

April 24, 2014

Via Email (AC90.comments@uspto.gov)  
James Engel  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of Deputy Commissioner for Patent Examination Policy  
US Patent and Trademark Office  
600 Dulaney Street  
Alexandria, VA 22314

Re: Docket No. PTO-P-2013-040, Comments on Changes to Require Identification of Attributable Owner

Dear Mr. Engel:

The Medical Device Manufacturers Association (“MDMA”) appreciates the opportunity to comment on the United States Patent and Trademark Office (“USPTO”) Notice of Proposed Rulemaking, Proposing Changes to Require Identification of Attributable Owner.<sup>1</sup> MDMA is a national organization representing hundreds of innovative, entrepreneurial medical technology companies. Our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies. The proposed changes to require identification of attributable owner would be extremely costly and burdensome for medical technology companies, the majority of which are small, privately held companies. Furthermore, the penalty of abandonment is far too severe and would have devastating consequences for companies and patent practitioners working in good faith.

The issue of patent trolls is real in a variety of industries, including medical technology. However, the proposed change would do little, if anything, to get at these abusive practices, while at the same time crippling innovative medical technology companies working in good faith to develop the medical breakthroughs of tomorrow. Below please find the areas of most concern to MDMA members. In addition, we strongly support the more detailed comments submitted by others in the life science community, including The Cook Group.

### **USPTO Has Significantly Underestimated the Costs of Compliance**

The medical technology industry relies upon physicians, engineers and innovators working together to develop new therapies. The complexity of the proposed changes and the variety of new definitions would be extremely burdensome, costly and complex for

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<sup>1</sup> 79 Fed. Reg. 4105 (January 24, 2014)

companies to comply. Furthermore, as technologies evolve and claims expanded, new analysis would be required to determine whether there is a “change to the attributable owner”. The proposal also fails to account for the increase in legal costs to cover the additional malpractice insurance that will be required in cases that result in abandonment.

Every dollar spent by emerging medical technology companies on compliance and legal fees is one less dollar spent on research and development. In addition, venture capital investment in medical technology has already seen a significant downturn in the past 5 years. Diluting precious investment dollars to be spent on compliance will only further exacerbate this funding dynamic.

### **Concerns with Establishing New Definitions**

The proposed changes attempts to import definitions outside the USPTO, often developed for very different purposes. As a result the definitions are unclear and confusing. For example, many of our members have been unable to ascertain from the proposal which company is “the ultimate parent entity” when a company is owned by a holding company. Related, it is unclear which company is “the ultimate parent entity” when a company has set up a holding company to own its patents, which is not an uncommon structure for commercial medical technology companies.

### **Proposal Disproportionately Impacts Smaller, Privately Held Companies**

According to the Department of Commerce 80% of all US based medical technology companies have fewer than 50 employees. 98% have fewer than 500 employees. The overwhelming majority of these companies are privately held. Under the current proposal, privately held companies and their investors are placed at a significant disadvantage. The requirement to identify and list the residence and corresponding address of each stockholder is unreasonable, unworkable and will create another disincentive for individuals to invest in life-saving technologies. For example, an angel investor who prefers to remain silent in an investment will now have his/her name made public and their address. This will result in countless future solicitations and possible harassment from others seeking investment. As a result, fewer and fewer individuals are likely to invest in start-up companies.

Private companies should be required to provide the same information as public companies under the proposed rule, providing the name of the company, business address and state of incorporation. If additional information is needed as a result of legal proceedings, this can be obtained in an environment with appropriate privacy safeguards.

### **Legal Titleholder Information is Sufficient to Achieve USPTO’s Objectives**

In an effort to limit unnecessary regulations and requirements, USPTO should only require identification of the legal titleholder of a non-provisional patent application or patent. As mentioned above, the overwhelming majority of medical technology companies are small businesses. Establishing additional administrative and legal requirements with no demonstrable, corresponding public benefit is not conducive to innovation, investment and job creation. Furthermore, because the statute does not

require assignments to be recorded, the USPTO cannot promulgate new rules that require assignments (and by extension “attributable interests”) to be recorded with the Office.

**Proposed Penalty of Abandonment is Extreme and Excessive**

Beyond the significant increased legal costs that will result from increased malpractice insurance requirements, the proposed penalty of abandonment is excessive and extreme. If adopted, USPTO would establish a new method to challenge the validity of patent claims. This is far too draconian of a punishment to deal with an administrative issue. In addition, on occasion, USPTO mis-records assignments. What will happen is USPTO cannot find a properly recorded assignment? MDMA recommends a more appropriate approach to promote the identification of legal titleholder information is to offer discounts on fees paid to the USPTO.

**Conclusion**

MDMA appreciates the opportunity to provide comments on this important issue. While we support targeted efforts to address abusive patent trolls, the proposed rule regarding changes to require identification of attributable owner, is overly broad, unworkable and will not address the abusive practices of these bad actors. We look forward to working with USPTO to develop more targeted and meaningful solutions to the issue of patent trolls.

Respectfully Submitted,

A handwritten signature in black ink, reading "Mark B. Leahey", written over a light blue rectangular background.

Mark B. Leahey  
President & CEO  
Medical Device Manufacturers Association