Introduction

The incidence of obesity has more than doubled in the last 25 years, now affecting around 33% of adult population in the United States according to the Centers for Disease Control & Prevention (CDC). The World Health Organization (WHO) predicts that obesity may soon replace more traditional public health concerns such as under-nutrition and infectious diseases, as the most significant cause of poor health. The healthcare cost of obesity in the United States (US) is estimated to be $147 billion annually (equivalent to 9.1% of total medical spending)\(^1\).

The principal treatments currently available for obesity include diet modification and exercise, pharmaceutical therapies and surgical procedures like gastric bypass and vertical banded gastroplasty. Besides these, the industry has witnessed a flurry of activities around the idea of using neurostimulation for treatment of obesity.

The market size for treatments related to obesity is also expected to grow significantly over the next decade (Figure 1).

Neurostimulation for Obesity Treatment

The concept of neurostimulation to affect functioning of organs has been extensively used in medical practice to treat various disorders such as Parkinson’s disease, multiple sclerosis, epilepsy, chronic pain, etc.

The use of neurostimulation for obesity treatment was first suggested in the early 1990s. Ever since, there has been a steady growth in Intellectual Property investments in this domain, especially in the US (Figure 2).

Figure 2: Patent filing trend in the US

The key players in this field include:
- Medtronic Inc
- Cyberonics Inc
- Advanced Neuromodulation Systems (now a part of St. Jude Medical)
- Biocontrol Medical Ltd
- Leptos Biomedical Inc
- Enteromedics

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Intellectual Property in Neurostimulation

Intellectual Property (IP) investments and the patents granted in this domain can be classified into three broad categories (Figure 3) –
- Neurostimulators
- Stimulation methods
- Stimulator peripherals

Identifying anatomic locations for stimulation has been the most prominent patenting field. The industry has also seen significant IP investments, especially in patents related to stimulators for autonomous nerve or more specifically Vagus nerve. However, not many patents are present in the field of neurostimulators specific for Splanchnic nerves.

Most of the patents related to neurostimulators belong to Advanced Neurostimulation Systems and Biocontrol Medical. Cyberonics dominates the field of stimulation methods while Medtronic has made considerable investments in stimulator peripherals.

Stimulation of Vagus nerve has received extensive focus from these industry leaders resulting in significant patenting activity in this domain.

This article presents a detailed analysis of the evolution of Vagus nerve stimulation technology. Further, it provides insight on related technology areas that offer scope for innovation and an investment opportunity for IP protection.

Figure 3: Patent Classification
The idea of stimulating the Vagus nerve to treat obesity was conceived and patented in the year 1991 by Cyberonics. Thereafter, many players have adapted and actively entered the field of Vagus nerve stimulation (Figure 4).

The technology evolution tree shows the entry and activity of key players in the domain in the last 20 years. It can be observed that Cyberonics entered the field first, followed by Neuro & Cardiac Technologies. Biocontrol Medical Method entered the domain in the year 2001. Biocontrol was started by an entrepreneur named Yossi Gross who also founded companies like DuoCure, Beta Slim which work in the domain of Vagus nerve stimulation.

The players in the field of Vagus nerve stimulation have focused their research resources on few specific areas. For instance, Medtronic entered this field in 2002, and developed its footprint in the area of ‘Screening & Monitoring Methods’ for Vagus nerve stimulation. Similarly, Enteromedics and Biocontrol Medical have many patents on ‘Use of Control Unit’, while Neuro & Cardiac Technologies has focused on development of ‘Communication facilitation & other peripherals’.

There are technology areas related to Vagus nerve stimulation that have not witnessed significant patenting activity till date. These areas include ‘Stimulation signal patterns’, ‘Neurostimulator designs’ along with ‘Gastric bands with electrodes’, and ‘Transcutaneous neurostimulation’.

There are significant number of patents related to ‘Screening & Monitoring Methods’, ‘New Stimulation locations’ and ‘Communication facilitation & other peripherals’.

In technology areas that have higher number of patents, claim-wise mapping of the patents may help in understanding the protection provided by them. Apart from this, claim-wise mapping also throws some light on the possibility of overlap among the patents in question.

To illustrate this, a detailed claim-wise overlap analysis of patents in ‘Screening & Monitoring methods’ is explained in the next section.

**Screening & Monitoring Methods: Claim-wise Map**

A significant number of patents that deal with Vagus nerve stimulation discuss ‘Screening & Monitoring methods’. Many companies have ventured into this technology area and filed for patents with Medtronic and Cyberonics leading the pack. Figure 5 shows the claim-wise overlap analysis of the patents in this area.

The analysis helps in identifying the key players and their focus areas. Medtronic is the major assignee in this sub-domain with 5 patent applications. These patents are related to modulating the stimulating signal based on the feedback received from the patient. Cyberonics also has a significant presence in this sub-domain, with 4 patent applications. The applications relate to giving stimuli prior to the induction of therapeutic stimulating signal.

The claim wise overlap analysis further helps in identifying the features that are extensively covered by the existing patents and applications. For example, features like ‘determining stimulating parameters’, ‘modulating the signal based on feedback’ and ‘stimulating after feedback’ have been covered in various patents and applications. On the other hand, features like ‘detecting condition of the nerve’, ‘redelivery of signals after temporary signal halting’ and ‘using imaging techniques for monitoring’ are present in just one patent / application each.
The concept of neurostimulation for treatment of obesity has gained momentum in the past decade. There has been substantial patenting activity related to Vagus nerve stimulation. However, there are ample opportunities in the field of Splanchnic nerve stimulation for the new players who wish to venture into obesity treatment using neurostimulation.

For those interested in Vagus nerve stimulation, there is scope for innovation around design of neurostimulators and understanding the signal patterns and their application. On the other hand, screening and monitoring methods used in Vagus nerve stimulation have been extensively patented.

For the players that wish to develop products related to screening and monitoring methods used in Vagus nerve stimulation, it would be beneficial to perform a detailed FTO, especially if they are planning to include features like modulating the signal based on feedback and stimulating after feedback. On the other hand, innovation and product development around detecting condition of the nerve, redelivery of signals after temporary signal halting and using imaging techniques for monitoring can be less risky.
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