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Winning wellness: strategic IP and regulatory considerations in Canada's booming natural health products industry

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Natural health products (NHPs) are increasingly popular, offering a diverse range of organic and wellness products to Canadian consumers. There has been a remarkable surge in the Canadian NHP industry, growing from an estimated $4.3 billion in 2007 to over $13.2 billion in 2021.[1] This popularity presents new opportunities, but in seizing those opportunities, it is critical that companies pay attention to intellectual property (IP) management and regulatory compliance in the realm of NHPs.

IP rights and regulatory requirements form the bedrock of a company's competitive advantage and market success. This article delves into these two critical domains, underscoring how a strategic approach to IP and regulatory vigilance can furnish companies with a competitive edge in the thriving NHP marketplace. Additionally, we offer an update on the latest legislative and regulatory amendments impacting NHPs and highlight imminent changes.

What are natural health products?

NHPs are naturally occurring substances used to restore or maintain good health, often called "complementary" or "alternative" medicines that are sold without a prescription.[2] They are often made from ingredients such as plants, animals, microorganisms and marine sources.[3] NHPs come as tablets, capsules, creams, solutions, drops and in other forms, and include many products such as vitamins and minerals, herbal remedies, homeopathic medicines, probiotics, traditional medicines and everyday consumer goods like toothpastes, shampoos and facial products.

NHP IP

In a market crowded with NHPs, IP can be used to differentiate a company's products. IP rights can create a unique identity for a product, making it more recognizable and trusted by consumers. This is particularly valuable in a regulated market where consumer confidence is paramount.

Patents provide a company with a legal shield against competitors by granting exclusive rights to use and commercialize the invention, deterring others from copying or selling obviously similar products and enabling legal action if those rights are infringed. This

exclusivity can be a significant competitive advantage, potentially leading to increased market share and revenue. For companies wishing to generate investment or to expand, a patent is a useful asset that can showcase new technology, encourage investor confidence and facilitate growth.

Despite these advantages, the prevalence of NHP patents appears notably limited. This could be attributed to the belief that NHPs, by virtue of being "natural products," are ineligible for patent protection in Canada. However, like any other product, NHPs are patentable in Canada provided they meet the requirements for patentability — namely, they are novel (meaning not previously publicly disclosed), non-obvious and useful.

Even if the natural substance within a NHP has been publicly disclosed, which would make the natural substance itself unpatentable, patent protection may be available for

- combinations of known natural substances that together provide a surprising and unexpected result
- processes applied to the natural substances (i.e., extracting, isolating or synthesizing these substances)
- new uses of the natural substances
- novel compositions of the natural substances for use in the treatment of a particular condition
- new dosage amounts of the natural substances or regimens for their administration

Obtaining a patentability opinion evaluating the patent potential of a NHP, along with the company's specialized know-how involved in its production and uses of the NHP, may uncover opportunities for securing patent rights, even if the NHP includes natural substances that are already known. If patenting, it is important to do so before selling or publicly disclosing the invention in the product, to preserve rights worldwide (although there is a one-year grace period to patent after a disclosure in Canada and the United States).

Additionally, while the level of support required to ground a health claim for a NHP licence requires scientific evidence, such as a clinical trial or scientific articles from reputable sources, and that some of the submitted data reflect human use,[4] the level of support for a use claim in a patent can be much lower. An invention claimed by a patent can satisfy the "useful/utility" requirement for patentability with *in vitro* data or animal studies. This lower threshold for utility often makes it easier for companies to file for patent protection much earlier in the development process than when they file for NHP product licences. By securing patent rights early, companies can navigate the regulatory landscape more effectively, ensuring that their products are not only compliant but also enjoy a longer period of market exclusivity.

NHP Regulations

NHPs are generally perceived to carry a lower risk profile compared to pharmaceutical drugs; however, they are not devoid of risk. Recognizing this, the federal government implemented the *Natural Health Products Regulations*[5] in 2004 (the NHP Regulations) granting Health Canada authority to oversee NHPs. These NHP Regulations conferred upon Health Canada the responsibility to ensure that NHPs meet the necessary criteria for safety, effectiveness, and high quality.[6]

Following the implementation of these NHP Regulations, every NHP sold legally in Canada requires a product licence, and facilities involved in manufacturing, packaging, labelling and importing these items needed a site licence. Since their inception in 2004, these licences have

mandated particular labelling and packaging standards, adherence to good manufacturing practices, and the provision of evidence for safety and efficacy to Health Canada.[7]

Achieving regulatory milestones, such as obtaining product or site licenses, can significantly enhance the value of a company's product and IP portfolio. These milestones serve as validation of a product's marketability and can be leveraged in licensing deals, partnerships, and even in raising capital. By proactively tracking regulatory changes and anticipating shifts in the compliance landscape, companies can adeptly navigate the complex approval processes, avoid costly delays, and capitalize on first-mover advantages. This vigilance is key to unlocking market opportunities, fostering consumer trust, and ultimately, cementing a company's standing in the competitive arena of NHPs.

Recent regulatory developments

Over the past few years, NHP companies have faced a series of updates to the NHP regulatory framework. Below, we highlight some of these changes, which encompass

- amendments to the *Food and Drugs Act* (FDA) introduced through two omnibus budget bills, Bill C-47 and Bill C-69[8]
- new labelling requirements as a result of the *Regulations Amending the Natural Health Products Regulations*[9]
- proposed adjustments to the fee structure by Health Canada in their NHP Fee Proposals[10]

NHPs are therapeutic products under the FDA

In June 2023, an omnibus budget bill (Bill C-47), which in part amended the FDA, received royal assent. One of the most notable FDA amendments, which took immediate effect, is that the definition of "therapeutic product" was expanded to include NHPs.[11]

This change alone provided Health Canada with more NHP oversight, including the ability to order a recall of NHPs that present a serious or imminent risk of injury to human health, to require label changes or package modifications to prevent serious injury and to impose higher fines and penalties for non-compliance.[12]

While NHPs are currently considered therapeutic products under the FDA, this may change. A private member's bill (Bill C-368) has been introduced seeking to redefine "therapeutic product" in the FDA so that NHPs are once again excluded from the definition. This move was prompted by concerns over rising costs for NHP consumers and companies.[13] Having successfully cleared its second reading in the House of Commons on May 29, 2024, the bill has now advanced to the committee stage.[14]

New Ministerial powers

Fast forward to June 2024, when another omnibus budget bill (Bill C-69), also encompassing significant amendments to the FDA, received royal assent. The most significant of these changes are the granting to the Minister of Health (Minister) of new powers to do the following:

- exclude therapeutic products from certain requirements of the FDA or its regulations, as long as specific preconditions (relating to level of health, safety or environmental risk) are

met[15]

- rely on information or decisions of a foreign regulatory authority regarding a therapeutic product, deeming that the information meets FDA requirements, provided the preconditions are met[16]
- issue orders to establish rules in respect of the importation, sale, conditions of sale, advertising, manufacture, preparation, preservation, packaging, labelling, storage or testing of the therapeutic product for the purpose of preventing, managing or controlling the risk of injury to health when there's a concern that using a therapeutic product for something other than its intended purpose might be risky to health, even if there is uncertainty of said risk[17]

Excluding a NHP from certain requirements of the FDA or deeming that FDA requirements are met based on a decision of foreign regulatory authority may result in less regulatory burden on NHP companies. Companies seeking a competitive edge should determine whether such exemptions are available to them.

While the introduction of new Ministerial powers to establish supplementary rules introduces a degree of unpredictability, it can be a powerful competitive differentiator for forward-thinking companies. This unpredictability arises from the broad scope of these potential rules, which may be enacted in response to *uncertain risks* associated with unintended uses. Moreover, the lack of clarity regarding the timing rules can be established (i.e., before or after a product licence is issued) further compounds the unpredictability. By proactively engaging with the regulatory process and building a flexible compliance strategy, companies can quickly adapt to new rules, potentially influence their development and secure a market-leading position.

Imminent changes

Labelling changes

The *Regulations Amending the Natural Health Products Regulations*[18] came into force on June 21, 2022. However, for provisions related to the labelling requirements (sections 17 to 22), there is a delayed coming into force date of three years to June 21, 2025.

These labelling changes include new mandatory requirements such as those for general legibility and labelling of food allergens and gluten. A products facts table containing medicinal ingredients, uses, warnings and allergens is also mandatory for NHPs that do not fall within enumerated exceptions.[19]

It is vital for companies to stay informed of the new labelling requirements applicable to their products in order to avoid costly delays and repercussions.

Fee changes

Still further changes impacting the NHP industry are already in the pipeline. Health Canada proposes, starting in 2025, to expand cost recovery to NHPs. Currently, NHPs are the only health product line for which Health Canada does not charge fees and instead relies on taxpayer funding. These proposed fees will allow Health Canada to recover some of the costs of their NHP regulatory activities.[20] This is a significant change as the NHP industry now faces more responsibility for fees, which could greatly impact the operations of many companies within the sector.

There are also concerns about the incentive to pay such fees for NHP approval, particularly when many NHPs are not patent protected.[21] In this context, it becomes essential for companies to strengthen their IP protections. By developing and focusing on solid IP strategies, companies can ensure that their innovations are secure and that they receive market protection in return for their investment in regulatory fees. This approach is particularly crucial as companies navigate increasing operational expenses, ensuring that they maintain a strong market presence and competitive edge.

Conclusion

In the competitive and regulated world of NHPs, the interplay between IP management and regulatory compliance is not just a legal necessity but a strategic enabler. Companies that recognize and capitalize on these two domains can secure a formidable position in the marketplace. By ensuring that IP considerations inform regulatory strategies and vice versa, companies can protect their innovations, comply with industry standards and create a sustainable competitive edge.

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[1] Karolina Zarichna, "Plain-Language-Labelling Impact on Industry" (31 May 2023).

[2] Government of Canada, "Natural health products" (last modified 27 June 2024).

[3] Government of Canada, "Proposed fees for Natural Health Products" [PDF] (May 2013).

[4] Government of Canada, "Pathway for Licensing Natural Health Products Making Modern Health Claims" (last modified 6 July 2022)..

[5] *Natural Heath Products Regulations*, SOR/2003-196.

[6] Government of Canada, *supra* note 2.

[7] Government of Canada, "Proposed fees for Natural Health Products" [PDF] (May 2013).

[8] *Food and Drugs Act*, RSC 1985, c. F-27.

[9] Regulations Amending the Natural Health Products Regulations: SOR/2022-146, (2022) C Gaz II.

[10] Bill C-47, *An Act to implement certain provisions of the budget tabled in Parliament on March 28, 2023,* 1st sess, 44th Parl, 2021 (assented to 22 June 2023); Bill C-69, *An Act to implement certain provisions of the budget tabled in Parliament on April 16, 2024*, 1st sess, 44th Parl, 2021 (assented to 20 June 2024); Government of Canada, "Revisions to proposed fees for natural health products" (last modified 15 April 2024).

[11] *Food and Drugs Act*, RSC 1985, c. F-27, s. 2.

[12] Government of Canada, "Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) Amendments to the Food and Drugs Act (Bill C-17)" (last modified 4 July 2023).

[13] Paul Cowley, "Red Deer MP's natural health product bill passes second reading" (31 May

2024).

[14] Bill C-368, *An Act to amend the Food and Drugs Act (natural health products),* 1st sess, 44th Parl, 2021 (second reading 29 May 2024).

[15] Bill C-69 at s. 30.05.

[16] Bill C-69 at s. 30.06.

[17] Government of Canada, "*Charter Statement – Bill C-69: An Act to implement certain provisions of the budget tabled in Parliament on April 16, 2024*" (Budget Implementation Act, 2024, No.1) (last modified 31 May 2024), at s. 30.01.

[18] *Regulations Amending the Natural Health Products Regulations:* SOR/2022-146, (2022) C Gaz II.

[19] *Ibid* at ss. 2.1, 2.4 and 5.1.

[20] Government of Canada, "Revisions to proposed fees for natural health products" (last modified 15 April 2024).

[21] Stan Bardal, "Natural Health Products: The Gap between Perceptions and Realities" (2015) 7:1 UBCMJ at 11–12.