EDWARDS LIFESCIENCES CORPORATION

Global Unilateral Pro-Innovation (Anti-Copycatting) Policy

Effective Date: November 15, 2019

INNOVATION STATEMENT

Edwards Lifesciences respects the dedication of our employees, our competitors, and the many scientists and engineers who innovate and seek to solve some of the most deadly diseases, lengthen life and improve the quality of patient life by creating or improving upon medical devices. Innovation is imperative to serving patients and requires decades of investments and risk-taking. Edwards is committed to innovation and the benefits that innovation brings to patients and all of society. To honor this commitment, Edwards Lifesciences adopts this unilateral pro-innovation policy which will govern our behaviour as it relates to those entities and individuals who interact with, provide information to and support those entities (“Copier” or “Copiers”) who do not innovate but instead largely copy, reverse engineer, and duplicate innovative devices and undermine the intellectual property of innovators.

These Copiers make little attempt to build new, innovative technologies or contribute to science. Instead, they simply attempt to copy a trusted and proven medical technology, undermining the incentive for innovative companies to invest resources and take the necessary risks to bring innovative, life-changing therapies to physicians and patients. In the long-term, these tactics are harmful to patients and all of society.

As such, Edwards strongly believes that we should limit our interactions with such Copiers and the individuals and entities with which they interact. We do this in accordance with applicable law and in a tradition of upholding the high ethical standards of our Credo—that through our actions we are trusted partners with customers, colleagues and patients.

DEFINITIONS

Copier – company or companies that largely copy, reverse engineer, or duplicate the devices and intellectual property of innovative companies, with little attempt to advance the technology or science with new technologies.

PURPOSE

Edwards Lifesciences Corporation and its subsidiaries (“Edwards”) innovates in all segments of structural heart and critical care monitoring. For example, we pioneered the development of the SAPIEN family of transcatheter heart valve systems and the TAVI/TAVR procedure. Edwards routinely collaborates with clinicians, institutions and suppliers in the development of these new and innovative products and procedures. There are many other innovators in this field who also improve the TAVI/TAVR procedure, and collaborate with the same clinicians, institutions and suppliers on their products. However, there have recently been companies who have not
developed, innovated, or created their own product, but instead have manufactured copies of the Edwards’ products. The purpose of this Unilateral Policy is to adopt an approach to how Edwards will work with clinicians, institutions and suppliers and others, in light of their interactions with the Copiers. A central part of this program is our commitment to improve the lives of patients through innovation, regardless of who innovates, and not to impede those innovators who build upon our innovations. Also central is our strong desire to ensure our ingenuity, ideas and innovation are not provided to Copiers and used to further undermine innovation.

SCOPE AND APPLICABILITY

This Policy applies throughout Edwards. All Edwards’ employees, directors and entities working on behalf of Edwards are expected to comply with this Policy, even if local law is less restrictive. Specific practices will conform to the legal, regulatory and cultural requirements of the countries where Edwards operates. Further detail on such specific practices may be documented in Pro-Innovation Guidance.

This Policy and any Pro-Innovation guidelines are intended to comply with and are subject to compliance with Intellectual Property, Antitrust, and Unfair Competition Laws. Since Edwards’ business entities are required to always comply with relevant local laws and regulations, such laws and regulations are to be followed even if they conflict with certain aspects of this Policy and related procedures.

The determination of whether a company meets the definition of a Copier company and is affected by this Policy will be made solely by the Edwards Executive Leadership Team.

The determination of whether a particular individual is serving as a researcher, clinical investigator, proctor or promoter for a Copier company will be made by a Vice-President with approval from an Edwards Executive Leadership Team member. A list will be maintained by Legal and circulated as appropriate.

As of the effective date, this Policy is implemented.

POLICY

Edwards adopts this unilateral pro-innovation policy (the “UPIP”) in order to maintain, protect and to further enhance the Edwards commitment to innovation, and to encourage innovation in the fields in which we participate. The UPIP applies to those interactions by Edwards with various clinicians, institutions, distributors and suppliers of those kinds of services respecting this UPIP. The UPIP will not apply to any sales, consignment or other type of sales relationship. Edwards, unilaterally and in its sole discretion, will limit its interactions with clinicians, institutions and suppliers who also support Copier companies with the same kinds of interactions.
Research/Clinical Trial Principal Investigators or Subinvestigators:

For any physician or clinical investigator or researcher that participates in a research trial or clinical trial of a Copied device sponsored by a Copier company, Edwards will unilaterally and in its sole discretion, as applicable:

- Not involve the physician in future EW research or clinical trial work
- Not renew sponsorship agreements or grant arrangements (IIT, IIS, fellowships etc)
- Not renew or initiate any consulting agreements

Proctor, Investigator, Physician Advisor:

If a Proctor, Investigator or Physician Advisor knowingly and willingly aligns themselves with a Copier company by doing such things as performing or supporting a Copied device case at a congress or performing a Copied device case and promoting it, then Edwards will, unilaterally and in its sole discretion, as applicable:

- Not renew Edwards proctoring agreements
- Not renew Edwards sponsorship agreements or contracts (IIT, IIS, fellowships etc)
- Not use the Proctor, Investigator or Physician Advisor in future Edwards publications or Edwards presentations
- Not renew or initiate any consulting agreements

If a Proctor willingly proctors a case of a Copied device, unilaterally and in its sole discretion, Edwards will:

- Not renew Edwards proctorship
- Not include in any consulting agreements

Distributors:

Unilaterally and in its sole discretion, Edwards will not distribute through distributors that also distribute Copied devices, subject to applicable law.

Finally, Edwards does not seek, nor will we accept, any agreement or assent from clinicians, institutions, distributors and suppliers of those kinds of services respecting this UPIP, either now or at any future time. This
UPIP is being established by Edwards unilaterally and is not therefore subject to negotiation. We reserve the right at any time to modify this UPIP, to establish new or different policies or to discontinue any or all of such policies. This UPIP shall remain in effect until modified or terminated by us. We believe that this UPIP is clear and unambiguous. Should you have any inquiries regarding this UPIP, however, please direct them to the Edwards Law Department.

**Do not discuss** (seriously or in jest) or exchange information regarding the following:

**ANY REACTIONS OR CONVERSATIONS WITH OTHER PHYSICIANS**, including:
Don’t share the substance of UPIP related conversations of a physician with other physicians; keep the conversations isolated to the particular physician you are talking to and what that particular physician is doing.

**MAKE NO AGREEMENTS, EXPRESS OR IMPLIED**, including: Do not seek, nor accept, any agreement or assent implied or otherwise from clinicians, institutions, distributors and suppliers respecting this policy or respecting any Copier company and their behavior.

**DO NOT REFUSE TO SELL**, including:
Do not state (seriously or in jest) or imply that Edwards will refuse to sell product, or raise prices to a physician or institution as a result of this policy. Edwards will not refuse to sell, and Edwards will continue provide all necessary support to enable the potential for the best result of the cases.

**COMPETITION.** Continue to follow the principles outlined in our Titanium Book regarding our interactions with Competition and our Sales and Marketing practices, which includes not seeking non-public confidential competitive information from any third party.

The exchange of information as it relates to this policy should be limited to emphasizing the unilateral nature of this policy, that Physicians are able to choose whom they will work with, and that Edwards would never withhold the sale of product to them if they are a trained and qualified physician.

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