Interview: Paola Pozzi – Head, Office of Biotechnology Transfer, San Raffaele Scientific Institute (SRSI), Italy

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Dr. Paola Pozzi, the head of the Office of Biotechnology Transfer at the San Raffaele Scientific Institute, discusses the crucial role the OBT occupies as a link between the industry and early-stage research at the institute, as well as her views on the changing culture surrounding the commercialization of research among scientists in Italy.

The Office of Biotechnology Transfer acts as an interface between the San Raffaele Scientific Institute and the business community in the life science sector. To start, can you give us a brief overview of the responsibilities and operations of OBT?

Our office is charged with evaluating the patentability requirements of promising new inventions produced by the research conducted at the institute. We have over 1000 researchers working on both basic and translational projects here. Each year we perform around 50 to 60 patentability evaluations on new technologies and inventions arising from basic, translational and clinical research. To handle this, we have set ourselves up to be very selective in what projects we take on, because the evaluation is stringent and needs to assess novelty, inventiveness and industrial applicability as well as potential competitiveness. We have a limited budget, and this means we need to be efficient in our allocation of resources.

Our role as an interface as you say, means that everyone working in the Office for Biotechnology Transfer recognizes the importance of being able to effectively communicate with each party

involved. As a result, we all have a scientific background, but we are also educated in legal and IP, as well as business development. We need to understand medical and market needs and speak different languages (science, law and business) to interact effectively both with the scientific community and with the industry. It is important for us to be fluent in each of these so that we can be effective in our role.

For myself, I started in science and worked as a researcher in laboratories both in Italy and in the US. When I decided to switch to technology transfer I obtained a Master's in legal and IP, and also underwent training in Business Development to aid me in my capacity here.

What does your current patent portfolio look like?

It is quite extensive. As I said we are necessarily selective in the patents we choose to file, and we can also choose to abandon patents if the feedback from the market is not positive. Nevertheless, in 2014 we had a total of 220 patents alive worldwide, divided in 47 patent families, though most of these fall into the gene- and cell therapy area, as well as oncology, which together account for around 87 percent of our current live patents.

Your mission is to create value from the resources and facilities available within San Raffaele. In that capacity, what have been some key milestones for OBT?

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In 2014 we established a new spin-off of the San Raffaele Scientific Institute (SRSI) called Genenta Biosciences. This was the work of Luigi Naldini at San Raffaele Telethon Institute for Gene Therapy, who also heads two major alliances we have with GSK and Biogen. For Genenta, we were able to out-license two major patent families covering a platform technology for selectively driving expression of a transgene/drug in desired subsets of cells, as well as some other patents which the company has under option. This was very successful, and in around six months Genenta was able to raise around ten million euros, including significant amounts from private investors. I truly believe that this was achieved through the quality of the science at the foundation of the project.

Are you seeing an increased recognition from the different industry stakeholders that collaboration with scientific institutes is the way forward?

Yes, I would say so. It is clear that early-stage research, which constitutes the vast majority of our work at San Raffaele, is where innovation starts developing. This is something that the biotech companies, the pharmaceutical industry and also the venture capitalists have begun to recognize. Especially on the venture capitalist side we are being increasingly approached by interested parties

looking to invest in promising early-stage projects. This, together with biotech, should bridge the gap which has traditionally existed here and allow us to bring more projects up to the clinical stage, where the pharmaceutical industry can then push it through development.

San Raffaele has, as stated, had some notable collaborations with Big Pharma, such as Merck Serono in neuroregenerative diseases in 2014, and with GSK with TIGET. What is OBT's strategy in terms of fostering these partnerships? Is it an active or a more opportunistic one?

I would say that it is both. What works best, is having a scientist who is very well known in their field heading the project. This makes it far easier to find interested parties and to build confidence in the project. After these investors have indicated they want to become committed to the project, we need to start working on the legal structure and framework around the collaboration, and this requires a lot of work and competencies available at the OBT, also in tight collaboration with external lawyers.

For attracting partners in the initial stage, whether passively or actively through events such as BIO, having a solid scientific foundation is absolutely crucial. Finally, besides networking events we also have a successful website which has proved to be very important in putting external parties into contact with our office.

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Biotech companies often develop as spinoffs from research institutes or work very closely with them, and Italy has a very large community of biotech companies. How much does the OBT work with big pharma companies like Merck and GSK and how much does it interact with smaller biotech companies?

For a number of reasons, our collaboration with Italian biotech companies around early-stage research tends to be rather limited. For the clinical research we do have many partnerships with Italian companies, and these are managed by our clinical trial office directly.

For San Raffaele's basic and translational research, we work mostly with the headquarters of foreign companies. The primary reason for this is that we are talking about the development of very innovative treatments, and most of the scientific research is carried out at the headquarters of large, international companies.

You work with a variety of stakeholders, from the institute to the private life sciences sector, to merchant banks and venture capitalists. What are the challenges you face in

terms of understanding and reconciling all these divergent interests and priorities?

Our job is to facilitate and build successful relationships with the industry, in order to ‘bridge the gap’ and bring very early stage projects to the market for the benefit of the patients. As you say this involves bringing together different stakeholders, and coordinating their efforts and priorities towards the common good of the project. This can be very challenging, and the most important aspect here is to understand what each party is trying to achieve, the unique strengths which they can bring to the table, and their way of doing business. It comes back to understanding the three languages I mentioned earlier, which in turn requires a staff of very committed, multi-disciplined people working here at the OBT.

For instance, in Italy, as technology transfer is new to the country, our scientists are traditionally not as involved in patenting the fruits of their research. They want to publish their work openly and see that as the ultimate aim. This means that we need to foster a shift in culture and knowledge, and actively encourage them to patent their results before disclosing them to the public if they have real market potential. Indeed, we see patents as a ‘tool’ to attract the industry to invest in early stage projects. Importantly, we do not ordinarily delay any publication, we do our best to prioritize and carry out the evaluations of new technologies ahead of any deadline for publication. This is still a work in progress, but the results we have achieved, especially in the last two years, have been very encouraging with some major successes for all parties involved.

The other big shift we are seeing, is that scientists at the institute are beginning to talk to each other more freely, sharing not only their research but also their experiences of the patenting process and commercial exploitation. That has helped spread the word on the benefits our office can bring the academic community at the institute, also in term of additional financing that further supports San Raffaele’s research, and I think it is a very promising sign that a real change in attitude is on the horizon.

Finally, the key strength of our organization is that we have the scientific institute, the hospital and the university all in close proximity and working together. This brings additional value to the process of educating future scientists and MDs and fostering translational medicine in a highly collaborative environment through a two-way street “bench-to-bedside” approach.

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