



INNOVATION PARTNERSHIPS

UNIVERSITY OF MICHIGAN

Socially Responsible Licensing: Our Experience & Lessons Learned

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Michigan Research at a Glance

Fiscal Year 2024

\$2.04B

total research
expenditures

1,931

research awards

615

new inventions

28

new startups

IT'S OUR JOB TO MAKE SURE THAT EVERY
U-M RESEARCH DISCOVERY HAS AN
OPPORTUNITY TO CHANGE THE WORLD.



MAXIMIZE POSITIVE SOCIETAL IMPACT

An Inventor-Centered Approach to Maximizing Positive Society Impact

Branding for Social Impact



28% of innovations have a non-med/eng. inventor

Broad Dissemination Models

Pediatric Sleep Questionnaire: Sleep-Disordered Breathing Subscale 07012

Child's Name: _____ Study ID #: _____
 Person completing form: _____ Date: ____/____/____

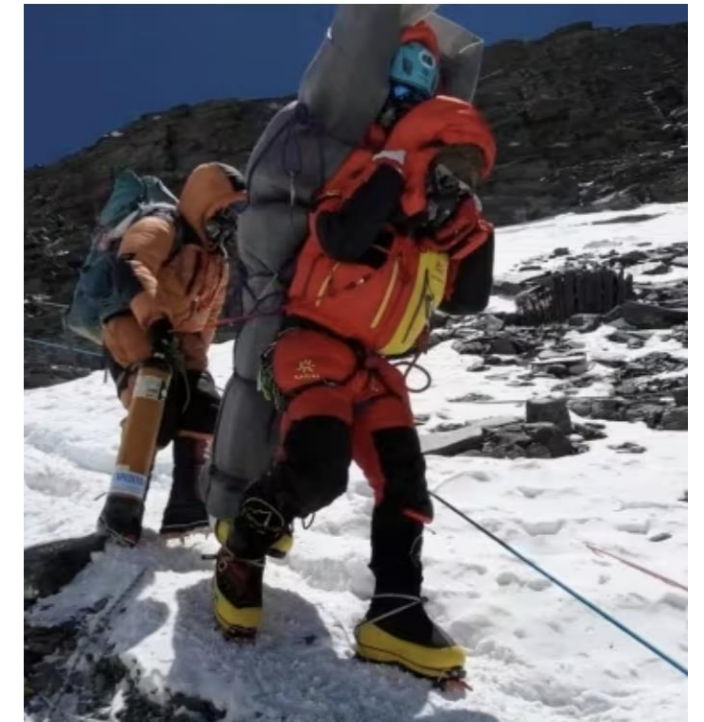
Please answer these questions regarding the behavior of your child during sleep and wakefulness. The questions apply to how your child acts in general during the past month, not necessarily during the past few days since these may not have been typical if your child has not been well. You should circle the correct response or *print* your answers neatly in the space provided. A "Y" means "yes," "N" means "no," and "DK" means "don't know."

1. WHILE SLEEPING, DOES YOUR CHILD:			
Snore more than half the time?Y	N DK	A2
Always snore?Y	N DK	A3
Snore loudly?Y	N DK	A4
Have "heavy" or loud breathing?Y	N DK	A5
Have trouble breathing, or struggle to breathe?Y	N DK	A6
2. HAVE YOU EVER SEEN YOUR CHILD STOP BREATHING DURING THE NIGHT?			
	Y	N DK	A7
3. DOES YOUR CHILD:			
Tend to breathe through the mouth during the day?Y	N DK	A24
Have a dry mouth on waking up in the morning?Y	N DK	A25
Occasionally wet the bed?Y	N DK	A32
4. DOES YOUR CHILD:			
Wake up feeling unrefreshed in the morning?Y	N DK	B1
Have a problem with sleepiness during the day?Y	N DK	B2

>1.5M patients given a voice through UM patient reported outcomes" (last 10 yrs.)

30+ active patient reported outcomes across multiple domains at UM

Inventor-Centered



- **Service** approach
- **Inventor** as best situated to make important decisions
- We are not gatekeepers, not police, not even the experts... we are **sherpas** (guides)

Why is SRL Important to UM?

Central to our mission to **maximize positive societal impact**

- bringing a product to a market may not be enough
- early signatory to “AUTM’s 9 Points”

Platform technologies may have **unethical uses** (e.g., CRISPR or AI)

This is what our inventors want

- can drive **inventor engagement & satisfaction**

Policy setting & professional standards can be slow

- licensing practices can serve as proving ground for policy setting



Licensing Activity

Last fiscal year

240 nonexclusive licenses

43 exclusive

31 startups

12 existing co.'s

Life Sciences Product Pipeline

40 approved **products**
(since 2000)

21 products in **clinical trials**

70 licensed products in **preclinical**
development

Reserved Rights

&

Compulsory Sublicensing

2.2 Without limiting any other rights it may have, MICHIGAN specifically reserves the right for it and its affiliates to practice and have practiced the PATENT RIGHTS for research, public service, internal (including clinical) and/or educational purposes, and the right to grant the same limited rights to other non-profit research institutions.

Good: broad right to practice (or have practiced the licensed patent) for any public service purpose

Shortcomings:

- limited to only the university patents (ineffective if licensee has their own patents)
- some negotiation difficulties (particularly later stage)

Access Plans

Upon regulatory approval, requires licensee to **disclose** to university:

(1) Low & middle income countries (**LMICs**) not being pursued

(2) **actions to be taken** to support affordable access in such LMICs (or other underserved markets)

Good:

-helpful **information sharing**

-applies to the **drug** (not just university patents)

-most of pharma. industry already doing this (**77%** of late stage drugs subject to access plans)

**Originally developed by Amir Naiburg at UCLA and Andrew Goldman with Medicines Patent Pool

4.7 LICENSEE shall provide to MICHIGAN an Affordable Access Plan of the scope defined in Appendix 4.7 within three (3) months after the first marketing approval of a LICENSED PRODUCT received by LICENSEE or a SUBLICENSEE from the U.S. Food and Drug Administration or the European Medicines Agency. LICENSEE agrees to use reasonable efforts to make progress toward completing the plans stated in the Affordable Access Plan, as it may be amended from time-to-time.

Appendix 4.7

A. "Affordable Access Plan" means a written statement setting forth: (a) the specific LMICs in which neither LICENSEE nor any SUBLICENSEE intends to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territories"); (b) actions to be taken by LICENSEE and, if applicable, SUBLICENSEE(s) that reasonably intended to support affordable access in the Non-Commercialized Territories by patients to products that would constitute LICENSED PRODUCTS if covered by one or more of the PATENT RIGHTS; and (c) actions to be taken by LICENSEE and, if applicable, SUBLICENSEE(s) that are reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S. Such actions, as referred to above, shall at a minimum include strategies, such as licensing or partnerships (which may include, for example, partnerships with non-profit organizations), and timelines therefor. As used herein, "LMICs" means Low and Middle Income Countries as the term is defined and/or used by the World Bank Group, its primary recognized member organizations, and/or successor of any of the foregoing. Upon LICENSEE's request, MICHIGAN agrees to meet with LICENSEE to assist in the drafting of the Affordable Access Plan.

B. Notwithstanding the foregoing, in lieu of providing an Affordable Access Plan, LICENSEE may instead submit a reasonably detailed written explanation as to why LICENSEE believes that an Affordable Access Plan is unreasonable or infeasible (the "Infeasibility Statement"), which is due on the same date that the Affordable Access Plan would have been due. After LICENSEE submits an Infeasibility Statement to MICHIGAN, LICENSEE agrees to promptly (but in no event less than two months thereafter) meet with MICHIGAN in person or by video conference to discuss the Infeasibility Statement (the "Initial Discussion"). If, following such meeting, MICHIGAN concludes that the Affordable Access Plan requirements of this Agreement are reasonable and desirable, LICENSEE shall nevertheless provide an Affordable Access Plan to MICHIGAN within three (3) months after MICHIGAN'S written request following the Initial Discussion (and, for clarity, the remaining provisions relating to the Affordable Access Plan shall apply).

C. If LICENSEE fails to follow any plan, take any action, or meet any milestone by a deadline that is specifically or generally stated in the Affordable Access Plan, it shall promptly and in good faith negotiate an amended Affordable Access Plan with MICHIGAN. In addition, within thirty (30) days after a request by MICHIGAN (but not to be requested any more than once in any calendar year), LICENSEE agrees to confer with MICHIGAN in good faith to review LICENSEE's progress, and to consider in good faith any reasonable modifications suggested by MICHIGAN concerning LICENSEE's Affordable Access Plan ("Progress Discussion"). MICHIGAN may invite a designated entity to join either the Initial Discussion or Progress Discussion, provided that such discussions shall at all times be made subject to the confidentiality obligations of this Agreement (or another mutually agreed-upon nondisclosure agreement).

U-M Therapeutics Licensing

Maximizing the positive societal impact of U-M biopharma research discoveries.

U-M has a rich history of discovering compounds that lead to FDA approved treatments. [An analysis by “Drug Discovery Today”](#) found that U-M is the largest single contributor among academic institutions in creating FDA approved new molecular entities. U-M relies on partners to advance the early-stage discoveries from U-M labs through pre-clinical and clinical studies to achieve regulatory approval so that these new treatments can improve, extend and even save lives.

As an early adopter of [AUTM’s Nine Points of Licensing in the Public Interest](#), U-M prioritizes responsible stewardship of intellectual property to drive innovation and maximize public benefit. Our therapeutic licensing approach balances the significant investment required to develop early-stage discoveries with the need for diligent development and broad accessibility, ensuring that new treatments reach patients and create meaningful societal impact.

Learn more about Innovation Partnerships’ licensing process [here](#).



[See U-M’s template for an exclusive patent license here.](#)

Experience With AAP

Included in last **9** new exclusive therapeutics licenses.

- 6 closed **funding rounds** (totaling over \$95M)
- also added in one amended license (in **late-stage clinical trials**)

After original discussions, AAP provision is now **readily accepted** by UM's most frequent startup law firms

- includes world's most active VC law firm

Talking points:

- explain what this is (**information sharing**)
- most large pharma companies have their own affordable access plans (i.e., they are **already doing this**)
- major U.S. universities doing this (Michigan, UCLA, Berkeley, Columbia, etc.)

Thank you!

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