

THE REMARKABLE STORY OF KAFGON

The product and its application: KAFGON -an innovative herbal medicine for treatment of asthma, cough and cystic fibrosis, has been developed by Mrs.Raj Katyal, a herbal medicine practitioner based in Jalandhar, Panjab. It is being supported under a unique innovation promotion program- TePP under the Deptt. Of Scientific and Industrial Research (DSIR), Ministry of Science and Technology, Govt. of India.

How the story began: The story of KAFGON started in the year 2006, when an old lady entered the gates of National Institute of Pharmaceutical Education and Research (NIPER). She was Mrs. Raj Katyal and her family had been practicing medicine for more than three generations. Originally from “Jhang” district in pre-partition Panjab, famous for the love story of “Heer-Ranjha” she had now settled in Jalandhar. She had a wealth of knowledge about herbal medicines but nobody in her family was interested to carry it further. She was tormented by the fact that her unique knowledge would die with her. However, if she disclosed it to others, she would be cheated- getting neither money nor credit. What to do? Dr.Parikshit Bansal, In-charge of the Intellectual Property Rights (IPR) Cell, at NIPER, Mohali gently told her not to worry- there was a way out. Filing a patent application. In the application, her knowledge would be fully documented and be available in public domain- even after her death. It would benefit society and not be lost forever. However, in return for her disclosure, she would be granted 20 years legal rights over her invention, in form of a patent. She could not be cheated as ownership rights would be hers.

The starting point: Reassured, Mrs.Raj went ahead and disclosed to Dr.Bansal a rare formula for a herbal medicine for asthma and also severe cough, which were difficult to treat. As Dr.Bansal started to draft the patent application, he was surprised by the remarkable simplicity of her medicine. In contrast to her medicine of only 5 herbs, similar medicines for asthma patented in Europe and USA were extremely complex, comprising of 12-15 herbs. After the patent was filed, Dr.Bansal informed her and thought she would be happy.

The Challenges:

She was not. She asked Dr.Bansal that what was the use of the Patent? She wanted him to add value to her medicine, to evaluate it scientifically and make it benefit society. Dr.Bansal guided her to apply for TePP support to carry out detailed studies at NIPER. Support was promptly granted! Thus started a massive scientific effort spanning nearly 3 years which culminated in a remarkable product called KAFGON.

Preliminary evaluation: Preliminary evaluation of the medicine was carried out by Dr.P.Bansal in his own family and also by Dr.(Mrs.) Lata Kumar, Ex-Head, Department of Pediatrics, PGIMER, Chandigarh. Both were surprised by the remarkable efficacy of the medicine and felt it was worthy of further development and exploration.

Fingerprinting: The first step was to develop suitable analytical methods so that batch to batch variation of the product was avoided. Dr.I.P. Singh of the Natural Products Department, NIPER did a thorough study of the herbs and developed rugged protocols for ‘HPLC fingerprinting of the herbs’ to ensure uniform quality of the medicine.

Formulation development: The next step was to develop a formulation in which Dr.Arvind K.Bansal, from the Formulations Lab, Deptt. Of Pharmaceutical Technology, NIPER put in his skill and effort. He developed a formulation in form of a wet syrup. It failed completely and was not stable! Unlike formulations of pure compounds, the present innovative medicine based on powdered herbs was not sterile. It fermented the sugar solution used in the formulation. Stumped, the scientists began the development work again. After several trials and failures was born a rugged, delicious and stable formulation. It was tested again and again and found stable.

In vitro studies: To understand the mechanism of action, the activity of the formulation was tested against known antibiotics, using microbial cultures obtained from the Microbial Type Culture Collection (MTCC), IMTECH Chandigarh. The studies were performed by Mrs. Neena Bedi, a faculty member in Deptt. Of Pharmaceutical Sciences, GNDU, Amritsar. The in vitro studies revealed a remarkable anti-microbial activity profile- almost equal to the well-known antibiotics.

Regulatory approvals and manufacturing tie-up: The next step was to make a test batch after getting regulatory approval and conduct a clinical trial. For this Dr.Parikshit Bansal talked to a few manufacturers. Dr.Shaleen of Shaleen Pharmaceuticals, Panchkula agreed to make the formulation and applied for necessary license. It was refused! The Drug Approving authority indicated that such a combination for asthma treatment had not been disclosed before. What was the supporting data on safety and efficacy? Dr.Bansal sought a meeting with the authorities. He explained it was an innovative medicine- how could it

be documented? That's why a patent had been filed for the same! He showed the drug controller the extensive analytical, formulation development and in-vitro work done regarding the formulation. He also provided supporting literature regarding the herbs- all well-documented, safe and in use for hundreds of years. Convinced, the authorities granted the license.

Scale up studies: When test batch manufacture was started, a peculiar problem arose. The formulation developed by Dr.Arvind had been developed in a modern lab, using special equipment, which was not available in the traditional Ayurvedic unit of Dr.Shaleen. The equipment in Dr.Arvind's lab was too small to make a test batch of few kilograms. What to do? Dr. Parikshit Bansal tried to find if the machine could be purchased? Yes, but the cost was too high and it would take a few months to buy it. What to do? The team of scientists at NIPER again came together, tested a few innovative approaches and solved the problem- eliminating the equipment altogether and enabling the formulation to be manufactured in a very low-cost, effective manner.

Clinical evaluation: A test batch was successfully made under the tradename of KAFGON and free samples provided to leading doctors- ayurvedic and allopathic for their feedback. The feedback came-remarkable results! Very effective in cure of all types of cough and also remarkable relief in asthma. A few samples were provided to the Pediatric Deptt., PGIMER, Chandigarh. The encouraging results prompted them to seek approval for a full-fledged clinical trial to assess the therapeutic potential of this unique formulation.

A remarkable new application found accidentally: While this story was going on, another unique event took place. A few children suffering from a rare and painful condition called CYSTIC FIBROSIS (CF) were under treatment at PGI. In this, the lungs get filled with mucus and child finds it difficult to breathe. No proper medicine in allopathy is available for treatment of CF. The worried parents pestered the doctors on whether any alternative or innovative product was available? The doctors provided them with KAFGON, hoping it would work. The patients had come all the way from Bhopal to Chandigarh. Slowly the days passed. And then came the good news- the medicine had provided remarkable relief and the children were feeling much better! A new application of the medicine had been found- indicating a very fundamental mechanism of action.

Further plans

The clinical trials process has been initiated at PGI to evaluate the potential of the medicine in asthma treatment and is likely to be completed by Dec. 2009. Evaluation in cystic fibrosis will also be carried out. Based on scientific evaluation till date, there are strong possibilities of the medicine acting against tuberculosis as well for which studies can be planned separately.

Thank you TePP- The story of KAFGON is remarkable in another way- it shows how a small effort on part of the government in funding grassroot innovations, can result in remarkable achievements and technology breakthroughs!

Concluding remarks

The story of KAFGON is truly remarkable- demonstrating the tremendous power which is unleashed in the fight against disease, when traditional wisdom and modern science combine together. It also indicates the tremendous power of intellectual property rights and patents in unlocking secrets. In giving confidence to traditional medicine healers to part with their knowledge- rare knowledge which would die with them and be lost to mankind forever !
