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A sense of "déjà vu"?

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I read a report in which it was announced that in a German court Edwards Lifesciences has succeeded in obtaining a sales injunction against Medtronic. Last month, Edwards defeated Medtronic in a previous court case in relation to the "Spenser patent"[1].

My first reaction is "déjà vu", in the sense that I recall when the Palmaz-Schatz stent design became a contentious legal argument revolving around the patent, which some considered generic for every intracoronary dilating scaffold device. At the time, the other party was the Wallstent. The crux of the matter lay in the design aspect, a balloon-expandable versus a self-expanding design. Years later, Julio Palmaz wrote in his book that he brought along his dog to the court hearings – if I'm not mistaken, the dog was ironically named "Rusty". Rusty had received six stents some years earlier, which allowed Julio to demonstrate the origin and original dates of his design.

From what I understand this current case concerning Edwards Lifesciences versus Medtronic is, once again, centring around a patent (the Spenser patent in this case). I downloaded the patent from the European Patent Office (EPO) and it used, amongst other handwritten illustrations, the description of a SAPIEN design. For the layman, how a balloon-expandable design can infringe upon a self-expanding device seems to me quite strange. Thankfully, Edwards has granted exceptions for the use of Medtronic CoreValve in Germany, for instance in those cases when a subclavian approach is indicated or when the aortic annulus is larger than 28 mm.

While I fully respect a company's demand to respect and protect its intellectual property and patents, the community should consider that this is a commercial war, where the patient and not the patent is the real casualty. This war between these leading device companies leads me to question how this will impact on all the other start-ups and smaller companies who are working on their devices. If a self-expanding device is the bone of contention, will other companies become involved in legal battles as well?

As doctors, one of our duties is not to get involved in any commercial war whose ultimate goal is to make a maximum amount of money as opposed to the medical needs which are gradually moving in the valvular field from the inoperable patient to the high-risk patient and now on to the intermediate and perhaps even low-risk patients. Similarly, another aspect of this court case which I find troubling is its potential to distract us from the pursuit of evidence-based medicine along with the continued introduction of new products that might be beneficial to patients. An example of what I am talking about is how this endangers ongoing trials; SURTAVI, for instance, could be impeded.

Why was the case heard in Germany? Germany is the medical giant of Europe, though one can imagine similar proceedings in other European countries and maybe even the USA. Is this a transient, judicial vehicle to achieve a major deal between the two companies? In the past, many of these patent infringements, fuelled by the lawyers, were resolved by out-of-court settlements leading to, in some cases, an exchange of technology. Naturally, it is not for me to say who is right or wrong, after all, I'm just a doctor. I don't fully understand these developments, but the reason I am worried is that earlier this year one company paid the other $83 million to settle another case, money that could have been invested in research and trials[2].

And now we come to our paradox.

I mentioned earlier the SURTAVI trial, of which I openly declare myself to be the chairman, and which has European and American governance. Before continuing, I would like you to note that next month EuroIntervention will be publishing a paper from Italy reporting on a 1,157-patient TAVI registry[3]. However, in Italy, you cannot conduct a trial if the local investigators do not purchase the valve. The same scenario exists in Belgium. Belgium, like Italy, cannot participate in SURTAVI as the studied device is not reimbursed. Therefore, any attempt by the physician to promote evidence-based medicine would be at the cost of the physician and only after the publication of the data will the state become involved. I'm sure we all agree that this sounds too much like the "horse after the cart".

Trial participation relies on the goodwill and investment of doctors and patients and unfortunately not by the health authorities and the nation state. The physician should be rewarded for collecting data for furthering our evidence-based medicine through a policy of reimbursement. As a matter of fact, this is what takes place in the USA. There the so-called investigational device exemption (IDE) trials allow for the investigational device to be used in a clinical study in order to collect safety and effectiveness data with the American physician being reimbursed for the generic treatment, for example a valve replacement trial. I know some physicians who are reimbursed $23,000, as this is what a surgeon asks for to perform a valve replacement. Some physicians, however, were even reimbursed $56,000, quite a wide disparity, but, nevertheless, the US physicians are reimbursed. Now let's consider the SURTAVI trial (a randomised trial with surgery versus TAVI) in which 1,300 TAVIs will be performed, half of which will be European cases. That is an approximate investment in Europe of 13 million euros (650 cases×20,000). Then place this rather simplistic calculation in the context of the $83 million spent on litigation fees that we mentioned above. There is something inherently wrong in the pursuit of profit through a legal battle instead of using that money for progressing further and rapidly our research in medicine. And you must remember that most of us have seen this all before in the field of stents, with all the money at stake and the complexity of the products, with court cases in many countries encompassing all the industry's major players, and many of the smaller ones as well.

In conclusion, although this commentary is my personal reaction to what is happening, with no endorsement from any company or organisation, I would like to think that we could replace my current "déjà vu" with a "presque vu", and that that there is an inherent epiphany occurring which will transform the way we act, leading us to enter a new enlightened phase with industry, free of litigation and bound by the will – together – to achieve further scientific breakthroughs.

References

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