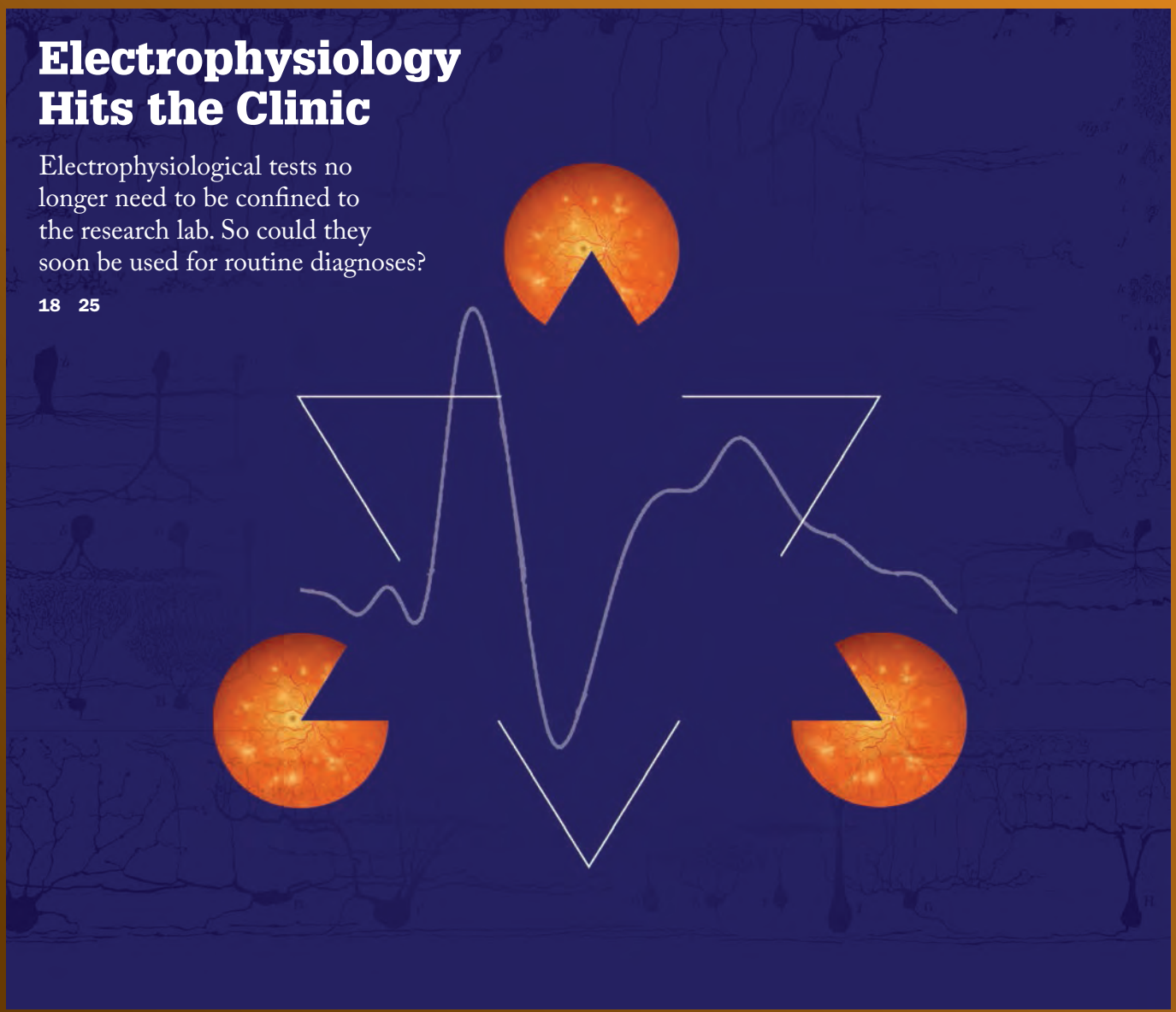
NOVEMBER 2014 # 13

the Ophthalmologist

Electrophysiology Hits the Clinic

Electrophysiological tests no longer need to be confined to the research lab. So could they soon be used for routine diagnoses?



Mark Latina

Latina, an internationally renowned glaucoma specialist, is associate clinical professor of ophthalmology at Tufts University Medical School in Boston and currently a staff member at a number of eminent Massachusetts hospitals, as well as being in private practice. Latina invented Selective Laser Trabeculoplasty (SLT) for the treatment of open angle glaucoma, has over 75 publications and chapters, and holds 10 patents. In his free time, Latina enjoys cooking, bicycling, kayaking and clamming. Read Mark's article on how electrophysiology is about to hit the clinic in a big way on page 18.

Günther Grabner

Grabner studied medicine at the University of Vienna and went on to found Austria's first eye bank in 1977. After spending time in California, he returned to Austria, where he is now director and full professor of the Salzburg Paracelsus Medical University Eye Clinic. He has edited several journals, published over 300 articles, and recently gave the Ridley Medical Lecture at the 2014 congress of ESCRS. His research interests include corneal and intraocular presbyopia and astigmatism. Günther introduces us to the IC-8 IOL on page 28.

Cathy Schanzer

Medical director and chief surgeon at Southern Eye Associates in Memphis, Tennessee, Schanzer is mother to seven adopted children. She first traveled to Africa to participate in mission work in 1988 and in 2006 committed to establish and support the Serabu Eye Clinic in Sierra Leone with her husband, Tom Lewis. She now travels to the clinic twice a year to perform surgery.

M. Stewart Galloway

Galloway graduated from the University of Tennessee College of Medicine and is now at Cumberland Eye Care and Cookeville Eye Specialists in Tennessee. He has been volunteering with the World Cataract Foundation since 2001, making annual trips to Guerrero, Mexico, to perform surgery. He is married with two children and enjoys golfing, diving, and underwater photography.

Read Cathy and Stewart's summary of dropless cataract surgery on page 30.

Nikki Hafezi

After earning a master's degree at the Swiss Federal Institute of Technology, Hafezi served as a development executive for a private hospital and a national public health agency. She later moved to Switzerland and, due to her expertise in intellectual property management, became managing director of GroupAdvance consulting and CEO of EMAGine AG, a spin-off company from the University of Geneva that develops CXL technology. She lives in Zug, Switzerland, with her husband and two daughters. Nikki's guide to getting great ideas turned into reality starts on page 46.

Profession

Your career
Your business
Your life

You Have a Great Idea. Now What?

How to translate a 'light-bulb moment' into a commercially viable reality.

By Nikki Hafezi

Necessity is the mother of invention: a problem needs solving, someone has a good idea, an invention is born. In clinical medicine, ideas often arise from the act of treating a patient; someone considers how to improve a treatment modality's speed, efficiency or both – an invention is born. Notably, the more straightforward the idea, the more likely it is to be realized or translated into practice. Here, I discuss the four important milestones along your commercialization journey, and highlight what you need to consider to stand the best chance of success.

1. Patents: is your idea novel and inventive?

Once you've had your idea or developed your invention, you'll likely want to protect your intellectual property (IP) with a patent. A patent represents a limited monopoly. From an IP perspective, an invention must satisfy two criteria for a patent to be granted: it must be (i) novel and (ii) useful or inventive. Proving that your invention is novel is almost always the hardest obstacle when trying to obtain a patent for a medical device or a pharmaceutical entity. Novelty is defined as being clear of any prior art before the actual filing date of the patent application. What do we mean by "prior art"? The term includes (but is not limited to) any public presentation, scientific publication, poster, or any other form of public information about the invention. Before going down the long and potentially expensive path of patenting your invention, you need to check for prior art (or even potential patent infringement) – and this no simple task.

The first step is to search – extensively. There are publicly available online databases (such as the European Patent Office, http://www.epo.org/searching.html, or Google Scholar, http://scholar.google.com/), but there are many other search options, and sometimes it can be worthwhile paying for a search report to be performed by a national IP institute.

The art of drafting a patent application is a seemingly contradictory balance. On the one hand, you must include as much of the area surrounding the patent as possible without infringing on any other IP or including prior art, but at the same time be sparing or even vague with sensitive information to reduce the risk of a simple "invent-around." It's actually this delicate balance that becomes the major pitfall for many first-time inventors, who usually want to include everything in their application in the hope of receiving a limited monopoly on their idea or invention. However, what usually happens is that after 18 months from the filing date – which is not usually enough time to develop and bring a medical device to market – the application is published and potential competitors receive information to facilitate a market counter-attack. For them, the more proprietary information included the better! Of course, if the invention is not properly covered by the patent in terms of specific claims, then it can be hard to enforce, which is not good either.

In the medical devices field, most people consider IP the safest insurance an inventor can have. But there are some companies that bring medical devices to market without any IP protection at all. Such companies compensate with rapid speed of entry to the market, "podium power", and (later) competitive prices to maintain their market share. The latter often proves to be the challenging part; it's incredibly difficult to maintain a high market share with no IP, because you make it easy for competitors – they've seen what you've done, and there's nothing stopping them from copying you.

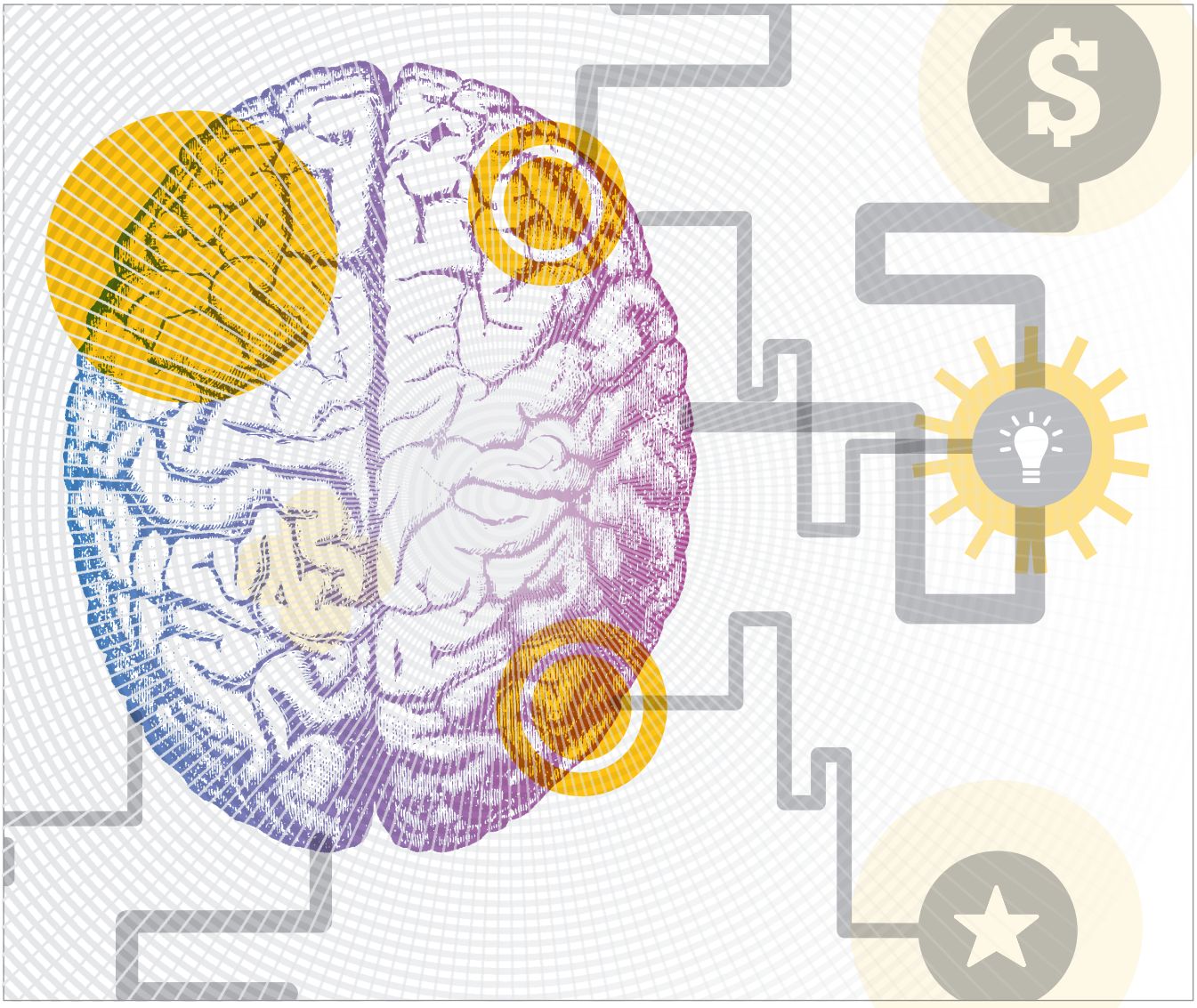
2. Contracts: double-check your rights and obligations

Shuji Nakamura was one of the three recipients of the 2014 Nobel Prize for Physics "for the invention of efficient blue light-emitting diodes, which has enabled bright and energy-saving white light sources". His discovery, which made the blue LED possible, came in the 1990s when he was working in his spare time, but his employer, Nichia Corporation, took the rights to the discovery – as per the terms of his employment. They paid him a bonus of ¥20,000 (€150) at the time – and may have made over US$1.1 billion in profits from the invention since then…

The lesson? You must seriously consider your employment contract before filing for patent. For inventors working in academic institutions both in the US and the EU, contracts explicitly state that all IP generated is fully owned by the university. However, the inventor has the right to license the technology – the "right of first refusal".

At a Glance

- *Proving that your idea is novel and inventive is key to obtaining a patent*
- *You need to understand your obligations when negotiating contracts – and set your expectations accordingly*
- *Regulatory affairs: understand what regulatory bodies need from you is central to gaining approval*
- *Hard decisions: do you finance and develop yourself, or license or sell your innovation?*



If the university decides not to pursue IP rights for an invention, then the inventor is free to do so at his or her own risk and expense.

Industrial collaboration agreements that specifically refer to any IP generated (in an exclusive field) for the duration of the collaboration must also be considered carefully.

Often, when industry provides funding for a researcher, the company has a specific paragraph in their agreement that protects the company's interests. Specifically, the paragraph would state that the company would either own the right to license – the right of first refusal – in the case of an academic collaboration or "work made for hire", which states that the company is paying for the researcher's services and owns anything that results from their work.

These contract obligations are not necessarily a bad deal for the inventor. Often, the academic institute has a

"Although you think you've solved a problem or made something better, you now have to prove it."

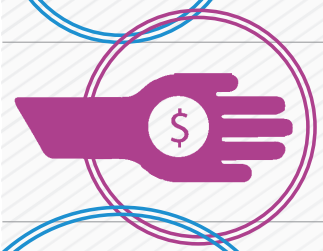
	Finance	*Pros*	*Cons*
	*Self-finance*	Fastest, limited obstacles to progress	Risk losing private money. Required funds are always more than expected.
	*Fundraise: private foundations & governmental funding*	Typically, "free money" or in other words without obligation to pay back.	Long waiting periods (~1-2 years). Risk of not being funded; time lost.
	*Prizes*	Typically, "free money". Domino effect: once one entity grants a prize, the likelihood increases of receiving additional prizes.	Sometimes, the entity will request a certain percentage of shares of future company. Sometimes, IP is not protected. In the case where the patent application is not yet published, it can be risky.
	*Venture Capital (VC)*	"Cash injection". "Smart money"; typically, the company receives management and business-related services in addition to funds to improve on its sales, marketability and overall value.	VCs want to know when the return on investment will be. If the invention is at an early stage, the likelihood of getting funds is relatively low.

Table 1. The pros and cons of funding options.

technology transfer office that will offset the costs of the patent drafting and submission fees until a licensing agreement is secured. These offices have a team of advisors that judge the technology's market worth, meaning that the motivation for a technology transfer office to approve the payment of these fees will be determined by how fast the funds would be recuperated in a potential licensing agreement. In the case of industrial agreements, the inventor is almost always named on the patent application, and may receive compensation in the form of a consultancy – or in some cases a non-compete clause to deter "re-invention".

3. Regulations: how to approve your invention in Europe and North America

Although you think you've solved a problem or made something better, you now have to prove it. Depending on the type of invention, this step may be the most time- and money-consuming.

Europe

In the case of a medical device in Europe, ultimately, the extent of the proof will be dependent on the regulatory body responsible for issuing a CE mark.

If you can prove to the regulatory bodies that your invention is similar to a device already on the market (with similar product specifications), then the threshold may be met. If there is nothing similar on the market for the medical indication, then a scientific file, with peer-reviewed publications, will be required. The more supporting information submitted, the higher the chances of a rapid decision in favor of a CE mark. However, if you do not convince the regulatory body of the already proven safety and efficacy of the treatment/device, then you will most likely need to start conducting research to create a scientific file. Sometimes, a full clinical trial will be needed, which translates into many years and significant financial burden.

North America

While the same basic principle holds true in North America, especially in the US, the FDA can be more rigorous with its requirements. In fact, the expectation of long delays and large expenses related to the approval process leads some ophthalmic companies to forgo the process altogether and not sell in the US. In particular for non-US start-up companies, the amount of funding and know-how required to enter the US can be too much to handle in the first 5–10 years of business. Unfortunately, though the FDA's rigorous requirements can result in higher safety standards for its citizens, it can sometimes come at an expense: cutting-edge treatments or devices may be delayed or simply never become available.

4. Crossroads: finance/develop or license/sell?

As noted, the capital required to conduct research for regulatory approval can be substantial, so you may find yourself at an all-important crossroads. There are several ways of raising funds but, fundamentally, you must determine what is really feasible. Table 1 offers funding options alongside their advantages and disadvantages.

> *"Nothing slows down the progress of bringing a product to market more than the emotions and attachment of the inventor."*

If the finance and development route seems too daunting or simply impossible, you are probably interested in licensing (or selling) the invention. Once again, there are a number of considerations that need to be taken into account to maximize the earning potential. For a medical device-related invention, you should consider:

- What exactly are you trying to protect? And who do you want to avoid knowing the secrets of your invention? Why?
- Who/what would benefit from your invention? (For example, who: patient, distributor, user/surgeon, manufacturer; what: faster, safer, easier, improved outcomes, cheaper, smaller, lighter).
- Would your invention help sell existing procedures or machines/devices?
- What companies already have existing technology? Does the invention improve the company's existing procedure/treatment? If not, would a competing company be interested in entering the market?
- Can your invention be translated into any other fields or applications? Why or why not?

Be a businessperson

The "crossroads" is always difficult because it forces you into a new role. You must learn to separate the invention from your own idea and start treating it as a business idea/concept that needs financing. From my personal experience, nothing slows down the progress of bringing a product to market more than the emotions and attachment of the inventor. Therefore, a pivotal question at this stage is: are you ready for your new role of businessperson?

In summary, when translating an idea into a possible commercial product, you must consider these four key aspects. My guidance here is based on my personal experience of working with and for academic institutions in North American and Europe, primarily in the medical device sector, so, as a caveat, I should say that each invention should be treated individually. All ideas/inventions have special circumstances, so it is important to adapt any guidance accordingly.

As a final word, I cannot recommend enough that it is important to include as many experts in the respective field as possible to assist you through the initial processes. You'll save time (and money), which will come in very handy to further develop the invention and, hopefully, your start-up company.

Nikki Hafezi is the managing director of GroupAdvance Consulting GmbH and the CEO of EMAGine AG; both companies are based in Zug, Switzerland.