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A Place for Patent Protected and Unprotected Theranostic Approaches in Research and Clinic

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I thank Dr. Notni for his recent letter in which he provides his perspective on one part of the success story of PSMA targeted theranostics (1). Success stories often come with conflicts and intellectual ownership discussions.

Dr. Notni makes important points. He acknowledges the pivotal role of the inventors of 177Lu-PSMA I&T in shaping the field (2). He also emphasizes our obvious responsibility to honor patent protection. I would like to highlight that both patented and unpatented compounds can be successful and become market drivers. It is important to allow free market forces to compete for business. For instance, one company is currently initiating a phase 3 clinical trial with the non-patented compound 177Lu-PSMA I&T in patients with castrate resistant prostate cancer (3). As another example, US Food and Drug Administration 9FDA) has recently granted a New Drug Application for the non-patent protected 68Ga-PSMA11 for a wide range of indications in patients with prostate cancer (4). This further establishes the high clinical relevance and impact of PSMA targeted PET imaging in the care of prostate cancer patients (5). Reimbursement will set the stage and prepare the market for several soon be approved compounds with comparable diagnostic performance. Then the market will decide which ones are most conveniently used clinically. It is thus important to recognize that both patented and non-patented compounds can address unmet clinical needs, improve patient outcomes and create significant revenues while following very different business models. I would however caution to exploit the lack of patent protection for rebranding long established compounds. This would simply create market and customer confusion.

Theranostics are rapidly growing and have generated substantial interest from industry. Both protected and unprotected compounds will have their place in clinic and research. Non-patent protected compounds could greatly facilitate translational research addressing, independent of Big Pharma, for instance resistance to PSMA targeted therapeutics.

Protected and non-protected compounds will give rise to larger and smaller companies all aiming to become fiscally solid despite very different business models.

They all are part of the new nuclear medicine ecosystem and make important contributions to patient care and will shape the further development of our discipline.

We should therefore appropriately appreciate the outstanding contributions that have given nuclear medicine an immense boost over the past 15 years.

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