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PIL Petitioner: NGO traced to Wockhardt Manager

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The mystery over the identity of Aadar Destitute and Old People's Home (ADOPH), the letter head Non-Governmental Organization (NGO) which had filed a public interest litigation against clinical trials of insulin by Biocon and streptokinase trials by Shantha Biotechnics is over.

The petitioner's address is the home of Mumbai-based Wockhardt's vice president (business development) Col. (retd) LJS Gill. Col. Gill lives in 1101, B Block, Brooke Hill Towers, IIIrd Cross Lane, Lokhandwala Complex, Andheri (West)Mumbai. He is also president, Wockhart HMI AIDS Relief Foundation (WHARF).

The petitioner, Mrs Preet Maju, 48, who claimed to be the trustee of ADOPH in the petition, does not live at this address. It is the house of Col. Gill. BioSpectrum has verified this by talking to the inmates of the address mentioned above and also from the MTNL telephone directory.

A team of Indian Express journalists has reported that Mrs Preet Maju lives with her husband in Bhilai. Mrs Maju is believed to be a sister-in-law of Col. Gill. Over a dozen telephone calls to Col. Gill to get his version on the episode remained unanswered. Wockhardt officials have confirmed that Col. Gill is their employee. Col. Gill has avoided all contacts with the BioSpectrum team, both at home and office.

Col. Gill

Col. Gill, aged 53, has a masters degree in Defence Studies and joined Wockhardt on August 16, 2000. Prior to joining Wockhardt he was the CEO of Atco Healthcare Products.

A detailed questionnaire was sent by BioSpectrum to Wockhardt chairman Habil Khorakiwala. He chose to respond through Wockhardt's deputy general manager (DGM) Shyam Kumar thus:

"Please refer to your mail addressed to Mr Khorakiwala. We are surprised at the various assumptions that you have made. Our company has nothing to do with the NGO. The various points that you have raised amount to an insinuation against Wockhardt and its employees. You must be aware that Wockhardt is a leader in recombinant biotechnology and have three

products in the market. It is wrong on your part to make such wild allegations against an organization, which has established its credibility over the last 40 years. If, however, we find that our name is sullied any way, we will be forced to take legal recourse against your publication."

The questions were specific and Wockhardt's reply has skirted all these questions.

1. A Public Interest Litigation against clinical trials of insulin by Biocon was filed in the Supreme Court in February 2003 which came up for hearing on August 20. The petitioner was a Mumbai-based NGO, Aadar Destitute and Old People Home (ADOPH). Investigations by journalists from BioSpectrum and Indian Express have discovered that this NGO is a "fictitious" organization. And in the address mentioned in the PIL, a senior employee of Wockhardt Ltd, Col. (retd) LJS Gill lives.

What is the connection between your employee and the "NGO"?

2. Wockhardt is a serious player in the insulin market, having launched your own biotech version in 2003. A PIL, which will delay the entry of a competing product, is bound to benefit Wockhardt. Why has a Senior Wockhardt manager resorted to such an unfair business tactic?

3. As a company, which prides on its corporate governance policies, does your organization support such a petition, which is bound to bring bad name to the entire biotech and pharma industry?

4. What remedial actions do you propose to take to enhance the reputation of your organization and also clarify the circumstances leading to the filing such a PIL?

5. The PIL has also complained against another Indian biotech company, Shantha Biotechnics, again based on information sent to the regulatory agency by a Bangalore-based NGO, Anikethan. This NGO too has based it complaints on information from Shantha's competitors and the complaint has been dismissed by the regulator. Why does one of your senior managers lend his name to tarnishing rival companies in the market place?

Meanwhile, the petition was taken up for hearing by the bench comprising Justice N Santosh Hegde, Justice SB Sinha and Justice AK Mathur on September 24. The judges denied the petitioner's request to order an injunction against the clinical trials being carried out by Biocon. According to a report in the Bangalore-based newspaper, Deccan Herald, the justices asked the petitioner's counsel, Mukul Rohatgi who was funding the NGO and for what purpose.

Deccan Herald has also reported that the Supreme Court judges have accepted the explanations given by the Ministry of Environment and Forests in its affidavit that on July 14, the ministry has condoned the procedural lapses in the human clinical trials of insulin by Biocon. The affidavit said the procedural lapse was due to some confusing guidelines.

N Suresh and Narayan Kulkarni

"We are shocked to learn that a senior executive of a company of the stature of Wockhardt is linked to the dubious NGO who attempted to undermine our interests in such a malafide manner.", said
Kiran Mazumdar-Shaw, Chairman and Managing Director, Biocon

Stupid Act

"This is a stupid act. To get the major pie in the short term, companies will indulge in such acts. In the long run, it won't survive. Big biopharmaceutical companies are taking safety measures while going for clinical trials of their rDNA products. This will have no effect on the growth of the bio services sector in India, which is just picking up in the last few years. Better regulatory controls/measures may bring down such acts in future."
Ashish K Dasgupta, director, Lambda Therapeutic, Mumbai

Undue Interference

"Though I do not fully know the details about this, in general I can say that all the pharmaceutical companies are following the guidelines of the Drug Controller General of India (DCGI). There are ethical committees, guidelines to maintain good clinical practices while conducting clinical trials and research. Organizations/agencies like Genetic Engineering Approval Committee (GEAC), DCGI are there to approve new drugs.

However extra efforts should be made to keep checks and balances without affecting the rights of the human being. Companies are concerned about the health of the poor. In this era of globalization, India should think bigger and also look for more scientific research to compete with global leaders. "

On interference by NGOs in the research activities he said, "We will face problems when non-technical people actively involved in NGOs try to interfere in the scientific activities. Some times this may force the organizations to look for alternatives."
Dr Ajit Dangi, director general, Organization of Pharmaceutical Producers of India (OPPI)

Fabricated Charges

"The NGO which has fabricated the charges was not functional and has made wild allegations. Even the complainant has not given his/her true identity. This is only to make quick money. In this country, you see many such acts of black mailing. And this will continue. We are not giving much weightage to such false and wild allegations. We respond to limited queries. One should also understand that no one takes such allegations by this NGO seriously. This will only create bad impression about NGOs. The credibility of NGOs will be hit by these acts. The companies are taking extra precautions. All efforts are being made to launch good and quality products. "
Dr M Venkateswarlu, deputy drug controller general of India (west zone)

Irresponsible Act

"The Indian biotech sector is in its infancy and needs nurturing and positive support. Irresponsible acts such as this are not only detrimental and deplorable but send a very wrong signal to the outside world. ABLE hopes that with the exposure of this irresponsible action, the biotech community will pledge itself to building this sector on a strong code of ethics and fair play."
Ms Radhika Chaudhury, Director, Association of Biotechnology-Led Enterprises (ABLE), Bangalore

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Bad Name for rDNA Products

The biotech head of a leading biopharmaceutical company, who requested anonymity said, "We, as a manufacturer, make all efforts to develop very good and quality products. We are responsible the people of India. I am sympathetic to the companies, which are really making efforts in developing recombinant products." Expressing concern over such frivolous acts, he said, "It would create unnecessary delay in launching genuine recombinant products into the market. I hope such acts will not repeat in future. "

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