



ATTORNEY GENERAL OF TEXAS
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April 21, 2004

Mr. Jeffrey S. Young
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OR2004-3250

Dear Mr. Young:

You ask whether certain information is subject to required public disclosure under the Public Information Act (the "Act"), chapter 552 of the Government Code. Your request was assigned ID#198903.

The Texas Tech University Health Sciences Center (the "TTUHSC") received a request for information related to a specific investigational study. You state that some information responsive to the request has been provided to the requestor. You claim that the remaining requested information is excepted from disclosure under sections 552.101 and 552.110 of the Government Code. Because you believe that the proprietary interests of Wright Medical Technology, Inc. ("Wright") are implicated by the request, you notified Wright of the request in compliance with section 552.305 of the Government Code. *See* Gov't Code § 552.305(b) (permitting interested third party to submit to attorney general reasons why requested information should not be released). Wright responded to the notice and asserts that some of the requested information is excepted from disclosure under section 552.110 of the Government Code. We have considered the exceptions you and Wright claim and reviewed the submitted information.¹ We have also considered comments submitted to this office by the requestor. *See* Gov't Code § 552.304 (providing that interested party may submit comments stating why information should or should not be released).

¹We assume that the "representative sample" of records submitted to this office is truly representative of the requested records as a whole. *See* Open Records Decision Nos. 499 (1988), 497 (1988). This open records letter does not reach, and therefore does not authorize the withholding of, any other requested records to the extent that those records contain substantially different types of information than that submitted to this office

We note at the outset that the requestor argues that the information is subject to section 552.022 of the Government Code. Section 552.022 provides that, except as provided by section 552.108, a completed report or investigation made of, for, or by a governmental body is not excepted from required disclosure under the Act unless the report or investigation is expressly confidential under other law. Gov't Code § 552.022(a)(1). You advise this office that a professor with TTUHSC Department of Anesthesiology, in connection with other TTUHSC anesthesiology professors, conducted a pilot research study between 1999 and 2001 involving ADCON-L. However, we find that the pilot research study at issue is not a completed report or investigation of the type contemplated in section 552.022(a)(1). Even assuming the requested information was subject to section 552.022(a)(1), sections 552.101 and 552.110 deem information confidential by law, and therefore we would still consider the applicability of these sections to the requested information.

Section 552.101 excepts from disclosure "information deemed confidential by law, either constitutional, statutory, or by judicial decision." Gov't Code § 552.101. This section encompasses information protected by other statutes. You claim that portions of Exhibits F and G are excepted from disclosure under section 552.101 in conjunction with section 161.032 of the Health and Safety Code. Section 161.032 provides in part:

(a) The records and proceedings of a medical committee are confidential and are not subject to court subpoena.

....

(c) Records, information, or reports of a medical committee . . . and records, information, or reports provided by a medical committee . . . to the governing body of a public hospital . . . are not subject to disclosure under Chapter 552, Government Code.

....

(f) This section . . . do[es] not apply to records made or maintained in the regular course of business by a hospital

Health & Safety Code § 161.0315(a), (c), (f). Section 161.031(a) defines a "medical committee" as "any committee . . . of (3) a university medical school or health science center" Health & Safety Code § 161.031(a). Section 161.031(b) provides that the "term includes a committee appointed ad hoc to conduct a specific investigation or established under state or federal law or rule or under the bylaws or rules of the organization or institution." Health & Safety Code § 161.031(b). Section 161.0315 provides in relevant part that "[t]he governing body of a hospital, medical organization [or] university medical school or health science center . . . may form . . . a medical committee, as defined by section 161.031, to evaluate medical and health care services" Health & Safety Code § 161.0315(a).

You inform us that TTUHSC's Institutional Review Board (the "IRB") is a committee established pursuant to federal law.² Federal regulations define an IRB as

any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects

21 C.F.R § 56.102(g). Thus, we conclude that TTUHSC's IRB is a medical committee created pursuant to federal law, and consequently, the IRB falls within the definition of "medical committee" set forth in section 161.031 of the Health and Safety Code.

Having concluded that the IRB constitutes a medical committee, we agree that portions of the submitted documents are confidential under section 161.032 of the Health and Safety Code and must be withheld under section 552.101 of the Government Code. *See Jordan v. Court of Appeals*, 701 S.W.2d 644, 647-48 (Tex. 1985) (determining that statutory predecessor extended to documents prepared by or at direction of committee in order to conduct open and thorough review, and privilege extends to minutes of committee meetings, correspondence between members relating to deliberation process, and any final committee product); *see also* Open Records Decision No. 591 (1991) (concluding that purpose of predecessor statute was to encourage frank discussion by medical professionals). Accordingly, TTUHSC must withhold the submitted documents we have so marked in their entirety.

You also argue that the remaining information is excepted from disclosure under section 552.101 in conjunction with section 51.914(1) of the Education Code. Section 51.914 of the Education Code provides in pertinent part as follows:

In order to protect the actual or potential value, the following information shall be confidential and shall not be subject to disclosure under Chapter 552, Government Code, or otherwise:

- (1) all information relating to a product, device, or process, the application or use of such a product, device, or process, and all technological and scientific information (including computer programs) developed in whole or in part at a state institution of higher

²See 42 U.S.C. § 289(a) (providing that Secretary of Health and Human Services shall by regulation require that each entity which applies for grant, contract, or cooperative agreement for any project or program which involves conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to Secretary that it has established "Institutional Review Board" to review biomedical and behavioral research involving human subjects conducted at or supported by such entity).

education, regardless of whether patentable or capable of being registered under copyright or trademark laws, that have a potential for being sold, traded, or licensed for a fee[.]

Educ. Code § 51.914(1). As noted in Open Records Decision No. 651 (1997), the legislature is silent as to how this office or a court is to determine whether particular scientific information has “a potential for being sold, traded, or licensed for a fee.” Furthermore, whether particular scientific information has such a potential is a question of fact that this office is unable to resolve in the opinion process. *See id.* Thus, this office has stated that in considering whether requested information has “a potential for being sold, traded, or licensed for a fee,” we will rely on a university’s assertion that the information has this potential. *See id.* *But see id.* at 10 (stating that university’s determination that information has potential for being sold, traded, or licensed for fee is subject to judicial review).

You state that the all of the information submitted as Exhibits F and G pertains to a pilot research study conducted by TTUHSC and its physicians and researchers concerning a specific application or use of ADCON-L. You also state that ADCON-L or a similar product could be manufactured and sold in the United States or overseas in the future, creating at least the potential for the delivery processes developed at TTUHSC to be sold, traded, or licensed for a fee in connection with such product. After reviewing your arguments and the submitted information, we find that a majority of the remaining information contained in Exhibits F and G directly reveals the substance of research or proposed research and is, therefore, within the scope of section 51.914. Accordingly, the information we have marked under the Exhibits F and G cover sheets must be withheld under section 552.101 of the Government Code in conjunction with section 51.914 of the Education Code.

The remaining portions of Exhibits F and G, however, contain only general background material, correspondence, invoices and other information tangential to the proposed research. You have not explained, nor can we discern, how the release of this information would reveal the details of the research at issue. *See generally* Open Records Decision Nos. 557 (1990) (stating that working titles of experiments are not *per se* protected by Educ. Code § 51.914 because release would not permit person to appropriate research nor does information directly reveal substance of proposed research), 497 (1988) (stating that information related to research is not protected if it does not reveal details about research). Accordingly, TTUHSC may only withhold the information we have marked under section 552.101 in conjunction with section 51.914 of the Education Code.³

³You claim that portions of the submitted information are subject to federal and state laws regarding the confidentiality of protected health information, including, but not limited to the Health Insurance Portability and Accountability Act (“HIPAA”). Because we have determined that all of the submitted information that contains protected health information is excepted from disclosure under other statutes, we need not address your claim that HIPAA applies. *See* Open Records Decision No. 681 (2004)(HIPAA, 42 U.S.C. §§ 1320-1320-8, does not make information confidential for purpose of section 552.101 of the Government Code).

Wright claims that the information at issue constitutes trade secret information pursuant to section 552.110(a) of the Government Code. Section 552.110(a) protects the proprietary interests of private parties by excepting from disclosure trade secrets obtained from a person and privileged or confidential by statute or judicial decision. *See Gov't Code § 552.110(a)*. Under section 757 of the Restatement of Torts, a "trade secret"

may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives [one] an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business in that it is not simply information as to single or ephemeral events in the conduct of the business, as for example the amount or other terms of a secret bid for a contract or the salary of certain employees. . . . A trade secret is a process or device for continuous use in the operation of the business. Generally it relates to the production of goods, as for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

RESTATEMENT OF TORTS § 757 cmt. b (1939); *see also Hyde Corp. v. Huffines*, 314 S.W.2d 763, 776 (Tex. 1958), *cert. denied*, 358 U.S. 898 (1958); Open Records Decision Nos. 255 (1980), 232 (1979), 217 (1978).

The following six factors are relevant to the determination of whether information qualifies as a trade secret under section 757 of the Restatement of Torts:

- (1) the extent to which the information is known outside of [the company's] business;
- (2) the extent to which it is known by employees and others involved in [the company's] business;
- (3) the extent of measures taken by [the company] to guard the secrecy of the information;
- (4) the value of the information to [the company] and to [its] competitors;
- (5) the amount of effort or money expended by [the company] in developing this information; and

- (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

RESTATEMENT OF TORTS § 757 cmt. b (1939); *see also* Open Records Decision No. 232 (1979). If a governmental body takes no position on the application of the "trade secrets" component of section 552.110 to the information at issue, this office will accept a person's trade secret claim under section 552.110(a) if the person establishes a *prima facie* case for the exception and no one submits an argument that rebuts the claim as a matter of law. *See* Open Records Decision No. 552 at 5 (1990).

Wright informs us that the document entitled "I.D.E. Clinical Study: A Randomized, Controlled Double-blind Multicenter Study to Evaluate the Safety and Effectiveness of ADCON-L for Inhibition of Postoperative Peridural Fibrosis Following Spinal Root Decompression" (the "study") is a document filed with the Food and Drug Administration ("FDA") as a precondition to clinical testing of a device. The study is included in Exhibit F. Wright argues that this information satisfies the definition and the six indicia of a trade secret under section 757 of the Restatement of Torts and, thus, qualifies as a trade secret for purposes of section 552.110(a) of the Government Code. Specifically, Wright states that the study is not known outside Wright's business, other than by the FDA, and that it is not subject to disclosure by the FDA pursuant to federal law. Further, Wright states that the study is maintained under "lock and key" by the company's clinical research department and is only shared with persons within the company who need to know its contents. Additionally, Wright explains that release of the study would place it at a serious competitive disadvantage. Because the company has invested countless hours of expensive clinical research in the study's development, the company argues, its release would allow a competitor or competitors to utilize the information without incurring the expense involved in developing the data and such a competitor or competitors could bring a product to the marketplace for significantly less expense. Further, Wright estimates that duplication of the study would cost the company approximately one million dollars. Finally, Wright states that it is not aware of any legitimate method by which the study could be obtained by another entity other than by the entity making the type of investment already made by Wright.

Although in his brief to this office, the requestor argues that TTUHSC has not and could not legitimately provide evidence of substantial competitive harm to TTUHSC, we note that TTUHSC is not required to submit reasons why information should be withheld under section 552.110. Instead, a governmental body such as TTUHSC may decline to release the information for the purpose of requesting an attorney general decision on behalf of a third party, as TTUHSC has done in this case. *See generally* Gov't Code § 552.305. Based on our review of Wright's arguments and the specific document at issue, we find that Wright has established a *prima facie* case that the study qualifies as trade secret information for purposes of section 552.110(a) of the Government Code, and we have received no arguments that rebut Wright's position as a matter of law. Accordingly, we conclude that TTUHSC must withhold the documents at issue that we have marked pursuant to section 552.110(a).

Finally, we address the requestor's argument that his client has a special right of access to the submitted information pursuant to section 552.023 of the Government Code. Section 552.023 gives a person or a person's authorized representative a "special right of access, beyond the right of the general public, to information held by a governmental body that relates to the person and that is protected from public disclosure by laws intended to protect that person's privacy interests." Gov't Code § 552.023. However, none of the statutes under which we have determined the submitted information is excepted from disclosure are intended to protect individuals' privacy interests. Therefore, we conclude section 552.023 does not provide the requestor with a special right of access to the requested information. *Cf.* Open Records Decision No. 556 (1990) (noting when a requestor seeks information concerning himself, governmental body cannot claim exception designed to protect requestor's privacy interest as basis for nondisclosure).

In summary, TTUHSC must withhold the information we have marked under section 552.101 of the Government Code in conjunction with section 161.032 of the Health and Safety Code. Additionally, TTUHSC must withhold the information we have marked under section 552.101 of the Government Code in conjunction with section 51.914 of the Education Code. Further, TTUHSC must withhold the document that we have marked pursuant to section 552.110(a). All other information must be released.

This letter ruling is limited to the particular records at issue in this request and limited to the facts as presented to us; therefore, this ruling must not be relied upon as a previous determination regarding any other records or any other circumstances.

This ruling triggers important deadlines regarding the rights and responsibilities of the governmental body and of the requestor. For example, governmental bodies are prohibited from asking the attorney general to reconsider this ruling. Gov't Code § 552.301(f). If the governmental body wants to challenge this ruling, the governmental body must appeal by filing suit in Travis County within 30 calendar days. *Id.* § 552.324(b). In order to get the full benefit of such an appeal, the governmental body must file suit within 10 calendar days. *Id.* § 552.353(b)(3), (c). If the governmental body does not appeal this ruling and the governmental body does not comply with it, then both the requestor and the attorney general have the right to file suit against the governmental body to enforce this ruling. *Id.* § 552.321(a).

If this ruling requires the governmental body to release all or part of the requested information, the governmental body is responsible for taking the next step. Based on the statute, the attorney general expects that, within 10 calendar days of this ruling, the governmental body will do one of the following three things: 1) release the public records; 2) notify the requestor of the exact day, time, and place that copies of the records will be provided or that the records can be inspected; or 3) notify the requestor of the governmental body's intent to challenge this letter ruling in court. If the governmental body fails to do one of these three things within 10 calendar days of this ruling, then the requestor should report that failure to the attorney general's Open Government Hotline, toll free,

at (877) 673-6839. The requestor may also file a complaint with the district or county attorney. *Id.* § 552.3215(e).

If this ruling requires or permits the governmental body to withhold all or some of the requested information, the requestor can appeal that decision by suing the governmental body. *Id.* § 552.321(a); *Texas Dep't of Pub. Safety v. Gilbreath*, 842 S.W.2d 408, 411 (Tex. App.—Austin 1992, no writ).

Please remember that under the Act the release of information triggers certain procedures for costs and charges to the requestor. If records are released in compliance with this ruling, be sure that all charges for the information are at or below the legal amounts. Questions or complaints about over-charging must be directed to Hadassah Schloss at the Texas Building and Procurement Commission at (512) 475-2497.

If the governmental body, the requestor, or any other person has questions or comments about this ruling, they may contact our office. We note that a third party may challenge this ruling by filing suit seeking to withhold information from a requestor. Gov't Code § 552.325. Although there is no statutory deadline for contacting us, the attorney general prefers to receive any comments within 10 calendar days of the date of this ruling.

Sincerely,



Cary Grace
Assistant Attorney General
Open Records Division

ECG/lmt

Ref: ID#198903

Enc. Submitted documents

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