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GETTING NANO TATTOOS RIGHT—A CHECKLIST OF LEGAL AND ETHICAL HURDLES FOR AN EMERGING NANOMEDICAL TECHNOLOGY

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Abstract

The nano tattoo represents a nascent technology designed to be implanted in the skin to provide continuous and reliable glucose detection for diabetics. Its potential benefits are compelling not only for its ability to prevent diabetic complications and decrease related social costs, but also for its ease of use and relative patient-user comfort. This Note aims to articulate a checklist of fundamental intellectual property, bioethical and system design issues that are appropriately considered in the pre-clinical, pre-commercialization phase of nano tattoo development. Early and regular consideration of these factors can increase the odds of a societally beneficial dissemination of this device by engaging relevant researcher, medical, patient-user and patient-advocate communities concerned with its appropriate application, as well as policymaking communities focused on effectively managing diabetes-related healthcare costs. The checklist of factors includes fundamental issues and is generally applicable to nanomedical inventions.

Keywords
Nano tattoo; bioethics; intellectual property; system design; commercialization

Introduction

The nano tattoo is an intradermally embedded array of biosensors, functionalized to emit visible color changes corresponding to target chemical markers in the blood stream. Much of the technology's development has focused on glucose detection and the potential transformation of
diabetic care. This device is poised to obsolesce the current glucose measuring standard of fingersticks, a method widely considered suboptimal in diagnostic efficiency and patient comfort. In the long term, the nano tattoo has the potential to decrease diabetic complications and its associated economic costs.\(^1\) Despite these potential benefits, intellectual property, bioethical and system design hurdles have yet to be rigorously considered. These matters are best addressed *upstream*\(^2\) — in the pre-clinical, pre-commercialization phase — before design choices lock innovators and patient-users into device configurations that can lead to unintended, negative outcomes.

**Technological Development**

Nano tattoo technology represents a significant refinement of the current diagnostic method for detecting glucose levels in diabetics. Historically, a patient applied a small fingerstick sample of blood to a sensor strip and then inserted the strip into a portable monitor where an electrochemical reaction provided the basis for measuring blood glucose.\(^3\) Subsequent integration of carbon nanotubes in the sensors led to greater sensitivity, more efficient electron transfer from enzyme to electrode, and the capability of increased catalytic modifications of this

\(^1\) Within five years of onset, in the absence of proper care, diabetes can lead to neuropathy, retinopathy and other complications. If diagnosed, the diabetic patient typically turns to “fingersticks” to monitor glucose levels, a technology that calls for extracting blood from a finger tip as many as four times daily.


external sensing process.\textsuperscript{4} The capacity for continuous internal glucose monitoring arose with the development of an implantable, fluorescence-based nano-biosensor.\textsuperscript{5} Later research addressed biosensor degradation, improved visualization of color changes and minimized host immune response.\textsuperscript{6} Combined, these developmental innovations represent the state of the art.

**Factor Checklist**

As the technology moves towards commercialization, we propose a checklist of factors designed to preemptively address potential legal, bioethical and system design issues that have historically threatened to impede the societally beneficial market introduction of novel medical devices. The non-exclusive list of seven factors includes: patent scope, patent thicket potential\textsuperscript{7}, patient


autonomy, beneficence, multi-dimensional justice, privacy and system design. We explain and apply each factor to nano tattoos below.

**Patent Scope**

It is not uncommon for nanotechnology-related patents to claim a broad area of functionality within the radius of their legal rights to exclude non-inventors’ uses. In order to avoid chilling experimentation for fear of patent infringement, as well as to safe-guard against post-commercialization invalidation of over-broad patents, nano tattoo patents should be narrowly tailored. Presently, patents covering this technology are not overbroad in scope, but our analysis suggests monitoring this art field as developments continue.

**Patent Thicket Potential**

Since nanotechnologies are often transdisciplinary, encompassing such fields as physics, chemistry, engineering and/or biology, it is not unusual for a single nano-enabled invention to be covered by multiple overlapping patents. By increasing ownership determination costs, these “patent thickets” exert a retarding effect on rates of technological development and dissemination. That fewer than ten U.S. patents have been issued covering fundamental nano tattoo-related inventions suggests that, currently, this area of innovation does not present a high probability of a patent thicket.

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9 Databases used for this search include the United States Patent and Trademark Organization, Web of Science, Pub Med, LexisNexis and Westlaw; the keywords were “nano tattoo” and “smart tattoo.”
**Autonomy**

Patient autonomy requires delivery of relevant and understandable information that enables patients to make informed decisions regarding diagnostic and treatment alternatives. Avoiding paternalism and upholding a patient’s right to self-determination necessitates not only articulation of a device’s benefits, but also disclosure of attendant risks. Nano tattoo-enabled management of glucose levels can lead to reduced instances of altered states of consciousness brought on by hyper- or hypoglycemia. We predict increased autonomy in the form of more opportunities for patient-users to make informed treatment decisions with clear minds.

**Beneficence**

Beneficence concerns improving quality of life or life expectancy, and can be assessed through clinical trials. A device should be more than merely technically innovative; the user should receive a tangibly beneficial result. Based on existing studies indicating that avoidance of hyperglycemic episodes results in decreased diabetic complications, nano tattoos will likely improve both quality of life and life expectancy, but this likelihood must be clinically confirmed to assure beneficence.

**Justice**

The principle of justice has meaning in at least three registers: socio-economic justice, distributive justice and environmental justice. Socioeconomic justice recognizes fair treatment of individuals and classes independent of their social position or material wealth. Relatedly, distributive justice is achieved when those who reap the benefits of an activity also bear its costs, instead of outsourcing the latter to the less powerful. And environmental justice aims to safeguard the ecosphere against spent nanoparticles whose transport paths and fates are presently
poorly understood. Nano tattoo commercialization will likely encounter hurdles related to justice issues in all three registers, since large portions of the estimated 25.8 million people constituting the U.S. diabetic community—children, African-Americans, Native-Americans, Asian-Americans, Hispanic/Latino Americans, pregnant women, the obese, the extremely ill—are also historically disadvantaged groups who have born the brunt of environmental costs of technological developments, who continue to receive sub-standard medical services, and who seldom share equitably in the fruits of medical technology innovation.10

Privacy

The power to control dissemination of personal information is of critical concern in the context of nanomedicine. Since nano tattoos will visually reflect glucose concentrations, third parties may intercept a patient-user's personal medical information. Such an unintended disclosure of health status would constitute a direct violation of patient confidentiality, presuming a traditional patient-doctor relationship. This type of unintended disclosure might be even more harmful to a patient once nano tattoos are designed to generate information concerning other socially stigmatized conditions, such as cancer, HIV-AIDS, or other infectious diseases.

System Design

Technologies are not apolitical artifacts that merely achieve their stated functional goal. Rather, through their designs, they tend to encourage certain types of behaviors and effects, while discouraging others. There are often multiple designs capable of achieving the main goal of a

technology, each of them entailing different cost/benefit ratios for users and society at large. Possible, and possibly competing, nano tattoo designs will likely implicate varied outcomes for patient-users and society. And all the other factors of the checklist will be touched by the technology's design: greater or lesser rates of subsequent innovation, more or less patient autonomy, beneficence, and realized justice. Important questions will likely be addressed by nano tattoo design decisions: Who will be capable of using the device? Who will monitor possible human and/or environmental impacts? Most fundamentally, which groups will be able to contribute to discussions about appropriate designs? Accordingly, the nano tattoo design process should be open to input from all communities that are likely to be impacted by its introduction: patient-users, the medical community, marginalized community advocates, scientific researchers, legal advocates, and policy makers.

Conclusion

The checklist factors implicate one another and occasionally overlap in their scope of concern. Though not exhaustive, they do address fundamental upstream intellectual property, bioethical and system design issues of nano tattoos, as well as other nanomedical devices. And the more promising the potential societal benefits of an emerging nanomedical device are, the more important does this upstream assessment checklist become.