of nutraceuticals and other health supplements:

- i. Section 3(d) of the Patents Act, 1970 can be reconsidered to liberalize accommodating the novelty inherent in nutraceuticals, thereby, granting patents to novel nutraceutical innovations in India.
- ii. Intellectual Property Awareness Program can be conducted for Small-Scale and large enterprises of nutraceuticals and health supplement industries.
- iii. Incentivizing the creative brains of the Indian Scientists on their novel innovation of nutraceuticals would not only appreciate their hard work but also encourage them to bring further innovations.
- iv. Encouraging the innovators of nutraceuticals would increase the export of such products reducing the importation of the same in the international market.
- v. Encouraging fair and equitable benefit sharing of the Traditional Medicinal Knowledge (TMK) globally and adds value to our Traditional Knowledge when such are added as a component in the novel nutraceuticals.
- vi. Commercial exploitation of Indian Traditional Knowledge can be prevented when India promotes the traditional knowledge in specifications as prior art in the patent applications.

47 Market intelligence, "*India nutraceutical industry*", date: 29th September 2020

<https://www.trade.gov/market-intelligence/india-nutraceuticals-industry>. Last Visited Jan.8, 2023.

48 Intellectual Property India, Government of India – Annual Report 2019 - 2020. [https://ipindia.gov.in/writereaddata/Portal/Images/pdf/IP\\_India\\_English\\_29.08.21\\_Final\\_.pdf](https://ipindia.gov.in/writereaddata/Portal/Images/pdf/IP_India_English_29.08.21_Final_.pdf)



The research concludes that the Indian nutraceutical industry can not only boost the immunity of Indians but also can contribute as a boon to the present health management systems globally. Such nutraceuticals with high value both

in health and socio-economic improvement can be treated under the Indian Patents Act as ‘public-health related patents’ with slight flexibility in the grant of patents concerning public health at large.



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